

Response ID ANON-DPZ8-G4UT-A

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
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Submitter profile

What is your name?

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What is your organisation?

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Buchanans Pharmacy Limited

Submitter Profile (tick all that apply)

Consumer

Industry body

Pharmacy organisation

If you select DHB, please state service area:

Northland

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).::

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).::

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).::

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C6 Pharmacy (and retail-only licence) sector and pharmacists**Pharmacy sector context****Future regulation of pharmacy business activities****Licence to carry out a pharmacy business****Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

Supply and advice cannot be separated. Too many prescriptions are currently produced in Pharmacy that are not either legal or correct in regards to dose, medicine etc. Pharmacists currently are the professionals who carries out the checks and balances to ensure patient safety. What onus would be on an organisation who was supply only - who didn't know the patient - who may not have access to past dispensing history. If they simply dispensed what was on the prescription then you will end up with a whole lot more people presenting at the doors of secondary care. Community Pharmacy is currently integral in patient care in Primary Care and are doing more every day that they are not funded for or paid for. If you change the distribution and supply arrangements to allow other organisations to enter the market who are not part of the community fabric then you are risking community pharmacy as a whole.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**Question C22 Which option do you support?**

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Strongly opposed to open ownership with pharmacist control.

Detailed questions relating to Option 1**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:****Question C25 - Are there ways in which Option 1 could be improved?:****Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:****Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:****Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:****Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:****Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:****Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

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Submitter profile

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Chris Higgins

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New Zealanders for Health Research

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Medical devices, Cells and tissues, Trial ethics

NGOs

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially don't support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Agree with the objectives as listed but believe that the way the objectives are numbered implies an inappropriately ordered hierarchy of importance, that there should be an additional objective relating to innovation, research and development, and that health outcome objectives should be considered at least as important as trade and economic objectives. We submit that the objectives should be set out as follows:

1. meets expectations of risk management and assurance of acceptable safety, quality and efficacy or performance of therapeutic products
2. supports consumer access to, and individual responsibility for, care.
3. supports New Zealand's health and health outcomes objectives
4. supports innovation and investment in health research and development of new therapies and interventions
5. supports New Zealand's trade and economic objectives
6. is trusted and respected
7. results in efficient and cost-effective regulation
8. is flexible, durable, up to date and easy to use
9. ensures high-quality, robust and accountable decision-making
10. is able to sustain capable regulatory capacity

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Paragraph 107 of the discussion document is potentially problematic for clinical trials because by definition it would not be possible to satisfy these criteria prior to the clinical trial being undertaken. For unapproved products, sufficient pre-clinical data supporting quality, safety and efficacy are likely to be unavailable.

We note that paragraph 131 of the discussion document states that the legislation would enable activities that would otherwise be unlawful to be authorised via a licence (s 123(2)). For example, a licence for a clinical trial could also authorise the supply of an unapproved medicine for the purpose of that trial. The one activity a licence could not authorise is one that involves a prohibited product, as these can only be authorised by a permit (s 81).

However it is not clear from the discussion document as to the criteria that would be used by the licensing mechanism, and we believe that this should be made fully transparent.

NZHR's submission is that the use of all putatively therapeutic products should be subject to the following process:

1. review by an independent expert technical committee to determine whether safety risks are such that the trial should not go ahead
2. provided the risks are deemed to be acceptable it would then be permissible for the proposed trial to be submitted for ethics committee approval
3. if the clinical trial receives ethics committee approval then the putatively therapeutic product would automatically be granted approval as an exempt product.

If this is deemed to be too open a process then, although not favoured by NZHR the circumstances under which the regulator would be permitted to not grant a license should be clearly articulated (ie it should not be allowed to be, or be seen to be, a discretionary and/or arbitrary process)

Where a putatively therapeutic product is demonstrated by a clinical trial to be efficacious its approval as an exempt product should continue after the conclusion of the trial so that trial participants are able to continue to benefit while awaiting the conclusion of the formal approval process. We note that it is considered unethical for a sponsor to discontinue supply of a therapeutic product to a clinical trial patient if the patient responds to the product, even after the trial has ended

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B22

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

NZHR submits that clinical trials should not attract additional compliance costs. There are already too many disincentives to investment in clinical trials which government policy should be seeking to mitigate rather than aggravate.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:
The Environmental Protection Authority Act should be added to list of Acts where there are interfaces with the proposed legislation.

No additional barriers should be introduced to involving genetically modified organisms in clinical trials.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Subject to previous comments and those below the proposed changes are generally supported.

A requirement for registration of specified trial information is supported in principle, subject to the following two paragraphs.

Currently there is no reliable and comprehensive single source of New Zealand clinical trials information, as illustrated by both NZHRC and ANZCTR reports, which gives rise to inconsistent information about New Zealand's clinical trials landscape. Furthermore the World Health Organization's International Clinical Trials Registry Platform has very limited capacity for undertaking other than very basic analysis.

NZHRC believes that there should be a comprehensive record of all clinical trials conducted in New Zealand which includes all therapeutic interventions, and which is not restricted only to trials involving therapeutic products. There should be consultation with the sector to determine the fields to be included in the register, the register should be fully searchable, and there should be built in requirements to ensure that data entry is accurate and complete.

The ability of the regulator to grant or refuse an application for a clinical trial licence without first seeking advice from the Health Research Council is not supported in principle. As stated previously NZHRC maintains that the use of all putatively therapeutic products should be subject to review by an independent expert technical committee and the circumstances under which the regulator would elect to not accede to the committee's determination should be clearly articulated.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

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Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
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Organisation:
New Zealand Self Medication Industry Association

Submitter Profile (tick all that apply)

Industry body

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

NZSMI wishes to request permission to address the select committee in person on this issue.

In this submission, our references to Direct to Consumer Advertising (DTCA) covers prescription medicines, OTC medicines and general sales medicines unless otherwise stated. We strongly contend that DTCA forms an integral part of the new draft legislation Part 1(3)(a), which states that:

The purpose of this Act is to protect personal and community health by ensuring acceptable safety, quality and efficacy or performance of therapeutic products across their lifestyle and the principle for the regulator and any other person exercising a power under this Act must be guided by the purpose of this Act and the following principles:

(i) (ii) (c)

(a) The likely benefits of therapeutic products should outweigh the likely risks with them;

(b) Regulation of therapeutic products should:

Be proportionate to the risks posed by the products; and

Support the timely availability of therapeutic products;

The administration of this Act should be carried out in an open and transparent manner.

Need for another review

NZSMI supports the existing DTCA legislation, including the ability to advertise prescription medicines.

It is frustrating to again be submitting on the value of DTCA when considerable work was done around this issue in 2002 with extensive consultation in preparation for a trans-Tasman

agreement, culminating in the Mike Codd report, and again with major submissions in 2006. The opposition to this policy has predominantly come from a small minority with recycled commentary and little substantive research.

The public are not at risk here.

A passionate advocate for the banning of direct to consumer advertising, Professor Toop, commented in 2002 this is "in essence a debate about freedom of information. In my view no one has the right or freedom to deliberately misinform for profit". Decades later, we would continue to agree with this statement as we did then.

We have a generic law, the Consumer Guarantees and Fair Trading Act, which is written to protect consumers and commerce from those who would seek to deliberately misinform for profit. Sellers of all medicines, whether they be complementary healthcare products, OTC, pharmacy only or prescription medicines, are subject to this law. In the case of medicines, extra protection is also provided by the regulations developed under the Medicines Act, soon to be replaced by the Therapeutic Products Bill. Anyone who thinks the existing law is not being properly enforced has several options. Complaints can be made to Medsafe in the case of the Medicines Regulations, and the Commerce Commission in respect of the Fair Trading Act. On top of this, there is the Advertising Standards Complaints Board, which administers advertising codes on behalf of the Advertising Standards Authority for many product areas, including medicines.

The number of complaints regarding DTCA are minuscule – recently one or two a year and often not upheld.

In addition, our own organisation NZSMI has a Code of Practice¹ which all members must adhere to and it contains several sections regarding advertising and behaviours in the marketplace around promotion of medicines. There are significant penalties for members not adhering to the Code of Practice.

Many opponents to DTCA cite that we are unusual in that New Zealand and the USA are the only two countries that permit direct to consumer advertising of prescription medicines, and these opponents seek to proffer that as a reason to change. We would argue exactly the opposite.

Firstly, the manner in which we conduct our DTCA is entirely different to the rules and regulations in the United States – so different in fact, they are really unable to be compared. New Zealanders have always prided themselves on leading the world in policy areas, whether it be women's suffrage or nuclear free port entry and there is no reason why we should seek, in this instance, to be a follower. In fact many countries are looking to the New Zealand example of regulated, moderated, certified DTCA as an opportunity and globally there is an increase of DTCA of over the counter and complementary healthcare products.

The supply of medicines to the people of New Zealand is not at all like the USA. Here we have Pharmacy Only and Pharmacist Only medicines. There they do not. Here we have Pharmac. No-one else has Pharmac. Here we have an advertising pre-vetting service. The US does not. There is NO drive or desire to be like the USA and the continuation of the current legislation will ensure we do not become like the USA. To suggest close similarities is simply an uninformed opinion.

Informed consumers

Since 2002, the level of information that consumers have easy access to has considerably increased. The worn out argument that DTCA results in overprescribing (with no proof that we can find) and that doctors are constantly being harassed by patients demanding product that they have seen advertised on television, is simply not real life.

In February 2019, NZSMI conducted a research project interviewing over 1,000 New Zealanders that represented a demographic mix (excluding similar to that of the most recent census. When 1,082 people were asked, "where have you previously seen or heard general information about health issues/prescription medicines/non-prescription medicines?". They responded that Google or general internet searches and friends and family were much greater informers than television or magazines. If one adds in those who searched specific digital health websites, or who took advantage of Healthline phone services, or Health Navigator websites, this disparity widens, proving that DTCA is less significant than the internet and friends and family.

Research regarding effects of advertising on GP interactions

In the same survey, 685 people were asked, "when you have seen a product advertised, did it create an opportunity for you to start a discussion with your doctor or health practitioner about your health and well being?". 27% answered yes, and less than half of these talked to the doctor about a product and over half talked about the condition, problem or ailment. This research shows consumers view DTCA as a tool to encourage conversation with their health professional, not as a

demand for a prescription.

Public concern around OTC and prescription advertising bans

In the survey 1,082 people responded to the question, "how concerned would you be if advertising for prescription or non-prescription medicines was banned in New Zealand?". Over three quarters of New Zealanders would be concerned, and over half would be extremely

concerned if advertising of both prescription and non-prescription medicines were banned. We contend that this research result shows there is no public drive to have DTCA banned and that the bulk of antagonists are minority special interest groups with little or no recent research indicating public behaviours, concerns and desires. A full copy of the research project is available via the following link <https://www.nzsmi.org.nz/wp-content/uploads/2019/04/Perceptive-Omnibus-Survey-Report-February-2019.pdf>

Value or helpfulness of medicine advertising in New Zealand

Not only would New Zealanders be extremely concerned if it was not available, but over half of New Zealanders think that advertising of prescription medicines is helpful and over two thirds think that advertising of non-prescription medicines is helpful. Consumers primarily find advertising through mainstream media channels to be the most helpful, including TV and Google.

Drivers for suggesting products to GPs

Opponents to DTCA regularly argue that it causes overprescribing (no presented evidence) and wastes doctors' time. When 1,082 people were asked, "have you ever suggested to a doctor a product that you might think be suitable to you?", 55% said no and 33% said yes, and of the 33%, 26% said they received the information from Google or a general internet search and 21% said they received the information on the product from friends and family.

This recent research demonstrates that the internet and friends and family are much greater influencers of patient behaviour when talking about specific products to a GP or a health professional than is DTCA.

The New Zealand Herald 8 reported on April 17th some interesting statistics around the number of people who had spoken to their GP's about medical cannabis. Even though there are no advertised medical marijuana products in New Zealand, 66% of GP's noted patient queries on the topic. In many cases the public appeared to have been better informed than the health professionals with 75% of GP's indicating they were somewhat informed to very poorly informed about the issue and products.

Dr Richard Medicott (Medical Director of the Royal NZ College of General Practitioners) is quoted as saying "GPs encourage patients to ask questions and discuss their treatment plans, so it's good to be able to have these conversations. However, this doesn't necessarily mean the GP would be supportive of this type of treatment".

Again, this study (like the NZSMI research) indicates that patients are getting their health information from a wide variety of sources; that they use this information to start conversations with their health professionals and this behaviour is encouraged by GPs; and further indicates that GPs do not respond to bullying and will make prescribing decisions based on their expertise – not just the requests of their patients.

Benefits of DTCA

We contend that DTCA is one of many facets of improved health awareness and patient education. We also know that it encourages patients to act on undiagnosed or poorly managed conditions and that patients feel better about medicines when they have initiated the discussion and been involved in decision-making processes. DTCA does not affect the doctor's independence or increases pressure to prescribe.

Patient rights

We believe that patients have a right to know about their health and treatment options and that DTCA helps promote these.

Any removal of the right to conduct DTCA of Prescription Advertising is likely to be in contravention of the NZ Bill Of Rights which provides a high threshold for those seeking to outlaw any form of communications. Evidence of harm must be so compelling and unambiguous that restraint of freedom of speech can be justified.

After pornography, health is the second most searched topic on Google, with over 3.5 million New Zealanders having access to the internet. 87% of New Zealand internet users search health information online and Web MD gets 300,000 unique New Zealand visitors each month.

It must be remembered that much of this information does not have any restrictions around its publication; or scrutiny of its accuracy. In contrast the vast majority of DTCA advertisements published in New Zealand have been pre-vetted by TAPS in line with well documented and well enforced regulations as previously discussed.

Any move to ban DTCA would not only contravene patient's rights to information, but would be patently unjust unless all internet advertising of medicinal products was to be included in the ban. This is neither possible nor useful.

Since DTCA has been allowed from 1981, major external forces like the internet have come into play and we contend that extensively regulated and reviewed advertising is an enormous benefit to New Zealanders rather than an impost on general practitioners.

Screening of advertisements

New Zealand regulation of prescription medicine advertising is particularly rigorous (far more so than the situation existing in the United States – so much so that direct comparison is neither useful nor relevant).

Companies do their self-assessment of advertisements undertaking scientific, legal, patient safety and medical reviews. All online and mainstream advertisements are then independently assessed for compliance with laws, regulations and industry codes by TAPS (Therapeutic Advertising Pre-vetting Service). We conclude that this independent review is globally unique and a vital component of continuing DTCA appropriateness. Australia did toy with the idea of abolishing compulsory pre-vetting, however, this service still exists and there is a good chance it will be reinstated. We see no value in making pre-vetting compulsory, particularly as our members are also signed up to a Code of Practice, which provides another layer of scrutiny, evaluation and consistency.

DTCA causing overprescribing

We can find no plausible evidence to support this often quoted notion.

NZSMI is aware that a number of Otago University employees have recently re-published a new analysis of an older study conducted in 2012/13. This Zadeh et al publication states:

DTCA can even result in doctors being pressured to prescribe a medication in instances where lifestyle changes would be more appropriate but on further analysis the reference provided is that of long time campaigner and instigator of a number of New Zealand reviews into DTCA, Prof L Toop. In the Zadeh et al referenced paper Professor Toop references his own opinions by referencing his own papers (*Aust Prescr*.2006;29(2):30-2) in a circular self-fulfilling narrative. He also notes that prescribers report they would not have prescribed the drug had it not been requested (again citing his own work and that of Mintzes et al) This raises the a potentially serious issue that New Zealand prescribers are not in control of the prescribing process and that it is controlled by the patient, who (as previously noted) is most highly influenced by the internet and friends and family.

There are numerous other instances of opinions being referenced as fact by referencing earlier self-publication. For example: "advertisements are not independently evaluated for quality and validity of scientific statements unless someone complains, and this system has not prevented misleading advertisements". This is simply not true as it fails to acknowledge the highly utilised and respected TAPS process. This research comment coming from Toop's

submission on DTCA in 2003.

Support for DTCA from Zadeh et al (2017) paper

This paper calls for regulatory changes regarding the advertising of medicines – it does not recommend banning of DTCA and analysis of much of the questionnaire in this study supports other assumptions and facts offered up in this submission.

It shows the vast majority of respondents are NOT affected by the DTCA with between 88.4 to 88.6 % not engaging with their doctor or pharmacist in any way as a result of the DTCA advert for a drug.

Q1: "As a result of seeing an advertisement for a drug, have you asked your doctor for a prescription ?"

Response: only 11.4% (n= 234) respondents answered yes. The Majority of respondents (88.6%) said they did not ask a doctor even after seeing the DTCA advertisements

This paper appears to conclude that, far from being a major nuisance to doctors or influencers of prescribing habits, DTCA is not particularly effective !!

It is interesting to note that 15.9% of patients in the survey instigated a conversation with their doctor as a result of seeing an advertisement. While this is a good result in terms of aiding doctor/patient communication it is interesting to note that over double that number (34%) searched the internet as a result of seeing an advertisement. The conclusion has to be that DTCA is a useful tool in enhancing the quest for health information.

Perhaps a disappointing result, in this instance, is that DTCA did not encourage more people to talk to their pharmacist (Only 16% meaning 84% did not). This could have been because the survey only used the word "DRUG" when referring to medicines and there was no definition of what this meant – prescription medicine, OTC or Pharmacist-only medication.

It should also be noted that over 30% of respondents believed DTCA was helpful for consumers. This result provides a parallel view to the NZSMI research that indicated over 75% would be concerned if DTCA was banned.

These supportive results for DTCA are weakened, however, by the authors acknowledgment that the whole paper is self-reported data and so " might not reflect individuals actual behavioural responses ". At best the study refers to responses as "perceived behavioural responses"

And that:

" causal relationships/inferences could not be made" (due to nature of the data) so one can't make any link between DTCA and any of the other variables.

In short, this paper does not have the robustness to be used as a definitive argument either for or against DTCA.

DTCA forms a vital step in Consumer Health Education

Recent research conducted by WSMI (World Self Medication Industry Association)6 concludes that:

- Even in the absence of illness there is a period prior to need recognition that is important to the eventual search process. 3
- Advertisements provide information about branded products and what health benefit they can be expected to provide.
- The Main purpose of this advertising i s to create awareness and differentiate products from each other
- This Does not mean that every viewer of an advertisement is interested in the products or that every exposure leads to a sale .
- Advertising in the absence of a self-care need is "crucial because they shape the initial consideration set"
- Since no advertiser would know when a person has recognized a health concern that they wish to address, they cannot provide "just in time" information about their products
- Having Consistent messaging about solutions to self-care health needs available through the channels preferred by different people increases the likelihood that when a health needs arises there is an awareness of some initial opportunities to address that need. 4
- For example, someone watching a sporting event may see an advertisement for an athlete's foot remedy. This information has value for those seeking a treatment for that condition but if the person watching the commercial does not have that condition , it is unlikely that they will feel the need to investigate this any further. However, should they eventually experience the symptoms of athlete's foot they already have an awareness of a possible choice that they can pursue.
- As an awareness tool, product advertising is a very valuable input but once a person has recognized a need and decided to take further action, advertising plays the least significant role in the final selection of an appropriate product.

- When a person decides that some action is desired to manage their health concern they begin a search by seeking information to inform their decision
- The vast majority of the touch points during the information search phase involve consumer-driven information seeking5

Furthermore, research from CHPA (Consumer Health Products Association (USA) 7 reinforces the NZSMI proposition that health practitioners, friends and family and the internet are far more influential in the consumer decision making process than advertising.

Conclusion

NZSMI supports the retention of DTCA, including the advertising of prescription medicines. Change is not necessary.

The system that has worked well for decades, continues to work and is safe.

It aids health literacy by providing vetted advertisements of approved products.

It is welcomed by a vast majority of New Zealanders who are NOT calling for change.

There is scant proof that DTCA leads to patients pressuring doctors to prescribe and more proof that the internet is a much more utilised source of data which may influence this supposition.

Many New Zealand patients use DTCA to open conversations with their health professionals over symptoms, disease states and, in a small number of cases, about product.

Restricting DTCA will likely lead to complaints over abuse of the Bill of Rights.

New Zealand and the United States should not be directly compared as similar markets when referencing DTCA – they are vastly different.

There is NOT widespread demand for a change to DTCA but a recurring vocal minority recycling old arguments.

References

1 NZSMI Code of Practice – www.nzsmi.org.nz

2 NZSMI Survey on Direct to Consumer Advertising – Conducted by Perceptive Research February 2019

3 Court, D., Elzinga, D., Mulder, S., & Veltk, O. J. (2009). The Consumer Decision Journey)

4 Ipsos. (2014). The Benefits of OTC Advertising

5 Court, D., Elzinga, D., Mulder, S., & Veltk, O. J. (2009). The Consumer Decision Journey

6 WSMI Research Understanding Influences on Self-Care Behaviour 2014

7 Consumer Healthcare Products Association (USA) 2014 IRI Research – SelfCare Initiative; Understanding drivers and barriers of SelfCare

8 NZ Herald Wednesday April 17th 2019 "Two thirds of GP's quizzed about medical cannabis"

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4F3-T

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 13:08:09

Submitter profile

What is your name?

Name:

Jessica Fagan

What is your email address?

Email:

What is your organisation?

Organisation:

Australia and New Zealand Society of Nuclear Medicine, New Zealand Branch & Mercy Radiology

Submitter Profile (tick all that apply)

Consumer

Industry body, Retailer (non-pharmacy)

Medical devices, Medicines

Medicines

Professional body (eg, Colleges, Pharmaceutical Society etc), Private hospital

If you select DHB, please state service area:

Medical practitioner (excluding Surgeons), Other health practitioner (please comment)

If you select 'Other', please comment below::

Nuclear Medicine Technologist

Medicines (other than cells and tissues)

If you selected 'Other' please comment::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

No comment

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

categories of medicine (s 19): This needs further clarification as to what category Radiopharmaceuticals fall under. Radiopharmaceuticals do not require a prescription as they are not used like a drug. They are a necessary part of a given Diagnostic or Therapeutic Protocol. They are currently not administered by Pharmacists or in Pharmacies, as the handling of radioactives is beyond the scope of general pharmacies and Pharmacists. Currently in NZ there are no Radiopharmacies or Radiopharmacists employed by any institution or private or public organisation. There is also no University in NZ offering a program to train Radiopharmacists. There needs to be careful consideration on how Radiopharmaceuticals are classified as the implications could be massive for the field of Nuclear Medicine if Radiopharmacists and Radiopharmacies are required to manufacture, dispense, or administer these types of "medicines"

standing order and complying standing order (s 40): Could this apply to Radiopharmaceuticals if they were classed as prescription medicines? Again there needs to be clarification as to where Radiopharmaceuticals are categorized under s19.

Additionally where does things like IV Contrast for CT scans fall? The Bill is so vague as to how to categorize medicines as many items that are considered medicines for this bill DO NOT currently require a prescription

Our suggestion would be to add another category to the medicines heading, specifically titled: Radiopharmaceuticals, including both diagnostic and therapeutic radiopharmaceuticals. This would allow for professions who specialize in the manufacture, distribution, and administration of radiopharmaceuticals to be licensed under this new Bill to continue to perform their regular duties. These professions would be the following: Nuclear Medicine Technologists, Radiochemists, Radiophysicists, Nuclear Medicine Physicians, and Radiologists with a scope in nuclear medicine (PET/CT or SPECT/CT)

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

No Comment

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

No Comments

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

It is difficult to understand how the manufacture and distribution of Radiopharmaceuticals will be handled in this instance. As mentioned in previous comments a Pharmacist and Pharmacy would not have the required scope of practice to deal with Radioactives. Nuclear Medicine Technologists have the required scope of practice to manufacture, distribute and administer under the definitions of the Bill, however there is no clear area where a NMT would be authorized to continue to perform these skills under this Bill.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

This is quite clear as long as Radiopharmaceuticals are considered part of a Radiologist and Nuclear Medicine Physicians scope of practice

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

It would be my understanding that if Radiopharmaceuticals are considered part of a Radiologist's (Health Practitioner) scope of practice, then Nuclear Medicine Technologists (Health Practitioners Staff) would be able to administer these medicines. Would this apply to all medicines, even controlled substances?

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

no comment

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Section 76: As a consumer this is absolutely ridiculous. How do you plan to moderate the already high costs of prescription medication to New Zealand residents? How do you also plan to avoid a monopoly by certain "approved" drugs? It is quite common to find the same medicine manufactured by the same company but sold in another country via an online pharmacy that is nearly 40% less cost than in New Zealand.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

We are aware of a range of concerns about the current use of, and requirements for, standing orders. We intend to address these, where appropriate, when developing these regulations and will engage with relevant stakeholders to help inform this process.

As you have stated in the comment above - there needs to be further development of the regulations for standing orders and how these would apply to medicines.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

no comments

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

We would like to be informed of the continuing development of this section of the bill. Especially regarding time frames of when applications need to be received for approval of products.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

We would like to be informed of the continuing development of this section of the bill. Especially regarding time frames of when applications need to be received for approval of products.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

none

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

none

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

none

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

none

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

none

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

none

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

none

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

none

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

none

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

none

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

none

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

none

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

none

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

none

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

none

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

none

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:
none

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:
none

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:
none

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:
none

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:
none

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
none

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:
none

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
none

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
none

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
none**

**Question C4 - Please provide any comments on the approach to post-market controls.:
none**

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

281 Needs further clarification especially with regards to Radiopharmaceuticals. Manufacturing of Medicines of this nature need clear and concise guidelines.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

none

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

no comment

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

no comment

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

no comment

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

no comments

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

none

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

none

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

none

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Not at this time

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

no comment

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

no comment

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

no comments

Question C4 - Please provide any comments on the approach to post-market controls.:

no comment

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

no comment

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

no comment

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

no comment

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

no comment

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

no comment

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

no comment

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

no comment

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

no comment

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Currently there is no adaptation for Radiopharmaceuticals. There is currently not a single Radiopharmacy in New Zealand and there is not a single Radiopharmacist in New Zealand. Regular Pharmacies and Pharmacists do not have the current scope to handle Radioactives. If this Bill categorizes Radiopharmaceuticals in the pharmacy or pharmacist category there will be serious ramifications to the area of Nuclear Medicine, including PET/CT.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

There needs to be some sort authorization for Nuclear Medicine Technologists, Radiochemists, Nuclear Medicine Physicians and Radiologists to manufacture, distribute and administer approved Radiopharmaceuticals under this proposed new Bill.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

no comment

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

no comment

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

no comment

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

no comment

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:
no comment

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
no comment

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
no comment

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
no comment

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:
no comment

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
no comment

Question C34 - Are there ways in which Option 2 could be improved?:
no comment

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
no comment

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

I definitely think remote access to a pharmacist should be allowed. There are not enough Pharmacists to be present in every single pharmacy, especially in smaller rural.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No Comment

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
no comment

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
no comment

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:
no comment

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
no comment

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
no comment

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

no comment

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

no comment

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

This area is quite broad and I hope the requirements will be outline clearly. There are a number of situations where this would/could apply from things like Contrast administration for diagnostic CT scanning and Radiopharmaceutical administration for Nuclear Medicine and PET scanning. It is important that these areas are part of your consideration.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

no comment

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

no comment

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

no comment

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

no comment

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

I do if the health practitioner is trained on the type of medicine and potential adverse effects. This would be related to their scope of practice, training and clinical expertise.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

I do if the health practitioner staff is trained on the type of medicine and potential adverse effects. This would be related to their scope of practice, training and clinical expertise.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

no comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

no comment

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

no comment

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

n/a

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

n/a

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

no comment

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Sounds reasonable

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Disagree with this, unless something is done to reduce the cost to consumers purchasing non PHARMAC prescription medications

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

yes

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

no comment

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

no comment

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

no comment

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

no comment

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

no comment

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

already commented previously

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

already commented previously

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

no comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

no comment

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

no comment

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

no comment

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4UP-6

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 13:34:06

Submitter profile

What is your name?

Name:

Carmelle Penney

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Teva Pharma (New Zealand) Limited

Submitter Profile (tick all that apply)

Medicines

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

No comments.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

No comments.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

We fully endorse and support the requirement for a person who is not the product's sponsor, to have written consent of the product's sponsor, or an authorization given by a licence, permit or provision in the regulations, to import an approved product. The scope of this requirement should extend to unapproved products being imported and supplied to cover short-term supply situations. A person should be required to obtain written consent from the local subsidiary of a product distributed overseas by their parent company, as part of the permit application to commercially supply an unapproved product (refer comments in response to Question B20).

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

No comments.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

No comments.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

No comments.

Question B7 - Please provide any comments on the authorisations for health practitioners :

No comments.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

No comments.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

No comments.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

No comments.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

We support the conditions of section 79 whereby the authorization for supply of an unapproved product as a personal import and not commercial supply.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

We support continued direct-to-consumer advertising of prescription medicines (DTCA).

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

The terms of the contract/agreement between the sponsor and manufacturer should be defined by both those parties and not be prescribed by the legislation or Regulator (s 97 (c)).

We support a status quo position of "no more" and "no less" information than currently available from Medsafe's website, being accessible on a publicly available product register (s 113).

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

No comments.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

We agree with the proposed classes of product that would fall under the approval-exempt category.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

We agree a sponsor should be excluded of liability for approved products imported without their consent.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

No comments.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

We acknowledge the provisions for controlled drugs are outside this consultation however we wish to note this is an area of interest as a sponsor.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

No comments.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

We support the control of importation and supply of unapproved medicines through permit grant. The permit application should discourage a parallel importation scenario and could include the requirement for the applicant/importer to obtain written consent from the local subsidiary of a product distributed overseas by their parent company.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

No comments.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

No comments.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

No comments.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

No comments.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183–196).:

No comments.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197–199):

No comments.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200–204):

No comments.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

We support the ongoing option of an abbreviated evaluation regulatory pathway through recognition of work done by overseas regulator whilst retaining locally decision making.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

No comments.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

No comments.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

No comments.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

As a sponsor, cost recovery from industry is accepted if commensurate with service, particularly with respect to product approval timeframes.

We support and acknowledge that greater responsiveness to change and the flexibility to provide tailored authorisations and requirements is an important factor.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

No comments.

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

No comments.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

No comments.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

No comments.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

No comments.

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

We support the option of notifying minor changes via consolidated updates at a set frequency and to align with European and Australian models where appropriate.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

No comments.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

We would envisage a pragmatic approach to allow transition to occur in a realistic timeframe.

Question C4 - Please provide any comments on the approach to post-market controls.:

No comments.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

No comments.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

No comments.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

No comments.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

No comments.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

No comments.

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

No comments.

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

No comments.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

No comments.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

No comments.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

No comments.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

No comments.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

No comments.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

No comments.

Question C4 - Please provide any comments on the approach to post-market controls.:

No comments.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

No comments.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

No comments.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

No comments.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

No comments.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

No comments.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

No comments.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

No comments.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

No comments.

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

No comments.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No comments.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

No comments.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

No comments.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No comments.

Question C25 - Are there ways in which Option 1 could be improved?:

No comments.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

No comments.

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

No comments.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

No comments.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

No comments.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

No comments.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

No comments.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No comments.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No comments.

Question C34 - Are there ways in which Option 2 could be improved?:

No comments.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No comments.

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

No comments.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No comments.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

No comments.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

No comments.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

No comments.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

No comments.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

No comments.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

No comments.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

No comments.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

No comments.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

No comments.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

No comments.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

No comments.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

No comments.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

No comments.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

No comments.

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No comments.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No comments.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No comments.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No comments.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

No comments.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

No comments.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We agree direct-to-consumer advertising of prescription medicines should continue to be permitted.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Consideration should be given to the situation where the approved indications/dosage regimen for a generic medicine may not align with the innovator for patent/intellectual property reasons. If a prescriber were to prescribe the generic product for an unapproved indication, which is currently approved for the innovator product, this in theory would be off-label use and SCNSA required until such time that intellectual property constraints ceased.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

No comments.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

From a sponsor's perspective, we would determine whether it is logistically feasible and financially viable to import the unapproved medicine. We also reiterate our earlier feedback that should an importer wish to supply any of our company's products (approved or unapproved in New Zealand), they should not do so without our written consent and there should be no opportunity for parallel importation.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

In exceptional circumstances, where there were no other avenues available and there is a significant clinical need, authority to personally import medicines with the appropriate permit, should be possible.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

No comments.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

No comments.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

No comments.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No comments.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No comments.

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No comments.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No comments.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No comments.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We agree direct-to-consumer advertising of prescription medicines should continue to be permitted.

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

No comments.

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

No comments.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4KE-H

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:00:29

Submitter profile

What is your name?

Name:

Lil Handey

What is your email address?

Email:

What is your organisation?

Organisation:

Pharmaceutical Compounding NZ Ltd T/A CompoundLabs

Submitter Profile (tick all that apply)

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

s19. Suggest aligning the numbering with the Australian schedule numbers (e.g., Rx medicines would be category 4) so that there is less potential for confusion.
s28. The amount a Pharmacy is able to compound should be stated as 'limited to the maximum quantities set in rules' rather than 'limited to either no more than a patient needs or maximum quantities set in rules'. The maximum quantities are currently clearly stated in NZS 8134.7:2010 (New Zealand Standard: Health and Disability Services Pharmacy Services Standard) and leaving the wording in the Bill as it stands could create unnecessary uncertainty.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Do not agree with s52. In a situation where a medication has been withdrawn from NZ by the sponsor and the sponsor is unwilling or unable to provide written consent for another party to import then having to apply to the Regulator for approval to import could result in an unacceptable delay for the patient requiring the medication.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Will Pharmacy students and Pharmacy Technician students be considered to be pharmacy workers for the purposes of carrying out compounding or dispensing under the Supervision of a pharmacist?

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)**Question B20**

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

s157-8: These provisions will strengthen the position of the responsible person, and this will be particularly important if Option 2 (regarding Pharmacy ownership) is adopted, however the proposed legislation poses a potential for strained employment relationships.

s159: Agree that the requirement for a pharmacist to be present for a pharmacy to perform compounding or dispensing/supply of category 1-3 medicine should continue.

B8 Part 6 of the Bill: Regulator**Subpart 1: Regulatory powers and functions(ss 160–182)****Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

Subpart 2: Investigative powers (ss 183–196)**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)**Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B9 Part 7 of the Bill: Enforcement**Subparts 1 and 2: Enforceable undertakings(ss 223–232)****Question B29**

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Consider adopting category numbers aligned with Australian schedule numbers.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes; for example to permit a pharmacy worker to sell a Pharmacist Only medicine after confirming it is appropriate (e.g. via voice call or video link) with the supervising Pharmacist.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No. Removing this restriction could support establishment integrated of health clinics where pharmacist and other health practitioners can jointly own a pharmacy and/or health clinic. Measures would be required to preserve the patients' interest, so they do not feel pressured into presenting their prescription to any particular pharmacy.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes. Where pharmacies have an established and on-going demand for a particular compounded medication then it is essential that they be permitted to produce in anticipation of receiving a prescription from a patient.

1. Compounding in anticipation will assist pharmacies to avoid unnecessary delays in supplying medication to patients and potential disruption to continuity of therapies; especially important if the patient has delayed seeing their doctor until their current supply has almost run out - and this often occurs!
2. Compounding in anticipation allows the Pharmacy to plan compounding in a more orderly fashion rather than having to respond at short notice.
3. Compounding in anticipation also allows Pharmacies to keep the medications reasonably affordable for patients because it is more cost effective to prepare in batches (instead of one Rx at a time). The cost to set up the compounding process for a particular medication is effectively the same whether 1 bottle or 10 bottles are to be prepared. When the set-up cost is distributed over 10 bottles the average cost to produce per bottle can be significantly less than when produced 1 bottle at a time.
4. Being permitted to compound in advance (in larger batches, within allowed quantities) may also encourage pharmacies to invest in specialised compounding equipment designed to consistently mix blends to a high level of uniformity (i.e. a uniform distribution of active ingredient throughout a powder or cream) thereby reducing errors due to human judgment.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

We support the proposed changes.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Yes.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

We do not support the proposed process. It will result in unnecessary extra workload for prescribers, particularly in paediatric practice.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

The proposed special clinical needs supply authority could result in unnecessary extra workload for prescribers. Pharmacies are also likely to spend extra time to confirm whether a SCNSA has been completed when a prescription for a non-approved medication is received for a patient.

The ability to issue a SCNSA should not be restricted to medical practitioners. Where a practitioner group is authorised within their scope of practice to prescribe a particular medicine , then they should also be permitted to issue a SCNSA (e.g. for a compounded product) if a suitable approved medication is not currently available in New Zealand.

[Currently there is an unsatisfactory situation where authorised prescribers who are not medical practitioners (e.g. midwives) are not able to procure a compounded medication such as a progesterone cream for their patient from a NZ pharmacy and they must try to import the medication themselves.] However if the proposal is adopted in its current form we would support allowing other health prescribers to prescribe an unapproved product (including compounded medications) once a medical practitioner has issued a special clinical needs supply authority. The proposal could encourage greater collaboration between the medical practitioner and other health prescribers (involved in the care of a particular patient).

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

This appears to be over-regulation, restricting personal choice in order to address a relatively tiny issue. There will be many people on long term medication who have moved to NZ and prefer to continue using the original medication instead of changing to the NZ brand.

The amount of prescription medication being imported under the current system (whereby a person can import as long as they have a valid prescription/approval from the medical practitioner) will be a small fraction compared to the amount of approved medication being supplied through normal channels.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Yes; if it is within the scope of practice

Benefits include the patient having immediate access to the medication.

However there is risk that the practitioner could exploit their position of trust and pressure (directly or indirectly) their patients into buying these medications from them. There would need to be guidelines in place to address this risk.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Direct to consumer advertising is unnecessary and should not be permitted.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:.

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Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:03:42

Submitter profile

What is your name?

Name:

Sean Evans

What is your email address?

Email:

What is your organisation?

Organisation:

Novartis New Zealand

Submitter Profile (tick all that apply)

Medicines, Cells and tissues

Medicines, Cells and tissues

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Above all, transparency, openness (ss4(c)), fairness, collaboration with comparable overseas regulators and alignment with overseas standards should be the key principles of the implementation of this Act.

ss4(b)(i) Risk-proportionate regulation

Novartis strongly supports a risk-based approach of the new regulations.

ss4(b)(ii) Timely availability of therapeutic products

Availability of products in New Zealand is directly impacted by our ability to predict accurately registration timelines and the current therapeutic bill draft does not offer any statutory timeframes for approval procedures. Novartis would support a formal commitment from the regulator to undertake the review of therapeutic products in a legislated manner with key milestone dates similar to other regulatory agencies. It should be noted that the Therapeutic Goods Act (1989) in

Australia includes a 255 working day statutory timeframe.

It should be noted that comparable Health Authorities (included but not limited to the TGA), have statutory timeframes in place. Should Medsafe be introducing new processes than may lead to an increased financial and resource burden on industry, then accountability should be accepted for delivering outcomes in accord to New Zealand public sector accountability standards (<https://www.oag.govt.nz/2016/accountability/part2.htm#scrutiny>).

On a separate note, we have no objections to replacing provisional consent with conditional approvals (ss105-107) given that it seems to offer greater flexibility. Novartis also welcomes abbreviated pathways such as those based on comparable overseas regulators assessments or those based on medical needs (i.e. priority review) with dedicated evaluation timelines (ss4(d)). These should not be mutually exclusive pathways. Abbreviated submissions should be able to qualify for priority review as well, with the aim to accelerate further the submission to approval time versus to the abbreviated pathway or the priority review pathway alone.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Novartis considers the definition that a “person” is either a body corporate or an individual should be added. This is particularly relevant to sections such as ss30; 42; 44; 48, 52 and 83(2)(a)(i), where it is not always an individual person who imports, supplies or advertises a product. We also note that in some sections, requirements have been set for a “person”, when it may be clearer to readers to differentiate requirements according to whether the person is a body corporate or an individual. For example, see our response to definition ss47 and ss48, and our response to question B22.

ss27 meaning of clinical trial

The meaning of “clinical trial” should be added in accordance to international definitions, including the WHO’s definition.

ss28(3) meaning of compound and ss32(2) Meaning of manufacture, for medicines

ss28(3) and ss32(2) indicate that “compounding or dispensing a medicine is part of manufacturing the medicine”. Please provide further explanation for this as compounding or dispensing by a pharmacist or health care practitioner would not normally be considered as part of the manufacture of a medicine by the sponsor, who has already released the product to market, and cannot be responsible for the actions of practitioners.

ss30 meaning of import

The scope of persons who are importers under ss30 is very wide.

ss30(2)(a) indicates that this includes “a person who does the physical activity of importing the product”. We are concerned that this definition is broader than the definition of an importer under the Customs and Excise Act 2018, and that this may pass unreasonable responsibility and liability to a broader range of persons than the Medicines Act does, such as freight operators. We question the rationale for this broad definition.

ss31 meaning of manufacture, manufacturer, and responsible manufacturer

We recommend alignment with international norms for the definition of manufacture. The wording in the Bill suggests that not only the sites of production, testing, sterilising, labelling, packaging and release of the product would be considered manufacturers, but also any subcontracted sites involved in these activities.

Please explain why the relevant considerations for determining a ‘responsible manufacturer’ for a medicine or an AMI differs substantially to that for a medical device or type-4 product (ss31(4) vs ss31(5)). For medical devices or type-4 products, it is noted in ss31(5)(a) that a person may be a ‘responsible manufacturer’ “whether or not they personally undertake the manufacturer of the product”. Whereas for a medicine or AMI such a clause is not included. We infer that this difference may have been made to account for different characteristics of the different products and their manufacturing, but we do not believe this is necessary and we recommend that the considerations for the different products types are aligned.

We suggest that the same approach that is given for medical devices and type-4 products should be applied to medicines and AMIs.

Our reasoning is that for multinational pharmaceutical companies, the parent company (international headquarters) of the New Zealand sponsor, is often best placed, and best suited to be the ‘responsible manufacturer’ for a medicine or AMI. The international headquarters may not personally undertake the manufacture of a product, but they will have oversight of the full process and be responsible for the overall quality assurance and quality control in relation to the manufacture of the product(ss31(4)(b)), and its name or trademark would be attached to the medicine (ss31(4)(c)). In many cases, a standard practice for the pharmaceutical industry is that the parent company holds agreements with the many parties involved in manufacture of a medicine. Therefore, they would often be in the best position to assist with and supply of required manufacturing information back to the local New Zealand sponsor as and when required. The consideration that “a person may be a ‘responsible manufacturer’ whether or not they personally undertake the manufacturer of the product” should feature for all product types (medical devices and type-4 products AND medicines and AMIs).

We seek confirmation from the Ministry of Health that the parent company (international headquarters) of the local New Zealand sponsor could be nominated as the ‘responsible manufacturer’. We also ask that the Ministry take consideration of companies that are “outsourced” sponsors because there is no New Zealand affiliate of the parent company. In these cases, the New Zealand sponsor is usually procured by the parent company via an Australian or regional affiliate and the New Zealand sponsor does not hold any contracts directly with manufacturers. Please confirm whether an Australian or regional affiliate could be nominated as the ‘responsible manufacturer’. We stress that the Ministry must consider current company models and practices for New Zealand. The presence of multinational pharmaceutical companies is small compared to other territories, and many functions are outsourced to other countries. Regardless, Medicines New Zealand’s member companies ensure that they have the correct processes and controls in place for New Zealand. The ‘responsible manufacturer’ and contractual relationship requirements need to be more clearly explained for local affiliates, subsidiaries and outsourced companies who are sponsors of medicines in New Zealand. Please also refer to our response to question B13 for further comment regarding the contractual relationship requirements.

ss36 meaning of pharmacy business and pharmacy activity

ss36(3)(c) defines that a pharmacy business can supply medicines and medical devices by wholesale supply in circumstances permitted by regulations, and that this is a pharmacy activity. Paragraph 68 of the consultation document says “we intended to develop regulations to allow pharmacists to supply to other health practitioners, in the types of situations that currently occur under practitioner supply orders. We are also considering allowing a pharmacist to supply a medicine to a nearby pharmacy that is out of stock of the medicine requested by the patient”. We strongly recommend that if a pharmacy is permitted to supply by wholesale they must meet the requirements of a wholesaler as per Part 4 of the New Zealand Code of GMP, Wholesaling of Medicines and Medical Devices (i.e. facility suitability, stock control, temperature control and monitoring, invoicing, traceability of sales for purposes of recall), and attain a wholesale licence for such an activity. Additionally, allowing such an activity within a pharmacy licence rather than a separate wholesale licence may cause difficulties for suppliers to distinguish between customer types for the purposes of monitoring excessive or aberrant ordering patterns.

ss47 fit and proper person and ss48 meaning of senior manager

ss47 defines the test of whether a person (e.g. “person A”) is a ‘fit and proper’ person.

ss47(2) states that as well as “person A”, others are subject to the ‘fit and proper’ person test:

(i) each person “who is or has been a senior manager of person A”; and

(ii) each person “of whom person A is or has been a senior manager”. There is no differentiation given for whether person A is an individual or a company and this makes this requirement quite broad in its reach to different parties. It also does not give any consideration of the point in time when Person A was at a particular company, or in a particular role.

As an example, the way the Bill has been drafted, if Person A is an individual then the regulator would need to consider: (i) any company of which the person is or has ever been a director, CE, CFO, or similar; and (ii) any partnership or business where Person A has been a partner, or equivalent of a partner or director. It may also consider: (iii) any individuals that are currently or has ever been a “senior manager” of Person A, at any of the companies Person A has worked at.

As another example, if Person A is a Company (“Company A”), then: (i) any individual that is currently, or has ever been, a director, CE, CFO or similar of Company A; (ii) and any company that is able to exert significant influence over the management or administration of Company A.

We recommend that there be two definitions to differentiate between individual and company sponsors/licensees. The way it is currently written is unclear and confusing. We also suggest that there be a time limit or timeframe given in the senior manager definition. As it stands, it appears to be unreasonably wide-reaching for the ‘fit and proper’ person test.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

ss51 product approval required to import or supply medicine, medical device, or type-4 products

Novartis is supportive of the requirement to obtain product approval, approval exemption or an authorisation to import or supply a therapeutic product.

ss52 sponsor's consent required to import approved product

Novartis support the prohibition of parallel importation.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Ss53 Authorisation required for controlled activity

As stated in answer to question B2, we question the rationale for including compounding and dispensing in the definition of manufacturing a medicine (ss28(3) and ss32(2)). This decision appears to create additional uncertainty in ss53(2)(a) where it is stated that manufacturing a therapeutic product is a controlled activity. It had to be added in brackets “(which, for medicines includes compounding and dispensing)” in order to state that compounding and dispensing is also a controlled activity. For clarity, we would suggest these activities are separated from the definition of manufacture and listed separately as controlled activities in ss53.

ss55 Persons in supply chain must comply with regulations

The list of activities persons in the supply chain must comply with is very broad (ss55), and encompasses activities related to manufacturing of therapeutic products (packaging and labelling), supply (storage, transport, disposal and tracing/recall) and clinical practice (monitoring of conduct in relation to a supply order or special clinical needs supply authority).

The regulations must specifically apply requirements to different categories of persons in the supply chain, in light of the wide range of supply chain activities defined in s44(1).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Novartis strongly supports the adoption of EU principles and regulations in New Zealand. New or modified requirements compared to the EU would have had a level of unnecessary complexity. It is understood that Australia is also realigning with the European position on the matter

ss76 patient or carer importing medicine for personal use and ss77 Patient or carer importing medical device for personal use

It is noted that a patient is permitted to import certain medicines/devices without authorisation of the sponsor, provided that the medicine/device has been obtained legally and does not exceed a supply limit. There are no objections to the inclusion of these requirements. However, there is concern from a pharmacovigilance perspective that this may complicate the identification of a product belonging to a sponsor, and the sponsor's obligations relating to the imported product.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

ss78 Authorisation for unapproved product stock in supply chain

Novartis welcomes the ability of the Regulator to issue a 'use of current stock' notice. This is seen as a pragmatic improvement on the current regulation. Novartis would support a case by case approach to the implementation of these notices that should result from a discussion between the regulator and the sponsor. We would suggest these notices be published on the Regulator's website(s).

We would also propose that a 'use of current stock' notice could also be used in situations where a major change has been made (and approved) to a product and an amount of the original/unchanged product is still present in the market. This would allow a sponsor to 'transfer' a product's approval, TT50 number, and entry in the regulator's register to the changed product, and if any of the unchanged product was present in the market, it could be used. We believe this would be an opportune scenario to issue a 'use of current stock' notice.

ss79 regulations may grant authorisation

We support the intent of ss79 to allow for more tailored authorisations for specific circumstances

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

ss82 meaning of advertisement and related terms

Novartis has noted that ss82(1) defines an advertisement for a therapeutic product as "a communications made to the public or a section of the public for the purpose of promoting the product." We would propose that a definition of 'promote' should be added to the Bill to clarify the difference between promoting (advertising), and providing education.

We ask that the Ministry of Health consider advertising at international conferences in New Zealand. There are often products or indications that are approved in other countries such as Australia, that companies wish to advertise to international health care professionals at these events. These products/indications are regularly approved in other countries, but not New Zealand due to restrictions on public reimbursement of medicines. This is a common scenario particularly for Australasian conferences and scientific meetings of Australasian royal colleges. Under the Medicines Act, it is prohibited to advertise these in New Zealand and our reading of ss83(1)(a), is that this prohibition would continue under the TPB. It is common in other countries to permit this, provided there is a statement that the product/indication is not approved in the host country.

We suggest a permit system could be utilised to enable this activity in New Zealand, set conditions/requirements, and provide suitable regulatory oversight. A permit could authorise a company to advertise to international health care professionals at an international conference for products/indications that are not approved in New Zealand. We ask that the Ministry of Health consider a permit system to provide a limited exception to ss83(1)(a) for the described activity. This could assist international investment in these conferences, and long-term sustainability of holding scientific conferences in New Zealand. We suggest further discussing this suggestion with conference organisers.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

ss97 Criteria for sponsor of approved product

Whilst Novartis agrees that sponsors should be held accountable for post marketing safety activities and investigation of Quality Issues, Sponsors should not be considered responsible for all activities outside of their control. Responsibility is considered to be transferred to other supply chain partners (e.g. wholesalers, pharmacies), once the product has physically left the Sponsor's warehouse.

ss97 (c) Criteria for sponsor of approved product

It is considered reasonable to expect that a local sponsor may have a contractual arrangement with their overseas head offices which in turn have contractual agreements with all manufacturers involved in the production of the products supplied in New Zealand. It should not be expected that the local New Zealand sponsor has a direct relationship with all the relevant manufacturing sites. Hence the requirements of this contractual relationship should be more clearly defined in the proposed therapeutic bill. Novartis NZ, who is part of multinational pharmaceutical company, would not ordinarily hold individual agreements with each of the many manufacturing sites. It is standard practice for these agreements to be held by our parent company (international headquarters) and for there to be an agreement between the local affiliate/subsidiary and the parent company.

Ss98 Content of approval

It is not clear whether only the address of the place of the responsible manufacturer would be required to be included in the approval, or given the broad definition of manufacturer in s31, that it will be required to list an extensive array of sites directly and indirectly involved in product manufacture.

ss100 – Major changes results in new product

Having major variations resulting in a new product, would add significant complexity and regulatory burden onto sponsors and the regulator. Whilst we agree that traceability of the implementation of major manufacturing changes are important, we believe it could be done in a more practical manner. It is suggested that a new product identifier be issued only where the sponsor did wish to continue to have both versions of the product approved in New Zealand simultaneously.

This approach creates significant practical issues for sponsors. PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We understand that the intent of the approach is to ensure different versions of the same product (i.e the original product vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not believe the practicality of the major changes processes has been considered in the Bill and we strongly recommend further consultation is conducted with industry on this matter.

A solution would be to allow sponsors to nominate to replace the approval of the current product, with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product. This type of approach is used by the TGA, referred to as TGA Grouping.

For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s78)." We believe a major change to a product would be an appropriate reason to issue a "use of current stock" notice. We suggest this is also discussed further with pharmacists and prescribers.

In cases where the sponsor did wish to have both versions of the product approved and marketed, they could nominate to receive a new approval and TT50 number for the changed product.

ss101 – Sponsor must notify regulator of certain minor changes

Novartis strongly supports a post-approval lifecycle framework for quality changes/applications that align with that in the EU and Australia as these reduce the submission burden for sponsors and establishes activity-based timelines for evaluation of those that require approval. Flexibility is also required to allow companies to notify changes as they arise. We would expect further consultation be sought by the regulator on this matter once the guidance documents (regulations and/or rules) have been drafted.

ss103 – Duration of approval

Novartis supports perpetuity of product licence approvals until such time that the Sponsor or regulator considers cancelling the licence. This is standard amongst modern regulatory frameworks. Under the current system, the approval lapsed status after 5 years of no regulatory activity is considered confusing and too much of a passive approach.

ss104 Approval lapses on death, bankruptcy, or insolvency of sponsor

Novartis does not understand why a product approval would automatically lapse in these certain situations (death, bankruptcy, or insolvency), yet a licence or permit would be transferred to an executor of the person's estate, the Official Assignee, or to liquidator, receiver etc (ss151). The rationale for lapsing an approval is not clear to us and we cannot find an explanation in the consultation document.

the TPB proposes that the responsible person (called the sponsor) is responsible for all aspects of the product, extending from the manufacture, application, approval, importation and supply through to the supply channel. This wording relating to the "responsible person (called the sponsor)" in the consultation document, but it seems at odds with the wording in the draft Bill, where the responsible person is named on the licence, but is not necessarily the sponsor.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

ss105 – 107 – Conditions on approval

Novartis agrees that the regulator may have the right to impose conditions on approval and welcomes the fact that the sponsor also has an opportunity to comment.

ss108 – 112 – Cancellation of approval

Novartis agrees that the regulator may have the right to cancel an approval based on the grounds cited in s108 and welcomes the fact that the sponsor also has opportunity to comment.

Suspension of Approvals

Novartis notes that product approvals can be cancelled (ss108 – ss112), but not suspended. We suggest that the ability to suspend an approval should be maintained. It gives flexibility to resolve a temporary issue before an approval is resumed. Lifting a suspension of an approval offers a more reasonable timeframe and cost than if an approval were cancelled and a new application was submitted. We note that the Therapeutic Goods Administration in Australia have added the ability to suspend an approval. It was clarified at the Ministry of Health sector forums, that the mechanism to suspend a product approval exists through adding conditions on an approval (ss 105-107), which can be done on request of the sponsor or by the regulator after giving the sponsor opportunity to comment. For the reasons stated above, we believe a suspension mechanism is pragmatic. We seek confirmation that such a mechanism exists through ss105-ss107.

ss113 – Therapeutic products register

Novartis support the proposal to develop a Therapeutic Products Register (ss113) which contains a copy of the latest prescribing information and consumer medicine information for approved products. There are several points we seek clarification on. It is unclear whether the practice of assigning a registration number to the product (i.e. TT50 number) will continue under the new regulatory scheme. It is not clear whether only the address of the place of the responsible manufacturer would need to be included in the approval or if the approval will be required to list an extensive array of sites directly and indirectly involved in product manufacture, given the broad definition of manufacturer in ss31.

Novartis supports that information about all applications submitted to the regulator and all approved products is to be made publicly available, on a product register, which is routinely maintained by the regulator to ensure currency and accuracy. Withdrawals should however be kept confidential. This is consistent with the practice in other jurisdictions. The TGA for instance allows withdrawals without prejudice up until issuance of the Delegate's overview (i.e. prior to Milestone 6). This is particularly important when the regulator and sponsor disagree on the regulator's reasons for rejecting/not approving an application.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

ss114 – ss115 – Approval-exempt products

Novartis' understanding is that the regulator needs to have a sponsor (even for products that do not require an approval) so that they can contact someone in the event of any issue with the product. The sections regarding approval-exempt products (ss114-ss15) are unclear, and this raises several questions regarding them:

- (i) For a class of approval-exempt products, who would be liable for product quality/safety?
- (ii) If no one opts to sponsor a potential approval-exempt product, will the Crown or other entity be the sponsor?
- (iii) What is the process for the Crown to become a sponsor of a product?
- (iv) Would approval-exempt products be included on the proposed Therapeutic Products Register?

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

ss116-118 – Subpart 3 Obligations of sponsors

The scope of responsibility of sponsors appears to have widened significantly from the current legislation. The sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of quality issues, the sponsor cannot be held accountable for all activities after the product has left their control. There is responsibility that resides with the wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine. This section of the TPB seems to duplicate the intent of ss55, which places obligations on persons in the supply chain, who may not all be sponsors. The obligations should be limited to activities that those in the supply chain are licenced/authorised to perform.

Whilst we agree that sponsors should be accountable for complying with applicable obligations, we believe it would be unreasonable if the entirety of Part 8: Pharmacovigilance / applicable device regulations form part of the legislation. For context, in Australia only the following pharmacovigilance requirements are legislated: ICSRs reporting, SSIs reporting, pharmacovigilance contact person notifications and archiving of records.

ss119

Novartis concurs with the proposed legislation that Sponsors should not be responsible for approved products imported without consent

Additionally, these sections discuss the requirements for compliance with obligations and the penalties that apply to breaches. Details are lacking on what sponsor obligations for pharmacovigilance are tied to the penalties outlined in ss118(1) and ss118(2).

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

ss120 -122 – Protection of active ingredient information about innovative medicines

Maintaining a regulatory data protection period of 5 years seems at odds with the vision to future-proof legislation and seems inconsistent regulatory data protection for innovative veterinary medicines of 10 years made through the Agricultural Compounds and Veterinary Medicines Amendment Act 2016.

It should be noted that the EU which provides an 8-year period of data exclusivity, plus two years of marketing exclusivity (with a potential 1 year extension) and for orphan exclusivity. Furthermore, Canada also has a data exclusivity period of 8 years. Alternatively, Novartis would suggest that the regulatory data exclusivity of 5 years could reset at the time of the PHARMAC listing for innovative therapeutic products.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

ss123 What licence may authorise

Novartis agrees in general with the principle laid out in section ss123.

ss124 Content of Licence

While Novartis supports the concept that one licence may cover a broad range of activities involved in the running of a clinical trial, it is important that requirements and obligations are clearly specified in subordinate legislation including whether it is the sponsor of the trial or the investigators that seek the license.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

ss128 Criteria for granting licence

Ss128(1)(g) provides details about clinical trial licences. Either ethics approval, or exemption from a relevant ethics approval entity is required for any given trial. Novartis hereby expresses concerns that licence applicants may need to submit a significant amount of information to the ethics approval entity in order to allow a decision to be made that the trial does not need an ethics approval. It is unclear if applications not referred to the Health Research council will have the same quick timelines as those currently reviewed by HRC. It should be ensured that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g. observational trials, clinical audits). Appropriate rules and/or guidance are necessary to clarify which types of trials require ethics approval. Additionally, an efficient process needs to be implemented to provide timely certification that a trial does not require ethics approval.

ss130 Criteria for responsible persons

Currently, Medsafe will allow an overseas person to be listed on a licence provided there is a minimum of one New Zealand resident on the licence. The overseas person is usually a senior staff member (e.g a Regulatory or Quality manager) of the company where there is no resource for that company in New Zealand. This situation should continue to be permitted under the TPB. The number of employees in New Zealand of pharmaceutical companies is small, with many functions such as regulatory often based out of Australia or another country overseas. We submit that the drafting of the TPB must accept this commercial reality, noting that companies have appropriate controls in place to meet requirements. Furthermore, where a licensee is a body corporate, consideration should also be given to how they will demonstrate meeting the criteria for being a responsible person.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

ss131 What permit may authorise

ss131(1)(a) states that a permit can authorise a person to import a product without the sponsors consent.

We submit that this is an activity that needs to have very tight restrictions and controls on it. If this is not the case this would appear at odds with the policy intent of ss52 which is to prohibit parallel importation of therapeutic products.

Ss134(3)

We accept this section, provided that if the regulator is not satisfied that criteria will be met, that the applicant is provided with an opportunity to comment/opportunity to provide further information at the request of the regulator in order to meet criteria.

Ss135 Criteria for granting permit

Again, as in ss131 we submit that the granting of a permit needs to have very tight restrictions and controls on it. We support the explicit statement in ss135(b) that granting a permit must be "necessary or desirable in order to promote the purpose of the Act; and is consistent with the principles set out in section 4." Of particular importance to granting a permit would be ss4(a) "the likely benefits of therapeutics products should outweigh the likely risks associated with them". We seek further information on the intended situations where a permit would be authorised.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Ss136 Regulator may split application

We have concern regarding this section.

Specifically, ss136(2) gives the regulator discretion to assess the application together, or as discrete applications. We are concerned by the potential for inefficiencies to arise in the evaluation process that slow down application processing times. We seek further information on this aspect. We suggest that the process for splitting applications is explained clearly in guidance material, and that guidance material stipulates what types of applications would be likely to be split. There needs to be a clear policy in place by the regulator, so there is a shared expectation of applications the regulator should and should not split, and so that applicants may be able to prepare ahead of time an appropriate application so that it is processed as efficiently as possible.

ss137 Duration

A licence should remain valid for at least 3 years however Novartis believes that for reasons of practicality, licences for clinical trials should be for the expected duration of a particular clinical trial as identified in the trial's protocol.

Clinical trials are currently not regulated via licences and are unlike the activities that currently require a licence like pharmacy and wholesale. The proposed one size fits all approach is problematic. Further consideration, and specific engagement with the research sector is required to pragmatically regulate clinical trials

under a licencing system.

We suggest a similar approach to that proposed for conditional product approvals could be taken as in ss105-107, where product approvals do not generally have a maximum duration, but a duration could be set as a condition. If this approach to licences was taken, standard maximum durations for licences like pharmacy and wholesale could be specified in conditions set in rules, whereas a duration of a specific clinical trial could be set at the time of the licence application, based on the trial's protocol, or a date could be set for when further information is required for the trial licence to be continued. Our reading is that the mechanism for this approach to licences exists in ss139-141 but cannot be utilised because a maximum licence duration has been set in ss137 (i.e. ss137 appears to contravene ss139-ss141).

We reiterate that a three-year licence duration is impractical for clinical trials, and we recommend specific feedback is sought from the research sector on optimal mechanisms to maintain safe operation and delivery of clinical trials over varied time periods (rather than the proposed 3-yearly tick box approach).

Ss139 Regulator may impose conditions and ss140 Variation

Novartis seek further information on what changes will require a variation of a licence.

For instance, for a clinical trial licence will a change in the pharmacy or compounder of the medicine require a licence variation?

For all licences, would a staff change require a variation, or would the licence stipulate the job roles under the licence rather than a named person?

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

ss151 Death, bankruptcy, or insolvency of licensee or permit holder

ss151 details that if the licensee or permit holder dies, that the licence or permit is transferred to the executor or administrator of the estate, who has to notify the regulator of the event within 5 working days. We question the practicality of this process as we understand that an executor/administrator of an estate would often not be appointed within 5 working days of a death, let alone be in a position where they fully understand the assets within the estate and the action required to notify the regulator. It is therefore requested that a longer notification period be applied.

It is unclear what the consequence will be if the executor of the estate fails to notify the regulator within 5 working days. We note that the regulator would have the discretion to cancel the licence but would be required to give the licensee opportunity to comment, except in specific circumstances (ss144). We are concerned that the licensee death or failure to notify the death within 5 working days will result in a business continuity issue or the licence may lapse. There would be ethical and operational issues if a clinical trial had to be suspended as a result.

Furthermore, this clause would not necessarily be applicable for licensees or permit holders who are body corporates. We do not believe this one size fits all approach is practical. If the intent is that it is applicable to certain classes of controlled activities that are typically conducted by individuals (e.g. pharmacy), the TPB could be more explicit about this. For instance, the corresponding clause for product approvals (ss104) distinguishes between a product sponsor who is an individual, and a product sponsor that is an entity.

Paragraph 147 of the consultation document states that "...if a licensee or permit holder wishes to sell the business to which the licence or permit relates, the purchaser of the business must obtain their own licence or permit before they take over the business." This is quite a different position to that taken for product approvals (ss102) which will mean in the event of corporate mergers and acquisitions, a business may acquire the product approvals, but not the licence/permit(s) to import the product(s). We believe more consideration of this aspect needs to occur with further consultation with industry. The transfer of licenses or permits to another person/party needs to be a seamless process to ensure continuous supply of medicines in New Zealand.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

ss158 Responsible person must comply with regulations

ss158 requires the responsible person to comply with the requirements, in relation to the competency of workers in the licensee's business. At this stage it is unclear what the competencies are or how the responsible person is realistically able to comply with this requirement. Further clarification on this is sought.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

ss160 Regulator to monitor safety

ss160 allows the regulator to 'perform monitoring', with respect to safety monitoring. Novartis seek clarification if this would introduce the ability for the regulator to conduct regulatory inspections.

If so, the introduction of the power would require further vetting through industry consultation prior to implementation.

ss168 – ss171

We also seek clarification on whether "person" in these clauses relating to Directions orders and Product Prohibition orders extends to the sponsor or an individual only?

Ss178 Making regulatory order

ss178(2)(c)(i): mentions the “person who distributed the advertisement”. Clarification is sought whether “person” in this case also means the sponsor of the product being advertised. The definition of person in the TPB is currently unclear.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

The Bill links to the Search and Surveillance Act 2012 to provide the regulator with investigative powers. The regulator would have the following powers of entry:

- entry and search without a warrant (for routine monitoring & where there are concerns of non-compliance)
- entry and search with a search warrant (including dwelling houses & Marae)
- the right to inspect therapeutic products being imported.

The TGA can do this in the situation of a ‘for cause inspection’, however this power seems a little excessive for ‘routine monitoring’, unless of course this means that access cannot be prevented, in which case the powers we believe are similar.

Industry would need to be consulted in relation to the specific requirements. These should also be fairly aligned to other comparable agency requirements.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Ss197-199 Subpart 3 – Offences relating to regulator

In contrast to the Medicines Act 1981, there are different tiers of offences, depending on whether there is knowledge and/or recklessness as to whether the Bill is breached (i.e. while it is a strict liability offence, a more stringent penalty will be applicable where the contravention of the obligation was reckless, and an even more stringent one where the convention was done with knowledge). It will be a defence for any prosecution of an offence under the Bill if the defendant took “all reasonable steps to ensure contravention was not committed” (ss243). On that basis, it is considered that this provides adequate grounds to protect against unfair prosecution under ss197-199.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

ss200 Application for review of Regulator's decision

Novartis welcomes the proposal to have regulator's decisions in relation to product approvals, licences and permits reviewed through a new merits review process.

However, the proposed timeframe of 30 working days, in which the Sponsor is required to submit their application with any supporting data/justifications for review of a Regulator's decision, appear insufficient to allow for the appropriate consultation to take place within companies and to then prepare the application detailing the grounds for appeal. The 60 working days (i.e. approximately 3 calendar months) timeframe adopted by the TGA seems to be more reasonable. In any case, specific timelines should be included in the Act for both the regulator and Sponsor to ensure each party is held accountable to meeting their obligations in the process.

Furthermore, Novartis wish to clarify that in order for the applicant to respond to the regulator's decision, and apply for a review within the suggested timeframes, the regulator must provide their reasons for the decision at the time of notifying the person (as in ss208(b)(i)), rather than only advising the person that they are entitled to ask for a statement of reasons for the decision (as in ss208(b)(ii)).

Novartis wish to clarify that in order for the applicant to respond to the regulator's decision, and apply for a review within the suggested timeframes, the regulator must provide their reasons for the decision at the time of notifying the person (as in ss208(b)(i)), rather than only advising the person that they are entitled to ask for a statement of reasons for the decision (as in ss208(b)(ii)).

Ss201 Regulator to convene review panel

Novartis welcomes the proposal to have regulator's decisions in relation to product approvals, licences and permits reviewed through a new merits review process. We support the use of a convened review panel for this process, in replacement of the current review process under the Medicines Act which is conducted by a standing committee with a set membership. We agree that this will provide flexibility by allowing the membership of the review panel to be chosen based on the relevance of their expertise to the subject matter of each particular review.

We support the proposal to appoint three people (including a lawyer) who do not have a conflict of interest and who have not previously been involved in the decision. We welcome the proposal as we believe it will facilitate independent and unbiased review. Additionally, appointing subject-matter experts, people with appropriate knowledge, skills and experience, for the reviewable decision, is critical in ensuring there is a fair and equitable review of decisions.

As a separate comment, we ask the Ministry to provide evidence that the regulator will be able to convene a panel of appropriate, impartial subject-matter experts within a reasonable timeframe. We have concern that this will be difficult to achieve for highly specialist areas.

How will the Regulator secure relevant experts from within New Zealand (or from overseas)? e.g for medical devices decisions.

Furthermore, we note that there are no timeframes specified in the TPB for convening a review panel which we consider unacceptable. Please refer to our further comment on ss203 below.

Ss202 Procedure on review

We support the requirements specified in ss202(2) that the review panel must act independently and in accordance with the principles of natural justice. We support the specific reference made to the review panel meeting the principles of natural justice. This is important to state outright in the TPB, because there is minimal administrative detail provided in the Bill, in general, to otherwise provide assurance of a fair and transparent process being followed. This specific mention in ss202, ensures that the review panel is accountable to act fairly and in line with natural justice.

For similar reasons, we believe the same standard should be set for the regulator's decisions. We therefore submit that reference to the rules of natural justice should also be made in both the purpose and principles of the TPB (ss3 and ss4). To give effect to the principles of natural justice, it should also be defined in the interpretations section. Please refer to our response to question B1 for further information.

Ss203 Decision on review

There are no timeframes given for the review panel's process. Ss201, ss202 and ss203 do not specify any timeframe for convening the review panel, completing the review and notifying the applicant of the outcome, or even progress of the panel. Novartis requests that a timeframe equivalent to that suggested for review applicants in ss200 (i.e 30 or 60 working days), is specified in the TPB for review panel activity. It is prudent for each party, the regulator and sponsor/applicant, to be held accountable to act within pragmatic timeframes, thus facilitating timely review of decisions. Therefore, specific timeframes for the review process, for both the Regulator and the sponsor/applicant, should be stated in the TPB to ensure a reasonable and efficient process is maintained, and applications are not unreasonably held up. Businesses need a level of surety within which to operate and maintain source of supply. New Zealand, as a small country far away from major manufacturing centres needs to be cognisant of supply chain processes.

We have concern regarding the lack of specified timeframes in particular for reviews of decisions relating to refusals to revoke or vary regulatory orders. With no timeframes given for convening the review panel or that review panel providing a decision, the sponsor may be required to comply with the regulatory order (that they are seeking a review of), while waiting for the review panel to convene. The benefit of seeking a review will be lost if timeframes mean that the sponsor has already complied with the regulatory order (e.g conducting a recall).

We ask that:

- (i) changes are made to the Bill that provide timeframes for the review panel's activities (refer to details in our response above);
- (ii) there be an ability to request a panel to sit in urgency. For example, when a sponsor applies for a review of a decision to refuse to revoke a recall order because there is insufficient evidence that a recall is required. The applicant/sponsor would act to provide their application and supporting data/rationale under urgency. Where such a request is made, will the regulator commit to acting under urgency?; and
- (iii) if a decision is not upheld (i.e. the panel recommends a different decision be made), what steps will be taken by the regulator to compensate for any loss of supply, or the loss of product confidence of consumers, healthcare practitioners and manufacturers that has occurred?

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

Novartis supports the recognition of decisions from other comparable regulators for a more efficient registration process in New Zealand. The proposed bill (ss207) states that the regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. This is both logical and consistent with current practice for abbreviated submissions, as well as international regulatory practices.

This pathway should be available for all application types and attract lower fees. The evaluation time advantage should be made clear to the Sponsor and should be adhered to by the regulator. Predictable milestones comparable to other regulatory agencies would also be recommended as the current evaluation process and estimated approval is unpredictable. Clear and transparent timelines are paramount in being able to monitor progress, which is lacking under the current regulatory system. The consultation document only refers to targeted timeframes at this stage which provides no change from the current situation. In order to meet the principle of timely availability of therapeutic products (ss4(b)(ii)), the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance. There is no detail given in the TPB or in the consultation document regarding how this will be ensured. Therefore, we are seeking assurance that this principle in the TPB will keep the regulator accountable to making decisions in a timely manner. Novartis seek assurance that there will be appropriate accountability measures both within the regulator and external to the regulator to ensure appropriate timeliness is a lasting feature of the new scheme. We suggest that maximum evaluation timeframes are stipulated in regulations

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Novartis note that if the regulator accepts an undertaking, it must make publicly available the undertaking, its reasons for accepting it, any variations and notification of an undertaking ceasing to be in force (ss224). This could cause concern, as it makes an alleged contravention public in a situation where there has been no admission of guilt by the relevant party.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

ss233 – Penalties for Offences

Novartis request that the a rationale for the proposed penalty amounts, and the information used to decide on these amounts, be provided.

Novartis are concerned by the significant proposed increase to the penalties. Compared to similar modern legislation (Food Act 2016, Agricultural Compounds and Veterinary Medicines Act 1997, Hazardous Substances and New Organisms Act), the penalties proposed by the TPB are very high. The prison sentences are at the higher end of the spectrum, and it seems that the TPB imposes the highest fines out of the comparable modern legislation for both individuals and for companies. Therefore, we seek rationale for these proposed penalty amounts, and that the Ministry of Health provide the information that was taken into consideration when calculating these.

Novartis request that the Ministry of Health provide evidence that the penalties are at the appropriate level, and that they will be applied proportionately to given breaches, not punitively. Additionally, appropriate policies must be set to ensure responses to non-compliance are commensurate to the seriousness of the breach, and they are utilised to protect personal and community health as per the purpose of the TPB (ss3), not as a punitive tool.

Ss237 – Order to pay Regulator's expenses of mitigating risk harm

We submit that for the definition of "caused harm or a risk of harm" in ss237(3), the definition that conduct that indirectly "causes harm" (ss237(3)(i)) is a low threshold for paying the regulator's expenses. It is requested that this be qualified – as like ss237(3)(ii), (iii) and (iv) which are given the word(s) "significant(ly)". We suggest wording such as "causes material harm" or "causes harm that is not insignificant" which would be on the basis of reasonableness.

Subpart 4 – Attribution of liability and defences

Conduct of senior managers, workers and agents within the scope of that person's actual or apparent authority is attributed upwards to the relevant entity (ss239). As a reciprocal measure, if a body corporate contravenes the Bill then this will be attributed down to its senior managers (ss242). The Bill defines "senior managers" to include people such as directors, chief financial officers and chief executives (ss48). This is not an approach that appears to be taken consistently across New Zealand legislation and appears to be a rather stringent standard.

Defences

We do seek further information on some aspects. It is noted that Band A offences relate to offences that have a real potential to cause harm (paragraph 198 of the consultation document).

Should there be a defence that there was no real potential to cause harm by the conduct? The penalty (up to \$300,000) appears high for a strict liability offence.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

No comments provided

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

It is intended that cost recovery by way of fees or charges specified in the regulations be implemented as part of this reform. Whilst Novartis is not opposed to a cost recovery model, it is expected that the influx of capital will help the regulator provide greater transparency, adhere to predictable statutory milestones and embrace global dossier submission standards such as eCTD via submission portal.

In order to meet the principle of timely availability of therapeutic products (ss4(b)(ii), the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance. There are little details given in the draft bill or in the consultation document regarding how this will be ensured. We suggest that maximum evaluation timeframes be stipulated in regulations.

We support the approach of making the Therapeutic Products Bill (TPB) principles-based with operational details of the scheme in subordinate legislative instruments. We agree with the rationale that this will enable efficiencies in regulation and give flexibility for regulation to be maintained, to change over time to meet future needs and keep up to date with international best practice.

ss267 Consultation

We support the approach of making the Bill principles-based and having operational details of the scheme in subordinate legislative instruments. We agree with the rationale that this will enable efficiencies in regulation and give flexibility for regulation to be maintained, to change over time to meet future needs and keep up to date with international practice.

However, we wish to emphasise that this approach to the drafting of the TPB and consultation on the TPB creates a high level of uncertainty for stakeholders. There is a level of information asymmetry present, where stakeholders know significantly less about the intended operation of the new regulatory scheme, than the Ministry of Health knows. This has created difficulty for stakeholders providing feedback on the exposure draft of the TPB who do not have access to the full information. To alleviate this problem, we strongly recommend to the Ministry of Health that they have a much higher level of targeted, quality engagement with stakeholders during the drafting and consultation phases of the subordinate legislative instruments. The Ministry of Health has admitted they have not engaged sufficiently with some sector groups (e.g cell and tissue sector) prior to this consultation on the exposure draft of the TPB. To rectify this, the Ministry of Health should commit to forming working groups of sector groups affected by the TPB to facilitate drafting of regulations that are workable and fit-for-purpose. We

strongly recommend a consultation that provides sufficient time and opportunity for stakeholders to comment. We recommend formation and engagement with a medicines industry working group to provide insight and advice on the development of practical regulations.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

No comments provided

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

No comments provided

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

No comments provided

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

No comments provided

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

No comments provided

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Novartis understand that the approach to major changes to products, is to ensure that different versions of the same product (i.e original products vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposed process described in C1, paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued. It was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019 that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors as PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We do not believe the practicality of the major changes processes has been considered in the Bill.

A solution would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product. This type of approach is used by the TGA - TGA Grouping.

For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s 78)." We believe this would be an opportune scenario to issue a "use of current stock" notice. We recommend that this solution is further discussed with pharmacists and practitioners.

In cases where the sponsor did wish to continue to have both versions of the product approved, they could nominate to receive a new approval and TT50 number for the changed product.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Novartis note that this was discussed at the Medicines forum on 18 March 2019 that the proposed medicine category classification may create confusion for those

Sponsors working across both territories, Australia and New Zealand, as the proposal seems to be the exact opposite of the Australian classification. For instance a Category 1 prescription medicine in NZ would be a Schedule 4 Medicines in Australia.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Under transition arrangements, it is stated that a 3-12-month period will be allowed for applications for approvals and licences. Novartis strongly believes (from previous experiences) that this is inadequate and that a significant backlog is likely to result from an influx of applications therefore impacting submission processing time of all routine applications. Consideration should be given to extend the transition arrangements.

Transitional Arrangements

Novartis have some concern regarding the transitional arrangements (Schedule 1) and seek further information. We note that the policy intent is to allow the new regulator to efficiently deal with pending matters as soon as possible. We acknowledge the arrangements that will provide temporary approvals, licences and permits to applicants.

- What plans have been made to ensure the efficient processing of the large volume of applications?
- How will it be ensured that the regulator is sufficiently resourced to process the applications made in the transition period after the commencement date, as well as during normal business?
- What provisions does the regulator have for ensuring capacity and resources, including immediate access to qualified experts for evaluations?
- How long is it expected to take for the regulator to complete the transition? (i.e to replace all temporary approvals, licences and permits with permanent equivalents)

We note in the consultation document that "the new scheme would give the regulator greater flexibility to establish a number of approval pathways. These could be tailored to suit, for example, products with a long approval history in one or more recognised overseas jurisdictions... We envisage this flexibility would also be likely to encourage sponsors of many unapproved medicines currently supplied under Section 29 of the Medicines Act 1981 to seek approval for those products." We support the suggested approval pathway for products with a long approval history in one or more recognised overseas jurisdictions and the general flexibility intended to facilitate a range of product approvals.

Novartis have a number of products which it supplies under S29, and understand the intention for these medicines is they will either be available to patients via the Special Clinical Needs Authority scheme, or they will first need to receive a product approval under the new scheme. Our concern is that receiving these approvals will take a long time considering the number of medicines and device approvals that will be submitted, and the number of licence applications that will be received during the transition period. This would have an impact on clinicians and patients.

We do not see any specific transitional arrangements being provided for the section 29 medicines and we seek further information on this. We note on page 93 of the consultation document that "As a wholesaler, you would only be able to import an unapproved product if your licence specifically authorised this (s 51(1)(b)). In most cases, the import would be requested by a pharmacist or health practitioner prescriber because a doctor had issued a SCNSA. For some medicines, however, it may be necessary for the wholesaler to maintain a small stockpile of the product, so it is available for immediate release once a SCNSA has been issued. If so, the licence would authorise such stockpiling. This approach might be used, for example, for medicines that must be available urgently."

Will the transitional arrangements allow a wholesaler to apply for a temporary licence to continue the import of medicines currently supplied by the section 29 of the Medicines Act? We expect there will be a number of medicines (e.g anaesthetics) which will need to be stockpiled and have continuous import until they receive a product approval, or they are requested via the SCNSA scheme

Question C4 - Please provide any comments on the approach to post-market controls.:

Novartis agrees in principle with the measures proposed in the Bill and welcomes the plan to adopt ICH requirements across Adverse Event (AE) Management systems, Adverse Drug Reaction (ADR) reporting, Risk Management Plan (RMP) and PSUR/PBRER reporting.

The Bill itself is understandably low on the details of the enforceable requirements, and therefore the details are expected to be addressed in the resultant regulations. Given the breadth of the reforms, in the context of the separation of the in scope product to separately address Medicines (including cell tissue products and radiopharmaceuticals), Active Medicinal Ingredients (AMI) (including unapproved compounds), Devices and the new "Type 4" (future) products, we request that there be an adequate period of consultation for those new (and potentially numerous) regulations. This will allow for a thoughtful process of introducing new and/or amended requirements, to ensure those changes will be to the benefit of the safety of patients, and not unnecessarily onerous on either Medsafe or Industry.

The following points would however require clarification and consideration:

- Adoption of ICH Guidelines: In adopting the ICH Guidelines for Pharmacovigilance, will Medsafe continue to apply (in a legally enforceable manner) Part 8 (Pharmacovigilance) and Part 11 (Clinical trials – regulatory approval and good clinical practice requirements) of Guideline on the Regulation of Therapeutic Products in New Zealand. We are in favour of the PV requirements that are currently furnished in Part 8 and Part 11 of Guideline on the Regulation of Therapeutic Products in New Zealand and welcome further harmonisation of PV requirements to align with the Australian requirements
- Pharmacovigilance Contact Person: will there be a requirement introduced for the PV contact to be a NZ resident. Currently this person can be based overseas as long as they are contactable during NZ business hours. As the location of primary PV activities conducted for NZ for many companies is not within NZ, the introduction of this requirement would require significant (potentially prohibitive) amendment to the operating model for the PV department without any foreseeable benefit to patient safety.
- Risk Management Plans (RMP): Will Medsafe accept the EU RMP as is? We would welcome a continued, pragmatic approach, i.e. to accept the EU RMP rather than introducing country-specific requirements such as a New Zealand specific Annex. We suggest these may only be considered for higher risk molecules where Medsafe and the Sponsor agree there may be unique risks to New Zealand patients that cannot be adequately mitigated by measures described the EU-RMP.
- Electronic Submissions: It would be beneficial for both Medsafe and industry should Medsafe introduce capacity for electronic ICSR reporting, for example via E2B functionality. Our experience with the TGA and in other jurisdictions indicates that this would be an efficiency gain for both parties.
- PSMF: We would not seek to have a country specific Pharmacovigilance System Master File (PSMF), as the benefit to both sponsor and Medsafe to have a country specific requirement, is insufficient when reviewed in the context of the company maintaining a companywide PSMF and the additional resources required to maintain and review such a document
- PV inspections: Will the inclusion of the allowance to enter premises without a warrant, enable the introduction of PV Inspections? If this is planned, we ask that Medsafe consider the rationale for commencing this approach, in the context of the ongoing requirements for PV inspection of many other equivalent regulators,

including Australia (by TGA). We would also ask for further details on the planned approach to introducing such a program, including the risk-based framework that will be adopted for such inspections. Consideration should be given to first conducting a pilot program to ensure an aligned understanding between the Health Authority and sponsors with respect to the interpretation and application of PV requirements. In addition, information on the funding mechanism to support Medsafe's PV inspection program should be articulated.

- PBRER/PSURs: What requirements would be enforced in relation to submissions of these periodic documents? Novartis suggests that these may only be required for higher risk molecules.
- Transition period: what is the planned approach to the transition period to the new Act and associated regulations? We would request a reasonable period of time to allow for the adoption of any changes, considering the potential necessity to update complex PV systems that will require alignment of both local and global stakeholders.
- Funding: will there be plans for the agency to introduce a model of fees or charges to fund any of the additional activities associated with modernising Medsafe's PV activities? Any additional costs imposed on industry should be in line with the New Zealand government cost-recovery guidelines and subject to public scrutiny

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Refer to response to Question B2.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

Novartis supports in principle the intent of the new hawker scheme which would enable licensees to have secure online access to its database to enable them to maintain an up-to-date record of their own mobile staff and their territories and products. This approach will improve efficiencies for both the regulator and companies.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Overall, Novartis considers appropriate the proposal to regulate cell and tissue products with similar requirements for quality, efficacy and safety applying to advanced therapy medicinal products (ATMPs) in Europe. Similarly to the process in the EU, we would recommend that a classification committee be established to allow sponsors to discuss the level of requirements that would apply on a case by case basis.

However, the directives in the EU covering collection of cellular starting materials are not considered suitable for New Zealand. Novartis believes raw material collection for further processing should be overseen by the finished product manufacturing site(s). This would ensure there are no additional regulatory requirements in place around collection. The quality standard and laboratory testing accreditation at a collection site should be aligned to national guidelines such as those used at bone marrow transplant centres. In essence, Novartis does not believe it necessary to adopt Foundation for the Accreditation of Cellular Therapy (FACT) or Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) accreditation or manufacturing licenses for the collection of starting raw materials such as leukapheresis.

Also Novartis would like to draw the regulators attention to the topic of Hospital exemptions. In Europe it appears that under Hospital exemptions ATMPs are able to completely 'bypass' the authorisation process which may not be a desired outcome of the regulations.

The continuity of supply of products to patients is significantly important. The importation and supply of products that are not therapeutic products before commencement of the Bill, but that would be therapeutic products requiring an approval after commencement, should continue while applications for their approval were being considered.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Novartis understand that the approach to major changes to products is to ensure that different versions of the same product (i.e. original products vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposed process described in C1, paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued. It was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019 that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors.

PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We do not believe the practicality of the major changes processes has been considered in the Bill.

A solution would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product. This type of approach is used by the TGA - TGA Grouping. For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s 78)." We believe this would be an opportune scenario to issue a "use of current stock" notice. We recommend that this solution is further discussed with pharmacists and practitioners.

In cases where the sponsor did wish to continue to have both versions of the product approved, they could nominate to receive a new approval and TT50 number for the changed product.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Novartis agrees in principle with the measures proposed in the Bill and welcomes the plan to adopt ICH requirements across Adverse Event (AE) Management systems, Adverse Drug Reaction (ADR) reporting, Risk Management Plan (RMP) and PSUR/PBRER reporting.

The Bill itself is understandably low on the details of the enforceable requirements, and therefore the details are expected to be addressed in the resultant regulations. Given the breadth of the reforms, in the context of the separation of the in scope product to separately address Medicines (including cell tissue products and radiopharmaceuticals), Active Medicinal Ingredients (AMI) (including unapproved compounds), Devices and the new "Type 4" (future) products, we request that there be an adequate period of consultation for those new (and potentially numerous) regulations. This will allow for a thoughtful process of introducing new and/or amended requirements, to ensure those changes will be to the benefit of the safety of patients, and not unnecessarily onerous on either Medsafe or Industry.

The following points would however require clarification and consideration:

- Adoption of ICH Guidelines: In adopting the ICH Guidelines for Pharmacovigilance, will Medsafe continue to apply (in a legally enforceable manner) Part 8 (Pharmacovigilance) and Part 11 (Clinical trials – regulatory approval and good clinical practice requirements) of Guideline on the Regulation of Therapeutic Products in New Zealand. We are in favour of the PV requirements that are currently furnished in Part 8 and Part 11 of Guideline on the Regulation of Therapeutic Products in New Zealand and welcome further harmonisation of PV requirements to align with the Australian requirements
- Pharmacovigilance Contact Person: will there be a requirement introduced for the PV contact to be a NZ resident. Currently this person can be based overseas as long as they are contactable during NZ business hours. As the location of primary PV activities conducted for NZ for many companies is not within NZ, the introduction of this requirement would require significant (potentially prohibitive) amendment to the operating model for the PV department without any foreseeable benefit to patient safety.
- Risk Management Plans (RMP): Will Medsafe accept the EU RMP as is? We would welcome a continued, pragmatic approach, i.e. to accept the EU RMP rather than introducing country-specific requirements such as a New Zealand specific Annex. We suggest these may only be considered for higher risk molecules where Medsafe and the Sponsor agree there may be unique risks to New Zealand patients that cannot be adequately mitigated by measures described the EU-RMP.
- Electronic Submissions: It would be beneficial for both Medsafe and industry should Medsafe introduce capacity for electronic ICSR reporting, for example via E2B functionality. Our experience with the TGA and in other jurisdictions indicates that this would be an efficiency gain for both parties.
- PSMF: We would not seek to have a country specific Pharmacovigilance System Master File (PSMF), as the benefit to both sponsor and Medsafe to have a country specific requirement, is insufficient when reviewed in the context of the company maintaining a companywide PSMF and the additional resources required to maintain and review such a document
- PV inspections: Will the inclusion of the allowance to enter premises without a warrant, enable the introduction of PV Inspections? If this is planned, we ask that Medsafe consider the rationale for commencing this approach, in the context of the ongoing requirements for PV inspection of many other equivalent regulators, including Australia (by TGA). We would also ask for further details on the planned approach to introducing such a program, including the risk-based framework that will be adopted for such inspections. Consideration should be given to first conducting a pilot program to ensure an aligned understanding between the Health Authority and sponsors with respect to the interpretation and application of PV requirements. In addition, information on the funding mechanism to support Medsafe's PV inspection program should be articulated.
- PBRER/PSURs: What requirements would be enforced in relation to submissions of these periodic documents? Novartis suggests that these may only be required for higher risk molecules.
- Transition period: what is the planned approach to the transition period to the new Act and associated regulations? We would request a reasonable period of time to allow for the adoption of any changes, considering the potential necessity to update complex PV systems that will require alignment of both local and global stakeholders.
- Funding: will there be plans for the agency to introduce a model of fees or charges to fund any of the additional activities associated with modernising Medsafe's PV activities? Any additional costs imposed on industry should be in line with the New Zealand government cost-recovery guidelines and subject to public scrutiny

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

The continuity of supply of products to patients is significantly important. The importation and supply of products that are not therapeutic products before commencement of the Bill, but that would be therapeutic products requiring an approval after commencement, should continue while applications for their approval were being considered.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

The continuity of supply of products to patients is significantly important. The importation and supply of products that are not therapeutic products before commencement of the Bill, but that would be therapeutic products requiring an approval after commencement, should continue while applications for their approval were being considered.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

The ability to have one licence to cover a range of activities involved in the running of a clinical trial is broadly supported, however it is important that requirements and obligations are clear in subordinate legislation including:

- whether it is the sponsor of the trial or the investigators that seek the license
- license duration - 3 years is too short for many clinical trial activities. Would it be possible for a clinical trial license to be granted for longer rather than relying on extensions?

Clarity around requirements of when a licence can cease is also requested ie. is the licence required during treatment phase only or until all activities in the clinical trial have completed and clinical site is closed, or until the completion and reporting of the trial (please take into account that a study can complete in New Zealand but continue in other countries).

Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current clinical trial approval process concern remains that the licence cannot be issued until the ethics approval is granted and what impact this may have on timelines.

As a further point, it is unclear if applications that do not require ethics approval will have the same quick timelines as those currently. It is imperative that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g. observational trials, clinical audits).

Please refer to our response to questions B18-B22 for further comment.

It is also requested to align the clinical trial terminology with international terminology and definitions (i.e. ICH GCP definitions), in order to avoid confusion both locally and internationally.

We have some additional comments on some specific aspects:

Exporting biological samples (blood/serum) and tissues

We couldn't find reference to provisions for the export of samples or tissues derived from clinical trials (e.g. for testing, storage). We seek assurance that sensible provisions are in place, such as an authorisation to do so as part of approval of clinical trials.

"The regulator also has the power to monitor trials and audit Clinical trials sites." (paragraph 422 of the consultation document)

This is currently being proposed by the TGA under consultation. A major concern is how outcomes of such activity are reported to ensure data quality reputation (which is currently high) remains intact. We seek further information/detail about the intentions.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

With regards to section 424, trials that have been approved by the Director-General of Health under section 30 of the Medicines Act 1981 would automatically be covered by a temporary licence, which would stay in force for at least 12 months. Novartis would suggest that in the regulations or rules the meaning of "12 month" be clarified. It is unclear whether this only relates to the NZ trial duration or, in the event of a global study, the duration of the study in all participating countries?

Additionally, clarification is sought whether the 12 month period includes observational phases (e.g. post-trial survival follow up)

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Novartis supports that there must be provision in the Bill for the supply of an unapproved product.

It is important that requirements for supply via the proposed mechanism are clear in the regulations, including:

- Responsibilities for Adverse Event reporting
- Requirements for notifying local sponsor of supply
- Provisions for a cross-over period should an unapproved medicine supplied under a SCNSA become approved
- Under what circumstances wholesalers are able to have on hand a small stockpile of unapproved medicines ("urgently needed" needs to be defined, as does "small")

- Measures of control of products imported by "buyers' clubs" and/or healthcare professionals bulk importing unapproved medicines.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

We support the intent of the new hawker scheme which would enable licensees to have secure online access to its database to enable them to maintain an up-to-date record of their own mobile staff and their territories and products. This approach will improve efficiencies for both the regulator and companies.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

No comments provided

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

1. Novartis New Zealand welcomes the fact that the status quo regarding direct-to-consumer advertising (DTCA) of prescription medicines is maintained under the TPB, and we note the enhanced range of enforcement options and higher penalties that would be available for advertising breaches.

2. While Novartis New Zealand is supportive of the advertising requirements proposed in the TPB, our view is that the regulator's range of enforcement tools (i.e. penalties, infringement fines, and advertising remediation orders) will rarely be required for advertising of prescription medicines. Our view is grounded on existing and historic data and experiences of all parties within the current government regulation, co-regulation and self-regulation environment. All of which has provided stringent pre-publication control on the content and quality of DTCA, and remediation if required.

3 DTCA by the prescription medicines industry is currently well-regulated from both a government regulation (see paragraphs 5 -7 below), and an independent co-regulation perspective by the Therapeutic Advertising Pre-vetting System (TAPS) in conjunction with input from Medsafe (see paragraphs 4 and 8 below). The prescription medicines industry via the Medicines New Zealand Code of Practice, and the Advertising Standards Authority (ASA) via the Advertising Standards Code and Therapeutic and Health Advertising Code add a further level of self-regulation (see paragraphs 9 and 10 below).

4 The current independent review process, via TAPS, of advertisements for prescription medicines ensures that promotional claims are accurate and substantiated by quality references, and that all information is consistent with the Data Sheet and Consumer Medicine Information documents, both of which are approved by Medsafe. These are tools to facilitate the protection of consumer and community health. In addition, TAPS has regular contact and discussion with Medsafe to ensure that advertising is compliant with the relevant legislation.

5 New Zealand has strong and effective legal requirements that control the marketing and advertising of prescription medicines. Relevant existing statutes include the Medicines Act 1981 (which will be superseded by the proposed legislation), the Commerce Act 1986, the Fair Trading Act 1986, the Misuse of Drugs Act 1975, the Consumer Guarantees Act 1994, the Privacy Act 1993.

6 The Medicines Act 1981, and the proposed legislation, establishes the basic legal guidelines for DTCA of therapeutic products, devices and services. The Medicines Regulations 1984 lay down more detailed requirements regarding the inclusion of statements in medicines advertising about authorised uses, appropriate precautions and contraindications. It is certain that the future regulations, yet to be generated under the proposed legislation, will also make clear the requirements, thus protecting personal and community health.

7 The Commerce Act 1986 establishes the legal framework for fair competition and the environment within which prescription medicine advertisers have to do business. The Fair Trading Act 1986 legislates against unfair and misleading advertising. The other Acts mentioned previously (see paragraph 5 above) also have bearing on how pharmaceutical companies market and sell prescription medicines.

8 While therapeutic products, due to their nature, do require a reasonable level of government regulation, independent co-regulation also brings public policy or "good government" advantages. This is true both in adopting and in enforcing standards and protecting public and community safety around promotion. For example, over 10 years ago, after safety concerns over Vioxx (a Cox-2 inhibitor) were raised, the New Zealand pharmaceutical industry agreed to immediately remove all Cox-2 inhibitors advertising after discussions and consultations with TAPS, the ASA and in consultation with Medsafe. This is a good example of where both self- and co-regulation work together with the Government's regulation system.

9 Additionally, the industry self-regulation via the Medicines New Zealand Code of Practice sets the industry standard for marketing of prescription medicines and associated promotional activities. It defines and ensures high standards of conduct that match those required by law. Acceptance and observance of the Code is a condition of membership and companies must comply with both the letter and spirit of the Code. Breaches of the Code around DTCA are determined by an independent Code of Practice Standing Committee that can impose sanctions ranging from the suspension of the advertisement or marketing practice to a fine of \$80,000.

10 The ASA's Therapeutic and Health Advertising Code also requires advertisers to comply with the Medicines New Zealand Code of Practice and as such captures any non-Medicines New Zealand pharmaceutical companies.

11 The evidence that all forms of current regulation highlighted above are effective for DTCA is seen in the extremely low number of complaints made to ASA for

prescription medicines advertising. It is noted that complaints to the ASA can include aspects of consumer safety, lack of clarity and false or misleading statements. Interestingly, over the past 7-year period out of a total 5446 complaints received only 19 (0.45%) were regarding prescription medicines and only 2 of those complaints were upheld as bona fide issues requiring remediation, which were actioned by the advertiser.

In conclusion, while we are supportive of continued government regulation and enforcement of DTCA for prescription medicines, we note that this should not be in lieu of the continued mechanisms already established independent of the regulator. We further note that all regulatory systems together will continue to maintain the quality and content of all prescription medicine DTCA to ensure that both the purpose and principles of the proposed legislation are upheld and followed.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Novartis New Zealand's strongly held view is that regulated direct-to-consumer advertising (DTCA) of prescription medicines should continue to be permitted.

We note that the purpose of the TPB described in ss3 is to "...protect personal and community health". Therefore, in order to ban DTCA a large body of empirical evidence must be delivered to indicate that the current practice of DTCA in some way breaches that purpose. There is, however, no significant robust evidence to indicate that the personal and community health is at risk, and so we believe that the well-regulated DTCA of prescription medicines should remain in force given all the benefits it provides.

We note that empirical New Zealand-based evidence overwhelmingly concludes that regulated DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. It does not create any personal or community health issues

All prescription medicines advertised by DTCA are registered with Medsafe (the current Regulator). Medsafe reviews the scientific dossiers and confirms the safety and efficacy of the medicines. This means that all prescription medicines advertised by DTCA are regulator-registered medicines and adhere to a core principle of the proposed regulation - that the "likely benefits of the therapeutic products should outweigh the likely risks associated with them". Therefore, this set of prescription medicines not only meet this principle but also meet the purpose of the proposed legislation of assuring public safety by regulator oversight.

Furthermore, in comparison to the vast quantity of un-regulated health information available on the internet, DTCA of prescription medicines comprises only a small percentage of advertising readily available to patients. The focus of any regulation it seems should not be on banning the already well-regulated DTCA of prescription medicines, but on the un-regulated internet sites and activities which represent a clear risk to both personal and community health

It is clear that interest groups on either side of the DTCA debate hold their own views, yet data and analysis of studies and surveys on consumers (who are the audience and focus for DTCA) seem to have no major concerns with the practice and indeed express concern for if the practice of DTCA were to be banned. No major issues have been highlighted in a range of studies and surveys.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4U8-E

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:04:44

Submitter profile

What is your name?

Name:

Noor Hassan

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Dispensing is defined incorrectly here . Dispensing is NOT just the supply of the medicine . A pharmacist defines dispensing as the whole process , of checking the clinical concerns of the patient , their history and what else is relevant , as well as the preparation of the medication for the patient , the correct labelling , being relevant to the patient and advising the patient on the medicine and how to take it etc . This is not a process for some computerised robot.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

The supply of medicines between pharmacies is fine. It can get better patient outcomes and cost savings

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

In emergencies and in small quantities

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Agree with the proposal

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Do not agree . We are too small a market for things like vending machines.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

I do not agree with dispensing at a rest home facility. Pharmacies need to dispense medicines in their dispensaries.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Short term emergencies ok

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Agree.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Keep it like it is . The idea of seperating the functions is wrong and a recipe for disaster.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Safest , best option and will give the best patient care .

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

If open ownership, there is no effective control . There is never enough resource to audit properly . Owners put too much pressure on their employees - pharmacists , at the expense of patient safety and are driven soley by profit .

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Yes . It is not the right way to go .

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

In emergencies

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No . There needs to be an independent check , for patient safety . We see many errors daily . If the prescriber does not pick these up , it would be very dangerous ,if they then dispensed as well. A real high risk .

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

NO. The Dr's and other practitioners are with their patients , in private rooms and would have no control on what was happening.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that

medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Yes

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Keep it as it is

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G48C-V

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:25:37

Submitter profile

What is your name?

Name:

Podiatrists Board (Annabel Whinam, Registrar)

What is your email address?

Email:

What is your organisation?

Organisation:

Podiatrists Board of NZ

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

Regulatory Authority

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

Response ID ANON-DPZ8-G48B-U

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:32:30

Submitter profile

What is your name?

Name:
Ivan Wong

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Optimus Healthcare Ltd

Submitter Profile (tick all that apply)

Active ingredients

Medicines, Veterinary medicines

If you select DHB, please state service area:

Other health practitioner (please comment)

If you select 'Other', please comment below::
Director, Retired Pharmacist

If you selected 'Other' please comment::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially don't support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Some health practitioners specialise in a clinical specialty whereby a number of therapeutic medicines used are regarded unapproved (off-label). Requiring an application for SCNSA for each occasion will prove time consuming and may possibly impart delay to time sensitive treatments.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Requirement by a veterinarian to seek a SCNSA for each unapproved medicine will be onerous.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Response ID ANON-DPZ8-G417-9

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 14:36:29

Submitter profile

What is your name?

Name:

Pamela Low

What is your email address?

Email:

What is your organisation?

Organisation:

iNova Pharmaceuticals

Submitter Profile (tick all that apply)

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

No specific comments on this section of the proposed Bill - all principles are aligned with International regulatory requirements .

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Generally the definitions and meanings are aligned with those currently accepted for use in other territories.

However, confusion may be caused with respect to the terminology adopted regarding the (legal) manufacturer of a medical device. When it comes to medical device terminology and requirements to prevent confusion and unwitting non-compliance, given that most of the proposed amendments with respect to medical devices are harmonization with the EU and Australia, that the terminology and requirements with respects to legal manufacturer and sponsor of devices also be made consistent.

Additional clarification would also be appreciated with respect to the terminology and requirements around 'Standing Orders', as this has the potential for misunderstanding.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

No specific comments with respect to product approval controls, however, care should be taken that the controls proposed to not add significant regulatory burden/time in instances where unapproved products require to be imported for seriously ill patients.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Greater clarity is required with respect to when a licence or a permit are required, how long these are permitted to be in place for.

Greater clarity should also be provided with respect to what is required from Supply Chain personnel with respect to the packaging and labeling of the product (as outlined in ss 55).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

No comments regarding this section

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

No comments regarding this section

Question B7 - Please provide any comments on the authorisations for health practitioners :

See previous comments with respect to not impinging upon the ability to source unapproved medicines, where deemed absolutely necessary, for specific patients.

It will be easier to comment on the proposals when the underlying framework is available for review and comment.

Will the proposals with respect to SCNSA be open to interpretation and stymie physicians ability to use clinical judgement?

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

No specific comments with respect to this at this time, although more detail with respect to how this would be managed and, if necessary, policed would be helpful.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

No specific comments

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

No specific comments

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

No specific comments

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

No specific comments

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Additional detail needs to be provided with respect to how the details with regards to approvals etc would be managed and coordinated. At the present time the proposals provided are broadly consistent with International regulatory requirements and schemes.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

No specific comments - additional detail regarding how this will operate, as will likely be provided in the Regulations and Rules is required.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

No specific comments - additional detail is required.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Consideration should be given as whether the definition of Sponsor is too restrictive and would cause Sponsors who only have limited business in New Zealand and thus work through a third party etc difficulties.

In general the conditions set out for Sponsors appear reasonable. It would be difficult for Sponsors to be responsible for product quality throughout the entire Supply Chain if, for example, product is stored incorrectly, however. Consideration should be given to how this could reasonably be managed.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

No specific comments

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

There is confusion with respect to when a licence versus a permit might be required as the criteria appear to overlap . More consideration/detail should be provided regarding this.

Generally what is proposed with respect to the content, effect and grant of licences seems appropriate. More detail with respect to the mechanisms by which this scheme would be managed would be ideal.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Generally what is proposed with respect to the grant of licences etc seems appropriate. More detail with respect to the mechanisms by which this scheme would be managed would be ideal.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

See previous comments with respect to licences, where there is a lack of clarity with respect to when a licence or a permit may be required, as there is some overlap.

More detail is required with respect to how such scheme would practically be managed to ensure that it can run quickly and efficiently.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Consideration should be given to a formal simplification of the application process in the event that a licence or permit is being simply renewed, without a change in scope.

See previous comments with respect to the lack of clarity between a licence and a permit, specifically with regards to duration - if a permit is intended for emergency situations, why would a 2 year approval be required? The difference between a 3 year licence and a 2 year permit appears limited and not aligned with the scope.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

No specific comments.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

The proposals as currently provided appear reasonable. Attempts should be made to ensure that any employee who reports non-compliance should be protected as far as possible and that this should be enshrined in the Bill.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

The regulator's powers, as outlined in the present document, appear reasonable and broadly aligned with other International territories. Consideration should be given to the mechanisms for implementation of these and further discussion and consultation will be required with respect to the details.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

No specific comments

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

No specific comments.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Consideration should be given as to whether the impacted party, other than the Regulator, should have some right of veto on the members present in the proposed review panel in the event that it is believed that they may be unreasonably prejudiced for some reason (a suitable justification would be required).

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

No specific comments as the proposals indicated are broadly aligned with International requirements.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

No specific comments.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

No specific comments

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:
No specific comments

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

The proposals with respect to Cost Recovery seem reasonable, although the regulator should be aware that cost recovery for activities from the Industry does leave the regulator open to accusations of being 'paid for by industry', particularly when contentious decisions need to be made. The Regulator may also want to consider whether more frequent review of fee charging than every 3 years is required.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:
No specific comments

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:
No specific comments

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:
No specific comments

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
No specific comments

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

No specific comments

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Given that the proposed approach for making changes to approved products aligns with that adopted in International territories the proposed approach seems reasonable. Detail and consultation must be provided with respect to the exact mechanisms proposed in this regard.

Clear guidance must be provided with respect to the data requirements for different types of changes.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

No specific comments with respect to this - more detail is required on how this would actually be proposed to work in practice.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

No specific comments

Question C4 - Please provide any comments on the approach to post-market controls.:

Given that the proposed introduction of post-marketing monitoring appears to align with the approach adopted in International territories this seems reasonable.

More detail with regards to how reporting would practically be completed is required, as are guidelines underpinning the requirements.

It would be recommended that training by the Regulatory be undertaken prior to implementation of this plan. Consideration should also be given to whether it is proposed to audit suppliers/manufacturers and how this could be completed.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

No specific comments

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

Consideration should be given to how this could practically be achieved. Would the term 'hawker' be considered to refer to a pharmaceutical company representative, even if the company were not actively involved in wholesale activities for the products in New Zealand and instead worked through a third party. Is so, how could such licencing be achieved?

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Generally speaking, based on the information provided at this time, the approach seems reasonable from a harmonization perspective.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

As per previous comments with respect to the approval of non-Cell based medicines.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

No specific comments

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

No specific comments

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

No specific comments

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

No specific comments

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

No specific comments

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Yes.

Based on recent experiences with breast implants, the potential health ramifications of purely constructed or ill conceived devices can be life threatening.

Products which are inserted as implants, or in close contact with the eyes are a particular concern and should be required to be managed and provided to market place at equivalent standard to therapeutics.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Alignment with EU requirements is desirable.

However, alignment should be introduced in all regards e.g. with regards to the definitions of Legal Manufacturer etc, otherwise there is a potential for issues and confusion.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

As per previous comments on regulating changes to approved products.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

The proposal seems reasonable, although additional details are required with regards to the proposed mechanisms which would be adopted.

Question C4 - Please provide any comments on the approach to post-market controls.:

Alignment with the EU post market controls for medical devices is desirable.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

More detail with regards to data requirements and consideration of a longer transition period may be necessary - particularly for those devices which are domestically manufactured and have never required supporting documentation. Development of a QMS and appropriate systems is likely to take a considerable period of time.

Activity-based controls**Questions C5 - Please provide any comments on the manufacturing-related definitions.:**

See previous comments regarding harmonization with regards to the terminology for Legal Manufacture of a product.

This is important, as not harmonizing with respect to this key definition will cause confusion.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

More detail with regards to data requirements and consideration of a longer transition period may be necessary - particularly for those devices which are domestically manufactured and have never required supporting documentation. Development of a QMS and appropriate systems is likely to take a considerable period of time.

C4 Clinical trial sector**Question C16****Please provide any comments on the change in approach to regulating clinical trials.:**

No specific comments

Question C17**Please provide any comments on the transitional arrangements for clinical trials.:**

No specific comments

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

In general, preventing patients from importing prescription medicines via post and courier is advisable.

Where the proposals may impact upon speed of availability of product where the use has been requested by an appropriately qualified physician this may cause issues and should be considered carefully.

Hawker's licence**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

See previous comments with respect to how this would operate for pharmaceutical companies who may have representatives, but handle supply of via an external company. How would this practically be managed?

Transition**Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:**

Given the timelines for the introduction of process and procedure for medical devices (e.g. QMS and appropriate Technical Files) a 6 month transition may be inadequate.

C6 Pharmacy (and retail-only licence) sector and pharmacists**Pharmacy sector context****Future regulation of pharmacy business activities****Licence to carry out a pharmacy business****Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

No specific comments

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No specific comments

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

No specific comments

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

This appears the most pragmatic option and is focused on in-pharmacy control of quality systems and practices.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No specific comments

Question C25 - Are there ways in which Option 1 could be improved?:

No specific comments

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

No specific comments

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

No specific comments

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

No specific comments

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

No specific comments

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

No specific comments

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

No specific comments

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No specific comments

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No specific comments

Question C34 - Are there ways in which Option 2 could be improved?:

No specific comments

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No specific comments

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

No specific comments

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No specific comments

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

No specific comments

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

No specific comments

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

As previously outlined, there may be issues with the proposals if there is a potential delay in the supply of unapproved medicines to critically ill patients. Consideration should be given to how to achieve efficiencies with the treatment of critical patients.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

No specific comments

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

No specific comments

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Given that there will be changes for specific product types (e.g. medical devices) it is important that there be appropriate consultation and training for retailers on the proposed changes and requirements. Otherwise retailers may unwittingly not comply with the requirements of the Bill.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

No specific comments

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

No specific comments

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

More detail is required in this regard, as the currently available information is limited and confusing.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Will the proposed approach have the effect of limiting clinicians ability to exercise clinical judgement? Additionally, will this make physicians more liable should a patient subsequently experience an adverse reaction?

With this in mind, how is it proposed to police and monitor that effective reporting is occurring?

Consideration and information regarding these details is required.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

The specific proposals in regards to medical practitioners seem reasonable as clinical consideration is required before an unapproved medicine is administered.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Preventing importation of medicines via post or courier directly to patients seems appropriate as a clinicians should be involved in consultation prior to administration of a prescription medication.

However, the requirement for pharmacies and wholesalers to have a specific licence in place to import unapproved medicines may slow the process of making unapproved medications available for critically ill patients.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

No specific comments

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

No specific comments

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Possibly.

Much would depend on ensuring that the health practitioner in question was appropriately qualified and knowledgeable with regards to the pharmacy medicine in question and its uses and potential side effect profile. Consideration should be given as to how this could be established and managed.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Possibly.

Much would depend on ensuring that the staff member in question (and the corresponding health practitioner) was appropriately qualified and knowledgeable with regards to the pharmacy medicine in question and its uses and potential side effect profile, and whether there was sufficient oversight. Consideration should be given as to how this could be established and managed.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No specific comments

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No specific comments.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

No specific comments

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

No specific comments

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No specific comments

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Consideration should be given as to how easily this would be to police, monitor and enforce. Additionally, do the proposed changes reduce the ability of a clinician to use clinical judgement?

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

See previous comments in this regard

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Preventing patients from having direct access to prescription medicines without consultation with a physician is preferred.

However, where the proposals may result in delays for critically ill patients in sourcing unapproved medicines consideration should be given to how to manage this most efficiently.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

See response to C18 - in some instances this may be necessary.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

No specific comments

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

No specific comments

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

This seems most pragmatic

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No specific comments

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No specific comments

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No specific comments

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No specific comments

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No specific comments

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No specific comments

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Yes

Products which are implanted or inserted into the eye need to be of a sufficient quality not to cause harm to the end user. These products should be monitored and manufactured in compliance with the principles of GMP, as the consequences of not doing so could be fatal.

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

No specific comments

Response ID ANON-DPZ8-G4UJ-Z

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 14:41:42

Submitter profile

What is your name?

Name:

Ailsa Surman

What is your email address?

Email:

What is your organisation?

Organisation:

Amgen New Zealand Limited

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medical devices, Medicines

Medical devices, Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Medical devices

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's largest independent biotechnology companies and is developing a pipeline of medicines with breakaway potential. Amgen is committed to taking an active role in contributing to future public policy that is relevant to biologic medicines and industry development in New Zealand.

Amgen supports the purpose of the Bill that regulation of therapeutic products and associated activities is necessary to protect both individual and community health. Amgen further supports the principles that the likely benefits of therapeutic products outweigh the likely risks, that such regulation should be risk proportionate and support timely availability of products, that there should be international cooperation and alignment with international norms, and that the regulation of such activities should be open and transparent. In addition we suggest that the regulator should operate not only with openness and transparency, but also with a principle of fairness.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Amgen notes that the meaning of advertisement in section 82 of the draft Bill refers to communication(s) for the purpose of promoting a product, and that there is no definition of promotion or promoting in the Bill. Provision of information in response to unsolicited enquiries from healthcare professionals is a legitimate activity for sponsors of therapeutic products, as is seeking advice from local experts to aid with product development. The Bill should be specific about the meaning of promotion such that it is clear that it excludes appropriate educational or non-commercial activities.

We suggest that careful consideration is given to the requirements in the Bill concerning the relationship between concepts relating to product approval and those relating to advertising. Section 100 indicates that a major change results in a new product. In the absence of clear information about the definition of major change, this has potential for a change unrelated to the product's efficacy to result in a product being considered a different product and therefore not being able to be promoted until approved. Whilst this would be appropriate for matters such as new indications or new dosage forms (and where the understanding would be that it would only be the new indication or dosage form that may not be promoted), it may not be appropriate for technical manufacturing changes that would not be visible to users or consumers of the product. In addition, the relationship to section 78(1)(b) concerning use of current stock notice needs to be considered. If such a notice is in place, it would be appropriate to be able to advertise the product encompassed by the notice.

New Zealand is a small country and healthcare professionals are often members of Australasian professional societies. Promotional activities directed at healthcare professionals may occur at events held under the auspices of these societies. Where these events occur in New Zealand a majority of attendees may be Australian residents. In addition, international professional society events may be held in New Zealand. Under current NZ legislation there is no facility for promotion of products that are approved in Australia, but not New Zealand, to the Australian resident members of Australasian societies. Amgen encourages consideration of a mechanism within the legislation to allow for promotional activities directed at international residents attending international events in New Zealand, even where the product is not approved in New Zealand.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Amgen supports continuation of the current concepts in place in New Zealand regarding advertising, namely that advertisements are for approved products only and that advertisements are consistent with the product's approval, and not false or misleading. Further, Amgen supports retention of the facility for Direct to Consumer Advertising (DTCA) of prescription medicines in New Zealand as an activity that is consistent with the principle of risk-proportionate regulation proposed in the draft Bill. Self regulation of advertising is an important concept that supports responsible advertising in New Zealand, and relies on a principles-based legislative framework accompanied by sector specific codes. The current controls on advertising of prescription medicines are robust and well established in New Zealand, with the Medicines Act 1981 providing principles, the Advertising Standards Authority Therapeutic and Health Advertising Code setting standards for advertising, and utilising the Therapeutic Advertising Pre-vetting System (TAPS) administered by the Association of New Zealand Advertisers. TAPS is a well administered scheme that seeks to ensure a consistently high standard of advertising for therapeutic products (not just prescription medicines). This is evidenced by the very small proportion of complaints made to ASA on prescription medicines in relation to complaints concerning the Therapeutic and Health sector overall.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G487-G

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:46:32

Submitter profile

What is your name?

Name:

Susan Wilson

What is your email address?

Email:

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

The definition of dispensing a medicine is totally wrong . It is not just a manufacturing process. It involves a clinical assessment of the patient's medicines as well . It involves the supply to the patient and advice being given to ensure the best outcome .This step can not be seperated.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

It is OK for pharmacies to transfer medicines between pharmacies to meet a patient's need . It will reduce wastage and provide better health outcomes.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

No to vending machines idea

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

I do not agree with this , where a rest home can dispense . It needs to be done in a pharmacy.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

For urgent situations, short term.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

I agree , as best for patient safety.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Keep the current system

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I strongly believe that the current ownership model gives the best patient outcomes. The rules are being relaxed and need strengthening.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Open ownership would be dangerous and very hard to control . It would be a disaster for NZ . We have a great pharmacy system that would be ruined by open ownership .

Question C25 - Are there ways in which Option 1 could be improved?:

Tighten the rules

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

2-3 years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

removed

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Big powerful non-caring multinationals ruining our industry , driven by profit and don't care about patients .

Question C34 - Are there ways in which Option 2 could be improved?:

Scrap the idea.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No as too much pressure from the owners .

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Only via skype etc.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Yes and their family members also .

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Agree

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes , to save time , when done correctly.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

In emergencies

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No .

Very dangerous as it just compounds an error . An independent advisor (pharmacist) is essential in the chain for the safe supply of medicines . Errors in prescribing are a daily challenge for us .

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No.

The health practitioners are in private rooms and have no idea of what is happening with their staff most of the day.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No - I don't agree with this practise.

Response ID ANON-DPZ8-G48U-E

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 14:47:07

Submitter profile

What is your name?

Name:

Ruth Savage

What is your email address?

Email:

What is your organisation?

Organisation:

University of Otago, submitting as private individual

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Medical practitioner (excluding Surgeons)

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

As a former general practitioner over three decades, a senior lecturer in general practice and a pharmacovigilance expert (New Zealand Pharmacovigilance Centre 20 years and WHO Programme for International Drug Monitoring, I am making a personal submission.

Direct to Consumer Advertising of prescription medicines

1. Like most advertisements these tend to be very emotive, a recent advertisement implies that a man with diabetes will now be able to be there fore his grandchildren if he uses a new insulin formulation. Many patients with Type 2 diabetes will never need insulin and if they do there are various formulations to suit each patient. If patients feel that they are not caring for themselves or their families sufficiently without the promoted medicine they may purchase it whether or not they can afford it. Health Practitioners have to walk a very tight line when trying to give the right advice while also maintaining a positive relationship with the patient in this situation.

2. Advertisements can be misleading or even flout advertising rules. Even if there are resources to deal with these the advertisements have been shown many times before they are changed. This is particularly inappropriate for substances that are prescription only and therefore have the potential for significant harm as well as benefit.

3. DTC advertising tends to focus on newly marketed medicines that have not been approved for funding or to announce that they are now funded. Prescribers are encouraged to use medicines about which there is well established knowledge unless only more recent ones are appropriate for the patient. Newer medicines have little postmarketing safety data. Two examples of the effects of this approach are Vioxx (rofecoxib) and Reductil (sibutramine) both of which were eventually withdrawn across the world because of serious cardiovascular adverse effects. While there was clear biological plausibility for these adverse effects and increasing evidence promotion continued.

I full agree with the submission for the Centre for Adverse Reactions Monitoring , New Zealand Pharmacovigilance Centre including the possibility of generic advertising in health professional establishments to increase patient awareness and involvement in choices.

Response ID ANON-DPZ8-G4E6-V

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:51:50

Submitter profile

What is your name?

Name:

Jo Mickleson

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

DHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Nelson Marborough

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Looks good.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Generally looks good

(32)(3) Suggest add "(c) or in accordance with a protocol approved by clinical governnace processes within a hospital setting.

(38)(5)(b) - not sure what this is about??

(49) - consider adding volunteer or making it clear that getting paid or having a contract is not necessary - imortant during industrial strikes

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Looks good but it is unclear to me re active medicinal ingredients (referred to in this section of guidance but relates to (53)(2)(c))

E.g. This DHB makes a special child's mixture from the raw ingredients (i.e. not tablets) levodopa and carbidopa - we need to be able to do this within the law.

I couldn't specifically see that this was allowed for. Also I guess for e.g. omeprazole raw ingredient which is used to make many mixtures in community pharmacy. Unclear where this fits

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

As above otherwise looks good.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Special Clinical Needs Supply Authority (SCNSA) is regularly referred to throughout the proposed legislation – including for Vets.

I don't believe it is appropriate nor reasonable for vets to have to complete a SCNSA for animals as this is impractical and onerous.

For "Section 29" unapproved medicines – I understand this as a way to make prescribers seriously think about whether a patient really needs an unapproved medicine. BUT to require this for NZ registered medicines which are being prescribed outside their approved indication is fraught with difficulty. I suggest that to make it workable:

- a) Needs to be electronic – along the lines of special authorities
- b) Must never ever be pharmacy's problem to track this down – it is currently implied that pharmacists would need to ensure there is a SCNSA - arguably this should be the case when the medication is truly unapproved and has to be imported (out of field use). DHB's would likely have to fund a general "chasing up of prescribers" and they do not necessarily have the diagnoses information they would require to know this. I believe this needs to remain with prescribers and a SCNSA should sit in their clinical record and not be in any way part of the pharmacist responsibility.
- c) Prescribers often have no clue what indications a medicine is approved for so this will be difficult to enforce. A huge education or smart software that links indications to meds will be required.
- d) Pharmac unapproved but funded medications need to be automatically exempt (e.g. Avastin)
- e) Hospitals do not want to have to chase up SCNSA's on admitted patients in order to prescribe these medicines and we may not even know initially that it is off-license use.
- f) Exemptions need to be made for emergencies
- g) It is also confusing and misleading to refer to animals as patients
- h) It is also confusing to have to check whether an animal is "in NZ or ordinarily resident in NZ". Understand the aim (to prevent dodgy dealings where animal medicines are imported for subsequent illicit human use) but the wording needs to change.
- i) I think this is sorted but must exclude an "out of stock" situation – e.g. Span K imported under "Section 29" as Slow K unavailable.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

(60)(1)(c)(ii) direct supervision - needs defining and there needs to be an understanding that the way hospital pharmacies operate is quite different from community and that technicians need to carry on working even if there is no pharmacist in the pharmacy - they may be all out on the wards preventing errors. Without doubt all dispensing needs to be checked by a pharmacist but that shouldn't prevent a technician getting anything prepared. Similarly if a ward pharmacist has completely annotated and initialled a patient chart which is e.g. faxed to pharmacy (so from a ward to the hospital pharmacy) then a PACT technician should be able to do a final check on that dispensing as a pharmacist has already done the clinical check - so no pharmacist being involved in the supply process despite this not being a "repeat" prescription. This may already be covered for in potential rule setting but the legislation needs to allow for it.

Question B7 - Please provide any comments on the authorisations for health practitioners :

(61)(1)(c) - just checking that this shouldn't allow for say diplomats or government appointments or volunteers who are required to be overseas for longer periods of time

(61)(2)(b) I see the practicality of this for OP's but there are many loose tablets put in envelopes by GPs so I think it needs to be clear that part packs are not acceptable unless in the original manufacturer's pack or are dispensed in accordance with requirements

(62)(1)(b)(i) etc. - please refer above to concerns re SCNSA and note that for devices this may cause a great deal of admin work for hospital stores staff who are in no position to argue.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

(65) looks good

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

(66) please note previous concerns re the use of the word "patient" for animal - perhaps "animal under the veterinarian's care" might be better and clarify whether it is the animal or the owner of the animal that needs to be ordinarily resident.

(69) Please also note previous concerns re SCNSA as this would seem to be impractical for animal use when human products can be prescribed routinely. Perhaps vets simply need to note their clinical justification of the use of all medicines and also the quantities prescribed.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

(76)(4)(b) should animal be included? ..., the patient or animal is travelling with...

(76)(4)(c)(i) although I think this is dealt with elsewhere and I know that other countries have different rules but should this have a limit - e.g. one year's supply? - or the same as in (76)(5)(c)? Would make it easier to interpret perhaps?

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

(73) - seeking clarification - is this meant to include the general public - so if they share their preventer inhaler (give one to) a neighbour - can they be prosecuted. Would need advertising clearly.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

My only note on advertisements is to ensure that surreptitious advertising doesn't occur - e.g. the ad is purportedly about encouraging people to use these preventers but they use an orange one which is clearly Flixotide or similar.

(88) I think this is meant to pertain to advertisers of approved products BUT if it is NOT meant to apply to e.g. therapeutic claims of an alternative medicine then I think it needs to clarify that by therapeutic product you are limiting it to the categories in this bill. If not, i.e. if e.g. Rescue Remedy is claimed to cure cancer and this is considered a breach of (88) then this is HUGE and requires a lot of work on definitions. I think this is confusing.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

No comment - no expertise/experience in this area

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

No comment - no expertise/experience in this area

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

No comment - no expertise/experience in this area

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

No comment - no expertise/experience in this area

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

No comment - no expertise/experience in this area

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Looks good

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Looks good

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Looks Good

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

3 years is great.

Maybe a note that in a declared emergency then seek advice from Civil Defence if for any reason the conditions of a license/permit may be breached. E.g. pharmacy burned down or under threat and needs to relocate

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

157 great - would be great to ensure this is emphasised with pharmacy students and interns.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

(159)(2)(b) An exception needs to be considered for hospital pharmacies - especially in smaller DHB's. As previously stated dispensing should be able to occur in a hospital pharmacy with no pharmacist there as long as the pharmacist has done a clinical check and a pharmacist (or PACT tech) then does the final check.

Vehicles - agree but again - what if tech is preparing something while a pharmacist is in the marae?

Also, pragmatically hospitals may from time to time need a Duty Nurse Manager (or similar) to access the pharmacy out of hours. If this is of concern then perhaps camera's could be considered?

Maybe allow rules to sort this out rather than prescribe this in the legislation.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

(163)(1) Recalls are tricky - especially in hospital. The benefits MUST outweigh the risks and it seems that this is not always the case.

Perhaps grades of recalls would help as (163)(1) is too black and white.

Except in clearly life threatening situations I disagree that pharmacies, especially hospital pharmacies, should have to comply with recall notices immediately by law. I think the risk/benefit needs to be taken into account when there is no clear alternative treatment (or stocks are low) and where the risk is largely theoretical or minor (e.g. wrong expiry date which can be remedied if necessary on site). These situations have happened. A way forward may be to ensure there are relevant hospital prescribers and pharmacists involved in any decision about a recall. In any event I think the legislation as proposed puts pharmacists in the line of fire if they fail to comply with a recall in the best interests of the patients. A stepped approach may be necessary.

(172)(2) - consider adding (c) "the individual is a suspected supplier/seller" or similar

Actually I think it would be helpful to consider requiring prescribers to have a (preferably random) blood test or similar in any such case to confirm that the person is actually taking the medicine. Most of NZ's illicit supply of such meds is through prescription.

(178)(a) - add and relevant health professionals (as previously stated - to ensure benefit outweighs risk)

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

I am reminded of the recent case where a bank gave details to the Police at their request and has been found in breach of privacy requirements.

I only skimmed this section but if it doesn't already state this, then it perhaps should include a note as to whether this legislation or the privacy legislation takes precedence if Police require information - or any other authority. Would clarification around search warrants be helpful?

All health professionals find this area tricky.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Looks good

Subpart 4: Review of regulator's decisions (ss 200–204)**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200–204):

Looks good

Subpart 5: Administrative matters relating to the regulator (ss 205–222)**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):

Looks good.

B9 Part 7 of the Bill: Enforcement**Subparts 1 and 2: Enforceable undertakings(ss 223–232)****Question B29**

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):

No expertise - seems OK

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**Question B30**

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):

No expertise - seems OK

Subpart 6: Infringement offences (ss 249–255)**Question B31**

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):

No expertise - seems OK

B10 Part 8 of the Bill: Administrative matters (ss 256–274)**Question B32**

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):

No expertise - seems OK

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments**Subpart 1: Repeals and revocations (s 275)****Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)****Question B33**

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):

Assuming this is all in sync - haven't reviewed

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**Question B34**

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):

No expertise - haven't reviewed

B12 - B15, Schedules 1 - 4**Schedules**

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

No comment

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

I think this is a very sensible approach to maintaining flexible and responsive legislation

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

Not that I can think of.

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

No comment (or expertise)

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

I like it but please be aware that pharmacies sometimes use AMI's when compounding (e.g. NMDHB uses Levodopa and carbidopa for a child's mixture) so perhaps AMI's should not be exempt from any Sections of the legislation. Sorry I may have mentioned this earlier and it's a while since I started this so have forgotten where it was!

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

No comment (or expertise)

Question C4 - Please provide any comments on the approach to post-market controls.:

No comment (or expertise)

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

All good.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

I think this draft allows for actual practices that are currently in place and that are safe.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Yes - but I have no expertise in this area.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

No comment

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

No comment

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

No comment

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

No comment

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

No comment

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

No comment

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

No real expertise but I would like demo devices (that is a dummy device that is the same as a device for therapeutic purposes) that will be directly used by patients (e.g. inhaler) to be well labeled and made available readily for training of staff and patients - even if users (e.g. DHB's) have to pay for them.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

No comment overall on devices except that if considering software then this needs to be wifi capable with GPS trackers where appropriate

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

No comment

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Will be tricky in practice to get users to complete form when used outside of intended or approved purpose. Needs to be IT enabled, easy and idiot proof - e.g. "tick the box for the purpose", include an "Other" option and ask for details.

Question C4 - Please provide any comments on the approach to post-market controls.:

It would be great to have an overall tracking system so we know where all devices went and (if appropriate) the patient ID - on a national database.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

No comment

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

No comment

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

No comment

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

No comment

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

No comment

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

I think this is largely sensible even if it feels like a loss of freedom for some genuinely motivated people who perhaps cannot get endorsement from a health professional.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

No comment

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

No Comment

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

I would like to see then safe enabling of a split between the supply and cognitive functions of dispensing. While I think there will always be a place for both to occur together, we need to be aware that our workforce is dwindling and our IT is (slowly) improving so that robotic can perform the supply task. However I firmly believe that the "authorising pharmacist" (for the purposes of this question) is the the pharmacist who has the direct relationshipwith the patients and/or carer and who authorises the robotic centre to "dispense" the medication. Further - I believe the medication should be supplied only the authorising pharmacist (or work colleague) to ensure patients/rest home cares etc are appropriately counselled. This should include e.g. short supply and change of brand situations. In essence I do not believe the patient or prescriber should have a direct relationship with the "supplier". However a robotic business could have a direct relationship with a patient/carer/prescriber if they also had an authorising pharmacist in their own right who was carrying out all the cognitive functions that a pharmacist would for a patient under their care. The authoring pharmacist and/or work colleague will carry overall responsibility for ensuring that patients receive medication that is safe for them to take but this will not include a final check on the medication if the supply has been outsourced - in the same way that they don't currently assay the ingredients of a tube of ointment.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

I think the draft has covered this off, except that there needs to be provision for pharmacy owners to also be prescribers of funded medicines - especially in rural or isolated areas - or even simply when there is no GP available. With good software that is easily auditable (including benchmarking) and where any prescribing is automatically notified to a GP or supervisory officer of health of some sort (if no GP) then I think the benefits far outweigh the risks.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

We need to consider telepharmacy - if our workforce declines then we may need to use overseas pharmacists to provide cognitive services and this may also allow for 24 access which may suit shift workers, public hospitals etc.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I would like to tick both boxes! Option one is more important than option two. In a nutshell it is important for patient safety and the control/safe-keeping of medicines to have a pharmacist with real professional control in charge of a pharmacy. However small one-man band pharmacies are not ideal for the broader services that pharmacies need to be able to offer and while this is not the direct concern of this legislation, it is important. Also, if I consider Green Cross Health, they have been innovators in pharmacy and generally have a reputation of high quality services and professionalism and it would be a retrograde step to lose this group of pharmacies. I do not pretend to understand their shareholding model and to be frank I don't care what it is as long as the pharmacist in charge is truly in charge.

However, there are other chains that I am not enamoured of where a great deal of cherry picking easy services (and easy patients) does a disservice to out high need and poorer outcome populations and also places an unfair burden on other neighbouring pharmacies who subsequently bear the burden of the "non-cherry" work. While it could be argued that it is the DHB's responsibility to sort this out within the contract, it is unlikely that DHB's will ever have the funding to micro-manage this BUT in the meantime the very populations we need to take the most care of suffer. If a pharmacist was "truly" in charge of these other chains then I suspect this would never be a problem as they would recognise the raw health need. So I do not believe that even placing disincentives on bad non-pharmacist (or pharmacist) owners will make the difference you seek. The reality is that whistle-blowers get contaminated and will find it hard to get further work so they don't blow the whistle (very often) - they simply move on. I wish it wasn't like this but it is and pharmacy is not alone unfortunately in this regard.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

As above

Question C25 - Are there ways in which Option 1 could be improved?:

Hmmm. Maybe consider licensing owners and managers themselves. Make sure they really understand what they're taking on and what behaviour is expected??

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Leadership (this is kept as it indirectly affects patient safety), including knowledge of staff management which in turn should include legal responsibilities.

Accountability for quality and safety

Safe rostering of staff

Monitoring of standards

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

This is where the rubber hits the road! Tricky. I think they could be separated where a majority pharmacist owner can demonstrate in an auditable way that they encourage, indeed insist on, high professional standards and that they role model this.

Maybe it helps to have a Board or corporate management structure that is pharmacist heavy. That might ensure a corporate owner is "safe".

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

I would rather have one good pharmacist own multiple pharmacies than have one bad one own one - if that makes sense. I think the number is a bit immaterial as for direct control then 2 or 3 is probably the limit. But someone with good business skills, measuring what they do in terms of quality and patient benefit, could manage potentially hundreds. Easier said than done. I think 5 pharmacies is a bit random these days as physical presence in a pharmacy (while laudible) is no

necessary to ensure they are run well. There are internet cameras and customer and staff satisfaction surveys and now the possibility of APPS (which should be considered mandatory! - I am a dragon!) where the public can give feedback on the soft issues we have never previously been able to capture well. "Did you feel listened to", "were you told about any unwanted effects that might occur" etc etc.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
I guess five for every pharmacist.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Only as discussed above

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Depends on how it is implemented - if simply as is then I guess a couple of years?

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No they definitely should not be exempt.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Benefits when there is a corporate that truly understands the business they are in and that there is a patient at the end of every prescription/sale of restricted medication.

Not good when each prescription item is treated as a grocery line.

Risks of bad guys (e.g. gangs) getting hands on drugs. But we would be naive to think that misuse and abuse of medicines is limited to gangs. It is endemic and across all socioeconomic groups - and even within the health professions at times (including pharmacy) but in my view there is a much lower chance of pharmacists being a problem than any other owner. They come to pharmacy with a passion to help in the provision of healthcare to the population and I believe non-pharmacist business people and entrepreneurs lack that assured motivation.

Question C34 - Are there ways in which Option 2 could be improved?:

As mentioned above - maybe there needs to be say >50% board members and/or corporate management that are pharmacists.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

I don't think the well intentioned deterrents in the draft will work - well not enough anyway. On paper they look good, but as previously mentioned, human behaviour willfully the whistleblower and the need for a good reference for future jobs is constantly a disincentive for people to make official complaints about their line managers and/or owner/employers

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes I do. This might include hospitals where all pharmacists are out of the pharmacy but within the building. I also think technicians should be able to open up and start working before a pharmacist is present as long as the pharmacy is not advertised as being open.

In terms of community pharmacy, we still have a number of sole operators and I would like to encourage community pharmacists to be more involved in health prevention (e.g. attending a multi-disciplinary meeting with local medical centre or giving a talk to local diabetes patients) so it would be great if there was a way that they could be allowed to close the pharmacy (or at least no pharmacist activities) for say an hour to do so, if they can't find a locum.

Also, sole operators are pretty much always in breach of employment law when they employ a locum as they can't ensure they have a break. Perhaps we should consider a pharmacy being able to remain open but have no pharmacist activities so technicians can still dispense but no final checks or restricted medicine sales for say (an advertised) half hour to allow for a meal break.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Depends. I don't think non-pharmacist prescribers should have an interest in a pharmacy and this may put undue duress on a pharmacist employee. However there may be situations where isolation leaves no choice and I think Medsafe should be able to make a call. I don't have any numbers to hand, but it feels to me like doctors have a higher incidence of addiction to medicines and that is another reason which concerns me.

For reasons stated earlier I believe a pharmacist owner/prescriber, which enough checks and balances in place, will be a welcome addition to dealing with isolated populations and the expected shortage of GPs and the tsunami of baby boomers heading our way.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Maybe. Perhaps where there is a specific need, e.g. rheumatic fever prevalence or measles outbreak etc.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Looks OK. Need to be careful not to be too onerous with depots or pharmacies won't use them and this may further isolate already isolated and therefore vulnerable communities

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Sounds great

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes - especially in hospitals or where a pharmacy services a specific need (e.g. STD clinic)

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

MPSO's are already essentially wholesale. They are also a good way for doctors who have drug misuse issues to get multiple supplies of their drugs of choice under the radar. So if we can fix that then we will be doing OK!

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Not substantially.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

No. I have recently been to Scotland where there seem to be a lot of pharmacist prescribers and they are doing wonderful things for vulnerable populations. Bring it on!

Pharmacists are almost by definition well-educated prescribers. They need to sharpen up their diagnostic skills and know when to refer.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Yes I do but not until we have the IT capability and integration to do so. In the meantime we need to rely on the insight and professionalism of all our clinicians.

However - there needs to be flexibility. So say there is a midwife who has a usual scope but who also has an interest in diabetes and works in the diabetes clinic dealing with non-pregnancy related diabetes as well as pregnancy related diabetes. If she/he is competent then they should have this added to their scope AND I do not believe they need to undertake much in the way of extra training to do so BUT they need to pass (100%) an assessment and also be credentialed in some way. We don't want to lose a perfectly good resource just because they were too busy to undertake extra study to know what they already know through their work. If they fail the assessment then they keep working as they are or they sharpen up for the next assessment. I think it's important that we don't undervalue on-the-job learning.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

I think they look good but I guess the people administering need to have the knowledge of whether the standing orders are within the scope of the prescriber. How will they know that for sure?

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

As previously stated I think it will be a potential problem and I don't want pharmacists to be left "holding the baby". I have taken the opportunity to ask a number of doctors about this and they all stared at me blankly and said they wouldn't have a clue what medicines (apart from very recent ones) were officially indicated for in NZ. So there will be gross, albeit unintentional) non-compliance with this. So as previously stated I think slick IT will be required to make this relatively painless. I think doctors go by best practice and evidence and don't usually consider whether a medicine is licensed for an indication - only whether it's funded. Special authorities are an exception but they are not part of this legislation as such.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

If they have to come in at all then this seems OK as long as good and/or essential care is not delayed.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Great in this situation.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Only in an emergency or if they are that person's GP. This is a health and safety issue.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Don't know enough about it to answer

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Yes - generally I think this is sensible - as long as within scope.

Not in hospital as double dosing or potential inappropriate care could ensue.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

If they are well trained/experienced and know when to refer. There are some fantatsic pharmacy technicians and practice nurses out there.

Any and all such supplies must be noted within the patient notes.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Not sure I can add to this.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

I don't like it. I understand that it may let the public know about new medicines and that is the only upsaide. In my view if we consider this importnat we should fund it ourselves (i.e. MoH).

This advertising puts undre pressure on prescribers and ends up with the assertive worried well getting a greater chunk of PHARMAC's budgeted spend and (arguably) those with less health literacy and vulnerable populations getting less.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

Don't like animals being referred to as patients. And the copy and paste from human legislation doesn't make sense - can an animal be ordinarily resident in NZ??

Also, while I abhore any unnecessary cruelty to animals, I think vets should be able to use whatever they like to treat animals (that are not subsequently meant for human consumption!). It seems over the top for vets to have to do extra paperwork if a medicine is not licensed for use for an animal. I have no idea about this but I would guess that there are far fewer studies done on human drug use in animals (non-ed ble pets especially!) so this could be quite onerous. Let the owners decide perhaps.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:.

No expertise but I don't want ads for prescription medicines paraded as health promotion.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

As above

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

As well as being a health professional, I am a patient and I have to trust that my health professional has my best interestd at heart (hard to legislated for this) and while I don't want to be poisoned! equally I don't want unnecessary impediments put in place or delays in getting a medicine that may be just what I need (e.g. considered good practice but not licensed for use).

One of these potential impediments is doctors practising defensively. I might miss out on a medicine I need because a doctor is worried about be sued 9 even if this is a very unlikely outcome. This works both ways - I might get an enti-depressant I don't actually need because a doctor doesn't want to be the one who failed to prescr bed and then had a patient suicide. Fear of HDC/ACC complaints and sanctions are real drivers of, arguably, as much under-prescr bing as over-prescribing. I don't know what the answer is but we have to be mindful or unintended consequences and ensure that by protecting a few patients from negligent prescr bing, we are not depriving a great many more of helpful and safe care I guess.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health

practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Seems OK. Maybe a pharmacist might be a better choice? Also maybe the answer for all of this is simply to have another member of the multi-disciplinary team endorse the move. If no-one will then it's probably a poor idea and if someone does then it's probably accepted practice.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

I guess as a patient, if I wanted a drug that PHARMAC wouldn't fund, and my doctor didn't know enough about to endorse, and I was prepared to pay and take the risk for it then maybe I should be able to, as long as it had no black market potential - included for euthanasia. Tricky - how much do we protect people from themselves. Don't want to be accused of being a nanny state but don't want people importing poison for their unwitting spouses either!

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Yes - as above when my healthcare professional has endorsed it.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

I want to be able to chose which pharmacy I use and over what medium (e.g. internet)

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Too biased to answer this as a patient!

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I want a pharmacist who puts my health interests before their profit

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Tricky question for a patient to answer!

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Tricky question for a patient to answer!

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Tricky question for a patient to answer!

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

As long as they know what they're doing.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No comment

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

No comment

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

I think overall this is very enabling legislation that should be flexible enough to respond to changing technology and workforce to meet my health needs.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G41G-S

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 14:52:24

Submitter profile

What is your name?

Name:
Rebecca Greaves

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
John's Photo Pharmacy

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

The definition of dispensing has changed significantly. I am concerned about this change.

Under the draft TPB, dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading.

Pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively, it is the central component of a pharmacists role as a primary health care team member.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

I support the removal of the ability to parallel import a medicine, medical device or type- 4 product.

This is positive for patient and by default the safety of the community by ensuring that medicines supplied in New Zealand are exactly as labelled.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

The ability for pharmacists to supply an emergency supply of a medicine to a patient should be maintained.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

This type of supply between pharmacies should be supported, as it would greatly benefit patients by giving them ready access to their prescribed medicines, particularly in the case of medicines that are uncommon.

This allowance should reduce wastage, particularly with high-cost medicines.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

this should only apply to pharmacists

Question B7 - Please provide any comments on the authorisations for health practitioners :

Medication use and purpose are a pharmacists main focus, other health practitioners should be able to utilise pharmacists expertise whilst focusing on their own areas. Considerable university level training is required to become a Pharmacist and this training is used to ensure medicine efficacy, patient safety, and to prevent misuse, overuse, and abuse. Pharmacists are also bound by a code of ethics, that other areas of health are not bound by in relation to medicine supply.

Every step of the supply process from storage, transportation, potential for misuse, interactions with other medicines, reporting of harm, and creating systems enabling patient follow-up and product recalls is and should continue to be overseen by a Pharmacist in a pharmacy .

The only way to ensure this occurs is to continue with strict regulations which can be defined an audited.

If health professionals were regulated to supply Category 3 medicines, they would need to meet the above requirements, and have their staff supervised by a pharmacist.

I support increased prescribing rights, allowing other health practitioners to prescribe the required medication within their scope of practice, and so increase access, through proper channels, for the patient.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

The ability for a health practitioner to supervise their staff to supply these medications under direct supervision is limited due to consultations generally occurring behind closed doors.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

I agree with the concerns around the importation of counterfeit and substandard medicines and that the importation of medicines should only occur through the appropriate regulated channels to ensure patient safety is not compromised.

Equivalent medicines to those that are available in New Zealand should be restricted in the same manner that they are here.

The restriction should also be applied to category 2 (pharmacist-only) and category 3 (pharmacy only) medicines as they should only be supplied with the professional advice provided in a pharmacy setting with a pharmacist oversight.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Vending machines should only be authorised for use when patients do not have suitable access to a pharmacy or pharmacy depot- not just when they are closed. Definition of suitable access needs to be clarified.

Vending machines should also be required to be linked to the pharmacy licence of a full service pharmacy to ensure appropriate clinical oversight and provision of advice to patients.

I support the current process by which medicines are reclassified to “prescription except when...”. Extending the ability of pharmacists to supply prescription medicines in specified circumstances increases ease of access to medicines.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

I do not support dispensing and supply at an aged care facility.

How can medicines be dispensed outside of a pharmacy dispensary which has rigid licensing requirements and SOP's required for entire process- dispensing is not purely a supply function.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

The licence should be attached to the premise-pharmacy, not person

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

I am supportive of the introduction of permits for shorter-term and urgent situations. It will be important that the permits system is responsive enough to deal with these situations quickly eg Waipu pharmacy fire- ability to set up temporarily rather than cancel licence would have been preferable- it would minimise disruption to patient access

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

I am supportive of increasing the period that licences are valid for, from one year to up to three years, as this would greatly reduce compliance costs for both the sector and the licencing authority- unless quality concerns during term had not been promptly addressed.

see above for reference to variation being allowed under extreme circumstance rather than cancellation and reissue

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

see above for reference to variation/transfer being allowed under extreme circumstance rather than cancellation and reissue

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

Pharmacists are bound by code of ethics and held to account. Unless they are personally responsible for a premises licence there is no way of ensuring that commercial interests are not put first by other such 'responsible persons'.

I personally have worked (in Australia) for a family owned business. When the licence holder pharmacist was not on site, I was pharmacist in charge but the husband/co owner would direct staff what to do, and himself sell medicines in large and unsafe quantities for financial gain- he had no licence to loose it was my "ticket" on the line.

It would be hard to monitor and enforce any such offence.

A pharmacist should be present at all times, it is again impractical to monitor and enforce that all category 1-3 medicines are safely secured at other times the licence should relate to the premises interlinked with the ethically bound and registered pharmacist

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply

authority, a pharmacy, or a wholesaler?:

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional- Dr GOOGLE is not a reliable source of advice.

there is no way for a personal importer to assess the safety or efficacy of a product

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Dispensing should be provided face to face by the pharmacist to the patient

The process of dispensing a prescription medicine and advising patients on the medicines safe and effective use, is very different to the sale of a retail commodity. It is not a sole a supply transaction.

I am all for improving patient health outcomes , but not at the expense of patient safety or the integrity of the community pharmacy distribution model.

Any alternative distribution or supply model that is considered, must not undermine the integrity and safety of the current system or current levels of access to community pharmacy services for all New Zealanders.

face to face contact is required- delivery via courier, or other untrained persons of parcels
should not occur- even when ticked sign for delivery things are left on doorsteps- what's to stop a neighbours child taking medication and causing harm, or medication to be left in unsuitable conditions- weather, heat, etc.

Dispensing should be provided face to face by the pharmacist to the patient

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No the current requirements do not create barriers. They provide a framework for safe and effective provision of pharmacist services that involve medicines for patients.

I do not see how medicines can be dispensed outside a properly-equipped and staffed pharmacy dispensary.

Patient safety must always be assured before transitioning to another untested model.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

I think the current Zoom model that is being promoted by certain DHBs and GP practices undermines current systems.

Dispensing should be provided face to face by the pharmacist to the patient

delivery via courier, or other untrained persons of parcels
should not occur- even when ticked sign for delivery things are left on doorsteps- what's to stop a neighbours child taking medication and causing harm, or medication to be left in unsuitable conditions- weather, heat, etc.

I am supportive of service innovations such as providing marae-based services or providing pharmacist services at events and see it as a great way to address health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional..

I do not support dispensing outside of a pharmacy dispensary.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

We are dealing with medicines, health and community wellbeing.

I have experienced first hand (overseas) financial incentives towards owners coming before well being of communities- sales of pseudoephedrine products in large quantities to persons known to be misusing them, by staff other than pharmacists because the pharmacist had no control, and the other staff had no "ticket" to loose.

I strongly believe that there is great benefit to the community in a healthy network of community pharmacies, owned by pharmacists who are in control of, and accountable for, the decisions made in the interests of their patients' care.

Pharmacist ownership and effective control assures the public that patient care is the focus of community pharmacy.

Pharmacists are under a professional obligation to provide services and a standard of care that requires adherence to higher standards than those that may be imposed by the regulator. A non-pharmacist investor owner is more likely to focus on meeting minimum compliance standards at minimum cost which will have a negative impact on the range and scope of services the investor owner is prepared to provide.

Medicines are not a normal item of commerce and pharmacies are not like other small businesses in a free market environment.

Requiring community pharmacies to be owned by pharmacists under Option 1 means that health professionals with 'skin in the game' focus first and foremost on delivering quality health outcomes to maximise their professional and business goodwill.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Benefit:

Pharmacist ownership and control of a pharmacy maintains the integrity of the professional relationship between pharmacist and patient, with pharmacists being directly accountable and liable for the services they provide.

I believe that corporate owners would offer reduced or limited services compared to current system if there was no funding to incentivise owners to provide them

Question C25 - Are there ways in which Option 1 could be improved?:

Option 1 could be improved by legally mandating that the owner pharmacist have a 'veto share' so that this pharmacist is always in control of all voting rights, giving them effective control of all activities, operations and governance matters related to patient safety.

There needs to be some official scope for some flexibility for an owner to seek external funding for investments in pharmacy assets while retaining effective control of all pharmacy governance and operational matters. And young pharmacists need to be able to work towards ownership- and businesses be of value for current owners to sell.

The primary goal should be to ensure public safety. No other class of share should be able to out vote the owner pharmacist where matters of public safety or pharmacy practice are concerned.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

All clinical activities within a community pharmacy setting that require a pharmacy licence, such as the provision of medicines.

Medicines need to be used safely with input and advice of trained staff- I have overheard shelf packers at the supermarket give advice to customers on how to take ibuprofen! A pharmacist will work within their ethical obligations to ensure patient safety is maintained in all areas of their pharmacy.

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

yes the majority owner should be a pharmacist

Effective control provisions are grounded in pharmacist owners' obligation as registered health professionals under the Code of Ethics, pharmacists are highly trained medicines experts who must put their patients' interests first, before profits or shareholder value, which are the driving motivations of any normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

the current maximum 5 limit has an important benefit to the public, replacement or change would be detrimental.

there is no way an individual can have awareness or practical input on day to day running on a larger scale, and the locations could not be practical- i do not have enough information from the proposal to comment with certainty but i would oppose a change, certainly an increase- it opens loopholes for corporate dominance

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

I am comfortable that effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both would be legally responsible for ensuring compliance with governance and operational obligations.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

I would be concerned as a current owner looking to increase my shareholding that my financial investment will be devalued, and the industry as a whole will be similarly affected- causing ripple effects in the viability of providing a level of care and advice to our communities.

young pharmacists looking to enter ownership will find it difficult if owners are unable to realise their investments and sell

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

A transition period to offset potential financial risks is vital.

An immediate change would lead to a loss of value, where investors would no longer see pharmacy as an attractive investment.

It would also make it difficult for pharmacists exiting the business on retirement and the introduction of new pharmacist shareholders.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:**Detailed questions relating to Option 2****Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

I am strongly opposed to option 2

risks would be to patient safety and service level decreases at expense of financial gain of owners with no ethical obligation

Owner-pharmacists have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so they don't risk loss of registration and, therefore, loss of value in the pharmacy. In addition, owner-pharmacists are accountable to the public through their registration. A non-pharmacist owner would be accountable to their shareholders in the first instance.

Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. By placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Government effectively 'raises the stakes' for non-performance.

Trained pharmacists in a non-pharmacist investor owned pharmacy are likely to be operating under quite strict productivity requirements with a financial orientation and hence a potential conflict with spending time on activities that may be of public good benefit but provide very little private benefit for the investor owner. This may mean that pharmacies focus on increasing product turnover and margin rather than on consumer experience or outcomes, in a manner similar to some consumer product chains.

Question C34 - Are there ways in which Option 2 could be improved?:

no it should not occur

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Trained pharmacists in pharmacies where there is not a 'pharmacist investor' are likely to operate under investor-mandated sales-related requirements and turnaround time that conflicts with the need for patient engagement and in a way that provides little benefit for the investor owner.

Other changes to pharmacy licensing requirements**Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:**

No

unless their is direct physical oversight of all activities undertaken in the pharmacy patient safety and confidence in services will not be guaranteed

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

yes restriction is required. their is an ethical issue-increased prescribing would lead to increased prescriptions and increased profitability for the pharmacy and owners- conflict of interest. currently patients are not supposed to be directed to a particular pharmacy, even though we know this happens when pharmacies are located in same building, or via the zoom setup.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

yes but exceptional circumstances need to be defined to stop exploitation of quick pop up scenarios

exceptional ie waipu fire, chch earthquake etc.

Permits would be useful for pharmacies to get up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Depots should only be authorised via the licence of a linked full service pharmacy.

there needs to always be pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

airport , or island ie rarotonga "pharmacies" with no pharmacist spring to mind: customers are expecting professional advice and receiving info from shelf stackers- devalues profession and puts community safety at risk

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Patients that import medicines for personal use miss the opportunity to receive the appropriate care and advice from a health professional.

important to ensure safety and efficacy of medicines

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

It is safer to produce a larger quantity of a compounded product when there is appropriate staffing and space in the pharmacy to do so in a safe manner. If pharmacists and pharmacy workers are only able to compound when a request is made this could have significant impact on workload and risk to patient safety.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

I think it is appropriate, and guided by pharmacists code of ethics, for pharmacies that do not have a wholesale licence to provide medicines by wholesale where medicines are supplied between pharmacies of common ownership, and where medicines are supplied to other pharmacies to reduce the wastage of medicines, particularly high cost medicines.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Support

Currently, when medical practitioners prescribe unapproved medicines, they are often unaware that they are prescribing an unapproved medicine.

This additional step will ensure that patients receive the appropriate advice and care to ensure their rights to make an informed decision are maintained.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

I think it is appropriate for legislation to continue to only allow medical practitioners to access unapproved medicines. Other health practitioner prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

I am supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No

Pharmacist oversight is required at all stages of the pharmacy medicine process- storage, information to patient, interactions with other medication conversations.

significant training is required to work in and own a pharmacy, pharmacists are ethically obliged to refer for further assessment clinical conditions of patients, other health practitioners should have to "refer" to a pharmacist for the appropriate medicine advice.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No

I do not support the authorisation for all health practitioner staff to supply category 3 medicines to the patients of health practitioners. Typically, health practitioners would be in consultation rooms separate from their other staff, this would make it practically challenging for health practitioners to provide general supervision to staff. I have been told that the supply of medicines would occur only after immediate consultation with a patient's health practitioner, but would like to understand what the expectation is for advice and counselling to these patients.

In a pharmacy, a pharmacy assistant or technician would have ready access to a pharmacist on duty. Pharmacy staff are trained appropriately to ensure the safe and effective supply of medicines. They are also trained to know when to refer patients onto the pharmacist. The ready availability of the pharmacist provides significant benefits in the ability to provide treatments for minor ailments in a timely manner.

I would also expect that to safely supply medicines to patients, they would have to be handled and stored to the same level that is required within a pharmacy.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

DTCA should not be allowed

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

DTCA influences patients expectations. we get customers asking for Richie McCaw's turmeric because they saw it on TV. Only once questioned and counselled do they become aware that it may not be necessary/appropriate or harmful in conjunction with their existing medical conditions, or other medications.

We should be informing people about their health and well-being, not using marketing strategy to increase the spending on products. often only unfunded brands dtca and patients are unaware of options

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4UE-U

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:02:42

Submitter profile

What is your name?

Name:

Andrew Gaudin - Chief Executive

What is your email address?

Email:

What is your organisation?

Organisation:

Pharmacy Guild of New Zealand (Inc)

Submitter Profile (tick all that apply)

Industry body

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

We support the overarching purpose and principles guiding the provisions in the draft Bill. In particular we note and support the emphasis on the protection of personal and public health, along with transparent administration and a proportionate approach to risk by the Regulator.

We note licensing and ownership provisions are not provided for under ss 3- 4, although they are extensively covered in the Bill and consultation document, and that their regulation supports the overarching purposes of protecting public health.

We support the objective of ensuring "high quality, robust and accountable decision-making". To support this, we see that the principle of Regulator decisions being made fairly and adhering to the principles of natural justice should be added to the principles under section 4. We see that it is important that the Regulator is fully accountable for acting fairly.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Dispense a medicine (s 29) – the definition of dispensing has changed significantly.

The Medicines Act states that dispensing, in relation to a medicine, includes, without limitation, —

(a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and

(b) the packaging, labelling, recording, and delivery of that medicine

Under the draft TPB, dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading.

We consider a fundamental change to the definition of dispensing in the draft Bill, without any legitimate or objective policy justification for that change will risk significant adverse impacts on the provision of health services in community pharmacy. We note there is a critical piece of work being undertaken as part of Integrated Community Pharmacy Services Agreement to provide an objective basis for whether the splitting of dispensing activities is in the public interest. The downstream details of how such activities are provided is a subsequent step in the process. This piece of work, and any accompanying recommendations, are yet to be completed. Any consultation on the provision of activities in a legislative process therefore is, in our opinion, premature and risky from a public safety lens.

Dispensing a medicine has more depth and involves the vital process of matching the medicine to the patient. This process is dependent on clinical and social considerations as well as patient and clinician goals of therapy. Each of these factors is highly dependent on the individual, the medicine, and the situation. Defining dispensing as a mechanical manufacture process not only diminishes the vital clinical role pharmacists provide, but most importantly exposes patients to unnecessary risks.

Community pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

Given the unprecedented level of offence this change in definition caused in the pharmacy sector during ICPSA discussions, the Guild is concerned that the "same message in a different package" will be met with significant opposition from the sector. We polled pharmacy owners and staff at our ICPSA road shows in March and April 2018 asking the question "Do you support the split of dispensing into medicine supply and professional advice?". The poll received 572 responses, with 96% answering no, 3% answering not sure, and only 1% answering yes.

Section 42 (meaning of supply) has no reference to the recipient of the therapeutic good, ie, the patient, and describes supply as a "mechanical function". This combined with the proposed definition of dispensing means there is no consideration of the patient at any stage of the process. The Guild is concerned that the patient is not central to the dispensing process alluded to in the draft Bill. This can be amended by recognising the established and practical definition of dispensing, which is an end to end process which centres around patient need.

There is no reference to advice required to be provided with "supply" of a therapeutic good. This again highlights the omission of the patient (recipient) perspective which again, should be central.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

We are supportive of this from a patient safety lens as this measure promotes surety that therapeutic products supplied are exactly as labelled and will enable efficient supply chain responses in the event of any product recalls.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

In the consultation document (as part of the explanation for section 59) you note considering allowing one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine requested by a patient. The Guild and our members would be extremely supportive of allowing this type of supply between pharmacies.

This would greatly benefit patients by giving them fast access to their prescribed medicines, particularly in the case of medicines that are uncommon.

This allowance could also help with medicine wastage issues. Pharmacies can often claim wastage for high cost medicines not dispensed to patients (per PHARMACs wastage rule), allowing supply between pharmacies could result in pharmaceutical budget savings.

We are concerned how the word "appropriate", used in "determined that the medicine is appropriate for the patient", will be interpreted in practice. A medicine that is simply prescribed for a patient could be determined as "appropriate" and with no patient focus in the definitions of dispensing and supply, this implies a low level of clinical insight.

We cannot see a clause relating to any requirement of advice needing to be provided alongside therapeutic goods. We believe this combined with the interpretation of "appropriate" could lead to undesirable and low service community pharmacy models with reduced patient safety and outcomes.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

We agree with the supervision requirements for pharmacy workers, including any limitations a supervising pharmacist is subject to, also applying to the pharmacy

worker.

Question B7 - Please provide any comments on the authorisations for health practitioners :

Section 61(2) would authorise a health practitioner (including those who are not prescribers) to supply category 3 (pharmacy) medicines to patients if the medicine is relevant to a health service that is part of the practitioner's scope of practice. We do not support this change as there are issues with this model, including the risk of perverse financial incentives, and reduced medicine advice from medication experts (pharmacists). An example where there is an avoidable risk incentive element is the sale of NSS (unfunded) medicines where the practitioner could stock and retail to the patient at a premium price.

We believe there is a real level of risk that health practitioners will stand to benefit from the sale of category 3 medicines to patients' detriment. Current competitive landscape for these products encourages more affordable pricing and therefore more accessible medicines. The Guild believes this will lead to situations where there is a risk that patients of health practitioners will be offered limited product ranges at premium pricing without an explanation that they are available at other outlets (for example Veterinary medicine pricing compared to pharmacy pricing). We fail to see how this will benefit patients. It also risks incentivising prescribers to "sell" category 3 products that are also available on prescription for commercial gain.

Pharmacists are regarded as medicines experts and have undergone significant training to ensure that they have the knowledge and expertise required to enable patients to get the most out of their medicines. Along with the importance of supplying medicines appropriately, it is also essential that patients are receiving the appropriate advice with all medicines they receive.

Stored medicines require strict temperature monitoring to ensure they stay within their specified temperature limits. This process includes using a temperature monitoring device to actively monitor the ambient room temperature and recording temperatures daily as evidence that medicines are stored correctly. Regular validation of temperature monitoring devices is required to ensure that the devices are accurately reading the correct temperature. This process is regularly audited.

Pharmacies also require the presence of a pharmacist when open for business and while other staff are inside the pharmacy. This is to ensure that all medicines have appropriate oversight. Other health professionals often have various other staff who work within their practices and there can be times that the health practitioner responsible is not present while other staff are present. What requirements will be in place to ensure the safe and secure storage of medicines?

To ensure that all medicines are handled and stored in the appropriate manner, we would expect that if health practitioners were to be able to supply category 3 medicines, that they would need to have made the investment necessary to meet the same requirements that exist within a pharmacy, with the same need for regular audits.

If health practitioners did not need to meet audit requirements due to apparent low volumes this could create a more efficient and low-cost way to supply medicines, which could lead to significantly increased volumes of medicines distributed via health practitioners, leading to the establishment of "pseudo-pharmacies". We also note that category 3 medicines would not typically be regarded as urgent medicines, which would warrant the need for urgent and instantaneous access.

We are supportive of the addition of the special clinical needs supply authority (SCNSA) requirement in authorising the supply of unapproved products. Currently, when medical practitioners prescribe unapproved medicines, they are often unaware that they are prescribing an unapproved medicine. This additional step will ensure that patients receive the appropriate advice and care to ensure their rights to make an informed decision are maintained. In consideration of the practical realities of this authorisation, we also support the need to further simplify the term SCNSA.

We would be supportive of health practitioners supplying each other with small amounts of medicines in an emergency situation when a pharmacy is either not accessible or cannot provide the medicine in a timely manner. The legislation needs to be framed in a way to ensure that it does not allow the trading of stock between medical practitioners. The legislation also needs to clearly define what is regarded as a small amount of medicine.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

Section 65 would essentially broaden access to pharmacy medicines by also allowing their supply by staff of a registered health practitioner if they are under the supervision of that practitioner.

This would add an avoidable adverse financial incentive risk to health practitioners (prescribers) who could 'retail products' instead of providing the most appropriate treatment to patients, eg, selling retail diclofenac 12.5mg (category 3) instead of prescribing a more suitable form (eg, 75mg extended release (category 2)). This would risk situations where profits drive or influence decisions and would reduce health equity. We view this as a conflicting scenario, which is conceptually equal to prescribers not being able to financially benefit from their prescribing through ownership in pharmacies.

We do not support the authorisation for all health practitioner staff to supply category 3 medicines to the patients of health practitioners. We understand from the Ministry's TPB pharmacy forum that the intention is only for staff to process the sale of these medicines following a recommendation from the health practitioner, however this isn't clear based on the draft Bill and we have significant concern about the safe and appropriate supply of medicines to patients.

We would like to clarify the definition of general supervision. Typically, health practitioners would be in consultation rooms separate from their other staff, this would make it practically challenging for health practitioners to provide general supervision to staff. We understand from the forum that the supply of medicines would occur only after immediate consultation with a patient's health practitioner but would like to understand what the expectation is for advice and counselling to these patients.

In a pharmacy, a pharmacy assistant or technician would have ready access to a pharmacist on duty. Pharmacy staff are trained appropriately to ensure the safe and effective supply of medicines. They are also trained to know when to refer patients onto the pharmacist. The ready availability of the pharmacist provides significant benefits in the ability to provide treatments for minor ailments in a timely manner.

We would also expect that to safely supply medicines to patients, they would have to be handled and stored to the same level required within a pharmacy.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

We would expect that regulations permitting wholesale supply between veterinarians would be consistent with the requirements on pharmacies.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

We agree with the concerns around the importation of counterfeit and substandard medicines and that the importation of medicines should only occur through the appropriate regulated channels to ensure patient safety is not compromised. We support the restriction on personal importation of medicines or medical devices not allowing consumers to directly order medicines from an overseas supplier. We support the mechanism requiring a SCNSA when needing to obtain a medicine from overseas, and that the importation of the medicines is managed by the medical practitioner, a pharmacist or a wholesaler.

We would also regard it as appropriate to still allow people visiting or moving to New Zealand to bring in three months' supply of their own medicine prescribed by doctors in their home country. This is to allow sufficient time for people to find a new doctor locally and have their medicine re-prescribed.

We suggest that section 76 (5)(a) is amended to only allow the personal importation of category 4 medicines. Equivalent medicines to those that are available in New Zealand should be restricted in the same manner that they are available here. Category 2 and 3 medicines should only be available with the appropriate precautions and advice that would be received in a pharmacy setting. The importation of category 2 and 3 medicines should only occur when there is a clinical need that cannot be met by medicines available in New Zealand.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Vending machines should only be authorised for use when patients do not have suitable access to a pharmacy or pharmacy depot. That is, only to be used in rural towns that do not have the population to justify a pharmacy or pharmacy depot to ensure residents have an access point to medicines. Vending machines should also be required to be linked to the pharmacy licence of a full service pharmacy, to ensure appropriate clinical oversight. Vending machines would need to meet the same audit requirements for medicine storage as within pharmacies.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Section 124 would allow for, for example, dispensing and supply at an aged care facility. We do not understand how medicines are able to be dispensed outside of a pharmacy dispensary.

Pharmacies have all the required dispensary equipment, access to reference resources, and standard operating procedures, as per audit requirements.

How would dispensing at an aged care facility for example meet the above requirements, and would these dispensing activities be subject to audit?

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

We support this, noting that this extends the current criteria that are working well under current regulations.

The competency requirements should be set by the Regulator, noting that compliance against a set of competency requirements for responsible persons would add increased regulatory costs on the sector. If the responsible person is an employee, instead of an owner, for example, retraining would be needed every time that individual changed.

We consider that section 128 (1) (h) for the criteria for granting licence should be modified to “any other criteria specified in the regulations” (not in the “rules” which are established by the Regulator), noting that the legislation should be pitched at a level that remains significant to the design of regulatory requirements and not to technical and detailed matters. The establishment of appropriate legislative and regulatory requirements to achieve public safety needs to be separate and fully distinct from the regulator’s role of ensuring that these legislative and regulatory requirements are being met in practice.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

We are very supportive of the introduction of permits for shorter-term and urgent situations.

In the past some members have experienced licence issues following unexpected events, for example, a member pharmacy destroyed following a fire had their licence instantly cancelled, even though they were the only pharmacy in a small town.

Situations such as these would benefit from a permits system, provided the system was responsive enough to deal with unforeseen disasters promptly.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Increasing the period that licences are valid for, from one year to up to three years, would greatly reduce compliance costs for both the sector and the licencing authority.

Community pharmacies have experienced long wait times for licences in recent years, sometimes having to display an expired licence for six months while waiting for their new licence to arrive. While this expired licence remains legally valid, it has caused distress for some members, who are concerned this reflects badly on them.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

We support that licences and permits are generally non-transferrable.

We are supportive of automatic transfers in circumstances where such a transfer is required to ensure short term continuity of services to patients.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

We are supportive of these obligations, as they would mitigate the risk of commercial incentives overriding safety considerations and ensure staff that speak out are protected. This is the key reason why we support majority pharmacist ownership (option 1).

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator’s powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

The Regulators powers and functions around monitoring, announcements and orders seem appropriate. It is difficult however to comment on these issues with full consideration, given the form of the regulator is still to be decided. We would welcome the opportunity for early, transparent and ongoing engagement and consultation on the Regulators form, including its powers, functions, and structure.

In general, we see there is a high degree of uncertainty that exists around how the new regulatory scheme will operate. The best way to mitigate this uncertainty

is to provide enough time and opportunity during the drafting and consultation phases for stakeholders to comment. We seek that community pharmacy service providers be given this opportunity to ensure that there are no surprises.

We are particularly interested in the governance, and accountability arrangements that will provide assurance about the Regulators independence and impartiality to make decisions fairly. This includes the processes for the routine and regular independent assessment and monitoring of the performance of the Regulator.

We are interested to understand how the regulator, once its form is decided, will manage the risk of conflict between themselves and other bodies (eg, central agencies, DHBs, professional bodies), and how the performance of the regulator will be assessed.

We have significant concern for the sale of medicines outside of their consented category. We see many examples where general sale and pharmacy-only medicines are sold outside of their classification restrictions. We have concerns that the current regulators approach to monitoring and oversight of retailers that sell medicines is inadequate. We have concerns that where medicines are sold outside of their classification, they are not being dealt with in a timely manner, which presents a significant patient safety risk.

Some recent examples of where medicines have been sold outside of classification requirements include:

- Bulk deal promotions in a supermarket, effectively encouraging purchase in quantities that exceed the pack sizes consented for general sale use. An example we have seen included a promotion to buy two packs of Panadol for \$5.
- Various retailers selling pharmacy-only medicines without an appropriate licence. Examples that we have seen includes the sale of Elevit (pharmacy-only) in a general retailer, and sale of Proctosedyl ointment (pharmacy-only) in a general retailer.
- Supermarkets without an in-store pharmacy selling pharmacy-only medicines and in other instances, selling pharmacist-only medicines. Examples that we have seen include the sale of (what was previously) pharmacy-only medicine Gee's Linctus on supermarket shelves, and the sale of dextromethorphan capsules after the classification had changed to pharmacist-only.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

The offences listed seem appropriate. Although, it is difficult to comment on these fully, given the form of the regulator is still to be decided.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

We support the option of sharing information between regulators (s209), providing it is only relevant information to the performance of the other regulatory function.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

The consultation document gives an example (on page 44) of a licence holder failing a particular aspect of audit, stating the regulator would "be likely to first provide guidance on the non-compliance and allow an opportunity to address the issue". The Guild and our members would be supportive of this approach.

Currently community pharmacies experience issues post audit with auditors not willing to provide advice and guidance on addressing non-compliance, typically stating that they cannot offer any guidance, and that a licence holder must figure out how to address non-compliance themselves and come back to the auditor with their proposed solution.

Auditors/regulators being proactive in offering solutions to address non-compliance will ensure community pharmacies are compliant as soon as possible, minimising any possible patient safety impacts.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

We would like to better understand the rationale for deriving the proposed penalty amounts, noting that they appear high.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

We seek that there are robust and transparent cost recovery principles in place, which are related to each of the differing regulatory areas within the scope of the Regulator, making sure that the costs recovered are for regulatory matters only, not for policy development or other non-regulatory matters.

We see that the principle of recovering only the costs incurred for each regulatory area over time is necessary. We expect that early engagement, transparency and robust consultation processes for the development of the cost recovery principles and practices will take place.

We note that it would be useful to be clearer on what constitutes suitable consultation under section 267.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading.

Dispensing a medicine has more depth and involves the vital process of matching the medicine to the patient. This process is dependent on clinical and social considerations as well as patient and clinician goals of therapy. Each of these factors is highly dependent on the individual, the medicine and the situation. Defining dispensing as a mechanical manufacture process not only diminishes the vital clinical role pharmacists provide, but most importantly exposes patients to unnecessary risks.

Community pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

The Medicines Act states that dispensing, in relation to a medicine, includes, without limitation, —

- (a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and
- (b) the packaging, labelling, recording, and delivery of that medicine

Any change in definition will raise significant noise from the community pharmacy sector, as was seen during the DHB's community pharmacy contract consultation in 2018.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

We support this but ask that the term hawkers be replaced by a more appropriate term in the Bill, such as mobile salespeople, which is a term used in the consultation document.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading.

Dispensing a medicine has more depth and involves the vital process of matching the medicine to the patient. This process is dependent on clinical and social considerations as well as patient and clinician goals of therapy. Each of these factors is highly dependent on the individual, the medicine and the situation. Defining dispensing as a mechanical manufacture process not only diminishes the vital clinical role pharmacists provide, but most importantly exposes patients to unnecessary risks.

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- (b) the packaging, labelling, recording, and delivery of that medicine

Any change in definition will raise significant noise from the community pharmacy sector, as was seen during the DHB's community pharmacy contract consultation in 2018.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading.

Dispensing a medicine has more depth and involves the vital process of matching the medicine to the patient. This process is dependent on clinical and social considerations as well as patient and clinician goals of therapy. Each of these factors is highly dependent on the individual, the medicine and the situation. Defining dispensing as a mechanical manufacture process not only diminishes the vital clinical role pharmacists provide, but most importantly exposes patients to unnecessary risks.

Community pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

The Medicines Act states that dispensing, in relation to a medicine, includes, without limitation, —

- (a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and
- (b) the packaging, labelling, recording, and delivery of that medicine

Any change in definition will raise significant noise from the community pharmacy sector, as was seen during the DHB's community pharmacy contract consultation in 2018.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We are supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

We support this but ask that the term hawkers be replaced by a more appropriate term in the Bill, such as mobile salespeople, which is a term used in the consultation document.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Our members welcome and embrace opportunities and arrangements that promote patient health outcomes and do not compromise patient safety or the integrity of the community pharmacy distribution model.

Separation of prescribing and dispensing is a key principle in the New Zealand medicines system in primary care. A key safety feature in the system is the legal form of a prescription, which patients have personal control over (ie, choice over where a prescription is fulfilled) and any alternative distribution or supply model that is considered, must not undermine the intent, integrity, and security of the current system.

Drug related problems (DRP) account for up to 12.1% of hospital admissions, and 50% of these DRP are avoidable (Hamid, Ghaleb, Aljadhey, & Aslanpour, 2014) (Nivya, Kiran, Ragoo, Jayaprakash, & Sekhar, 2015). This figure is underrepresented as, for example, falls are not classified as DRP but up to 35% are related to medicines (Barnett, Athwal, & Rosenbloom, 2011). These figures are likely to worsen with an aging population and increasing polypharmacy trends. Alternate supply arrangements that lessen patient-pharmacist interactions, such as vending machines, need to be carefully and objectively evaluated to ensure patient outcomes are not compromised.

When considering the potential introduction of any disruptive distribution and supply arrangement, it is crucial to recognise that dispensing a prescription medicine is a service requiring specific clinical expertise supported by tailored professional counselling and advice specific to a particular patient at a particular time. This involves considering patient factors such as age, personal goals, social situation, psychological state, spiritual factors and clinical goals. This level of patient interaction can only be attained by building relationships with patients through face-to-face interactions.

The clinical process of dispensing a prescription medicine and conveying the health and safety requirements of that medicine to the patient is far different to the sale of a retail commodity. The quality use of a medicine applied in the specialised clinical service of dispensing should be provided face-to-face with the patient by the pharmacist. These views are shared by health sector regulators such as the Pharmacy Board of Australia who consider the indirect supply of medicines, such as internet and mail-order dispensing, as less than the optimal way of delivering a pharmacy service because communication may be compromised (Pharmacy Board of Australia, 2010).

The consultation around the proposed regulation of therapeutic products distinguishes between licence-based requirements for pharmacy activities and qualification-based requirements for pharmacists (which is covered under the HPCAA). In practical terms, the proposed regulations would enable situations where a pharmacist could administer medicines, but not have to be monitored against requirements that would normally apply regarding safe storage and handling of therapeutic products. This creates a level of ambiguity that needs to be resolved to mitigate any product-based risks in the broader therapeutic product supply chain. In resolving the ambiguity, it would be useful for the sector to understand and consider the modelled costs of monitoring compliance versus the benefits that would realistically accrue to the public from such distribution and supply arrangements.

Such an impact analysis should consider published studies into comparable distribution arrangements such as the 'Hub & Spoke' model. For example, research undertaken by the National Pharmacy Association UK (Hewitson & Jones, 2016) found that:

- Although Hub & Spoke could provide capacity to deliver more health care services through community pharmacy, the system is complex with a number of implementation problems.
- Many items cannot be supplied by a Hub, for example, controlled drugs, cold chain, and acute or urgently required items.
- Although it might be possible to reduce staffing levels at spoke pharmacies, this is a highly risky and potentially destructive option which defeats the purpose of freeing pharmacy teams to spend more time delivering care to patients.
- Hub & Spoke may have some advantages over manual prescription assembly for the accuracy of drug picking, however this is only one of many tasks in the dispensing process.
- Data entry at the Spoke is the critical process to make Hub & Spoke work safely – while intra-company hub & spoke models can reasonably enforce quality improvements in this activity, this would be extremely difficult to replicate between companies.
- There is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs.

References:

- Barnett, N., Athwal, D., & Rosenbloom, K. (2011). Medicines-related admissions: you can identify patients to stop that happening. *The Pharmaceutical Journal*.
- Hamid, A. A., Ghaleb, M., Aljadhey, H., & Aslanpour, Z. (2014). A systematic review of hospitalization resulting from medicine-related problems in adult patients. *British Journal of Clinical Pharmacology*, 202-217.
- Hewitson, M., & Jones, G. (2016). Hub & Spoke Evidence Based Policy Review. National Pharmacy Association.
- Nivya, K., Kiran, V. S., Ragoo, N., Jayaprakash, B., & Sekhar, S. M. (2015). Systemic review on drug related hospital admissions – A pubmed based search. *Saudi Pharmaceutical Journal*, 1-8.
- Pharmacy Board of Australia. (2010). Guidelines for dispensing of medicines. Melbourne.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No, current licensing requirements do not create any innovation barriers. The advancement of technology and the community pharmacy workforce over time will inevitably drive the development of new and innovative ways of delivering care to match the evolving needs of our communities. The public good aspects of alternate distribution and supply arrangements, and any public policy that supports it, must be considered against the incremental transaction costs, risk to patient safety, and any need for greater investment in supporting infrastructure such as information technology. Such an approach, that leans on objectivity and is backed by a robust approach, is a minimum requirement to ensure current and future innovations will provide an overall benefit to patients, the community pharmacy sector and the pharmacy profession.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Legislation should promote and ensure the safe and effective delivery of pharmacy services to the public, with the regulator ensuring compliance with legislation. The details of how services and activities are best provided should sit between the licensed service provider, the purchaser of those services and the service user. We consider any changes to legislation that prescribe the delivery of activities through changes to the end-to-end nature of dispensing activity without any

legitimate or objective policy justification for that change will risk significant adverse impacts on the provision of health services in community pharmacy.

We note there is a critical piece of work being undertaken as part of Integrated Community Pharmacy Services Agreement to provide an objective basis for whether the splitting of dispensing activities is in the public interest. The downstream details of how such activities are provided is a subsequent step in the process. This piece of work, and any accompanying recommendations, are yet to be completed. Any consultation on the provision of activities or supply arrangements, that change the fundamental nature of current safe and effective provision of services is premature and risky from public safety lens.

The examples of service innovation given include providing marae-based services or providing pharmacist services at events such as Fieldays. We would be supportive of these approaches as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this is about awareness and service provision, such as blood pressure checks, and would not include dispensing outside of a pharmacy dispensary.

The other examples given are a pharmacist visiting a rest home to supply particular medicines and enabling mobile pharmacies in the form of a vehicle set up to provide pharmacist services, including the supply of particular medicines.

We do not understand how medicines are able to be dispensed outside of a pharmacy dispensary. Pharmacies have all the required dispensary equipment, access to reference resources, and standard operating procedures, as per audit requirements.

While mobile pharmacy vehicles may be an alternative solution to servicing rural areas currently serviced by pharmacy depots, this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

The Guild supports pharmacist ownership of community pharmacies and supports Option 1 conditionally. Our responses to questions C24 and C25 elaborate on the necessary conditions that would improve the workability and practicality of pharmacist ownership and effective control under Option 1.

We firmly believe that there is strong public benefit in a healthy network of community pharmacies owned by pharmacists who are totally in control of, and accountable for, the decisions made in the interests of their patients' care. Pharmacist ownership and effective control assures New Zealanders that patient care is the focus of community pharmacy practice. Ownership rules requiring pharmacies to be owned by pharmacists and limiting the number of pharmacies each pharmacist can own, ensures a decentralised and diverse ownership structure. These rules ensure that pharmacies maintain an efficient, effective and patient centred service delivery focus.

Ownership of the pharmacy also helps ensure independence of the pharmacist's professional decisions. Having ownership rules in place encourages efficiency in the provision of community pharmacy services, while ensuring that those services are provided with high quality standards. Owner-pharmacists have an increased incentive to conduct themselves and their pharmacies ethically and professionally, so as not to risk loss of value in their pharmacy.

Pharmacists are under a professional obligation to provide services and a standard of care that requires adherence to higher standards than those likely to be imposed by the regulator. An investor owner is more likely to focus on meeting minimum compliance standards at minimum cost which will have a negative impact on the range and scope of services the investor owner is prepared to provide.

Requiring community pharmacies to be owned by pharmacists under Option 1 means that health professionals with 'skin in the game' focus first and foremost on delivering quality health outcomes to maximise their professional and business goodwill. It also prevents an over concentration in pharmacy ownership.

When one recognises the primary purpose of the community pharmacy network and the core responsibility it is tasked with on behalf of the Government, it becomes clear why the Option 1 community pharmacy model, with pharmacist ownership, is both effective and superior to any proposed alternative approaches. Indeed, where it has occurred in other countries, the market structure that has emerged following pharmacy deregulation has arguably not served the broader public interest.

Medicines are not a normal item of commerce and pharmacies are not like other small businesses in a free market environment. Prices for dispensing of PHARMAC scheduled medicines and community pharmacy services are agreed by DHBs and community pharmacy providers through funding mechanisms via the Integrated Community Pharmacy Services Agreement, which outlines the limitations on the commercial flexibilities that all community pharmacies can exercise on dispensed prices for funded items to consumers. Rather, community pharmacies are explicitly tasked to deliver better and broader primary health outcomes closer to people's homes as part of the New Zealand Health Strategy and Pharmacy Action Plan through the professional dispensing of Scheduled medicines and related services, working effectively as collaborative health providers for the Government to deliver equitable and accessible care in communities.

The success of the current commercial community pharmacy model provides strong support for the Government's ongoing stewardship and regulatory role in the sector. The Government has a legitimate interest in shaping the way in which publicly subsidised medicines and associated services are delivered, particularly as equity of access and patient outcomes are central objectives in public health policies. Given these objectives, it is valid and unsurprising that key features of the community pharmacy model differ from those that would emerge if competition and market forces alone were to determine ownership (as seems to be the case under Option 2), or if interdependencies with the broader health system were not important.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

There are a number of important public interest reasons for keeping ownership and effective control of pharmacies in the hands of licensed pharmacists. Ensuring that a pharmacist owns and controls a pharmacy practice is a social objective underpinned by legislation. It reflects the community expectations and desire to maintain the integrity of the professional relationship between pharmacist and patient. That relationship hinges on trust and personal service, with pharmacists

being directly accountable and liable for the services they provide. Needless to say, a level of accountability is also expected of employee pharmacists. However, the clear intent of the ownership legislation is to ensure that professional standards and principles are not subordinated to commercial objectives and pressures in the practice of pharmacy.

Rules regarding pharmacy ownership play an important part in achieving the Government's health policy goals, in terms of:

- preventing horizontal and vertical integration and therefore concentration of the pharmacy sector, thus minimising costs and financial risks to funders and to taxpayers
- ensuring that quality service standards are adhered to, since pharmacists who breach the standards risk losing the considerable human and physical capital invested in their pharmacy.
- ensuring equity of access to health services no matter where our populations choose to live.

Community pharmacies, under the current majority pharmacist ownership requirements, are delivering many benefits to patients and the wider health sector at no cost to patients or the funder. This includes resolving minor health-related issues quickly in the pharmacy and helping patients find the right health services to meet their needs – commonly referred to as pharmacy's unfunded triage and referral role. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. In contrast, pure investor owners would likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted due to the loss of commercial value from a sell down of private equity to align with the prescribed shareholding requirements under the proposed Option 1. The Guild considers the dollarised impact on the private sector could be substantial. There would be a significant write-down in the capital value of New Zealand's community pharmacies, which would be unfair to existing pharmacy owners and investors who have complied with all regulatory licencing requirements. This risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.

Even with grandparenting provisions, there is a risk of a reduced level of external investment from the proportionate dividend requirements under the proposed Option 1. Private and institutional investment in health-based SMEs is regarded as a prudent social investment opportunity to fund the greater level of equitable health care and services required to sustain an aging demographic that is living longer. Pharmacy owners require a level of external investment to sustain growth, respond to mounting competitive pressures, innovate, and ensure affordability of newer assets and technologies to serve our populations more efficiently. Absent a level of flexibility in equity investment – the ability to fairly remunerate, effectively innovate and invest in the community pharmacy sector is greatly diminished.

The financial impacts of strict dividend requirements will likely be felt by most community pharmacy owners across the ownership lifecycle, from initiating an ownership stake to divestment. The nature of these financial impacts on pharmacy businesses are elaborated under question C30 using realistic and practical examples. A prudent risk/impact minimisation and practical enhancement to Option 1 involves legally mandating that the majority pharmacist owner has a conditional 'veto share' so that this pharmacist is always in control of all voting rights on decisions that affect or have the potential to affect patient safety (patient safety being the veto condition). This effectively gives the pharmacist owner control of all activities, operations and governance matters related to the pharmacy. A veto share of this conditional nature ensures effective control is in the hands of a pharmacist and replaces the need for regulating dividend requirements in proportion to shareholding. This mechanism allows and retains some flexibility for pharmacist owners to raise capital, while maintaining the public safety elements, including how capital is deployed operationally.

Question C25 - Are there ways in which Option 1 could be improved?

Community pharmacy businesses are operating legitimately under the Medicines Act, however some of these may not be legitimate under the proposed Option 1. We believe that Option 1 could be improved with grandparenting provisions for pharmacy businesses that are operating legitimately under current rules.

The Bill should consider improving Option 1, and enhancing its practicality, by legally mandating that the owner pharmacist have a conditional 'veto share' so that this pharmacist is always in control of voting rights pertaining to operational and governance decisions that have an impact on patient safety (patient safety being the veto condition). A veto share in this regard ensures effective control is in the hands of the owner pharmacist and replaces the need for regulating dividend requirements in proportion to shareholding.

This would allow some flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a conditional veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety (the veto condition). The transfer of this veto share should only be possible to another pharmacist, and no other class of share should be able to outvote the owner pharmacist where matters of public safety or pharmacy practice are concerned.

We would also like to clarify that while pharmacies owned and operated by a hospital are exempt from any pharmacy business ownership requirements (per page 102 of the consultation document), that this exemption only applies to DHB hospital pharmacy departments, and would not apply to community pharmacies located on a DHB hospital site, including those DHBs have an ownership interest in.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?

All clinical activities within a community pharmacy setting, that is, those activities that require a pharmacy licence, such as the provision of medicines (all categories excluding category 4 general sales medicines).

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?

The Act needs to be clear about the definition of effective control. Effective control drives governance and operating decisions.

Effective control provisions are grounded in pharmacist owners' obligation as registered health professionals under the Code of Ethics, pharmacists are highly

trained medicines experts who must put their patients' interests first, before profits or shareholder value, which are the driving motivations of any normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public. These responsibilities cannot be safely separated, without accompanying analysis and information about where the final accountability would lie. Such information should be considered against the time-tested rationale for a pharmacist having effective control which is the centrepiece of the ownership policy.

We suggest that the Act include a provision for the effective control pharmacist to have a conditional 'veto share' on governance and operations decisions pertaining to patient safety (patient safety being the veto condition). This allows for flexible ownership arrangements while strengthening the requirement for pharmacist ownership, and effective control provisions.

Effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both are legally responsible for ensuring compliance with governance and operational obligations.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

A key feature of the existing pharmacy ownership rules is that they have preserved a broad pharmacist ownership structure, with reasonable levels of ownership concentrations. Such a structure provides crucial benefits to the Government, as it prevents a situation from emerging where the Government, to meet its objectives, would have to purchase community pharmacy services from suppliers with substantial market power. By avoiding those very high levels of concentration from arising, the ownership rules can secure a substantial public benefit.

We think appropriate oversight of a pharmacy is effective control – the owners need to demonstrate governance of the business, that is, they control the board. The day to day clinical oversight of the pharmacy can be delegated to another pharmacist.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

We are comfortable that effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both would be legally responsible for ensuring compliance with governance and operational obligations. The five-pharmacy limit could be applied by only allowing a pharmacist owner to have five conditional 'veto shareholdings'. This would mean that a pharmacist owner could only have effective control of up to five pharmacies.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Option 1, as described in the consultation document, would lead to a reduced level of investment in community pharmacy, which would impact on the sectors ability to innovate. We have suggested some improvements to Option 1 under questions C24 and C25 to effectively eliminate these concerns, while ensuring strong pharmacist control over all decisions affecting patient safety.

We believe the impacts of Option 1 as described in the consultation document would mostly be financial, which is a matter of great concern for the community pharmacy sector as the current operating climate is already facing strong fiscal pressure. A review of the New Zealand pharmaceutical supply chain conducted by Grant Thornton in 2016 found that pharmacies are making poor economic returns, impacting on their ability to invest.

The consultation document notes a range of potential impacts, which suggest that much of the sector would be impacted in some way by changes to the majority pharmacist ownership requirement. A detailed impact analysis is not reasonably achievable without full access to the shareholding makeup of current ownership structures. We are hopeful the Ministry may have access to greater information that would enable such an analysis. It is useful, however, to consider some realistic and practical examples that we have presented here that outline the nature of financial and investment impacts from proposed Option 1.

There is a risk that private investors may sell down their shareholding in pharmacy, leading to a significant loss in value for the pharmacy business. Investors may not view pharmacy as an attractive investment which may further degrade the financial value of the sector and make it difficult for pharmacist owners to exit the business. A barrier to exit for pharmacist owners creates a barrier to entry for aspiring pharmacist owners. These impacts are avoidable under Option 1 if grandparenting of current legitimate ownership arrangements was implemented and if it was legally mandated that the owner pharmacist had a conditional 'veto share' so that this pharmacist is always in control of all voting rights that relate to patient safety and has effective control. This would enable the Bill to consider flexibility for alternate financing arrangements in community pharmacy, by replacing the need for regulating any dividend requirements (in proportion to shareholding) and would maintain current investment value in the community pharmacy sector.

The Pharmacy Councils 2018 workforce demographics shows the profession has a very young workforce, with over 55% of registered pharmacists in their 20's and 30's. A result of a younger workforce is a growing number of aspiring pharmacy owners who are under 40. Indeed, the Guild has noted an increasing number of young pharmacy owners and shareholders amongst our membership ranks.

In this scenario, we follow the example of Mrs Jones, a 31-year-old practicing pharmacy manager and aspiring pharmacy owner who wants to pursue 10% ownership in the pharmacy she currently works in, with a view of increasing her ownership stake in the pharmacy over time. The majority owner of the pharmacy, Mr Patel, with 55% of ownership share wants to incentivise her continued performance and plan for his future succession through an ownership stake. Mrs Jones, Mr Patel and the other pharmacy shareholders (non-pharmacists) agree it is in the best interests of the pharmacy business to have Mrs Jones as a part owner.

A practical limitation on younger owners is effectively raising or readily arranging capital necessary for ownership. In our example, Mrs Jones is unable to afford the \$45,000 needed to 'buy' Mr Patel's 10% equity stake in the pharmacy. Mr Patel considers an arrangement whereby the ownership stake is financed through Mrs Jones pro-rated share of the pharmacy's profits. This arrangement is efficient in the economic sense as there is no reasonable alternative that is universally preferred in terms of the goals and preferences of the people involved.

The effect of mandating dividend returns in proportion to shareholding is uncertainty around the regulatory and legal implications of the financing arrangement. In a strict sense, Mrs Jones would not have a beneficial entitlement proportionate to shareholding as there is an absence of upfront exchange of capital and shares. Rather her dividends would accrue towards paying off the upfront cost of ownership and rights to 10% of the business. The dividends would proxy an ownership

financing instrument, the details of which would be captured in some form of private contractual arrangement between two independent persons acting in their best interests. From a public policy perspective, the financing arrangements have no apparent detrimental impacts on patient safety as this concerns a business financing decision with no impacts on operations and/or governance matters.

If such forms of financing arrangements were not permitted under the proposed Option 1 then there would be conceivable ownership entry impacts on young aspiring owners. In our example, Mrs Jones would have to consider other means of raising \$45,000 to finance ownership, either through a bank loan or through family members, either of which may not be the most efficient route to finance (ie, might be unaffordable).

Barriers for young pharmacists to attain a foothold in pharmacy ownership would also have impacts on established owners who wish to exit. A barrier to ownership entry for young pharmacists creates a barrier to exit for established pharmacy business owners and vice versa, in a vicious reinforcing feedback loop which leads to system wide loss of value and impacts on sector sustainability.

Such impacts on society could be considered a 'deadweight loss' in an economic sense due to allocative inefficiencies outweighing any efficiency effects. One way of measuring the magnitude and extent of any deadweight loss is via the price elasticity of demand for pharmacy businesses. In the example of a young pharmacist, the elasticity of demand would be high, in that an increase in the price of ownership would lead to a reduction in the quantity of younger pharmacists who demand ownership (due to increased opportunity costs). A probable long-run consequence would be an impact on the number of community pharmacies due to unaffordability constraints on younger pharmacists. There would be real health care accessibility impacts and downstream equity and health consequences on our communities as a result.

Pharmacy owners face an ever-evolving competitive marketplace and increasing cost pressures, with newer technologies and innovations creating a better and more efficient patient experience. Pharmacy owners need to constantly invest in effective and efficient staffing, processes, and technologies to remain relevant in the sector.

In this example, Mr Lee considers investment of \$300,000 in clinical and patient focussed services, technologies and business improvements necessary to remain financially viable and to continue to provide patient focused services to his community. Mr Lee owns 100% of company shares and the pharmacy has no outstanding debt obligations.

Mr Lee weighs up his options for equity financing, debt financing and a mixture of both financing instruments to meet funding requirements. As the following examples show, Mr Lee faces greater difficulty than current state in raising funds from any financing pathway due to the increased cost of capital for pharmacy financing. This increased cost of capital arises due to the increased risk profile for investors under strict dividend requirements under the proposed Option 1.

Equity route:

Mr Lee finds an interested investor, Mrs Pebble (not a pharmacist) who is willing to lend the full \$300,000 to fund future growth and sustainability of the business. Mrs Pebble considers the following:

- The business is valued at \$450,000 after raising capital - which means the \$300,000 investment equates to 67% equity financing.
- Since she is a non-pharmacist, the maximum she can claim in ownership equity is 49%. This means there is an \$81,000 contribution (18%) towards the financing that would need to be accounted for in the transaction.

There are a few options for Mrs Pebble if she chooses to invest in pharmacy, including:

• Value the shares at a premium not reflecting real market value. If this were the norm then the pharmacy industry would not attract any private investment. Potential investors do not want to overpay for any asset. When a business is overvalued, operators cannot, in the absence of amazingly good luck, reliably and legally deliver performance that will justify its price. The market is setting a bar that businesses cannot realistically meet. A risk of a market bubble could arise due to inflated valuations that do not reflect commercial reality. This is unpalatable and forces investors to consider other investment options. The resulting impact on the pharmacy sector is a barrier to capital investment and future growth opportunities.

Valuing shares at a premium would also require the investor to have a greater return on investment to justify the risk (risk premium). When investors increase the required rate of return, the cost of capital rises simultaneously. Again, this risk incentivises the investors to apply funds elsewhere and is consequently detrimental to the financial health of the pharmacy sector.

• Include a provision whereby the \$81,000 contribution is paid back through the surplus generated by the company and/or through a dividend or financing policy that pays the investor a premium towards additional capital investment not tied to equity. The equity investor may also consider a fixed term returns policy (from dividends) for the \$81,000 contribution through a debenture. In effect, Mrs Pebble would hold rights to shares that give her priority entitlement over dividend disbursements. These arrangements, in practice, would mean Mr Lee would not be entitled to a proportional share of his ownership stake. The crucial point is that Mr Lee would remain in effective and absolute control of how the financing is applied operationally if these requirements were mandated in legislation (or in a shareholder's agreement). This effective control mechanism ensures financing is deployed in a manner that is consistent with Mr Lee's obligations as an owner pharmacist (ie, not against the interests of public safety).

Under the proposed Option 1 there is effectively a cap on the amount of equity financing pharmacists can raise based on what parties to a private transaction perceive the proportionate shareholding to be worth. This has an adverse impact on the level and nature of equity investment that can be raised to afford new and innovative patient services and/or new and innovative technologies. This has downstream impacts on the financial return's pharmacy can afford shareholders. Providers of equity capital would be faced with a higher cost of equity as a consequence of the current definition of Option 1.

Raising debt capital:

Mr Lee approaches the banks for help, and considers the following:

- Banks are valuing the company at \$450,000
- Borrowing the full \$300,000 from the bank would mean the company is highly leveraged (debt to equity ratio around 200%). High amount of leverage (in most cases greater than 100%) is risky for any pharmacy business and for the institutions that provide debt financing.
- Debt financing would have a material impact on the pharmacy's cash flows as it has fixed payment cycles for medicine stocks, salaries, rent etc, as well as fixed income payments from the Government. Debt financing would cost the business interest until such time that investment in efficiencies and improvements yield savings greater than the cost of debt and/or when the debt is fully repaid.
- Debt instruments often contain restrictions on the company's activities, preventing management from pursuing alternative financing options.

The bank decides that it can only justify lending to Mr Lee if the interest rate on borrowed funds is high enough to justify the banks' exposure to risk. The bank considers, under legislation (current definition of option 1), that the sector is not attractive for private investment above a certain equity threshold (equity above 49% of pharmacy's net assets) and that pharmacies are thus generally inclined towards raising money from banks or unable to source willing equity investors. The sector wide default risk under this scenario is higher as the banks have now taken majority exposure to the capital-intensive financing risk.

The net impact of the current dividend requirements under option 1 is a high cost of debt, resulting in a higher interest cost than previously and compared to other small to medium businesses of the same size (for example a GP practice). There will also be a material impact on the business cash flows due to interest obligations. The 2018 pharmacy benchmarking survey by Moore Stephens Markham's shows an increasing constriction of cashflows in community pharmacy as indicated by reductions in the current assets to current liabilities ratios over time. This would materially worsen under the current definition of option 1.

Mixing equity and debt:

With an increased risk profile for an equity investor and the issuer of credit (debt financing), the effect on the pharmacy is likely to be an increase in the weighted average cost of capital (WACC). WACC depicts the rate of return required by the providers of capital (both debt and equity) having regard to the risk characteristics of the pharmacy.

Importantly, the WACC is determined by external conditions and not by management actions. Consequently, all pharmacy owners under the current option 1 would be subject to a higher WACC. Providers of capital (both debt and equity) tend to require additional return to assume additional risk for a higher WACC. A higher WACC also tends to make valuations fall, which is a real concern for the future financial sustainability of the sector.

As the above examples have shown, prescribing strict beneficial entitlement and financial disbursements based solely on shareholding creates the real risk of unintended and perverse consequences for the commercial value, investment potential, and resulting sustainability of the community pharmacy sector. This has avoidable downstream impacts on the level of patient centred pharmacy services that are affordable for owners to provide to their communities.

These risks could be mitigated, and potentially eliminated, by legally requiring the owner pharmacist to have a conditional 'veto share' so that the owner pharmacist is always in effective control of all voting rights on governance and operating decisions that have an influence on public safety. These rights would cover how the financial investments from external sources are applied operationally to ensure the investments align with the pharmacist owners' obligations to public safety.

From a public policy perspective, these types of private financing arrangements have no detrimental impacts on patient safety, as this concerns a business financing decision with no impacts on operations. In practice, the impact of liberal financing mechanisms coupled with strong effective control provisions for majority pharmacist owners is highly likely to be very favourable to the public. Prudent capital investment, with the patient's safety and health outcomes guiding and controlling operational decisions is a partnership that leads to better and more valuable health services for our communities.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

There should be provisions for grandfathering currently legitimate business arrangements that may not be constitutional under Option 1. The other (non-ownership and licencing related) provisions in the Bill should apply to these pharmacies.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

The Guild supports the ownership requirements under a conditional Option 1 and considers that the same type of concept should apply to Friendly Societies. However, in the case of Friendly Societies that are already established under the status quo (we understand this is only six pharmacies) and are unable to reasonably structure their effective control arrangements, grandfathering of ownership provisions should be maintained, as they have been operating legitimately under the current rules and regulations.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

We are concerned that removal of majority pharmacist ownership of a community pharmacy under Option 2 eliminates current majority pharmacist owner effective control provisions – which will be detrimental to patient safety, patient health outcomes, the pharmacist's professional obligations, and the pharmacy profession generally.

Trained pharmacists in an investor owned pharmacy under open ownership are likely to be operating under quite strict productivity requirements with a financial orientation and hence a potential conflict with spending time on activities that may be of public good benefit but provide very little private benefit for the investor owner. The strongest obligation on a pure investor owned enterprise, and its management, is to generate sufficient returns on investment for equity owners. The primary way to do this in an investor owned community pharmacy is to increase aggregate sales revenue and effectively manage cost of goods sold to generate profit, rather than expanding time-consuming, unremunerated or under-remunerated personal health services. This may mean that pharmacies focus on increasing product turnover and margin rather than on consumer experience or outcomes, in a manner similar to some consumer product chains.

The research shows a clear trend of industry consolidation has been observed in countries that have relaxed their pharmacy ownership rules. In some countries, this has been a gradual and ongoing process, in others (such as Norway and Iceland) the industry landscape changed very rapidly.

The empirical evidence suggests that deregulation has not delivered the expected results, nor has it produced the competitive market environment that may be said to be in the long-term interests of consumers. These are trends that are difficult or impossible to reverse once they have begun.

European countries that have removed ownership limitations provide guidance on the potential risks of regulatory change. Their experience suggests that although open ownership models may improve access for already well-served urban populations, there are increased risks of reduced access for rural populations, the quality of some pharmacy services, and less competitive market structures. If the European experience was applied to New Zealand, then a proliferation of pharmacies in major metropolitan areas is likely, which would put at risk the breadth of services provided by pharmacies as their economies of scale are reduced.

The economic impact of relaxing the current ownership laws is significant, with a clear risk of economic concentration of pure investor owned pharmacies over time, driven by mergers, acquisitions, vertical and horizontal integration and market consolidation. The experience of the European countries that have removed ownership limits suggests market dynamics can change quickly, with market concentration and vertical integration resulting in market structures that then require policy-makers in some jurisdictions to intervene to provide greater assurance of competition. For example, within four years of Norway's reforms 97% of all community pharmacies were absorbed by three main pharmacy groups, with 77% fully-owned, and with each of the groups integrated with wholesalers. Government policy interventions were needed to manage the emergence of an anti-competitive market structure that developed (Anell & Hjelmgren, 2002; Anell 2005).

Option 2 may also cause future workforce issues due to the reduced opportunity for pharmacists to progress in their careers. Community pharmacy currently benefits from a relatively young workforce, with many attracted to the profession by the opportunity to one day own their own business.

Very little if any public evidence supports non-pharmacist ownership of pharmacies. Community pharmacy is a crucial part of the health system, providing services to consumers on behalf of the New Zealand Government. Services, such as dispensing and the range of quality control, advisory and ancillary services, have a major impact on health outcomes, if they are not readily available to those who need them, or are not provided correctly, they can seriously damage the health and quality of life of consumers. The Government, and the community more broadly, therefore, have a vital interest in the provision of these services. That interest is made all the greater by the fact that community pharmacy, if it performs well, reduces the costs of achieving the overall objectives of the health system, while poor performance in community pharmacy increases the health system's costs, including the burden that then falls on other parts of the system, such as medical practices and hospitals.

Option 2 also points to the fundamental rationale that prevails in governance and ownership structures that lean primarily towards financial incentive, as would be the case for non-pharmacist owners who are primarily concerned about shareholder returns. The proliferation of discount pharmacy chains that focus on retail offerings and use dispensing as a loss leader marketing tool is putting pressure on the community pharmacy model. Community pharmacy under option 2 will see greater commoditisation of medicines, dispensing and the degradation of the profession in the eyes of the public which will have detrimental effects on the Government's policy for better equity and access to community pharmacy.

The Guild has previously supplied evidence that New Zealand operates a very cost-efficient system for the Government under current pharmacist ownership regulations, which outperforms comparable jurisdictions operating under a form of open ownership regulations in terms of the cost of the funder (in terms of funding per item dispensed). This analysis is covered in the Ernst & Young report (commissioned by the Pharmacy Guild, Green Cross Health, and EBOS Limited) provided to Ministry officials in July 2017. We are happy to resupply this report if required, as we would like this report to be considered as part of our response.

Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. Because ownership rules limit dilution of equity, pharmacists cannot spread the risk associated with that asset to other investors in the way a listed entity would. By placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Government effectively raises the stakes for non-performance.

Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so they don't risk loss of registration and, therefore, loss of value in the pharmacy. In addition, owner-pharmacists are accountable to the public through their registration. A non-pharmacist owner would be accountable to their shareholders in the first instance.

A realistic comparison of different futures under the two options involves a consideration for the ideologies, principles and priorities that guide current operating decisions:

- by community pharmacies owned by pharmacists who choose not to sell products such as tobacco and alcohol that are widely acknowledged as harmful to health
- by non-pharmacists who have ownership stakes in supermarkets that sell both tobacco and alcohol in the same premise as the pharmacy, and actively promote the latter through advertising to drive sales. The non-pharmacist owners' financial interests effectively override the pharmacist's obligations under the Code of Ethics.

Community pharmacy owners made public statements opposing sale of tobacco in their pharmacies, citing the sale of tobacco conflicts with their public health obligations, public image as health professionals, and goes against their Code of Ethics as pharmacists (1 News, 2017) (Long, 2018) (Dennett, 2017). The ownership rules under Option 1 therefore contribute to the trust consumers have in community pharmacy, which in turn helps achieve the Government's public health objectives of ensuring access to safe and effective medicines. Option 2, in contrast, will not be in the public's best interests.

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Question C34 - Are there ways in which Option 2 could be improved?:

We do not see Option 2 as a feasible option.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

It is worth noting that the potential deregulation of pharmacy ownership appears to be the sole driver for the new supervisory pharmacist role, that is, there is no

other clear reason for the new role except to provide for additional oversight in a deregulated market.

In a large pure investor pharmacy chain, although employed by the investor owner, the supervisory pharmacist will have multiple accountabilities – to the regulator, their profession, and their employer. This can be expected to raise fully avoidable tensions between professional and commercial interests, and lead to accountability and employment conflicts.

There would also be a workforce capacity issue, in that significant training would need to be invested into the young pharmacist workforce to ensure they have the essential skills to perform adequately in such a role. Balancing a yet to be formed Regulator, professional obligations under new legislation, and commercial interests of an employer would require changes in pharmacy curriculum and further development of programmes for currently registered pharmacists.

We see that the divided role responsibilities and accountabilities that would arise under Option 2 will ultimately lead to reduced performance. This would manifest itself through increased public safety risks and additional compliance costs, both which are fully avoidable.

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

All pharmacy activities that require a pharmacy licence need to be conducted either by a pharmacist, or under the supervision of a pharmacist. We do not see how these activities can be performed safely without the direct in person oversight by a pharmacist. We are concerned that any change in this space could lead to patient safety issues.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

We do not support removing the restriction around prescribers holding an interest in a pharmacy. In order to remove any conflict of interest it is essential that prescribing and dispensing remain separate. We feel strongly that there needs to be a clear distinction in order to maintain public trust and confidence.

The Pharmacy Action Plan has allowed for the development of clinical pharmacy services such as CPAMS and vaccinations. However, we are aware (as is the Ministry) that some prescribers have put a lot of pressure on their local pharmacies not to offer some of these clinical services, as they see it as direct competition to their own practice. The concern from some pharmacy owners is that if they proceed with broadening their service offering for patients to include services like vaccinations, they may damage their relationship with their local prescribers. This has contributed to approximately only one third of community pharmacies offering vaccination services to date. We have concerns that if the prescriber interest restriction in a pharmacy is removed and prescribers have an interest in pharmacies, they will be able to restrict these services from being established, which will lead to further disruptions in the establishment of new clinical service offerings in pharmacy.

We are aware that the directing of prescriptions is a significant issue in certain areas of the country. This issue is highlighted in areas where discount pharmacies are located. This practice goes against the Medical Council Good prescribing practice where under point 47, prescribers are encouraged not to pressure their patients to use a particular pharmacy and not to disparage or otherwise undermine patients' trust in a pharmacy or a pharmacist. If a pharmacy is concerned about a prescriber directing their patients, there is a process to notify the Medical Council. However, in order for the Medical Council to investigate these claims they must share the name of the pharmacy concerned with the prescriber. Due to fear of how this will affect their relationship with that prescriber, pharmacies typically feel they cannot proceed with their complaint.

We feel the process of directing of prescriptions is currently not being managed appropriately in accordance with the Medical Council Good prescribing practice. With the removal of prescriber interest restrictions in a pharmacy, we have significant concern that this will further compound the issue of directing prescriptions. We believe it is paramount that patients have the right to, without influence, choose which pharmacy they have their prescriptions dispensed by.

In response to the comment around the one-sided nature of the current provision, we appreciate the theoretical nature of a pharmacist holding an interest in a general practice. However, from our knowledge this would not be typical, we are not aware of any pharmacists that hold an interest in a general practice. We would not regard this as suitable justification for removing the restriction of prescriber interest in a pharmacy.

We feel there will be significantly clear incentives for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs in that pharmacy, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue. Only true transparency can come from genuine distancing between the two separate processes.

We strongly support retaining the existing restrictions preventing prescribers from holding interest in pharmacies, and to continue to allow for exceptions to be consented by the licensing authority under specified conditions (when it can be clearly demonstrated that there will not be a conflict of interest). We feel that it is paramount to ensure that commercial or financial interests do not lead to any conflicts of interest.

We are aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Permits would be useful for urgent situations, such as civil emergencies and unexpected events.

Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Depots should be considered on a case by case basis to provide pharmacy services that cannot be serviced by existing licensed pharmacies. We agree that

depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

Depots should be audited as part of the linked full service pharmacy's audit.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We are supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Batch compounding is an efficient method of managing workflow for items of high turnover, and therefore should be allowed to continue. Batch compounding is currently scrutinised thoroughly during audit to ensure quality. Examples of expanded circumstances would need to be understood before we are able to usefully comment.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

We see it being appropriate for pharmacies that do not have a wholesale licence to provide medicines by wholesale in the following situations:

- Where medicines are supplied between pharmacies of common ownership.
- Where medicines are supplied to other pharmacies to reduce the wastage of medicines, particularly high cost medicines.
- To private and public hospitals serviced by a community pharmacy rather than an in-house pharmacy.
- To support after-hours access.
- To ships and aircraft.
- To meet patient need in the event of widespread short-supply or discontinuation of a medicine.
- In circumstances requiring an emergency response.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

We are happy with the proposed approach given the relevant responsible authority under the HPCAA would first need to consult with any potentially affected organisations.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

We would welcome a consistent approach to prescribing provisions within health practitioners' scopes of practice, so that each scope clearly specifies who and what can be prescribed.

It would be great if this collated information was readily available to pharmacists, so they didn't need to access numerous websites in order to check a prescription was legally within a health practitioner's scope.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

We will wait to comment until the regulations are drafted.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

We are supportive of the addition of the special clinical needs supply authority (SCNSA) requirement in authorising the supply of unapproved products. Currently, when medical practitioners prescribe unapproved medicines, they are often unaware that they are prescribing an unapproved medicine. This additional step will ensure that patients receive the appropriate advice and care to ensure their rights to make an informed decision are maintained. We also believe that this will increase patient accessibility to a wider range of treatment options which is positive.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

We would see it as appropriate for the legislation to continue to only allow medical practitioners to access unapproved medicines. While other health practitioners

may be specialists in particular areas, currently they are required to be under supervision of a medical practitioner and therefore, if an unapproved medicine was required, they would already be expected to consult with that medical practitioner.

We also want to ensure there are provisions to allow for the continuation of supply of medicines in situations where approved products become un procurable. In some instances, when a suitable approved replacement cannot be found, an unregistered equivalent is used. However, this restriction will prevent other health practitioner prescribers from accessing the medicine until the original approved medicine is available again or another approved alternate is found. Permits may be able to resolve this issue.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We are supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

We would only support this in emergency situations and in situations where there was infrequent supply of medicines where part packs were needed.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

We would only support this in emergency situations and in situations where the device was infrequently required.

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

We are strongly opposed to this. We do not believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.

We believe there is a real level of risk that health practitioners will benefit from the sale of category 3 medicines to patients' detriment. Current competitive landscape for these products encourages more affordable pricing and therefore more accessible medicines. The Guild believes this will lead to situations where there is a risk that patients of health practitioners will be offered limited product ranges at premium pricing without an explanation that they are available at other outlets (for example Veterinary medicine pricing compared to pharmacy pricing). We fail to see how this will benefit patients. It also risks incentivising prescribers to sell category 3 products that are also available on prescription for commercial gain.

Stored medicines require strict temperature monitoring to ensure they stay within their specified temperature limits. In pharmacy this process includes using a temperature monitoring device to actively monitor the ambient room temperature and recording temperatures daily as evidence that medicines are stored correctly. Regular validation of temperature monitoring devices is required to ensure that the devices are accurately reading the correct temperature. This process is regularly audited.

Pharmacies also require the presence of a pharmacist when open for business and while other staff are inside the pharmacy. This is to ensure that all medicines have appropriate oversight.

To ensure that all medicines are handled and stored in the appropriate manner, we would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same requirements that exist within a pharmacy, with the same need for regular audits.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

We do not support the authorisation for all health practitioner staff to supply category 3 medicines to the patients of health practitioners. We understand from the Ministry's TPB pharmacy forum that the intention is only for staff to process the sale of these medicines following a recommendation from the health practitioner, however this isn't clear based on the draft Bill and we have significant concerns about the safe and appropriate supply of medicines to patients. We also do not understand how repeated sale of products would occur, for example in a medical centre environment, where the practitioner is not readily accessible.

Typically, health practitioners would be in consultation rooms separate from their other staff, this would make it practically challenging for health practitioners to provide general supervision to staff. We understand from the forum that the supply of medicines would occur only after immediate consultation with a patient's health practitioner but would like to understand what the expectation is for advice and counselling to these patients.

In a pharmacy, a pharmacy assistant or technician would have ready access to a pharmacist on duty. Pharmacy staff are trained appropriately to ensure the safe and effective supply of medicines. They are also trained to know when to refer patients onto the pharmacist. The ready availability of the pharmacist provides significant benefits in the ability to provide treatments for minor ailments in a timely manner.

We would also expect that to safely supply medicines to patients, they would have to be handled and stored to the same level that is required within a pharmacy.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We believe direct-to-consumer advertising should continue to be permitted, as it promotes health awareness and encourages patients to take a proactive role in

the management of their own health.

Research has found that direct-to-consumer advertising encourages patients to act on undiagnosed or poorly managed conditions and improves treatment adherence.

Direct-to-consumer advertising is also extensively regulated and reviewed, ensuring it is accurate and complies with all relevant legislation, regulations and codes.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We believe direct-to-consumer advertising should continue to be permitted, as it promotes health awareness and encourages patients to take a proactive role in the management of their own health.

Research has found that direct-to-consumer advertising encourages patients to act on undiagnosed or poorly managed conditions and improves treatment adherence.

Direct-to-consumer advertising is also extensively regulated and reviewed, ensuring it is accurate and complies with all relevant legislation, regulations and codes.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

We are supportive of the addition of the special clinical needs supply authority (SCNSA) requirement in authorising the supply of unapproved products. Currently, when medical practitioners prescribe unapproved medicines, they are often unaware that they are prescribing an unapproved medicine. This additional step will ensure that patients receive the appropriate advice and care to ensure their rights to make an informed decision are maintained. We also believe that this will increase patient access ability to a wider range of treatment options which is positive.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

We would see it as appropriate for the legislation to continue to only allow medical practitioners to access unapproved medicines. While other health practitioners may be specialists in particular areas, currently they are required to be under supervision of a medical practitioner and therefore, if an unapproved medicine was required, they would already be expected to consult with that medical practitioner.

We also want to ensure there are provisions to allow for the continuation of supply of medicines in situations where approved products become unprocurable. In some instances, when a suitable approved replacement cannot be found, an unregistered equivalent is used. However, this restriction will prevent other health practitioner prescribers from accessing the medicine until the original approved medicine is available again or another approved alternate is found. Permits may be able to resolve this issue.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We are supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

We do not support it being appropriate to authorise the personal import of medicines. We strongly believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine. The personal importation of medicines would not align with the concerns of the Ministry of Health around the risk of substandard and contaminated medicines.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Our members welcome and embrace opportunities and arrangements that promote patient health outcomes and do not compromise patient safety or the integrity of the community pharmacy distribution model.

Separation of prescribing and dispensing is a key principle in the New Zealand medicines system in primary care. A key safety feature in the system is the legal form of a prescription, which patients have personal control over (ie, choice over where a prescription is fulfilled) and any alternative distribution or supply model that is considered, must not undermine the intent, integrity, and security of the current system.

Drug related problems (DRP) account for up to 12.1% of hospital admissions, and 50% of these DRP are avoidable (Hamid, Ghaleb, Aljadhey, & Aslanpour, 2014) (Nivya, Kiran, Ragoo, Jayaprakash, & Sekhar, 2015). This figure is underrepresented as, for example, falls are not classified as DRP but up to 35% are related to medicines (Barnett, Athwal, & Rosenbloom, 2011). These figures are likely to worsen with an aging population and increasing polypharmacy trends. Alternate supply arrangements that lessen patient-pharmacist interactions, such as vending machines, need to be carefully and objectively evaluated to ensure patient outcomes are not compromised.

When considering the potential introduction of any disruptive distribution and supply arrangement, it is crucial to recognise that dispensing a prescription medicine is a service requiring specific clinical expertise supported by tailored professional counselling and advice specific to a particular patient at a particular time. This involves considering patient factors such as age, personal goals, social situation, psychological state, spiritual factors and clinical goals. This level of patient interaction can only be attained by building relationships with patients through face-to-face interactions.

The clinical process of dispensing a prescription medicine and conveying the health and safety requirements of that medicine to the patient is far different to the sale of a retail commodity. The quality use of a medicine applied in the specialised clinical service of dispensing should be provided face-to-face with the patient by the pharmacist. These views are shared by health sector regulators such as the Pharmacy Board of Australia who consider the indirect supply of medicines, such as internet and mail-order dispensing, as less than the optimal way of delivering a pharmacy service because communication may be compromised (Pharmacy Board of Australia, 2010).

The consultation around the proposed regulation of therapeutic products distinguishes between licence-based requirements for pharmacy activities and qualification-based requirements for pharmacists (which is covered under the HPCAA). In practical terms, the proposed regulations would enable situations where a pharmacist could administer medicines, but not have to be monitored against requirements that would normally apply regarding safe storage and handling of therapeutic products. This creates a level of ambiguity that needs to be resolved to mitigate any product-based risks in the broader therapeutic product supply chain. In resolving the ambiguity, it would be useful for the sector to understand and consider the modelled costs of monitoring compliance versus the benefits that would realistically accrue to the public from such distribution and supply arrangements.

Such an impact analysis should consider published studies into comparable distribution arrangements such as the 'Hub & Spoke' model. For example, research undertaken by the National Pharmacy Association UK (Hewitson & Jones, 2016) found that:

- Although Hub & Spoke could provide capacity to deliver more health care services through community pharmacy, the system is complex with a number of implementation problems.
- Many items cannot be supplied by a Hub, for example, controlled drugs, cold chain, and acute or urgently required items.
- Although it might be possible to reduce staffing levels at spoke pharmacies, this is a highly risky and potentially destructive option which defeats the purpose of freeing pharmacy teams to spend more time delivering care to patients.
- Hub & Spoke may have some advantages over manual prescription assembly for the accuracy of drug picking, however this is only one of many tasks in the dispensing process.
- Data entry at the Spoke is the critical process to make Hub & Spoke work safely – while intra-company hub & spoke models can reasonably enforce quality improvements in this activity, this would be extremely difficult to replicate between companies.
- There is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs.

References:

- Barnett, N., Athwal, D., & Rosenbloom, K. (2011). Medicines-related admissions: you can identify patients to stop that happening. *The Pharmaceutical Journal*.
- Hamid, A. A., Ghaleb, M., Aljadhey, H., & Aslanpour, Z. (2014). A systematic review of hospitalization resulting from medicine-related problems in adult patients. *British Journal of Clinical Pharmacology*, 202-217.
- Hewitson, M., & Jones, G. (2016). Hub & Spoke Evidence Based Policy Review. National Pharmacy Association.
- Nivya, K., Kiran, V. S., Ragoo, N., Jayaprakash, B., & Sekhar, S. M. (2015). Systemic review on drug related hospital admissions – A pubmed based search. *Saudi Pharmaceutical Journal*, 1-8.
- Pharmacy Board of Australia. (2010). Guidelines for dispensing of medicines. Melbourne.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Legislation should promote and ensure the safe and effective delivery of pharmacy services to the public, with the regulator ensuring compliance with legislation. The details of how services and activities are best provided should sit between the licensed service provider, the purchaser of those services and the service user. We consider any changes to legislation that prescribe the delivery of activities through changes to the end-to-end nature of dispensing activity without any legitimate or objective policy justification for that change will risk significant adverse impacts on the provision of health services in community pharmacy.

We note there is a critical piece of work being undertaken as part of Integrated Community Pharmacy Services Agreement to provide an objective basis for whether the splitting of dispensing activities is in the public interest. The downstream details of how such activities are provided is a subsequent step in the

process. This piece of work, and any accompanying recommendations, are yet to be completed. Any consultation on the provision of activities or supply arrangements, that change the fundamental nature of current safe and effective provision of services is premature and risky from public safety lens.

The examples of service innovation given include providing marae-based services or providing pharmacist services at events such as Fieldays. We would be supportive of these approaches as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this is about awareness and service provision, such as blood pressure checks, and would not include dispensing outside of a pharmacy dispensary.

The other examples given are a pharmacist visiting a rest home to supply particular medicines and enabling mobile pharmacies in the form of a vehicle set up to provide pharmacist services, including the supply of particular medicines.

We do not understand how medicines are able to be dispensed outside of a pharmacy dispensary. Pharmacies have all the required dispensary equipment, access to reference resources, and standard operating procedures, as per audit requirements.

While mobile pharmacy vehicles may be an alternative solution to servicing rural areas currently serviced by pharmacy depots, this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

The Guild supports pharmacist ownership of community pharmacies and supports Option 1 conditionally. Our responses to questions C24 and C25 elaborate on the necessary conditions that would improve the workability and practicality of pharmacist ownership and effective control under Option 1.

We firmly believe that there is strong public benefit in a healthy network of community pharmacies owned by pharmacists who are totally in control of, and accountable for, the decisions made in the interests of their patients' care. Pharmacist ownership and effective control assures New Zealanders that patient care is the focus of community pharmacy practice. Ownership rules requiring pharmacies to be owned by pharmacists and limiting the number of pharmacies each pharmacist can own, ensures a decentralised and diverse ownership structure. These rules ensure that pharmacies maintain an efficient, effective and patient centred service delivery focus.

Ownership of the pharmacy also helps ensure independence of the pharmacist's professional decisions. Having ownership rules in place encourages efficiency in the provision of community pharmacy services, while ensuring that those services are provided with high quality standards. Owner-pharmacists have an increased incentive to conduct themselves and their pharmacies ethically and professionally, so as not to risk loss of value in their pharmacy.

Pharmacists are under a professional obligation to provide services and a standard of care that requires adherence to higher standards than those likely to be imposed by the regulator. An investor owner is more likely to focus on meeting minimum compliance standards at minimum cost which will have a negative impact on the range and scope of services the investor owner is prepared to provide.

Requiring community pharmacies to be owned by pharmacists under Option 1 means that health professionals with 'skin in the game' focus first and foremost on delivering quality health outcomes to maximise their professional and business goodwill. It also prevents an over concentration in pharmacy ownership.

When one recognises the primary purpose of the community pharmacy network and the core responsibility it is tasked with on behalf of the Government, it becomes clear why the Option 1 community pharmacy model, with pharmacist ownership, is both effective and superior to any proposed alternative approaches. Indeed, where it has occurred in other countries, the market structure that has emerged following pharmacy deregulation has arguably not served the broader public interest.

Medicines are not a normal item of commerce and pharmacies are not like other small businesses in a free market environment. Prices for dispensing of PHARMAC scheduled medicines and community pharmacy services are agreed by DHBs and community pharmacy providers through funding mechanisms via the Integrated Community Pharmacy Services Agreement, which outlines the limitations on the commercial flexibilities that all community pharmacies can exercise on dispensed prices for funded items to consumers. Rather, community pharmacies are explicitly tasked to deliver better and broader primary health outcomes closer to people's homes as part of the New Zealand Health Strategy and Pharmacy Action Plan through the professional dispensing of Scheduled medicines and related services, working effectively as collaborative health providers for the Government to deliver equitable and accessible care in communities.

The success of the current commercial community pharmacy model provides strong support for the Government's ongoing stewardship and regulatory role in the sector. The Government has a legitimate interest in shaping the way in which publicly subsidised medicines and associated services are delivered, particularly as equity of access and patient outcomes are central objectives in public health policies. Given these objectives, it is valid and unsurprising that key features of the community pharmacy model differ from those that would emerge if competition and market forces alone were to determine ownership (as seems to be the case under Option 2), or if interdependencies with the broader health system were not important.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

There are a number of important public interest reasons for keeping ownership and effective control of pharmacies in the hands of licensed pharmacists. Ensuring that a pharmacist owns and controls a pharmacy practice is a social objective underpinned by legislation. It reflects the community expectations and desire to maintain the integrity of the professional relationship between pharmacist and patient. That relationship hinges on trust and personal service, with pharmacists being directly accountable and liable for the services they provide. Needless to say, a level of accountability is also expected of employee pharmacists. However, the clear intent of the ownership legislation is to ensure that professional standards and principles are not subordinated to commercial objectives and pressures in the practice of pharmacy.

Rules regarding pharmacy ownership play an important part in achieving the Government's health policy goals, in terms of:

- preventing horizontal and vertical integration and therefore concentration of the pharmacy sector, thus minimising costs and financial risks to funders and to

taxpayers

- ensuring that quality service standards are adhered to, since pharmacists who breach the standards risk losing the considerable human and physical capital invested in their pharmacy.
- ensuring equity of access to health services no matter where our populations choose to live.

Community pharmacies, under the current majority pharmacist ownership requirements, are delivering many benefits to patients and the wider health sector at no cost to patients or the funder. This includes resolving minor health-related issues quickly in the pharmacy and helping patients find the right health services to meet their needs – commonly referred to as pharmacy's unfunded triage and referral role. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. In contrast, pure investor owners would likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted due to the loss of commercial value from a sell down of private equity to align with the prescribed shareholding requirements under the proposed Option 1. The Guild considers the dollarised impact on the private sector could be substantial. There would be a significant write-down in the capital value of New Zealand's community pharmacies, which would be unfair to existing pharmacy owners and investors who have complied with all regulatory licensing requirements. This risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.

Even with grandparenting provisions, there is a risk of a reduced level of external investment from the proportionate dividend requirements under the proposed Option 1. Private and institutional investment in health-based SMEs is regarded as a prudent social investment opportunity to fund the greater level of equitable health care and services required to sustain an aging demographic that is living longer. Pharmacy owners require a level of external investment to sustain growth, respond to mounting competitive pressures, innovate, and ensure affordability of newer assets and technologies to serve our populations more efficiently. Absent a level of flexibility in equity investment – the ability to fairly remunerate, effectively innovate and invest in the community pharmacy sector is greatly diminished.

The financial impacts of strict dividend requirements will likely be felt by most community pharmacy owners across the ownership lifecycle, from initiating an ownership stake to divestment. The nature of these financial impacts on pharmacy businesses are elaborated under question C30 using realistic and practical examples. A prudent risk/impact minimisation and practical enhancement to Option 1 involves legally mandating that the majority pharmacist owner has a conditional 'veto share' so that this pharmacist is always in control of all voting rights on decisions that affect or have the potential to affect patient safety (patient safety being the veto condition). This effectively gives the pharmacist owner control of all activities, operations and governance matters related to the pharmacy. A veto share of this conditional nature ensures effective control is in the hands of a pharmacist and replaces the need for regulating dividend requirements in proportion to shareholding. This mechanism allows and retains some flexibility for pharmacist owners to raise capital, while maintaining the public safety elements, including how capital is deployed operationally.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

We are concerned that removal of majority pharmacist ownership of a community pharmacy under Option 2 eliminates current majority pharmacist owner effective control provisions – which will be detrimental to patient safety, patient health outcomes, the pharmacist's professional obligations, and the pharmacy profession generally.

Trained pharmacists in an investor owned pharmacy under open ownership are likely to be operating under quite strict productivity requirements with a financial orientation and hence a potential conflict with spending time on activities that may be of public good benefit but provide very little private benefit for the investor owner. The strongest obligation on a pure investor owned enterprise, and its management, is to generate sufficient returns on investment for equity owners. The primary way to do this in an investor owned community pharmacy is to increase aggregate sales revenue and effectively manage cost of goods sold to generate profit, rather than expanding time-consuming, unremunerated or under-remunerated personal health services. This may mean that pharmacies focus on increasing product turnover and margin rather than on consumer experience or outcomes, in a manner similar to some consumer product chains.

The research shows a clear trend of industry consolidation has been observed in countries that have relaxed their pharmacy ownership rules. In some countries, this has been a gradual and ongoing process, in others (such as Norway and Iceland) the industry landscape changed very rapidly.

The empirical evidence suggests that deregulation has not delivered the expected results, nor has it produced the competitive market environment that may be said to be in the long-term interests of consumers. These are trends that are difficult or impossible to reverse once they have begun.

European countries that have removed ownership limitations provide guidance on the potential risks of regulatory change. Their experience suggests that although open ownership models may improve access for already well-served urban populations, there are increased risks of reduced access for rural populations, the quality of some pharmacy services, and less competitive market structures. If the European experience was applied to New Zealand, then a proliferation of pharmacies in major metropolitan areas is likely, which would put at risk the breadth of services provided by pharmacies as their economies of scale are reduced.

The economic impact of relaxing the current ownership laws is significant, with a clear risk of economic concentration of pure investor owned pharmacies over time, driven by mergers, acquisitions, vertical and horizontal integration and market consolidation. The experience of the European countries that have removed ownership limits suggests market dynamics can change quickly, with market concentration and vertical integration resulting in market structures that then require policy-makers in some jurisdictions to intervene to provide greater assurance of competition. For example, within four years of Norway's reforms 97% of all community pharmacies were absorbed by three main pharmacy groups, with 77% fully-owned, and with each of the groups integrated with wholesalers. Government policy interventions were needed to manage the emergence of an anti-competitive market structure that developed (Anell & Hjelmgren, 2002; Anell 2005).

Option 2 may also cause future workforce issues due to the reduced opportunity for pharmacists to progress in their careers. Community pharmacy currently benefits from a relatively young workforce, with many attracted to the profession by the opportunity to one day own their own business.

Very little if any public evidence supports non-pharmacist ownership of pharmacies. Community pharmacy is a crucial part of the health system, providing

services to consumers on behalf of the New Zealand Government. Services, such as dispensing and the range of quality control, advisory and ancillary services, have a major impact on health outcomes, if they are not readily available to those who need them, or are not provided correctly, they can seriously damage the health and quality of life of consumers. The Government, and the community more broadly, therefore, have a vital interest in the provision of these services. That interest is made all the greater by the fact that community pharmacy, if it performs well, reduces the costs of achieving the overall objectives of the health system, while poor performance in community pharmacy increases the health system's costs, including the burden that then falls on other parts of the system, such as medical practices and hospitals.

Option 2 also points to the fundamental rationale that prevails in governance and ownership structures that lean primarily towards financial incentive, as would be the case for non-pharmacist owners who are primarily concerned about shareholder returns. The proliferation of discount pharmacy chains that focus on retail offerings and use dispensing as a loss leader marketing tool is putting pressure on the community pharmacy model. Community pharmacy under option 2 will see greater commoditisation of medicines, dispensing and the degradation of the profession in the eyes of the public which will have detrimental effects on the Government's policy for better equity and access to community pharmacy.

The Guild has previously supplied evidence that New Zealand operates a very cost-efficient system for the Government under current pharmacist ownership regulations, which outperforms comparable jurisdictions operating under a form of open ownership regulations in terms of the cost of the funder (in terms of funding per item dispensed). This analysis is covered in the Ernst & Young report (commissioned by the Pharmacy Guild, Green Cross Health, and EBOS Limited) provided to Ministry officials in July 2017. We are happy to resupply this report if required, as we would like this report to be considered as part of our response.

Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. Because ownership rules limit dilution of equity, pharmacists cannot spread the risk associated with that asset to other investors in the way a listed entity would. By placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Government effectively raises the stakes for non-performance.

Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so they don't risk loss of registration and, therefore, loss of value in the pharmacy. In addition, owner-pharmacists are accountable to the public through their registration. A non-pharmacist owner would be accountable to their shareholders in the first instance.

A realistic comparison of different futures under the two options involves a consideration for the ideologies, principles and priorities that guide current operating decisions:

- by community pharmacies owned by pharmacists who choose not to sell products such as tobacco and alcohol that are widely acknowledged as harmful to health
- by non-pharmacists who have ownership stakes in supermarkets that sell both tobacco and alcohol in the same premise as the pharmacy, and actively promote the latter through advertising to drive sales. The non-pharmacist owners' financial interests effectively override the pharmacist's obligations under the Code of Ethics.

Community pharmacy owners made public statements opposing sale of tobacco in their pharmacies, citing the sale of tobacco conflicts with their public health obligations, public image as health professionals, and goes against their Code of Ethics as pharmacists (1 News, 2017) (Long, 2018) (Dennett, 2017). The ownership rules under Option 1 therefore contribute to the trust consumers have in community pharmacy, which in turn helps achieve the Government's public health objectives of ensuring access to safe and effective medicines. Option 2, in contrast, will not be in the public's best interests.

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- 1 News. (2017, June 3). 'I'm shocked' – pharmacists outraged at suggestions they could end up selling cigarettes. Retrieved from 1newsnow: https://www.tvnz.co.nz/one-news/new-zealand/im-shocked-pharmacists-outraged-suggestions-they-could-end-up-selling-cigarettes?variant=tb_v_1

Access to pharmacy medicines

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We are strongly opposed to this. We do not believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.

We believe there is a real level of risk that health practitioners will benefit from the sale of category 3 medicines to patients' detriment. Current competitive landscape for these products encourages more affordable pricing and therefore more accessible medicines. The Guild believes this will lead to situations where there is a risk that patients of health practitioners will be offered limited product ranges at premium pricing without an explanation that they are available at other outlets (for example Veterinary medicine pricing compared to pharmacy pricing). We fail to see how this will benefit patients. It also risks incentivising prescribers to sell category 3 products that are also available on prescription for commercial gain.

Stored medicines require strict temperature monitoring to ensure they stay within their specified temperature limits. In pharmacy this process includes using a temperature monitoring device to actively monitor the ambient room temperature and recording temperatures daily as evidence that medicines are stored correctly. Regular validation of temperature monitoring devices is required to ensure that the devices are accurately reading the correct temperature. This process is regularly audited.

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To ensure that all medicines are handled and stored in the appropriate manner, we would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same requirements that exist within a pharmacy, with the same need for regular audits.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

We do not support the authorisation for all health practitioner staff to supply category 3 medicines to the patients of health practitioners. We understand from the Ministry's TPB pharmacy forum that the intention is only for staff to process the sale of these medicines following a recommendation from the health practitioner, however this isn't clear based on the draft Bill and we have significant concerns about the safe and appropriate supply of medicines to patients. We also do not understand how repeated sale of products would occur, for example in a medical centre environment, where the practitioner is not readily accessible.

Typically, health practitioners would be in consultation rooms separate from their other staff, this would make it practically challenging for health practitioners to provide general supervision to staff. We understand from the forum that the supply of medicines would occur only after immediate consultation with a patient's health practitioner but would like to understand what the expectation is for advice and counselling to these patients.

In a pharmacy, a pharmacy assistant or technician would have ready access to a pharmacist on duty. Pharmacy staff are trained appropriately to ensure the safe and effective supply of medicines. They are also trained to know when to refer patients onto the pharmacist. The ready availability of the pharmacist provides significant benefits in the ability to provide treatments for minor ailments in a timely manner.

We would also expect that to safely supply medicines to patients, they would have to be handled and stored to the same level that is required within a pharmacy.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We believe direct-to-consumer advertising should continue to be permitted, as it promotes health awareness and encourages patients to take a proactive role in the management of their own health.

Research has found that direct-to-consumer advertising encourages patients to act on undiagnosed or poorly managed conditions and improves treatment adherence.

Direct-to-consumer advertising is also extensively regulated and reviewed, ensuring it is accurate and complies with all relevant legislation, regulations and codes.

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G48H-1

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:03:34

Submitter profile

What is your name?

Name:

Valerie H Markham

What is your email address?

Email:

What is your organisation?

Organisation:

Private citizen

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Nurse, Other health practitioner (please comment)

If you select 'Other', please comment below;:

Professional Medical Researcher, now Actively retired advocate for people with Mental illnesses

Other (please comment)

If you selected 'Other' please comment;:

Advocate for people with mental illnesses

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Appears to be vast, much needed improvement in holding practitioners accountable.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Again, far-reaching modifications are huge improvement.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Improvement.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Good, comprehensive.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Great care needed in professional experience and expertise essential to safe prescribing practice.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

yes.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

This is a dangerous practice, but nevertheless reference to individual autonomy cannot be ignored.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
Cautiously approve.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Not sure that is a good idea,-- continuous medical assessment would be necessary to continue issuing authority. Danger of missed adverse effects unless clinically supervised.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Possibly, but still need some kind of continuing clinical supervision to be safe.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4FK-J

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:12:21

Submitter profile

What is your name?

Name:

Chris Fowlie

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Zeacann Limited

Submitter Profile (tick all that apply)

Medicines, Cells and tissues, Active ingredients

Medicines, Cells and tissues, Active ingredients

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

We support the general intention and these interpretations, with two important caveats:

New legislation should be introduced for Natural Health Products, as flagged at clause 16(3). Without this the existing Medicines Act and this proposed Therapeutic Products Bill have too wide a scope. We support using 16(3) to declare natural health products to not be therapeutic products.

Ensure the medicinal cannabis scheme is not made unworkable. Use the same clause 16(3) to declare products and activities licenced under the medicinal cannabis scheme to not be therapeutic products.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Medicinal cannabis products are mostly generic, reflecting the traditional use patterns and plant-derived nature of the products.

We are concerned the proposed approach may inhibit importing or manufacturing medicinal cannabis products. A sponsor could stake out the main dosage forms that patients know and want, without actually having researched or developed that dosage, simply by sponsoring a product first. This could be used in anti-competitive ways.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Recognising the objectives of the medicinal cannabis scheme, categories of medicinal cannabis products could be declared "approval exempt". For example low dose topicals, or single dose soft gel capsules.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

We only point out that the medicinal cannabis scheme may involve persons who have experience in illicit markets.

Moving forward, there should be no restrictions on offence categories that would not be considered offences if they had been licenced to do so.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We are concerned about any unintended consequences that may, in effect, reduce patient access to medicinal cannabis products.

Zeacann intends to import and distribute medicinal cannabis products, and we expect most products covered by the medicinal cannabis scheme to be unapproved.

We are concerned about how changes to the way unapproved medicines may be prescribed, dispensed and obtained may impact on the medicinal cannabis scheme.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

This licence seems outdated and no longer necessary.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

We support innovative arrangements that better enable patient access to the products and services they need. This includes using technology for online, mobile and remote dispensing.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

Quality control is what counts, not ownership.

Pharmacists should be freed up from the requirements of owning a small business, so they can concentrate on good healthcare for their customers.

Open ownership will result in patients having access to a wider variety of products at better prices.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Efficiencies from a business point of view.

Pharmacists focusing on what they're trained to do.

Patients receiving better service.

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

The existing separation is appropriate to managing risks.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Yes, there could be unintended consequences for access to medicinal cannabis products.

We expect most products covered by the medicinal cannabis scheme will be "unapproved" products. It is important these can still be imported and dispensed.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

The medicinal use of cannabis is widespread but poorly understood by many practitioners. Their patients may feel they know more than their doctor, however those using illicit cannabis medicinally may have little idea what it contains or their dosage history. In this circumstance it is really important there is good access to high quality information. We have concerns that any restriction on advertising may reduce access to the information prescribers, pharmacists, and patients need to make well informed decisions. There is already some difficulty providing clinical guidance to practitioners.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4UX-E

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:14:23

Submitter profile

What is your name?

Name:

Mitch Clarke

What is your email address?

Email:

What is your organisation?

Organisation:

Bayer

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medical devices, Medicines

Medical devices, Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

The purpose and principles of the Bill appear reasonable. Would propose that the section regarding alignment with international standards should be reworded to ensure the regulator is not obliged to adopt ALL standards and practices, but retains flexibility with what is adopted.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Explanation given in consultation document for hybrid products is "the regulator would be able to declare that a particular therapeutic product or class of therapeutic products is a medicine (or alternatively that it is a medical device) via a notice. Once this type categorisation has been determined, the product would follow the regulatory pathway that is appropriate for the product type, but importantly the technical requirements placed on that hybrid product would reflect its hybrid nature". The proposed wording makes planning difficult and could cause transparency issues. Would propose that the AU definitions be followed, as then the category would be able to be determined without a declaration from the Regulator. The need to classify on an individual basis is problematic as often technical documentation is prepared well ahead of the submission date, therefore clarity around technical requirements would be appreciated. Furthermore, if a notice is

required for categorisation, would the notice then be made public so that like products would be pre-determined?

Section 11 Grandfathered products - It is not clear if a grandfathered medicine that has subsequently had CMN's approved is treated as an approved medicine or if the grandfathering clause applies. It appears that if there has been no CMN under 24(1) within the last 2 years then grandfathering might apply?

Section 14 - Does not allow for approvals that are currently medical devices but will become medicines possibly? This does not appear to have been considered as a possibility.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Section 52 provides regulation on the importation of a medicine, where the person is authorised by a licence, permit, or provision of subpart 3 of Part 3 to import or supply the product without being approved. Subpart 3 of Part 3 does not appear to include wholesalers. Clarity around how these sections incorporate the importation of unapproved products by wholesalers would be appreciated.

Page 55 of the Consultation Document states that Regulations would be used to authorise importation and supply of unapproved medicines, stating an example where by a sponsor who has applied, and is waiting for, a product approval. What about a company that has not applied for a product approval?

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Section 54 talks about authorising the supply, by pharmacists, of prescription medicines such as trimethoprim and the emergency contraceptive pill in specified circumstances. Therefore, will the current situation used in classification to supply prescription medicines under exemption in some circumstances be maintained in the Bill (e.g. prescription except products)?

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Appreciate that the SCNSA process may allow for greater monitoring of off-label use, which currently is unknown. However, would be cautious regarding the process to ensure that registration of new indications doesn't become more for promotional purposes, as once a medicine is approved, a practitioner can use it for any indications with minimal paperwork.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

The issuer of the special clinical needs supply authority (s64(2)), a pharmacist (s58(5)), or a wholesaler (whose licence allows them to do so) could then import the medicine for the patient. This has been previously mentioned, but can't find section that enables wholesalers to do this.

Comments with regard to Section 52 and 76 of the Bill. Section 76 would continue to allow consumers to import category 2, 3 or 4 (non-prescription) medicines by post. However, this seems to allow consumers to do their own importing, and the amounts the Bill allows are could potentially cause Section 52 to be redundant. The section does seem to allow consumers access to everything available online, even medicines from largely unregulated countries. Counterfeit medicines imported from overseas for personal use could cause significant safety issues to consumers while having a significant impact to the regulator and pharmaceutical industry in NZ.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Obtaining medicines from vending machines – the scope of this should include devices, if not already.

In Australia, there are vending machine-sized pack sizes (usually single dose size) of paracetamol, ibuprofen etc that have been registered exactly for this purpose. Is including specific vending machines requirements within the legislation going away from the idea of a flexible Bill, may be better sitting within the regulations/rules to ensure the practicality of the requirements.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Section 104 states that the approval lapses if the sponsor is subject to an insolvency event. Approvals in such an event should still be able to be transferred to another sponsor, rather than lapsed.

Supportive of continuing to rely on reports or assessments made by recognised authorities when making an application. This is important to ensure harmonisation between markets on approval and reduce approval times. Would support extension of an abbreviated-type process to devices and variations. Although this will not be included in the legislation, making some variations notifiable where recent TGA approval of the same change has occurred would be a welcome addition for harmonised products across ANZ.

Would appreciate to know if there will be ongoing costs to remain on the NZ register for medicines, as there is currently no ongoing cost once registered with Medsafe.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Supportive of applications continuing to be publically available while pending, provided this is limited to the category of the submission only. The decision to make pending applications publically available is currently being reviewed by the TGA. Alignment across both countries would be appreciated.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

The protection period of 5 years for a pending application may be too short in some instances. Especially in cases of novel treatments, where considerable expert advice may be required (especially in the area of cells and tissues), an extended data protection period may be required for the pending application.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Section 137(3) - 20 days may be insufficient time, and potentially too specific to be in the Act. The regulator is likely to be unable to meet this timeframe, and so the roll-over clause will be the norm.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

Clarification on the responsible person section, especially in regards to organisation that split their business across ANZ, should be provided. Many companies operate their regulatory and QA functions out of Australia. If the tasks the responsible person in NZ is changing, this may require a change in company structures in NZ. Furthermore, it is not clear if the responsibilities of the responsible person can be delegated, or if the individual (as well as the company) is legally liable if there is a breach of the legislation. Also applies to section 245(1) where the defence of being reliant on another person does not apply if they work for the same organisation (it is not clear how this might apply across international borders). More clarification around the responsibilities of the responsible persons, liability and delegation would be appreciated.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

In line with previous comment, how will this system differentiate between approved products lawfully supplied, and unapproved products lawfully imported for personal use which may look very similar but be different.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Section 200 - It is not clear how much information is required in order to apply for a review. Applying for a review within 30 days of the decision may not leave enough time to build the case for review – does this need to be adjusted or have the specified timeframe removed from the bill if the detail of the review process has not been discussed?

Section 201 – suggesting that the complainant should be able to also suggest appropriate people for the review panel.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Section 267(3) – Consider revising clause 3. For transparency and consistency of the process, it should be mandatory for the regulator to follow process when implementing new rules.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Note the EU and AU can be different in regards to notifications categories, is there a preference? Would support the TGA method of recognising GMP for product site changes, significantly reducing evaluation timeframes for some changes.

Paragraph 262 states that approval relating to the unchanged product would remain in place. Is this intended to align with the current practice where approval of a variation via CMN does not void approval of the previously approved information? If this is not intended with the Bill, this will need to be clearly communicated with timings around sell of stock following approval of a variation. If this is intended, how will Medsafe know which varied product was continued to be supplied on the market?

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

This is a sensible approach that would minimise unneeded complexities and administration (as seen with the current system where the need to update records when a minor change occurs).

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

There are slight differences between device classes between the EU and TGA. These differences can cause significant changes in timelines for approval and documents required. One example is devices containing biologics that are Class IIb in the EU and Class III in AU. If the proposal is to follow the EU, sponsors will need to assess where the AU dossier differs from the requirements before the transition period.

Paragraph 354 refers to Essential Principles. This is a TGA term, where the EU/Global term is Essential Requirements, which is different. Please clarify if Medsafe implies they will follow the TGA's Essential Principles?

In Australia, each group of devices (or single device in the case of the higher class devices) have an AUST I number. How will Medsafe label devices? With a TT50 or something similar? The way devices are grouped, there will be numerous occasions where devices with different UDI numbers will be together under the same group.

The question regarding the regulation of devices with no therapeutic purpose - No, because they are not therapeutic devices. These would be better regulated

with consultation with other industry groups if there is no therapeutic purpose (e.g. cosmetic industry).

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

The wording for variations appears to be in exact alignment with the regulation of medicines. This may not be appropriate given the differences in the industry and with other regulators. In Australia, only the change in risk classification would mean it is a new device and would require an application for a new registration. The other changes are just variations. This technically differs from variations to medicines.

Changes to the name of a legal manufacturer should not be considered a major change, as long as there is no change to the actual site. Changes to the device name are often irrelevant unless it is Class III or higher as the name isn't registered. If this implies a change in the GMDN, it may be appropriate to require a new device application.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

A comprehensive outline of the definition of a medical device is required before thorough comments can be made. For example, would devices that enable patient's to administer their medications be captured here e.g. portable auto-injectors and nebulisers?

Please provide clarification around the transition period of devices. In Australia, the initial process was to provide a quick registration of all devices currently on the market, then conduct a more thorough assessment of grandfathered products at a later time point. It does not appear that a 6 month transition period would be sufficient time to allow for a complete transition to the new requirements. Furthermore, 6 months may not allow sufficient time for companies to arrange an acceptable submission package, if the classifications of devices differs from overseas, especially Australia.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

It is not clear if Medsafe intends to recognise the EC certificates issued by notified bodies? These certificates are a result of a notified body doing a conformity assessment / level audit of the legal manufacturer. Recognition of the EC certificates is recommended.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

The wording appears that this is only important for prescription medicines but not for OTC medicines? Substandard or falsified OTC's should also be of concern, meaning section 76 should be revised. Paragraph 621 also states the risks associated with OTCs are lower, but this is not true if they are substandard or falsified.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

What is the plan for products that need to be imported into the country to enable continuity of supply when a manufacturer is experiencing short term stock issues? Currently alternatives are often sourced that are not registered in New Zealand and are supplied under Section 29 with the agreement of PHARMAC. The volumes involved would be too high to expect medical practitioners to apply for a SCNSA for each patient. The need for supply of an unapproved medicine where there is an issue due with a sole supply product is an issue that is jointly shared by PHARMAC and the companies. A feasible solution to this to minimise increased burden to healthcare practitioners through paperwork would be welcomed.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Supportive. Direct-to-consumer advertising increases consumer awareness of the drug treatments and medical conditions, empowering people to take ownership and seek help for themselves. With the internet freely available people will look online. Regulated DTCA will ensure balanced information is available.

Response ID ANON-DPZ8-G421-4

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:14:38

Submitter profile

What is your name?

Name:

Olivia Clendon

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below::

If you selected 'Other' please comment::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4)::

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50)::

Ss15 – Therapeutic purpose –

The definition of therapeutic purpose in the Bill could arguably be applied to natural/complementary products. Given the withdrawal of the Natural Products Bill the exclusion of natural/complementary products is notable. It is my opinion that natural and complementary products should be included in the scope of this Bill.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101)::

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Direct-to-consumer advertising (DTCA) places New Zealand at variance with every country except USA, and provides patients with limited information on treatment options for their disease.

It is ineffective as a health education measure. Such information is readily available on the internet. It is intended to (and does) increase demand for a particular brand of medicine.

It is my opinion that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe) and no longer allow DTCA

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

This needs clarification as the implications are potentially substantial. I think the approach to unapproved medicines (SCNSA) is acceptable, but off-label use could create a high administrative burden for some areas (e.g. paediatrics), even if the requirements were substantially less than a full SCNSA.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4U2-8

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:16:00

Submitter profile

What is your name?

Name:

Nadia Kaienua

What is your email address?

Email:

What is your organisation?

Organisation:

Roche Products (New Zealand) Limited

Submitter Profile (tick all that apply)

Advertising

Medicines

Medicines

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Roche Products (New Zealand) Limited ("Roche") supports the purpose and principles as outlined in the draft Bill. We support the principle that the regulation of therapeutic products should be risk-proportionate, and that regulation supports the timely availability of therapeutic products to people that require them. We also support that administration of this Bill should be carried on in an open and transparent manner. In particular we welcome cooperation with overseas regulators and alignment with international standards and practice in the hope that synergies with other jurisdictions can be obtained, particularly with respect to assisting with medicine evaluation times.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

ss27 meaning of clinical trial

Roche recommends that the definition of 'clinical trial' follows international definitions, including the WHO's definitions and accepted ICH GCP terminology.

ss47 fit and proper person and Ss48 meaning of senior manager

Ss47(2) states that as well as "person A", others are subject to the 'fit and proper' person test - each person "who is or has been a senior manager of person A", or each person "of whom person A is or has been a senior manager". The scope of this requirement is very broad - the way the Bill is drafted states that if Person A is an individual, then the regulator would need to consider any company of which the person is or has ever been a director, CE, CFO, or similar, any partnership or business where Person A has been a partner, or equivalent of a partner or director. It may also consider any individuals that are currently, or has ever been a "senior manager" of Person A, at any of the companies Person A has ever worked at. Roche suggests that the definition of "senior manager" could be limited to those at the current company where Person A is employed.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

ss51 product approval required to import or supply medicine, medical device, or type-4 products

Roche support the requirement to have a product approval, approval exemption or an authorisation to import or supply a medicine, medical device or type-4 product.

ss52 sponsor's consent required to import approved product

Roche support the provision to prohibit parallel importation.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

ss55 Persons in supply chain must comply with regulations

The list of activities persons in the supply chain must comply with is broad. It is important that the requirements for different activities are clear in the Regulations and other subordinate legislation and Roche look forward to reviewing and commenting further on these requirements in due course.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

ss76 patient or carer importing medicine for personal use and ss77 Patient or carer importing medical device for personal use

Roche support the personal importation provisions in the Bill, in conjunction with ss119 which outlines that if someone imports a product without the sponsor's permission sections S116-S118 [Obligations of Sponsors] do not apply.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

ss71-75

Roche supports the authorisations created in sections 71-75

ss78

Roche support the intent of section 78. The ability of the Regulator to issue a 'use of current stock' notice is seen as an improvement on the current system; where Sponsors typically need to wait until the date of product expiry in the market before deregistering the product.

ss79

Roche support the intent of section 79 which will allow for more tailored authorisations for specific circumstances.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

ss82 meaning of advertisement and related terms

Roche asks that a definition of 'promotion' be added to the Bill in order to differentiate promotion (advertising) from educational activities.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Roche is supportive of the proposal (outlined in the consultation document) for a variety of different options for therapeutic product registration which ensures flexibility and pragmatism based on allowing appropriate regulation in relation to the size of the New Zealand market. With the tightening of unapproved supply, plus a high likelihood of increased fees, it is recommended that the regulator also consider an orphan designation/application pathway with associated reduction in fees for rare diseases. With New Zealand's very small population there may be a handful of patients treated each year in certain cases and for many products in this space it will not be commercially viable to register these in New Zealand. If there is an incentive such as a fee waiver in place this would help make it more attractive to pursue product registration and thereby provide the regulator with greater oversight over low volume products being supplied in New Zealand.

ss97(c)- A contractual relationship is required with the responsible manufacturer.

The rationale for this requirement is reasonable to enable the Regulator to request information and have a contact point with manufacturing sites located overseas via the local sponsor. However, local sponsors of large multinational pharmaceutical companies would not ordinarily hold individual agreements with each of the many manufacturing sites involved in the manufacture of a therapeutic product. These agreements are held by the parent company and an agreement between the local affiliate and parent company is standard practice. The requirements of this contractual relationship should be clearly defined for local affiliates who are sponsors of medicines, taking into account the primary contractual relationship described above for multinational companies .

ss97– Criteria for sponsor of approved product

The draft Bill proposes that the responsible person (called the Sponsor) is responsible for all aspects of the product, extending from the manufacture, application, approval, importation and supply through to the supply channel. This wording relating to the "responsible person (called the Sponsor)" is in the consultation document, but it seems at odds with the wording in the draft Bill, where the responsible person is named on the licence, but is not necessarily the Sponsor. The Sponsor should, rightly, be responsible for activities associated with product registration and manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of Quality Issues, the Sponsor cannot be held accountable for all activities after the product has left their control. There is also responsibility that resides with the wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine.

ss100 – Major changes results in new product

The draft Bill states that if a major change is made to an approved product, the changed product is taken to be a different product. The details of what changes are 'major' will be captured in subordinate legislation. Roche encourages the regulator to align the definition of 'major changes' with overseas jurisdictions and with thought to broader implications of changing the registration number i.e. in supply chain, ordering systems, Pharmac tenders etc. Changes to formulations would be reasonable as a 'major change' but the registration of a new manufacturing site and minor changes to manufacturing process would not. One possible option would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product e.g. grouping system used in overseas jurisdictions.

ss101 – Sponsor must notify regulator of certain minor changes

Roche supports the proposal for minor changes to an approved product based on a framework of risk-based assessment of minor variations. A post-approval lifecycle framework for quality changes/applications aligned with that overseas jurisdictions that reduces the submission burden for industry and establishes activity based timelines for evaluation is supported. Roche would support options for both a yearly notification schedule, as well as the flexibility to be able to notify individual changes at any point in time.

ss102 Change of sponsor

Roche support the requirements set out in ss102 for changing a sponsor (transferring an approval).

ss103 – Duration of approval

Roche agrees with the proposal for product licence approvals to generally not have expiry dates, thus licences are perpetual until such time that the Sponsor or regulator cancel the licence. This is aligned with current international practice. Roche considers this an improvement on the current New Zealand regulatory system where product approvals lapse after 5 years if there has been no regulatory activity and/or no commercial supply of the product. There does not seem to be any compelling reasons to assign an expiry date on the licence.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

ss105 – 107 – Conditions on approval

Roche supports the proposal that the regulator should have the right to impose conditions on approval; and that the sponsor has the opportunity to comment on such conditions.

ss108 – 112 – Cancellation of approval

Roche supports that the regulator should have the right to cancel an approval based on the grounds cited in ss108; and that the sponsor has the opportunity to comment prior to cancellation.

ss113 – Therapeutic products register

Roche supports in principle the proposal to develop a Therapeutic Products Register which details of approved products.

Roche supports that all applications submitted to the regulator and all approved products, should be made publicly available on a product register, which is routinely maintained by the regulator to ensure currency and accuracy. This practice is consistent with how other jurisdictions have embraced or improved transparency over recent years. However, we do not support declined applications automatically being made public as the sponsor should be given the opportunity to decide whether the non-approval recommendation from the regulator is made public. For example, other international jurisdictions (like Australia and EU) have specific evaluation milestones, and if a negative recommendation is received after a particular milestone, irrespective of whether the sponsor

withdraws the application, the outcome becomes public. However if a sponsor withdraws the application prior to a specified milestone, the withdrawal/rejection is not made public. Therefore, in New Zealand, following receipt of a negative decision on the application, the Sponsor should have the opportunity to voluntarily withdraw the application (consistent with other jurisdictions), without having this included or made public on the Therapeutic Products Register. This is particularly important when the regulator and Sponsor disagree on the regulator's reasons for rejecting/not approving an application.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

ss116-119 – Subpart 3 – Obligations of sponsors

Roche agree in principle with ss116-119; however it is important that the specific requirements are clearly outlined in subordinate legislation and we have the opportunity to comment on these as part of a consultation. Requirements should also be aligned to other comparable agency requirements. ss116-119 outline the requirements for compliance with obligation and the penalties that apply to breaches. It is important that clarity on what these obligations entail are outlined in subordinate legislation. Whilst we agree that sponsors should be accountable for complying with applicable obligations, we think it would be unreasonable if the entirety of Part 8: Pharmacovigilance / applicable device regulations form part of the legislation. The following are examples of the following PV requirements are legislative requirements in overseas jurisdictions :

- Reporting of ICSRs
- Reporting of SSIs
- Notification of the PV contact person
- Archiving of records

The draft Bill proposes that the responsible person (called the Sponsor) is responsible for all aspects of the product, extending from the manufacture, application, approval, importation and supply through to the supply channel. The scope of responsibility of sponsors has widened. The Sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of Quality Issues, the Sponsor cannot be held accountable for all activities after the product has left their control. There is also responsibility that resides with the wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine.

Roche supports the introduction of a new tiered offence structure for offences. The offence structure and associated penalties should be aligned with that in other equivalent legislation.

ss119 – Roche agrees that the usual obligations and requirements for a sponsor are not applicable for approved products imported without consent of the sponsor.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

ss120 -122 – Subpart 4 Protection of active ingredient information about innovative medicines

The data protection provisions set in the draft Bill at 5 years from approval of the medicine are unchanged from the current provisions. The regulator cannot disclose the information (derived from years of pre-clinical research and clinical studies) or use the information to decide the registration application by a generic company. This prevents generic companies from relying on clinical data submitted by the innovator as part of product registration. The protection period includes a first protection period that starts when the application is received and ending on the earlier of 5 years later or when the second protection period starts. The second protection period starts on when the regulator grants or declines the application and ends 5 years later.

Maintaining a regulatory data protection period of 5 years does not align with the vision to future-proof legislation. This decision is inconsistent with the increase to regulatory data protection for innovative veterinary medicines from 5 to 10 years made through the Agricultural Compounds and Veterinary Medicines Amendment Act 2016. It is also inconsistent with EU legislation, which provides an 8-year period of data exclusivity, plus two years of marketing exclusivity (with a potential 1 year extension). New Zealand is currently negotiating a trade agreement with the EU. The continuation of 5 years of regulatory data protection does not appear to support New Zealand's trade and economic objectives. New Zealand's current and proposed 5 year data exclusivity provisions from when the regulator approves the product, although consistent with Australia (5 years), slightly lags behind other international jurisdictions, such as Canada (8 years) and Japan (8 years). Also, it does not account for the lengthy period between product approval and reimbursement by PHARMAC and also does not preclude entry by a generic company using their own clinical data. For a consistent approach on regulatory data protection, that reflects international norms, New Zealand should move to align with the EU and others.

The draft Bill does not appear to allow for a 5 year data protection period for combination medicines (containing 1 or more active moieties) where 1 of the active moieties has previously been approved by the regulator. Roche requests that the Bill be revised to include a data protection period for combination medicines.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

ss123 What licence may authorise

Roche support ss123

ss124(1) (e) – The Bill indicates that the licence will list the therapeutic products covered by the licence. As product registrations are constantly changing, and it is indicated in ss137 that licences remain in force for 3 years, consideration needs to be given to the administrative burden for both the sponsor and the regulator to continually vary licences (for example a Licence to Wholesale) due to changes in product registration during each 3 year period.

ss127 Grant of Licence

Roche supports the requirements of ss127. Ss127(3) explains that if the Regulator is not satisfied that the criteria [of the licence] will be met, the regulator must refuse to grant a licence. We support this provision, provided that if the Regulator is not satisfied the applicant has been provided with an opportunity to comment/opportunity to provide further information in order to meet criteria, at the request of the Regulator

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

ss128 Criteria for granting licence

Ss128(1)(g) outlines that in order to grant a clinical trial licence, ethics approval, or certification from a relevant ethics approval entity that ethics approval is not required for the trial, is required. Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current Clinical Trial approval process concern remains that the licence cannot be issued until the Ethics approval is granted and what impact this may have on timelines. It is unclear if applications which are not referred to the Health Research council will have the same quick timelines as those currently reviewed by HRC. It should be ensured that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g observational trials, clinical audits). A key factor in attracting clinical trials to New Zealand is the current quick time to study start-up and provisions in the Bill (and other subordinate legislation) should not jeopardize this. Clarity is requested for the process for providing evidence to the regulator that ethics approval is not required. We suggest that appropriate rules and/or guidance are created so it is clear which types of trials do not need ethics approval, and that there is an efficient process in place for certifying that a trial does not need ethics approval.

ss129 Criteria for licensee

Roche supports the criteria in ss129.

ss130 Criteria for responsible persons

Roche supports the criteria in ss130; however the qualifications, training and competency requirements for a responsible person will need to be clearly defined in the rules and we look forward to providing feedback on these in due course.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

ss131(1) (a) – It is important that the criteria for importing an approved product without the sponsor's consent will be outlined and specified in the Regulations or other subordinate legislation. The implications for product complaints and AE reporting will also need to be clearly outlined in the subordinate legislation.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

ss137 indicates that a licence remains in force for 3 years. However, if changes are required eg if individual therapeutic products are named on the licence (i.e. the Wholesale licence) consideration needs to be given to the timeframe and cost involved with making multiple updates during this time period.

Roche suggest that clinical trial licences should be able to be granted for the duration of the trial (as per the trial protocol) to avoid unnecessary burden for the regulator and sponsor to be requesting licence extensions or new licences.

ss139 Regulator may impose conditions and ss140 Variation

Roche supports ss139-140.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

ss151 details that if the licensee or permit holder dies, the licence or permit is transferred to the executor or administrator of the estate, who has to notify the regulator of the event within 5 working days. The practicality of this process is queried. In some cases an executor would not be appointed within 5 working days, and the executor is unlikely to meet the criteria for a 'responsible person' to be able to hold a licence. It is unclear what the consequence will be if the executor of the estate fails to notify the regulator within 5 working days. We are concerned that the licensee death or failure to notify the death within 5 working days will result in a business continuity issue or the licence may lapse. As an example, there would be ethical and operational issues if a clinical trial had to be suspended. Roche would instead propose that two or more persons be named as responsible on a licence and consider removing the provision for automatic transfer of licence or permit to executor of the estate to prevent such circumstances occurring.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

ss158 requires the responsible person to comply with the requirements, in relation to the competency of workers in the licensee's business. The details on what the competencies are or how the responsible person is realistically able to comply with this requirement will be provided in subordinate legislation. Roche looks forward to more detail around these requirements once the legislation has been drafted and anticipate providing more feedback on the requirements at the time of consultation of such legislation.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

s160 allows the regulator to 'perform monitoring', with respect to safety monitoring. This would introduce the ability for the regulator to conduct regulatory inspections.

We do not object to the inclusion of this provision, however the introduction of the power would require further vetting through industry consultation prior to implementation.

The consultation slide deck includes the following:

The Bill links to the Search and Surveillance Act 2012 to provide the regulator with investigative powers. The regulator would have the following powers of entry:

- entry and search without a warrant (for routine monitoring & where there are concerns of non-compliance)
 - entry and search with a search warrant (including dwelling houses & Marae)
- the right to inspect therapeutic products being imported.

The TGA can do this in the situation of a 'for cause inspection', however this power seems a little excessive for 'routine monitoring', unless of course this means that we cannot prevent them access in which case the powers we believe are similar. As a general comment: we agree in principle, but would need to be consulted in relation to the specific requirements. These should also be fairly aligned to other comparable agency requirements

ss178 (2) (c) (i): mentions the "person who distributed the advertisement". Clarification is sought whether "person" in this case also means the sponsor of the product being advertised as the definition of person in the Bill is currently unclear

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Under the Bill investigative powers will be cross-referenced to the investigative powers under the Search and Surveillance Act 2012 (ss183, 185, 188, 191, 192). The powers that are granted under the Search and Surveillance Act 2012 are those used across a large section of New Zealand legislation that require investigative powers. Therefore, we consider the amendment to bring the Bill under the remit of the Search and Surveillance Act 2012 brings it into line with what is generally the standard set of investigative powers in New Zealand.

It would be important to clarify the potential tension between:

- a prohibition on shipping overseas any products that are subject a prohibition order (ss170(2)(f)); and
- an ability for therapeutic products that are seized by the regulator / border security to be returned to the country of origin if the regulator requires it (ss194).

In order to relieve this tension, we presume that this right to return products to a country of origin would be exercised by the regulator only where the product does not pose significant risk of death or harm. If this is not the intent, we are concerned that therapeutic goods that would otherwise be subject to a prohibited product order and therefore not able to be returned to their country of origin would be treated differently if seized at the border rather than if they were released to the sponsor (either erroneously or as they were subsequently found to have concerns).

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

In contrast to the Medicines Act 1981, there are different tiers of offences, depending whether there is knowledge and/or recklessness as to whether the Bill is breached (i.e. while it is a strict liability offence, a more stringent penalty will be applicable where the contravention of the obligation was reckless, and an even more stringent one where the convention was done with knowledge).

However, it will be a defence for any prosecution of an offence under the Bill if the defendant took "all reasonable steps to ensure contravention was not committed" (ss243). On that basis, it is considered that this provides adequate grounds to protect against unfair prosecution under ss197-199.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

ss200 – 204 – Subpart 4 – Review of Regulator's decision

Roche supports the proposal to have regulator's decisions in relation to product approvals, licences and permits reviewed through a merits review process instead of the current process of utilising an independent standing committee with set membership.

Roche support the proposal to appoint 3 people (including a lawyer) who have not previously been involved in the decision which will allow for an independent and unbiased review. Additionally, appointing subject-matter experts, people with appropriate knowledge, skills and experience, for the reviewable decision, is critical in ensuring there is a fair and equitable review of decisions.

However, the proposed timeframe of 30 working days, in which the Sponsor/Applicant is required to submit their application with any supporting data/justifications for review of a Regulator's decision, is not considered to be sufficient. Many Sponsors have global headquarters overseas preparing the data to support the review, and therefore consultation and agreement with overseas colleagues is required prior to submission of the application to the regulator. Depending on the magnitude of the issue being appealed, a 30 working day timeframe does not allow for the appropriate consultation to take place within companies and to then prepare the application detailing the grounds for appeal. A more appropriate timeframe would be 60 working days (ie approximately 3 calendar months). This timeframe is aligned with other regulators, such as the Australian Therapeutic Goods Administration (TGA).

The draft Bill (ss203) does not specify the timeframes given for convening the review panel nor any review timeframes for the panel to provide a decision. Roche requests that an equivalent timeframe of 30 or 60 working days is included in the Bill for this activity. It is prudent for each party, regulator or Sponsor, to be held accountable to meet their applicable timeframes, thus allowing for timely review of decisions.

Specific timelines should be included in the Bill for both the regulator and Sponsor/Applicant to ensure each party is held accountable to meeting their obligations in the process.

As there are currently no timeframes given for convening the review panel or that review panel providing a decision, if the review relates to refusal to revoke a regulatory order under the Bill, the sponsor may have to act on that regulatory order in respect of the therapeutic product. There is concern with how long this might take and what would happen in the interim period. If a regulatory order must be complied with, pending the outcome of the review, then it could be that the benefit of a review is lost as the timeframes mean that the order has already been complied with. It is suggested that:

- changes be made to the Bill that provide for timings for the convening of the review panel and the provision of decisions; and
- there to be an ability to ask for a panel to sit in urgency where, for example, a sponsor wishes a refusal to revoke a recall order be reviewed, as it believes there is no risk to health and safety.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):

ss207 Regulator may rely on recognised authorities

In relation to product approval, the draft Bill (ss207) states that the regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. Roche agrees with this proposal, which is both logical and efficient, and consistent with current practice for abbreviated submissions, as well as international regulatory practices. However, applications that are submitted to the regulator utilising evaluation reports from other recognised regulatory authorities must be accompanied by reduced evaluation time and fees. Additionally, the scope of the application types should include not only new chemical/biological entities, but also new indications, line extensions, and other updates. The types of applications that are eligible should be clearly defined in the Regulations to avoid uncertainty and confusion. The evaluation timeframes should be made transparent to the Sponsor, with predictable milestones at specified timeframes, to allow for greater predictability in overall approval timeframes. Clear and transparent timelines are paramount in being able to monitor progress and plan for resources, which is lacking under the current regulatory system. The current draft Bill only refers to target timeframes at this stage which provides no change from the current situation. Roche would like to see a maximum timeframe for evaluation outlined in the Bill; with details regarding target milestone timelines in subordinate legislation.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):

Roche support the proposed sections (ss 223-232) covering enforceable undertakings and a court's ability to grant injunctions. This is consistent with what happens in other jurisdictions like Australia. The ability to offer 'enforceable undertakings' provides useful flexibility in addressing alleged contraventions of the Act rather than having the regulator go straight to formal court-based enforcement.

It is noted that if the regulator accepts an undertaking, it must make publicly available the undertaking, its reasons for accepting it, any variations and notification of an undertaking ceasing to be in force (ss224). This could cause concern, as it makes an alleged contravention public in a situation where there has been no admission of guilt by the relevant party. However, this position seems to be relatively consistent with recent legislation, particularly legislation that is aimed at maintaining the public's health and safety (for example, under the Health and Safety at Work Act 2015, an enforceable undertaking is not considered to be an admission of guilt, but must be published on the Intent site maintained by the regulator under that Act). Therefore it does to be in-line with powers granted to regulators recently under New Zealand legislation and is commensurate with the overall objective of the new Bill.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Whilst Roche supports in general the proposed sections (ss 233-248) covering penalties, court orders, liability, defences and evidentiary matters for criminal offences; it is noted that the proposed penalties and prison terms seem high. It appears that the TPB imposes the highest fines out of the comparable modern legislation for both individuals and for companies. Roche requests alignment of penalties with other comparable legislation (Food Act 2016, Agricultural Compounds and Veterinary Medicines Act 1997, Hazardous Substances and New Organisms Act 1996, Biosecurity Act 1993).

ss237 outlines a requirement for the defendant to pay the regulator's expenses in mitigating any harm in certain circumstances . The wording includes a requirement that the defendant's conduct has "caused harm or a risk of harm"; which is further defined in the section. It is considered that conduct that indirectly "causes harm" is a low threshold for this indemnity and it is requested that this be qualified along the lines of the words "significantly increases harm" in s237(3)(a)(ii), with words such as "causes material harm" or "causes harm that is not insignificant" which would be on the basis of reasonableness.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

Roche support the proposed sections (ss 249-255) covering infringement offences and the related penalties and processes.

The infringement circumstances and the amount of the infringement fines will be determined in the regulations. This is considered to be in-line with recent New Zealand legislation which is following this two-tier infringement process, including the Food Act 2014 and the Financial Markets Conducts Act 2013.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

ss256 indicates that the intention is for cost recovery by way of fees or charges specified in the regulations. In addition the Regulator must review the cost recovery every 3 years. Whilst Roche supports a cost recovery model, this requires greater transparency by the regulator of evaluation timeframes, which would need to be monitored to ensure predictability for the Sponsor. This aspect is currently missing from the draft Bill. Roche would support a maximum timeframe for evaluation being legislated in the Bill, with further details about other evaluation milestones present in subordinate legislation. This is in line with overseas jurisdictions.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Schedule 2 – Reviewable decisions

Roche agrees with the list of decisions reviewable by the Applicant or Sponsor which are listed in Schedule 2 (Items 1 to 6) of the draft Bill.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Roche supports the details which will form the proposed subordinate instruments and looks forward to an opportunity to provide comment on these in due course.

Roche supports consultation on subordinate legislation that provides sufficient time and opportunity for stakeholders to comment. We recommend formation and engagement with a medicines industry working group to provide insight and advice on the development of practical regulations.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Section 100 indicates that a major change to an approved product results in a different product even though the physical product may have not changed. Further thought is requested on this as currently it appears that routine changes (such as registration of a new manufacturing site) would be classed as a 'major change' resulting in a different product which would have a different registration number. This has further impacts on supply and ordering, reimbursement contracts and existing Pharmacodes (see further feedback in response to Question B13).

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Roche supports the proposed categorisation system for medicines. We agree that having numbered categories (1,2,3,4) will be more future-proof than the current system of naming the medicine classification (Prescription, Pharmacist, Pharmacy and General Sale).

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

The transition provides for a 6-12-month period for applications for approvals and licences which need to be amended or are required under the new Act. Due to the widened scope of the scheme for example to cover additional products (e.g medical devices) and activities (e.g clinical trials for registered medicines), there will be a large volume of applications received. We are concerned that this will create significant capacity and capability issues for the regulator. Roche seek assurance that the Regulator will be adequately resourced during this transition period and continuing forward under the new scheme.

There does not appear to be any transitional arrangements for medicines currently supplied under Section 29 of the Medicines Act 1981 and we request further information around this.

Question C4 - Please provide any comments on the approach to post-market controls.:

Roche agree in principle, however note that the detail in terms of requirements which would be enforced in relation to post-market controls i.e. risk management will be outlined in subordinate legislation. Any requirements should be in line with international norms and not provide unreasonable burden for the New Zealand Sponsor. The ability to consult and comment on these at a future point in time is requested. Roche looks forward to reviewing and providing feedback on the requirements in due course.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Roche are supportive of legislation which aligns with overseas jurisdictions .

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Roche support the ability to have one licence to cover a range of activities involved in the running of a clinical trial. It is important that requirements and obligations are clear in subordinate legislation including:

- whether it is the sponsor of the trial or the investigators that seek the license
- license duration - 3 years is too short for some clinical trial activities. Would it be possible for a clinical trial license to be granted for the duration of the trial as specified by the protocol? Clarity around requirements of when a licence can cease is also requested i.e. is the licence required during treatment phase only or

until all activities in the clinical trial have completed and clinical site is closed, or until the completion and reporting of the trial (please take into account that a study can complete in New Zealand but continue in other countries)

- although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current Clinical Trial approval process concern remains that the licence can not be issued until the Ethics approval is granted and what impact this may have on timelines. It is also unclear if applications not referred to the Health Research council will have the same quick timelines as those currently reviewed by HRC.

Exporting biological samples (blood/serum) and tissues

We couldn't find reference to provisions for the export of samples or tissues derived from clinical trial participants. It would be preferable to ensure sensible provisions are in place, such as permission for this activity to be listed on the overall clinical trial licence.

The Regulator also has the power to monitor trials and audit clinical trial sites

Roche supports the regulator being able to perform audits of clinical trial sites.

Roche requests alignment of terminology in the legislation with international terminology and definitions (i.e. ICH GCP definitions) to avoid any confusion both locally and internationally

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

Schedule 1 – Transitional Arrangements

For ongoing trials which currently do not require approval under the Medicines Act, but will under the draft Bill, it is not practical in all circumstances for the principal investigator to apply for a temporary licence to carry on the activity. This should be changed to reflect either the 'proposed licence holder' or sponsor of the study.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

ss64

Roche supports the provision in the Bill for supply of an unapproved product via a Special Clinical Needs Supply Authority (SCNSA). It is important that the requirements for supply via this mechanism are clear in the rules, including:

- Responsibilities for Adverse Event reporting
- Requirements for notifying local sponsor of supply
- Provisions for a cross-over period should an unapproved medicine supplied under a SCNSA become approved
- in what circumstances wholesalers are able to have on hand a small stockpile of unapproved medicines ("urgently needed" needs to be defined, as does "small")
- measures of control of products imported by "buyers clubs" and/or healthcare professionals but importing unapproved medicines

Roche look forward to reviewing the requirements around this scheme once the rules have been drafted and anticipate providing further feedback at that point in time.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Roche welcomes the fact that the status quo regarding DTCA is proposed to be maintained at this stage (with an enhanced range of enforcement options and higher penalties for breaches).

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Roche believes the benefits for consumers far outweigh any purported negatives. DTCA in New Zealand is currently highly regulated and is required to be compliant with a number of regulations and codes. DTCA allows New Zealand consumers to access factual, high quality New Zealand specific information about therapeutic products. The current review process when developing an advertisement ensures that promotional claims are accurate and substantiated by quality

references and all information is consistent with the Medsafe Data Sheet and Consumer Medicine Information. In addition, under the new Bill, the regulator can issue Advertising Remediation Orders, which provides a further level of control if necessary. Empirical New Zealand evidence overwhelmingly concludes that DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. DTCA of prescription medicines comprises only a small percentage of advertising and considering the abundance of unregulated information on the internet readily available to patients, banning the regulated and controlled DTCA of prescription medicines increases the likelihood of New Zealand patients accessing unregulated information from overseas. We invite the regulator to consider the impact of banning DTCA on post-prescribing support materials and websites with specialist medical education which support health literacy and safe and proper use of medicines including identification and management of adverse events. These materials and sites are currently regulated and appropriately controlled under the Medicines Act. Without these specialist materials the patient is open to misinformation from global sources which are not relevant in the New Zealand healthcare context. Continuing DTCA reinforces patients' rights to find out about medicines available in New Zealand prior to and after commencing treatment.

Response ID ANON-DPZ8-G4ZW-J

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:25:03

Submitter profile

What is your name?

Name:
Ann Calder

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Pharmacist

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

I am concerned about the change in the definition of dispensing. The draft TPB dispensing a medicine is defined as part of manufacturing the medicine. Implying that this is only the supply of the medicine is misleading as we do more than this when we dispense a medicine. When we dispense a medicine we check any clinical issues ,make sure it there are no interactions with other drugs the patient is on ,then give all the required advice to the patient when we hand it out. It

appears that by changing the meaning of dispensing many different options could be proposed in the future . A patient needs to be able to physically see what they are being given to identify with the relating advice. These two services should not be separated if we want to improve adherence and patient safety.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

I agree pharmacies should be able to supply medicine to another pharmacy if the pharmacy nearby has stock the required stock . This is beneficial for the patient so am very supportive of supply between pharmacies. This would be very beneficial for uncommon medicine as would avoid wastage and stock expiring if a joint effort is allowed .

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

I am supportive of health practitioners supplying each other with small amounts of medicines but small has to be clearly defined. Obviously this would be beneficial in emergencies and when pharmacies are closed. However a tight legislation needs to be passed so that stock cannot be traded between health practitioners.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

I agree that the importation go medicines should only be allowed through regulated channels to make sure patient safety is not compromised.I also agree that SCNA is required when getting a medicine from overseas. The importation should be limited to a pharmacist , wholesaler or medical practitioner.Section 76 (5) (a) should be amended to only allow personal importation of category 4 prescription medicines. Medicines should be restricted in the same way that the equivalent ones are in NZ.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

There should only be a very limited use of vending machine with strict regulations surrounding their use. 1: only when there is no other option available 2:would have to be part of a pharmacy to ensure it is appropriately dispensed.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

If section 124 was to be applied there would have to be pharmacy at the aged care facility as the risk of incorrect dispensing to the patient would be too high if the staff were able to select and supply the drugs without a pharmacist being involved. We train for 5 years to ensure patient checks and safety is paramount.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

This is definitely required as permits for shorter term and urgent situations improve accessibility for the patients. The process needs to be speedy . An example of where this should have been implemented was when the Waipu Pharmacy burnt down and the pharmacist was not given a permit to dispense her patients prescriptions so had to drive all the way to Russell. No common sense in the present ruling.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

I agree licences should be permitted for up to three years . Would reduce compliance costs so win win all round.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

I support this decision as it is not a safe option to allow prescription medicines to be imported by an unqualified person . It is a very dangerous situation as there would be no medical follow up to ensure patient safety . As we already know a person will give away there antibiotics to fix her friend so this situation could get quite out of hand and end up costing the country a lot more money when the incorrect drugs have been taken, from the advice of the unqualified friend!

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Whatever the supply is it must not compromise patient safety or the present situation where a patient is supplied and given advice in the same transaction. We are not a normal retail industry in that everything we dispense or sell comes with correct advice from their health professional . The present Community pharmacy model we have works very well and many of the patients rely on the present way of supplying their medicine as there is very little confusion as to exactly what they are given, what it is for and how to take it with a pharmacist being involved in supplying and dispensing at the same time.If the supply of medicine was changed it would negatively impact both the patients and the viability community pharmacies .

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

The current licensing requirements do not create a barrier to innovation but ensure safe and effective pharmacist services. . The advancement of technology and the community pharmacy workforce will gradually evolve over time . It is important that if alternative distributions were considered that patient safety is not compromised . Alternative distributions and supply arrangements may reduce costs but may well put the public at higher risk of incorrect supply.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

We definitely need to be able distribute and supply various pharmacy activities in new ways particularly in areas of low health literacy. Pharmacists are in a position where their knowledge should be used outside the Pharmacyby going to Marae's etc . I believe our biggest barrier to improving health out comes with those of low health literacy is lack of education. Beginning with diet and exercise. Mobile pharmacies would greatly improve patients outcomes if we could go to them as many of them do not come to us until it is too late.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I support this option of Pharmacist ownership as I have worked in pharmacies in England where pharmacies can be owned by a non pharmacist. The biggest issue with allowing open ownership is that the non pharmacist owners are in it for the money . The sole reason for them to invest in a business is to make a profit. You can put whatever spin on it but the likes of the Countdown Pharmacies and the Chemist Warehouse are not in the game to make money . And this comes at a cost .Not always tangible but I will try and explain how community pharmacies operate as present.

1/ We train four 5 years not to run a retail business but to become a health professional to make a difference and improve the health outcomes of our patients and customers.

2/Our priority is to provide the best advice ,service , medical care information etc we can to our customers/patients.

3/We need to make a profit in our business to remain viable hence the extension to the retail area (not always by choice but a necessity to top up our government funding)

and as qualified health professionals we should be able to make a comfortable living.

4/ We quite often make decision where we lose money as the advice we give is best for the patient and but not necessarily a good commercial decision.

5/We are part of the community hence we go far and beyond what a regular retail business owner would do to support our customers. e.g .. free deliveries which includes cups of tea with the isolated and lonely we visit, arrange funerals for elderly patients with no one else except their community pharmacist I could write a book on the unpaid services I have provided over the last 30 years as a community pharmacist.

Pharmacist owners put patients first non pharmacist owners put profit first.

Detailed questions relating to Option 1**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

The benefits have to some degree been outlined in the previous question but there is no doubt in my mind that if a community pharmacy is owned and operated by a pharmacist then a higher clinical standard is offered as well as a safer environment for the customers whether it be purchasing medicines or having prescriptions dispensed.

Unfortunately I have witnessed some very unsafe practices operating while working in pharmacies in England that have been not been owned by pharmacists. One such incident was when the owner of the pharmacy (not a pharmacist) sold a customer a bottle of hydrochloric acid instead of acetic acid. The discovery was only made when the customer brought it back to me the next day querying why it was bubbling !!! If she had tipped it into her tomato sauce she would have been severely burnt.

Community pharmacies are very different from other retail businesses and should be treated as such. If the wheels not broken why fix it?

At present the pharmacy industry is being disrupted by large Australian multinationals wanting to get a piece of the pharmacy piethey are not here to improve our primary healthcare but to make a profit from our industry.

Many of the extra free services we do as part of the job benefit the patients at no extra cost to patients or the government . This would either not happen at all or any where near to the same level if non pharmacy ownership is introduced.

If a pharmacist does anything illegal and they own the pharmacy they lose everything so it is in everyones best interest to comply with the law.

This would not be the case if pharmacies are owned by non pharmacists as the temptation to flaunt the law to increase the profits is more appealing as the owner would not be sacrificing their career and business. There would also have to be a higher level of auditing as well to keep the industry clean.

A person can be perceived as fit and proper but still carry out illegal activities if the stacks are high enough i.e. selling certain drugs illegally could give you a very good return and to some fit and proper people it would be worth the risk to do this.

Question C25 - Are there ways in which Option 1 could be improved?:

option 1 could be improved with grandparenting provisions for pharmacy businesses that are operating legitimately under the current rules. However the pharmacist must always have a veto share so they will always have an effective control of all activities in the pharmacy to ensure patient safety. Public safety should always be priority with the improvements that are made. This can be achieved by making sure the Pharmacists are in control of governance and operation matters.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

All clinical activities within the community pharmacy setting that require a pharmacy licence, such as the provision of medicines (except general sales medicines).

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

If separation of responsibilities is done it must be decided who would be ultimately accountable for the decisions that relate to the wider operating policies that have an impact on the public. Effective control provisions could be shared by two pharmacists if they have equal ownership - both would be legally responsible for compliance and governance.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

It is unrealistic for 1 pharmacist to have overall control of running 5 different pharmacies on a daily basis. There would have to be an allowance that the overall standard of all the pharmacies is upheld by a managing pharmacist in each pharmacy . The managers need to be accountable to the owner to ensure a high level of patient safety is maintained. One suggestion is that the the owner of the 5 pharmacies should have their own internal audit system to ensure correct governance of the businesses .

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

If pharmacists jointly share up to 5 pharmacies it should be made clear in the ruling that it is only five and not say 10 pharmacies .

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

The potential impact would be financial as if young pharmacist want to own their own business then there needs to be some flexibility as to how they purchase it. Many would not have the funds to buy it outright so there needs to be some consideration as an alternative way of financing the business. Ie the young pharmacist has a veto share so is effectively in control to maintain patient safety.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

I'm not sure how this would be decided as very difficult to put a time on it but if the suggested grandfathering approach is taken this would be eliminated

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

I think this exemption should be removed after the transition period to be consistent

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

As a pharmacist owner operator I cannot see any benefits of non pharmacy ownership.

We are accountable for everything we do in the pharmacy and go way beyond what is required from a funding point of view .

We invest heavily in our customers as it is in our interests to provide our customers with the best possible service as we have a huge financial and emotional investment in our businesses.

The risks of non pharmacy ownership is that patient safety would be compromised as profit is the name of the game.

We are not a cash and wrap business and need to maintain it that way .

Question C34 - Are there ways in which Option 2 could be improved?:

No as do not agree with this at all

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No as I have worked in pharmacies not owned by pharmacists and you are put under intense pressure to bend the rules to improve the profit.

Patient safety is not always priority .

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

I think it would be unwise to provide clinical advice remotely unless it was a Skype type situation where you could actually see the problem and the person .If there was a rural area without a pharmacist accessible then as long as they were in a licensed premise there could be a limited need for this .

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Yes it is definitely necessary for prescribers not to be allowed a financial interest in a pharmacy . There would be a conflict of interest . Prescribing and dispensing need to remain separate.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Yes in situations such as earthquakes, fire etc. Access to pharmacy services is essential when unexpected natural disasters happen .

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Depot pharmacies should only be authorised via a licenced pharmacy with the oversight of a pharmacist available for any advice required.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Batch compounding should still be continued as is required for compound products we dispense on a regular basis.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Yes when wanting to share medicines with pharmacies that have a medicine they will not dispense to another pharmacy that needs it. This reduces wastage overall. So win win

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

I am in support of this with the addition of SCNSA requirement in authorising the supply of unapproved products. Sometimes practitioners are unaware they are prescribing unapproved products . Extra step ensure patients receive correct advice

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

It is appropriate to continue to only allow medical practitioners to access unapproved medicines

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Only in an emergency and where part packs were needed .

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No I do not . Risks is incorrect storage . We are regularly audited to comply with this

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No . We are trained to do this but health practitioners staff aren't.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

no as all medicines should be supplied by a medical practitioner ,pharmacist or wholesaler to ensure the safety appropriate advice and care is provided.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4UV-C

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:36:11

Submitter profile

What is your name?

Name:

Natalie Gauld

What is your email address?

Email:

What is your organisation?

Organisation:

Writing as an individual

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

I am writing as a pharmacist working on access to medicines, and with community pharmacy services. I have many years' experience in many facets of pharmacy including working in various community pharmacies, working with community pharmacists, working in a clinical trials unit, and working in research, particularly around access to medicines. I am also an expert in reclassification of medicines, experienced as a committee member of the Medicines Classification Committee (2004-2009), driving reclassifications in NZ, contributing to a working group on the new Appendix M for scheduling in Australia, and having researched barriers and enablers to reclassification across 9 countries, with two later projects in Germany and Austria. This includes interviews with regulators, committee members, and other stakeholders. The findings have been used to change reclassification processes in some countries. To be clear about my affiliations, I am a member of the National Executive of the Pharmaceutical Society of NZ, an Associate Member of the NZ Self-Medication Industries, an Affiliate Member of the Pharmacy Guild of NZ, and an Honorary Senior Lecturer at the School of Pharmacy, the University of Auckland. My clients include Green Cross Health, and some pharmaceutical companies. I am not speaking on behalf of any of these organisations in this submission.

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

I agree with 49a.

49e Where the regulator decides on whether a product is a medicine or device I think it would be helpful for industry if there is international consistency, so that a product that is typically considered a medical device in Australia and Europe would also be considered a medical device in NZ. This would help with access issues, as currently some items may be a medicine in NZ and a medical device elsewhere which will prevent their registration in NZ.

49i - I completely support this potential for restriction and recommend it is used where possible. There may need to be expert advice from a committee on this,

similar to reclassification.

49k1 - completely agree, also because of the risk of counterfeiting.

49k2 - This decision by the regulator may need to have input from health professionals working at the coal face.

I disagree with mixing dispensing and manufacturing. Manufacturing is generally very large scale, with one specific medicine made in a single process as a batch for multiple people and subject to quality assurance checks as to purity, etc. Dispensing is completely different to manufacturing - it is about an individual patient, it has completely different processes, quality measures and is done in a completely different environment. A manufacturing site is nothing like a dispensary with an enormous range of pre-packaged medicines. Their standard operating procedures, qualifications of personnel, activities and the responsibilities of the staff are so different they should not be banded together. It will create confusion and difficulties.

I agree with being a little more flexible around what a pharmacy is. I do not expect pharmacists doing medicine use reviews or other cognitive services without supplying medicines needing to have a pharmacy licence. There needs to be consideration of a clinical trials environment - having a pharmacist taking professional responsibility for the medicines should be encouraged, but it may not need to be licensed as a pharmacy.

Remote depots where there is no pharmacy and the population has access issues seems reasonable with good oversight from a pharmacist and a pharmacist able to actively supervise activities.

Standing orders need to ensure that a Medical Officer of Health, for example, can issue them for health professionals in their region.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

I agree with point 52. Parallel importation should not be allowed unless in exceptional circumstances such as those provided.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Controls for prescription medicines should be extended to pharmacist-only medicines which are essentially "prescribed" by a qualified health professional after consideration of an individual's circumstances.

57. These should be considered by a committee where appropriate. Perhaps follow a similar path to Australia where the delegate can approve obvious ones but a committee or experts could be consulted as necessary to aid in the appropriate decisions.

60 The emergency contraceptive pill is not a prescription medicine. It is a pharmacist-only medicine. The regulations need to consider how the exemptions will be allowed, and a classification committee is probably useful here, providing it avoids the patch protection previously identified with this committee (ref: Gauld NJ, Kelly FS, Emmerton LM, Buetow SA. Widening consumer access to medicines: A comparison of prescription to non-prescription medicine switch in Australia and New Zealand. PLoS ONE. 2015; 10(3): e0119011.)

62 I would want to see the potential controls to include selling excessive quantities (e.g. more than a single pack), relevant for suicide risk (paracetamol) or misuse (e.g. loperamide).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

I agree with point 67 being explicit about the pharmacist doing pharmacist-only medicines, not staff.

71 . However, I do not think pharmacist-only medicines should automatically be available to other health practitioners who are not prescribers. Reclassification to pharmacist-only considers the pharmacist's expertise, controls, etc, and the preparation of the workforce. Other health practitioners who are not prescribers may not have the appropriate skill set, controls, recording, and could increase fragmentation of care. When I consider how much work has gone into the training, screening tools and other preparation of pharmacists, plus their under-graduate knowledge, in order to persuade a committee of the supply through pharmacists, it is completely inappropriate to then think that other health professionals with considerably less training on medicines and potentially little training on management of the conditions being considered should have this same access with no such considerations. I recommend that pharmacist-only medicines are treated in this regard in the same way as prescription medicines, and an exemption is provided medicine by medicine for pharmacist-only and for the relevant health practitioner group. This should be considered by a committee to ensure the benefit-risk profile is appropriate for this widened access.

73 Agree with SCSNA - currently unapproved medicines are often not understood or respected by prescribers, pharmacists and consumers. The approval should consider whether there is a currently registered and available product in NZ that fulfills this need and only where there is clinical need that the registered medicine is not suitable (e.g. allergy) that this is allowed. This is a much safer approach than the current one. There should also be consideration as to whether or not the product being brought in will be coming from a reputable manufacturer and is registered by acceptable regulatory authorities. For example melatonin has been shown in independent testing in the US and Canada to have contaminants and differ considerably from the label statement. The section 29 products in NZ have been subject to recalls. I know of multiple people who were not informed by a doctor or pharmacist that the medicine was not approved and that there was a registered product available. I am pleased this is being tightened. An unapproved medicine should still only be able to be prescribed by a prescriber, but not used under standing orders, etc. Could consider that the consumer also signs for the need where possible - currently one of the difficulties is that the consumer is not informed, and this might help the prescriber think about whether this is appropriate or not.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Personal importation of pharmacist-only medicines makes a mockery of the existing requirements for reclassification and the pharmacist skill set. It puts people at danger of delayed diagnosis, inappropriate use (where contraindications, precautions or interactions occur, or another medicine would be more suitable for the condition), adverse effects, misuse and counterfeit medicines. We have seen significant advances in the pharmacist-only space, e.g. Tamiflu, Xenical to improve patient access with important safety measures implemented. Pharmacists have five years of training and spend a lot of time on provision of non-prescription medicines in their undergraduate training. This provides NZers with safety assurances.

The limit on amount imported should be 3 months for prescription or non-prescription products, or 6 months for contraceptives. But allowing 3 or 6 months of a medicine that comes in a pack for 3 or 4 days when supplied in NZ as a non-prescription medicine would be inappropriate - 3-4 months of continual NSAID use or liquid paracetamol in children, or a proton pump inhibitor without a prescriber involved is completely inappropriate.

There is not an access issue to non-prescription medicines in NZ and there is an increasing quantity being brought into NZ with no safety information about these medicines. This is completely inconsistent with the purposes of the Bill and requirements for medicines to go through rigorous checks to ensure patient safety.

Even for pharmacy-only medicines pharmacists and pharmacy staff regularly make important interventions, some of which are life saving. Please see the following paper for more details of the range of significant concerns pharmacists have intervened on - particularly with the likes of paracetamol and ibuprofen liquids. Gauld N, Sullivan T. Double-Dosing and Other Dangers with Non-Prescription Medicines: Pharmacists' Views and Experiences. Pharmacy. 2018; 6(3): 59. In some cases these people are our most vulnerable - e.g. children and elderly at risk of double dosing on pain medicines. These medicines are pharmacy only for a reason and allowing their importation has important health risks. Current pharmacovigilance in NZ does not pick up delayed important diagnosis, inappropriate use, use inconsistent with quality use of medicines, and people often do not tell an emergency department doctor about non-prescription medicines used.

Furthermore, medicines from overseas will not have the labelling that the NZ regulator requires for NZ, with further safety issues.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

84 standing orders should not allow use of unapproved medicines, outside of hospitals.

92 Should have input from a committee like the Medicines Classification Committee - providing that all efforts are made to minimise potential for patch protection and a consumer representation and public health doctor are included.

95 vending machine provision of medicines provides some concerns around safety, temperature controls, and how would it have any controls (as were discussed even for category 4 meds?) Where is there an access problem that this is needed to overcome?

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

268 - needs to go to a committee and/or experts as for reclassification not be decided by a regulator alone. The committee needs to be well considered about its make up (see below)

269 - this sounds like the regulator could often do it alone, and I disagree with that as there are often important safety concerns that are raised at a committee level. The committee needs to be made up with pharmacists (at least one with recent community pharmacy experience, and at least one with excellent knowledge with pharmacy practice literature) and general practice expertise, a public health doctor, one person from the Ministry of Health, and consumer expertise. The chair would usefully be independent (based on a NZ regulator opinion in my PhD thesis). The people on it need to have good evidence-based decision making skills (with the exception of the consumer) and potential for patch protection needs to be minimised, e.g. by changing how they are chosen from the current mechanism.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

281 As noted before, dispensing or compounding for an individual patient is completely different to manufacturing. The staffing are different, the activities are different, the environment and quality controls are different. These should not be combined as it creates confusion and the requirements should be very different.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Some medical devices change often in a way that medicines do not, e.g. point of care tests. We need to allow access to the best technology that maintains safety. Some of this could be by allowing products in that are registered in the EU. NZ is a tiny market and we need to respect that we have to enable safe access. I note that a hepatitis C test I am using in a clinical study in NZ that has been endorsed by the WHO is not on the market in Australia because it would cost \$80k to get it there - which is not at all feasible. We could miss the best products if we have significant cost and time barriers to getting the product on the market. At the same time I appreciate that there is a need to ensure safety. Recognition of registration in selected overseas markets should be sufficient to allow the product to have access here.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

I completely agree with this and see a real benefit to doing it in patient safety, e.g. the ability in Australia to have a medical device for bacterial vaginosis restricted to pharmacist-only owing to the underlying condition.

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Possibly requiring pharmacies to carry certain items that may be completely unrelated to the services they provide is an issue.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Pharmacists do not only do distribution and supply. Presumably other activities such as cognitive services will be allowable outside of a pharmacy.

Pharmacists should be enabled to work in different environments such as clinical trials without necessarily needing to be in a licensed pharmacy.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I have answered this in the section for consumers. Please use that.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

I have answered this in the section for consumers. Please use that.

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Both is ok but both have to be able to be liable in a failure.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

See the Pharmaceutical Society position paper

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

3-5 years.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Be removed.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

I have answered this in the section for consumers. Please use that.

Question C34 - Are there ways in which Option 2 could be improved?:

I really do not want to see this happen, I am concerned for patient safety and pharmacist best practice and stress.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

I think there could be the potential for remote services where a pharmacist is already on site but to enable further services tele-consultations with another pharmacist are enabled (e.g. checks on vaccinations, pharmacist-supplied medicines). To aid staff shortages and access to medicines.

This depends on what is meant by remote supply also. Depot where there is no other possibility and access issues is ok with the pharmacist constantly in communication.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Doctors providing vaccinations and some other services have this already also.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

I see benefit in allowing Delegated prescribing currently and have suggested pharmacists utilise that. Hopefully it will be used sometime soon.

I have concerns about the standing orders in terms of whether there is appropriate auditing to ensure these are done correctly and the appropriate mechanisms are in place.

I think the way exemption to prescription is likely to be handled will mean that there may be less need for standing orders and more ability to ensure it is best practice if it has to go through a committee versus a standing order written by a doctor.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Yes.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

A standing order could be for a prescription or pharmacist-only medicine, as pharmacist-only medicines should not automatically be available to other health professionals who do not have the same training, expertise and standards to manage these.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

I have answered this elsewhere. I am confused by the special clinical needs supply authority - I thought the medical practitioner needed to apply for this, which I would agree with, not that the medical practitioner would issue it. The wording elsewhere in this document and in the bill is confusing. I agree with tighter controls so it needs to be applied for by the doctor unless in emergency situations. Hospitals might be exempt from this though perhaps. We need assurance that where registered products are on the market they are used, and there is good clinical reasons for using unapproved products in this case. We need assurance that the consumer has given informed consent to this. We need doctors and pharmacists to have a much greater understanding of the safety issues of this use, including counterfeit supplies, quality issues affecting safety and efficacy, overseas recalls not being known about in NZ, appropriate packaging and labelling, etc. We register products for a reason, to ensure safety and efficacy. Use of unapproved products should be exceptional but is not.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Sounds like a good idea. Even if a wholesaler sources them there are still considerable issues - melatonin 2 mg slow release is the key case in point where access to an unapproved product not approved anywhere in the world as a medicine, with dubious quality, and recent recalls is being supplied to consumers instead of a registered medicine, often without discussion with the consumer. Patient safety and informed consent need greater attention.

Personal importation needs to be limited, to 3 or 6 months, and should be discouraged as much as possible. This needs to be for prescription medicines and pharmacist-only medicines. See other information I have written through this consultation document.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Where it overcomes a barrier to access, e.g. Boostrix vaccines cost \$45 delivery, so to buy one or two vaccines at a time would be excessively expensive for the patient who would likely go without, or for the pharmacy which would choose not to offer these, affecting access.

We need to ensure this is able to be done but not in large quantities. If health practitioners provided medicines to other health practitioner prescribers we could see our excellent wholesaling system which minimises the risk of counterfeits entering the supply chain being circumvented and counterfeits inadvertently brought in by a health practitioner and then onsold to others.

This could end up being parallel importing, which needs to be discouraged for safety reasons.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Again, there are safety/quality issues here and potential for counterfeits.

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Pharmacy only is ok but not pharmacist-only.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No. I have answered this elsewhere, please see that detail

Pharmacists are always in a pharmacy overhearing conversations about OTC medicines and intervening on a regular basis (see for example Gauld N, Sullivan T. Double-Dosing and Other Dangers with Non-Prescription Medicines: Pharmacists' Views and Experiences. Pharmacy. 2018; 6(3): 59.) Other health practitioners' staff will not have the knowledge about these products, and will not have the oversight - a hovering pharmacist with flapping ears (something we are really good at) for intervention.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that

medicine for a patient?:

I agree that this needs to be tightened. Patient safety is put at risk often with no information to the patient. A requirement should be that the patient or their guardian has consented to this supply also (unless in exceptional circumstances, e.g. unconscious, emergency use. Doctors misunderstanding of this is huge, including their medical organisations. There is a lack of understanding of the risk, a lack of informed consent to consumers, and a lack of understanding in pharmacy also.

I completely disagree with point b that others can prescribe them, although administration in a hospital would be fine. People are already too lax about this and having others prescribing them is problematic.

See also my answers elsewhere in this document about this in terms of the dangers, and my recommendations.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Yes, agreed.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Yes, in exceptional cases there will be a good reason to do this.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Pharmacists should be able to dispense in clinical trials environments without it necessarily being a licenced pharmacy. This will add safety given pharmacists' training and skills in managing medicines, managing interactions, and ensuring good dispensing and compounding processes and documentation.

There are considerable risks in dispensing large amounts of medicines outside of a pharmacy, and perhaps there needs to be some controls around upper limits for a non-pharmacy. The concerns are storage, stock rotation, access to the medicines, keeping appropriate records, doing recalls, ensuring stock is in date and in appropriate temperatures, incorrect selection of products, use of products that are not ideal because those are the ones in stock or got on the right deal, checking drug interactions, being a second check for prescriber errors, counselling. I am particularly concerned that aspects of dispensing will not be understood as to their importance to patient safety without a pharmacist involved. Will the product be labelled with the patient's name, directions for the medicine, dispensing date, expiry date (if applicable) and so on as a pharmacy needs to? Furthermore, I am extremely concerned about delegation of the dispensing, even if it is illegal, to non-prescribers. I have seen this before with an oral surgeon. There is a need to ensure doctors are well informed that this is not possible.

Presumably medicines funding in primary care will be limited to medicines dispensed from a licensed pharmacy premise, or medicines administered onsite in a medical practice, which would help minimise the quantity provided in many cases.

I am also very concerned that cold chain needs to be equally audited in pharmacy and in general practice and action able to be taken.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Please see the Pharmaceutical Society position paper on ownership for the evidence. The environment will be better for the patients and pharmacists if there is pharmacist ownership. Pharmacists will be vulnerable to pressure from non-pharmacist owners, e.g. to not stock expensive medicines, to pass on compounding to other pharmacies, to have unsafe staff levels, to cut corners, and will struggle to be heard in an environment with open ownership. This is likely to lead to sub-standard service delivery - unsafe working environments (profits before safety and lack of understanding from the owner as to what is safe). Pharmacists have ethical responsibilities, but they also need to have a job and pay the mortgage. Under unrelenting pressure from a boss who does not understand or want to understand the ethical responsibilities of a pharmacist, and where the alternative is unemployment, a pharmacist is put in a very difficult position.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Benefits:

A pharmacist understands medicines like no others. Having a pharmacist owner will reduce the risk of inappropriate storage, supply, management, etc of medicines, and reduce inappropriate pressure on pharmacists to act unethically. See the Pharmaceutical Society position paper on ownership for more details.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Risks - An increase in the number of pharmacies in suburban areas that will see more small pharmacies with a single pharmacist employed limiting their ability to step up on new services, to have a safe dispensing environment, to have time to counsel patients, to have time to check interactions, to be proactive in offering public health initiatives such as vaccinations.

Reduced pharmacist coverage even in multiple-pharmacist pharmacies to increase profitability - affecting safety, and affecting ability to do new services, have safe dispensing, time counselling patients, etc as above.

Increased pressure on staffing will add stress to the pharmacy workforce (pharmacists and others), affecting their performance and their ability and desire to deliver services to their community.

There will be more cherry picking, and pressure on pharmacists to work outside of their ethical requirements. There will be increasing treatment of medicines as commodities rather than items that need to be respected. Increased pressure on sales targets will also be seen, potentially leading to inappropriate recommendations by pharmacy staff, and the pharmacist may have little control over these people.

Please see the PSNZ position paper on ownership for evidence and further key points. This is an important document to consider.

I see no benefits to patients or to pharmacy.

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

This is fine, providing they are related to their care.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No. They do not have the training and knowledge required. See the paper: Gauld N, Sullivan T. Double-Dosing and Other Dangers with Non-Prescription Medicines: Pharmacists' Views and Experiences. *Pharmacy*. 2018; 6(3): 59. People make many mistakes with medicines - double-dosing, wanting to use with contraindications or precautions or interactions, using for inappropriate reasons. The findings in this paper were disturbing.

Pharmacists intervene on pharmacy-only medicines with important safety advice and finding inappropriate behaviour. In pharmacies, pharmacists have their dispensary close to the OTC medicines, and must always be on-site. This ensures they can listen in on conversations, are readily accessible, and can intervene where necessary in supplies of pharmacy-only and general sales medicines, both when a pharmacy assistant refers a patient to them, or when something is overheard. When working in community pharmacy I frequently intervened on pharmacy-only medicine supplies e.g. an elderly person requesting an anti-inflammatory or cough-cold remedy. This is a very important part of a pharmacists' role.

In other environments there will be no health professional able to overhear. There will not be the same level of training or understanding of the different non-prescription medicines as happens in pharmacy.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G485-E

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:36:27

Submitter profile

What is your name?

Name:

Sarah Benge

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Cancer Trials New Zealand, University of Auckland

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

NGOs, Other (please comment)

If you selected 'Other' please comment;:

Non commercial clinical trials coordinating centre based in the University of Auckland

Next steps after the consultation

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

I am in favour of all clinical trials being regulated and requiring authorisation. I am very glad to see devices being brought under the legislation and reference being made to the ICH documents, international standards and good research practice.

The problem with the present system is that HDEC are not directly responsible for assessing the scientific validity, they rely on the scientific peer review for that (which in theory should be fine), whereas SCOTT undertake scientific assessment of clinical trial applications but only some clinical trials (see below). SCOTT's

panel comprises of researchers, clinicians, biostatistician and Pharmaceutical Society of NZ recommendations. Currently the only trials that SCOTT see are those involving new (unapproved in NZ) medicines and those involving an unapproved formulation of an approved medicines (e.g. IV when approved as oral). These types of trials are looked at by HDEC and SCOTT, the latter assessing their scientific validity.

In my line of work we deal with clinical trials in the area of cancer, so serious disease and toxic drugs. A big concern that I have with the current system is around those trials of approved medicines used in a different indication to that for which they were approved. So a toxic cancer drug could be used for a non-cancer condition and SCOTT/Medsafe would not know it was going on.

Such trials are only looked at by HDEC, they will of course be peer reviewed (but if the funding did not come from say the HRC, for example then the scientific peer review can be by one person and would not necessarily have the rigor) - I would sleep much better if I knew that SCOTT had also reviewed and approved the trial.

So as long as the process for obtaining authorisation under the new Bill assesses the scientific validity (like SCOTT currently) then I am in great favour of all clinical trials being assessed in this way. as this would give me assurance that each of our trials had been reviewed fully – scientifically and ethically

This is the model in the UK where I spent a great deal of my working life in the area of clinical trials, I was shocked on coming to NZ that not all drug trials needed regulatory approval so I am very pleased to see that now being rectified. – all drug trials need regulatory approval – so I guess that's what I grew up with!

As in the UK and as you say the new SCOTT-like process and the HDEC process can be done concurrently to capitalise on time. That coupled with the regulatory body taking a risk based approach will not add significant time to what we do currently, most importantly it will provide assurance and transparency.

I am also very heartened to see that the this new system will feed into a database so NZ will finally know the numbers of clinical trials it is involved with and in what area.

An area I sadly see has not changed is around who applies for approval/licence to run a clinical trial. For our clinical trials, the University of Auckland is the sponsor (GCP definition), they hold the insurance, take on the risk etc. In the current and proposed legislation a suitably qualified individual within that organisation has to put their name to the application. - this is generally the lead investigator. I think there should be an option for the actual sponsor of the trial to be the one applying for approval, this then ties in sponsor's responsibilities according to GCP and the responsibilities of the applicant for approval/licence. The lead investigator can be named as carrying on the tasks for the sponsor's responsibilities but ultimately the sponsor, the university, has to ensure it is compliant.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

These seem fine to me.

We changed from a paper based ethics system to an online one and from my team's perspective this was not too onerous. I see managing the transition time for this new process in a similar way.

People will benefit from clear training materials

Response ID ANON-DPZ8-G48P-9

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:44:55

Submitter profile

What is your name?

Name:

Elizabeth (Liz) Young

What is your email address?

Email:

What is your organisation?

Organisation:

Product Evaluation Health NZ (PEHNZ)

Submitter Profile (tick all that apply)

Consumer

Professional body (eg, Colleges, Pharmaceutical Society etc), Private hospital, District Health Board (DHB)

If you select DHB, please state service area:

National Representation from All DHB's and some Private NGO (clinical product coordinators CPC's)

Nurse, Other health practitioner (please comment)

If you select 'Other', please comment below;:

Multi disciplinary some CPC's are Anaesthetic Techs, most are or have been RN's

Crown entity, NGOs

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

We would still like to see further detail regarding the approval process and the rules while they are being developed.

We note this will not be the first and final consultation document released for this, and do look forward to further information, detail and opportunities to feedback if and when it progresses.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

There should be no exemptions, this aids a lack of consistency with regulator and also with potential users.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

At Forums, the speakers advised sponsors of products need only be a body corporate incorporated in New Zealand. Concerns around this with regard to the lack of control in the industry currently and that this will be unacceptable if no responsibility is outlined and enforced around the body corporate entities going forward. In particular, body corporate/representatives in New Zealand who are not the agent or the supplier, are not responsible for regulatory processes (Safety, conformance, recalls etc) required. There is no ownership of the 'sponsorship' just an address and name on the WAND Database.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

It remains completely unclear what role the regulator will have in this new world order. WAND database will not go across, as advised in session feedback, no guarantee Medsafe would be the Regulator moving forward, nor any clarity around whether an entirely new dept in a new location would be created.

What is necessary

- The regulator must have strength in legislation to reasonably control errant companies
- The regulator must be resourced to respond in a timely manner to issues that are raised with them
- The regulator must have procedures and protocols in place that require documented feedback to issues reported within an identified timeframe
- The regulator must be appropriately staffed to manage and meet their KPIs for responsiveness.

All of the above are known failings of the current Medsafe processes which is wholly under-resourced to perform well or appropriately/consistently.

- It was presented to the forum that WAND would be abandoned and a new process would need to be built, taking a time period of around 6 months. This goes back to a potential for a new regulatory body and ensuring adequate timely infrastructure requirements.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Current process wastes much time waiting for companies to respond when an issue has been reported to Medsafe. This is obstructive and delays can be critical. Regulator needs some teeth to demand timely, detailed responses.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

The current Bill is well overdue for updating, Medsafe has been well handicapped by the restrictions in 1981 document. Several issues arise from current exemption categories where companies are not regulated nor required to be compliant with Medsafe processes – of longstanding and suits their way of working. Given the reinforced approach to national procurement, there must be consistency in regulatory rigour so all categories are compliant for the right reasons.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

There is little clarity available on the cost recovery or how this will be addressed. NZ is not big enough to have our own therapeutic devices review process/team, an example of TGA taking up to 2 years to accept an application while they re-review a device already fully licensed by other notified bodies and costing much to Australian and other countries companies who want their items saleable in Australia. Is the government going to fund this?

We do have geographic impact issues in this country that make some of the licenses inapplicable as they don't reach the compliance requirements for NZS 3551 and associated safety regs – these may need extra review by the manufacturer before being accepted in to NZ for sale. There was forum discussion about upgrades to products (e.g. software or accessory upgrades) and at what point does this merely classify as an upgrade as opposed to a new product altogether given that the functionality or capability of the device may be changed significantly. How is this going to be regulated and at what point does an upgrade become a new product? Eg a device that is introduced as single use, is developed to become a reusable device requiring sterilisation/reprocessing – definitely not the same compliance or safety requirements to consider/approve.

Need a timeframe for applications to be approved by the regulator – must be a KPI to reference.

Use of words manufacture and remanufacture – need to be defined, not clear what intention is for description.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Categories used for this current Medsafe process of issuing or approving regulatory notifications for distribution are wholly flawed and misleading. They do not reflect the nature of the notification being issued, correctly or adequately. This needs to be addressed fully as part of the compliance changes.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

- Medicines –the Medicines Forum discussed the approval for S29's was discussed. The speaker advised PHARMAC does not want confusion around the approval of these and will decide if this needs to be patient specific or changes need to be made to the current process. The current S29 process is cumbersome and flawed. If special authority is considered necessary then an effort to improve the process is required.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

This requires a comprehensive risk analysis documented and communicated to all who use/order the item so there is clear accountability for off-label use. At present the Ministry advised they will have to think about how they regulate this

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

The device aspect of this legislation is stated as being 'in, on or for treatment of people'. While vets should be regulated in their industry, there are differences in the types of equipment and medicines/therapeutics to accommodate animal physiology and anatomy. They shouldn't be muddled with humans regulatory structure

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

****Comment below from member of group, However PEHNZ members do not really have any influence or commentary on Medicines unless they are potentially viewed as a device also.***

Difficult when you have an approved product that is not funded and prohibitively expensive for consumers to acquire for use in NZ. Don't think we should disadvantage people looking for approved options to import, if cheaper same product can be accessed this way.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G484-D

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:47:27

Submitter profile

What is your name?

Name:

Marissa King

What is your email address?

Email:

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below::

If you selected 'Other' please comment::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Totally disagree with the defintion of dispensing . This is not just the manufacturing process .

Dispensing;

This involves communicating with the patient initially to see what state they are in , the clinical assessment of their medications and then the process of making the medication . This involves the interaction with the patient on how to take the medication , what to look out for , if side effects , interactions etc and then how to store it .

Advise at the time of making the medication is essential.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Ok for pharmacies to supply each other with medicines when there is a need for a patient.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Ok in small quantities

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Agree with the proposal

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Medicines need to be dispensed only in a dispensary.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Yes

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Keep things as they are

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Strongly in favour of this option . In the best interests of patients this way . Safety will be maintained.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Community based pharmacies look after their patients better . I worked overseas and did not agree with the model in the UK.

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

A few years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Too risky . Dispensing driven by profit vs patient needs.

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Agree

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Ok in emergencies

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No . Too risky . Need someone else in the process to be involved to stop potential errors and improve patient safety . Prescribing we see is often wrong .

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No as health practitioner in a room and can't see what is going on.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Response ID ANON-DPZ8-G4X8-H

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 15:47:57

Submitter profile

What is your name?

Name:

Medicines and Therapeutics Committee - Canterbury District Health Board

What is your email address?

Email:

What is your organisation?

Organisation:

Canterbury District Health Board

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Canterbury

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

COMMENT in regards to Question A1

We support the intent and general design of the Therapeutics Product Bill in replacing the Medicines Act and endorse the principles based update and design.

We acknowledge that much of the detail is still to follow – in regulations, rules and notices, and note that without this level of detail it is impossible to know if the right balance has been struck in risk appropriate management.

We oppose the exclusion of Natural health/complimentary products (including rongo M̄ori and dietary supplements) from regulation under this proposed legislation.

We are aware of the history around this but we remain concerned and submit they should be considered for inclusion because they are currently available and are sold to and used by a large proportion of the NZ population with therapeutic intent.

These are a group of "therapeutic products" for which there is a great need for regulation. There is a huge amount of misleading advertising, their production is booming and there is a substantial risk of harm.

COMMENT in response to Question B1 -

We agree with approach to move from set legislative framework to a principles based legislative framework.

Regarding ss4 a) of the Bill

Please reconsider terminology - we submit that "potential harm" is more accurate than 'likely risk'.

1. The likelihood of a harm is a risk.

2. The use of the term "likely" suggests a high probability.

3. Prior to use, medicines have potential effects (beneficial and/or harmful)

"...the potential benefits of therapeutic products should outweigh the potential harms associated with them..."

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

We support the alignment with international definitions.

Ss14 – Health Practitioner Prescriber – We note this is defined differently to the Medicines Act - Authority to prescribe is to be established in, and bounded by, scopes of practice under the HPCAA (responsibilities of individual scopes of practice for individuals) and not in the regulations.

This is a substantive change. As scopes of practice are defined by each profession's regulatory body (e.g. nursing and medical council), inconsistencies may arise.

A process for harmonisation or oversight of prescribing roles may be needed.

Is there a legislative instrument to facilitate this if it is needed?

We noted the removal of categories of prescribers (authorised/designated/delegated). See also ss61 and ss276-285

Ss15 - Therapeutic Purpose definition - casts a net that is likely to be wider than intended or is appropriate. The key problem areas are

(a) "compensating for a disease, ailment, defect, injury". This would include many devices in the rehabilitation field that are internationally not generally considered medical/therapeutic devices e.g. corrective glasses, orthotics, hearing aids, speech recognition software (for those who can't type), aids to daily living for those with arthritis e.g. special spoons. Occupational Therapy could provide legions of examples..

(b) "Influencing...a human physiological process". This could inadvertently include all exercise equipment which would be inappropriate

(i) "a purpose connected with a purpose in paragraphs (a) to (h)...". This creates a circular reference that pulls into the net a vast list of support devices. While some of these might be excluded by regulations, others are included by default. e.g. bottles that contain medicines, a computer and computer program used for designing devices or medicines, computer software that supports almost any medical activity, simulation equipment

The definitions of 'therapeutic purpose' and 'intended for use for a therapeutic purpose' in this section of the Bill are applicable to natural/complementary products. Given the withdrawal of the Natural Products Bill, the exclusion of natural/complementary products is notable.

Ss19 - Categories of medicines – We note the change in terminology. We note the detail for how the categories are applied practically to packaging/labelling etc. will be contained in the rules and regulations to follow, but there is a financial/procedural risk (not clinical) if re-labelling to match the numerical categories supersedes the current labelling of "prescription medicines", "restricted medicines", "pharmacist only medicines" etc.

Ss20 – Active Medicinal Ingredients (AMI) - It is unclear which aspects of current medicines this covers. Presumably rules and regulations around AMIs would mainly apply to manufacturers, but would also apply to pharmacies who manufacture medicines using raw ingredients (e.g. lidocaine powder) to make a batch of product (for many patients and held in stock). We note potential implications for hospital pharmacy compounding and for externally sourced locally compounded products.

Ss21 – Medical device - We welcome the inclusion of software as a medical device, but note that there needs to be extensive clarification around precisely which software is to be included or excluded from regulation. As it stands, the definition appears to include guidelines for clinical decision making (ie HealthPathways), and Electronic Health Records.

a) These types of software meet the definition of therapeutic purposes as they are used for "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury"

b) These types of software also meet the definition of a medical device as they "achieve, or is likely to achieve, its principal intended action by means other than – (A) pharmacological, immunological, or metabolic means; or (B) the action of something that comprises, contains, or is derived from human or animal cells or tissues;"

This is a particularly broad and impractical definition of a medical device, which would require explicit clarification. The absence of standards or regulatory framework for medical software has placed substantial evaluation burden at a local level, and so some degree of regulation would be appropriate.

ss 25 - Prohibited products

We note that theoretically any therapeutic product could be made prohibited by the Regulator. We agree this is practical, but highlight that consideration needs to be given as to how this relates/impacts on other legislative tools for prohibition of substances e.g. the Misuse of Drugs Act 1975

Ss39 - Special clinical needs supply authority (SCNSA) - The extension of this approach to include off-label use of medicines that have been approved in NZ is a

major change with potentially very high compliance costs, and administrative burdens. Off-label use of medicines is common and in most cases is usual clinical care (eg. medication use in children and pregnant women; contraceptive pill for cycle regulation rather than contraceptive purposes; Sildenafil for pulmonary hypertension). SCNSA documentation of all off-label use could be excessively burdensome, even if the requirements were "minimal" compared to SCNSA for unapproved medicines. Even adding a 'tick box' as suggested in the consultation document, would incur development costs within electronic prescribing systems that are already in use.

Use of approved guidelines would be sufficient to cover the off-label use of medicines.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Ss51- Product Approval Requirements - This seems to prohibit parallel importing – which is currently legal in NZ.

Rare conditions may require access to new or seldom used (and unapproved) products that are likely to provide net benefit to the patient but won't have met the onerous regulatory standards required by the Bill. Supply issues for critical medicines are another example where this provision may be too restrictive. Clear provision of exceptions to cover this need to be included.

We feel this needs clarification and careful thought as to wider implications, particularly around monopolisation of supply and the future cost implications. It is also unclear how this would apply to importation of parts of devices, rather than the whole device (ie a new component for repairing an older device, or consumable components for a device).

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Ss53 Part 2, d) and i) – Authorisation Required for Controlled Activity - Inconsistent terminology; therapeutic product vs 'medicine'

Is it deemed that only "medicines" can be prescribed. This is inconsistent with clinical practice and the definitions of therapeutic products earlier in the Bill e.g. blood products

Overall the list of controlled activities is quite detailed for medicine-based Therapeutic Products, but less detailed/incomplete for other products (e.g. devices).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Ss57 – Pharmacists- This section refers to medicines. Is it intended that this regulation would cover medical devices, that could be sold (if Category 2) by a pharmacist? If so then a wording change would be required here. Or a statement of exemption for devices.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

We support authorisations for pharmacy workers. This allows delegation and clarity of scope for pharmacy workers by setting out the level of supervision required. For example, this will allow Pharmacy Technicians & others to compound products with "general" supervision of a Pharmacist, rather than "direct" supervision

Question B7 - Please provide any comments on the authorisations for health practitioners :

Ss61 - Health Practitioner Prescriber - Authority to prescribe to be established in, and bounded by, scopes of practice under the HPCAA (responsibilities of individual scopes of practice for individuals) and not in the regulations.

We note this is a change from the Medicines Act. As scopes of practice are defined by each profession's regulatory body (e.g. nursing and medical council), inconsistencies may arise. A process for harmonisation or oversight of prescribing roles may be needed.

Is there a legislative instrument to facilitate this if it is needed?

We noted the removal of categories of prescribers (authorised/designated/delegated). See also ss14 and ss276-285

Ss61 (2) - Health practitioner Prescriber (e.g. podiatrist, not a prescriber) can "supply" as well as administer category 3 medicines for patients under their care, e.g. for feet and limbs. We accept this extension from the current provision in the Medicines Act which allows administration but not supply of these medicines.

We note this has beneficial implications for patients, as they are able to receive full care from one provider, potential benefits of increased independent practice, and allowing practitioners to work at the top of their scope. This could be of benefit in removing burden from other areas of the health system, potential problems of increased isolation and decreased team practice could be countered through the use of primary care infrastructure such as Primary Health Organisations.

Ss61 (3)(c) - "the patient is in New Zealand or is ordinarily resident in New Zealand";

Please provide further clarification of the phrase "ordinarily resident", and further discussions about the implications of this clause.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (ss 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

We submit that more work is needed to clarify the proposals around personal importation of medicines.

Interpretation 1: It appears that these sections were intended to cover people immigrating to New Zealand, returning to New Zealand, or tourists who are passing through. However, if this is the case, then there needs to be a clause that states an end date to someone being able to import medicines. As it stands, it appears that people could move in and out of the country ad infinitum, bringing prescription medications with them each time. Or people could continually access their international prescriber (online type consultations are becoming increasingly common), and have ongoing access to medications via this route.

Oversight of care ought to be transferred to a New Zealand health professional at some point in time if the person is here for more than 12 months. We also note the potential for harm with abuse of some category 2 medicines.

Interpretation 2: Category 1 medicine can be imported if a medical practitioner is satisfied the consumer has a clinical need for medicine that cannot be met by medicine available in NZ. How does this differ from the need for an SCNSA?

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Ss83 (3) – Direct to Consumer Advertising- There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694–695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system. It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing.

If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised.

If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie ibuprofen, not Nurofen).

There would also need to be consideration that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat, when we have issues with Rheumatic Fever in New Zealand populations.

Ss93 – Health practitioner prescriber must not hold interest in pharmacy business - We acknowledge and agree with the concern about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions and conversely if suppliers owned prescribing businesses.

We submit that the issue of ownership be consistent across the health sector and not be focused solely on pharmacy businesses.

We also note that the definition of a "health practitioner prescriber" has been updated, and this may mean that the provision needs to be reviewed as well. There are queries around the implications of this section for Pharmacist Prescribers owning their own business, and for pharmacies located within General Practice.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Ss113. Therapeutic products register -For medicines, the therapeutic products register must list the active ingredient, we contend that this should be extended to include all ingredients. For example, to determine product suitability for people with allergies. This may be covered "any other information" specified in the regulations?

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Ss114. Approval-exempt products - Would this allow the small scale manufacture of products in NZ (e.g. Biomed make a number of products under s23, such as fentanyl infusion solutions, where full registration is difficult to meet but safer to manufacture in controlled environment than to prepare in a clinical environments, such as wards, operating theatres etc....)

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

Where possible, having data publicly available would be preferable. Noting that the risk to patients if the health system cannot independently evaluate information related to therapeutic products could be high. It is important that the evidence upon which regulatory decisions are made are open to scrutiny by health professionals and patients.

Therapeutic products are used by New Zealanders on the advice of New Zealand health professionals and potentially paid for by New Zealand taxpayers. We submit that full information about active ingredients is essential to safety and efficacy of medicines use.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

No matter the system used for granting licences, it should consider patient safety and maintain separation of prescribing and dispensing of advice re medicines/devices.

Whatever system is used should consider separation of ownership responsibilities and clinical responsibilities.

We submit that the issues of independent practice and ownership be consistent across the health sector and not be focused solely on pharmacy.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Ss137 – Duration - Currently Licences are issued for 12 months, new Bill allows Licences for up to 3 years – we support this extension in duration

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

For this to be effective it will be necessary for the Regulator to be appropriately resourced. This is could be difficult for NZ to manage, and close alignment and collaboration with other jurisdictions will be required.

Ss176 - Independent panels- Sufficient expertise to make up these panels may be difficult for NZ to effectively resource.

Ss172 – 176 Oversupplied persons- For persons oversupplied category 1 or 2 medicines (addicted/ abusing, etc.) this places a series of rules in place to limit prescribing and dispensing of these medicines to this person. It is also linked to the Privacy Act 1993/ new Privacy Bill

We note the increase in enforcement options – we support having a greater range of enforcement options to cover a range of infringements. We note this may have significant administrative costs and to be effective will need to be sufficiently resourced.

Ss267 (2) – Consultation – We note concerns that the Regulator is able to determine who is considered “appropriate” for consultation before developing rules, a notice, or an exemption. We also have concerns with Ss267 (3) which notes that despite clause 2 saying that the regulator “must not” make rules etc... a failure to comply with this clause does not affect the validity of any rules or regulations that are created.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

The regulator can set the fee to make up any cost not covered by government funding. We see this as a potential risk, and note that the benefits of regulation are to the taxpayer.

There is a natural tendency for regulators to minimise their risk. To reduce risk regulators have a tendency to increase complexity and potentially costs (increases the risk of bureaucratic overreach).

Conversely we note that a fee for service system can lead to a culture of customer service, and risk of putting the customer (applicant) ahead of the citizen (patients).

Financial independence from fees is a necessary component of regulatory independence.

- We submit that an external review process or independent fee setting should be considered.
- We submit that fee setting and revenue collection should be separate from regulation and enforcement to maintain the independence of the Regulator and recognise that the primary customer is the government on behalf of the people of New Zealand.

At the moment, registration of products in NZ is sometimes limited by cost, which has been a barrier. (E.g. section 29). If this becomes applied to devices and software as well we see this as a potential risk.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Ss256 - Regulator can set the fee to make up any cost not covered by government funding. We see this as a potential risk of significantly increased costs compared to current. Regulators are inherently risk averse and there is a tendency for Regulators to increase levels of scrutiny and thus costs. There is a risk this could limit innovation, and/or limit the products available in New Zealand. How will this risk be managed?

Enabling the regulator to charge fees to cover any costs not covered by government funding will likely result in an increase in costs to purchasers of medical devices as these fees will be passed on. Full transparency for any fee proposal with approval from a governing body representing purchasing agencies (including DHBs) would provide a mechanism to transparently manage these additional costs.

At the moment, registration of products in NZ is limited by cost (in some cases), which has been a barrier. (E.g. section 29) If this becomes applied to devices and software as well we see this as a potential risk.

Also devices are not currently charged – if devices become regulated and fees are charged compared to current (no charge) this would potentially be a big difference and could limit availability and innovation.

Ss267 – Consultation – We note concerns that the Minister and Regulator are able to determine who is considered “appropriate” for consultation before developing regulations, rules, a notice, or an exemption. We also have concerns with Ss267 (3) which notes that despite clause 2 saying that the above people “must not” make rules etc... a failure to comply with this clause does not affect the validity of any rules or regulations that are created.

Given that the regulations, rules, notices and exemptions are going to create the detailed structure of how the Act is applied, and that these regulations and rules need to work for the whole country, and the various ways of working, it is important that a variety of people are consulted, and that may require an independent advisor to determine suitability.

Ss268 – we support 5 yearly review of the policy and operation of this Act

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

We submit that defining roles of health practitioners within the HPCAA act is reasonable. (As per answers in B2 and B7)

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

We submit that Crown entities should be able to apply for review in addition to sponsors and license or permit holders. The regulator may make a decision that the health system may disagree with (e.g. DHBs).

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

1. We submit that the primary responsibility for pharmacovigilance should remain with the regulator AND that this capacity should be enhanced.
2. We submit that the Regulator be given powers to access health data for the purpose of pharmacovigilance.

At the same time pharmacovigilance has moved from a base of spontaneous reporting to a base of large health data analytics. With increasing digitisation this is likely to continue. We think this is a core responsibility of the health service.

Access to health data for this purpose should be by the crown and not by a sponsor with other potential interests in the data.

In recent years there has been increased emphasis on the responsibility of sponsors for pharmacovigilance. We have substantive concerns about the sponsors abilities to carry out this task.

- There is a direct and substantial conflict of interest, for example delaying (or not) by seeking greater certainty could have major financial implications for a sponsor.
- Safety issues identified in pharmacovigilance frequently apply to a class (rather than just an individual product), hence a broader view is required
- Sponsors do not have easy access to the relevant safety data, these are held largely by the public health system. Reporting and transfer of information from health services to sponsors is resource intensive.
- "As a clinician I ignore companies requests, their forms are lengthy and they always ask for more information. I don't have time to do this and I don't trust them, it seems like a business activity."

At the time of registration the sponsor holds the relevant data worldwide and this is the best source of safety information.

After registration, clinical data relevant to pharmacovigilance are held by the health service.

After patent expiry, generic manufacturers do not have the resources or expertise to carry out pharmacovigilance.

Other relevant points:

For spontaneous reports practitioners want a single point of reporting.

Large data sets allow for effective pharmacovigilance incorporating multiple variables. This is not possible with sponsor based pharmacovigilance and requires a public health approach.

Lack of industry motivation and financial interest, particularly once innovator products are replaced by generic products

We note that prior to registration the sponsor holds the data and should be responsible for reporting any subsequent data obtained through sponsor generated studies

We propose that pharmacovigilance is a public health activity and a core responsibility of the regulator.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Any non-medical devices that when used as intended, that has the potential to cause significant harm, should be required to be labelled advising of the risks. If such devices are being used by an operator to provide a service to another person, then the operator should be required to advise person of the risks (i.e. the cosmetic specialist using a high-intensity electromagnetic radiation should have to advise the customer of the potential adverse effects before starting treatment – possibly requiring signed informed consent).

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

General comment on medical devices –

We note difficulties in applying definitions and categorizing with substantial implications. For example electronic records with electronic clinical decision support versus the paper records with paper (and human) clinical decision support (guidance) it replaces.

We note substantive differences in the development cycle of different therapeutic products. For example new molecular entities in medicines are developed over decades, whereas software might be developed over weeks.

It is not clear to us how the Bill and subsequent Rules and Regulations may impact upon clinical activities. This is a new area and is likely to take many years to develop. It is important the Regulator and consulted parties are given sufficient time and resources to do this.

Many of the same issues raised earlier in our submission for medicines apply to other therapeutic products for example product vigilance and pharmacovigilance.

The International Medical Device Regulators Forum (IMDRF) defines software as a medical device (SaMD) as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”. The IMDRF definition is not in the TPB, but we expect NZ to follow this internationally established definition (rather than construct another).

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

Transition: The period of six months seems extremely short, for most medical device manufacturers to obtain the necessary data and submit an application it is likely to take years (as it does for medicines).

This has two potential consequences:

- 1) That multiple devices are no longer available,
- 2) That the regulatory requirements are set low to allow the time frame to be met, such that it becomes an administrative exercise rather than useful regulation.

We submit that an interim regulatory regimen may be required with provision for grandfathering time limited approvals for existing products.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Clinical trials are a transnational activity.

Expertise for effective clinical oversight of a clinical trials in many areas is scarce.

We submit that the requirements should be such to ensure regulation of clinical trials is explicitly aligned with Australia and Europe.

We note the existence of Health and Disability requirements for Ethics Committee approval etc. for Clinical Trials currently.

The addition of licensing adds a new administrative hurdle to research – several staff has expressed concerns about this.

We note that clinical trials are already constricted and there is concern within the organisation that further restrictions will make local level studies even more difficult to undertake.

We also note that clinical trial regulations ought to be split into categories with differing regulations. Medical Devices (software) would require different regulation to externally applied medical devices (CPAP machines), and yet another set of regulations for trialing internally applied medical devices (joints, implants etc). Medicines would be different again.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

As a general comment - greater flexibility is supported. We note that the historical origin of the Act was of manufacture and supply. Manufacture and supply are largely separate in the current environment and separate regulation of these activities is appropriate.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

Option 2 allows greater flexibility in ownership, and would support pharmacy's being developed to meet demand (e.g. mobile emergency pharmacy's, pharmacy's in remote areas, and pharmacy's in specialist clinical practices, possibly dispensing limited range of medicines to meet clinic needs that are not readily available in most pharmacies, e.g. expensive anti-cancer medicines, and new, expensive, and medicines that are usually only used in specialty practices).

Option 2 reflects business practices in other healthcare sectors (e.g. dental and medical practices do not need to be owned by dentists or doctors), provided adequate quality control systems are in place

We submit that the issues of independent practice and ownership be consistent across the health sector and not be focused solely on pharmacy.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Presence of a pharmacist as a surrogate for appropriate care was previously a practical solution. Physical presence is a poor surrogate for care in the current environment.

Responsibility and accountability for care would be more consistent with requirements towards health outcomes for patients.

We submit such requirements should be consistent across the health sector for provision of health services.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

As above in question B12 and C22

We submit that the issues of independent practice and ownership be consistent across the health sector and not be focused solely on pharmacy.

There are also potential benefits to cross-ownership in provision of integrated services. The balance of potential benefits and harms is not yet clear.

We submit this issue is considered further and addressed more broadly.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Examples include, provision of medicines for a research study or at a temporary site e.g. festival or other temporary shift in population.

Also to set up a temporary pharmacy following a natural disaster, allowing patients who have to leave their homes without medicines, and/ or need ongoing supplies (e.g. following earthquake, flood, or fire). A 'temporary pharmacy' may be required for period of weeks/ months.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Answered in questions B2 and B7

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Support in principle but note this is complex and there are substantial differences in both scopes of practice and practice environments as well as in associated training and skills. For example prescribing in a hospital environment is frequently reviewed, whereas prescribing in a community environment is often only reviewed at the point of dispensing

We suggest regulation should focus on achieving consistent outcomes, rather than consistent process, form and content, as the prescribing environments and requirements vary substantially.

This section also seems to refer only to prescribing medicines, should it apply to all therapeutic products?

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

We support the approach to standing orders. We envisage that the need will decrease, as scopes of practice change. To issue a Standing Order will be a controlled activity, and can only be done if individual has this in their scope of practice.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Off label - This needs clarification as the implications are potentially substantial, see above under question B2

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Support and would comment that in the normal course this should be a specialist medical practitioner within their scope of practice.

The detailed review undertaken by the Regulator for safety has not happened and hence such prescribing requires an exceptional level of expertise.

Consideration as to how these approvals will be documented against the patient such that other health practitioners can then continue to prescribe them is needed. (Will there be a national register?)

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

We agree health practitioners' should be authorised to supply pharmacy (category 3) medicines to patients. This allows health practitioners to provide full care of the patient, and ensure appropriate ongoing care after the clinic visit.

Currently the health practitioner may make a recommendation that patient purchases the required medicines from a pharmacy (which may/ may not be routinely stocked by the pharmacy), with limited involvement of the pharmacist, and potential for necessary medicines not to be purchased.

We note that health care is increasingly multi-disciplinary but aspects of the Bill retain concepts of separate and independent care rather than interconnected care. This has been well advanced in some respects but may need more work.

There is a requirement for consideration of applicability to the provision of therapeutic products other than medicines.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

We agree health practitioners' staff should also be able to supply category 3 (pharmacy) medicines, but only with the approval/ under supervision of the health practitioner. As above, this would help ensure patient is able to readily obtain medicine to continue treatment initiated by the health practitioner.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694-695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system.

It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing.

If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised. If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie ibuprofen, not Nurofen).

There would also need to be consideration that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat, when we have issues with Rheumatic Fever in New Zealand populations.

DTCA of antimicrobial agents may contribute to pressure to use and prescribe antimicrobial agents. We note the New Zealand Antimicrobial Resistance Action Plan (a Ministry of Health initiative) (<https://www.health.govt.nz/system/files/documents/publications/new-zealand-antimicrobial-resistance-action-plan.pdf>) that specifically highlights the need to review the appropriateness of the regulations around pharmaceutical advertising of human health antimicrobial agents

We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe).

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

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We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe).

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

This needs clarification as the implications are potentially substantial, see above under question B2

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Support and would comment that in the normal course this should be a specialist medical practitioner within their scope of practice. The detailed review undertaken by the Regulator for safety has not happened and hence such prescribing requires an exceptional level of expertise. Consideration as to how these approvals will be documented against the patient such that other health practitioners can then continue to prescribe them is needed. (Will there be a national register?)

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694-695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system.

It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing.

If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised.

If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie ibuprofen, not Nurofen).

There would also need to be consideration that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat, when we have issues with Rheumatic Fever in New Zealand populations.

DTCA of antimicrobial agents may contribute to pressure to use and prescribe antimicrobial agents. We note the New Zealand Antimicrobial Resistance Action Plan (a Ministry of Health initiative) (<https://www.health.govt.nz/system/files/documents/publications/new-zealand-antimicrobial-resistance-action-plan.pdf>) that specifically highlights the need to review the appropriateness of the regulations around pharmaceutical advertising of human health antimicrobial agents

We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe).

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4F5-V

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:54:09

Submitter profile

What is your name?

Name:
Phyllida Duncan

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Medicines New Zealand

Submitter Profile (tick all that apply)

Industry body

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines and vaccines. A central objective of Medicines New Zealand is to promote the benefits of a strong research-based industry in New Zealand.

A full list of our member companies can be found on our website: <https://www.medicinesnz.co.nz/who-we-are/our-people/>

Although Medicines New Zealand agrees with the stated purpose and principles (ss3 and ss4) of the Therapeutic Products Bill (TPB), we seek an important inclusion.

It is stated in paragraph 45 of the consultation document that the purpose and principles "act as a guide to actions and decisions under [the scheme]". Therefore, it is essential that it is stated, as a fundamental premise of the TPB, that decisions made under the scheme adhere to the rules of natural justice.

Our reasoning is that the TPB, as intended, is at a high-level only and is highly enabling to the regulator. There is too much reliance on subordinate instruments for details on decision-making. The TPB gives the regulator a huge amount of power and choice for making a decision (e.g deciding on the tool to be used to address non-compliance). We understand that further detail on appropriate considerations for decision-making will be determined in subordinate instruments. However, the omitting of administrative detail in the Bill is an area of concern. In essence, the Bill asks us to agree to a regulatory scheme, without the providing the 'how'.

We note that one of objectives for the regulatory scheme stated in paragraph 7 of the consultation document is to "ensure high-quality, robust and accountable decision-making". The lack of administrative detail in the Bill means we cannot be sure of this objective being met.

Enforcement is an area where the objective of "high-quality, robust and accountable decision-making" is particularly relevant. Part 7 of the Bill provides an array of tools for the regulator to use to respond to a given situation. We submit that the regulator's use and choice of responsive regulatory tools must be made fairly, and it must be a proportionate response to the given situation. However, because we do not see a specific reference in the purpose and principles of the TPB to these

decisions being made fairly and meeting the rules of natural justice, we do not have confidence that this will be the case.

We believe it is highly important that natural justice is enshrined in the purpose and principles of the Bill, so that stakeholders can have confidence that the regulator's decisions will be made fairly and will be appropriate to the given situation. To ensure the regulator is held accountable to act fairly, we submit that reference to the rules of natural justice should be made in the purpose and principles of the TPB. To give effect to the principles of natural justice, it should also be defined in the interpretations section (ss14-ss50).

On the basis that this inclusion is made, Medicines New Zealand otherwise agrees with the purpose and principles as outlined in ss3 and ss4.

Namely, we support the principle that the regulation of therapeutic products should be risk-proportionate and support the timely availability of therapeutic products. We also support the principle that the administration of the Act is carried on in an open and transparent manner, and that there should be co-operation with overseas regulators, compliance with international obligations and alignment with international standards and practice. We make further comment on these principles below.

- ss4(b)(i) Risk-proportionate regulation

We support the principle that regulation is proportionate the risk of the products (ss4(b)(i)).

We support the intent that regulatory requirements for different products and activities are to be tailored to accommodate their different characteristics and risk profiles.

We strongly support the intent to have a wide and flexible range of product approval pathways, dependent on risk. We support the proposal to replace the current provisional consent with the ability to have approvals with conditions (ss105-107). We believe these proposed pathways can be used to support the principles of the TPB, and we make specific comments on these in response to questions B13, B14, B28 and C1.

- Ss4(b)(ii) Timely availability of therapeutic products

We strongly support the principle that the regulatory scheme will support the timely availability of therapeutic products (ss4(b)(ii)).

We believe this is an essential principle because a successful regulatory scheme should ensure that people that need therapeutic products, receive access in the timeliest possible manner, while ensuring the appropriate checks have been made.

We believe a successful regulatory scheme should not create uncertainty or undue delay to the availability of therapeutic products. As mentioned above, we strongly support the intent to have a wide and flexible range of product approval pathways, dependent on risk. We believe these proposed pathways have the potential to support the principle of timely availability of therapeutic products.

However, in order to reasonably meet this principle, the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance. There is no detail given in the TPB or in the consultation document regarding how this will be enacted.

Therefore, we seek assurance that this principle in the TPB will keep the regulator accountable for making decisions in a timely manner.

We further seek evidence that there will be appropriate accountability measures both within the regulator and external to the regulator to ensure appropriate timeliness is a lasting feature of the scheme. In addition to the principle in the Bill, we suggest that maximum evaluation timeframes are stipulated in regulations. We make further comment on timeliness of evaluations in response to question B32.

- Ss4(c) Open and transparent regulator

We support the principle that the regulatory scheme is administered openly and transparently (ss4(c)).

As a public sector regulator, we should be able to expect this irrespective of a legislated principle in the Bill. Yet, we still seek further information on how the principle will be actioned.

With the 3 possible options for the form of the regulator, how will the regulator ensure that the scheme is administered openly and transparently? In particular, with regard to keeping processes, decisions, and policies open and transparent to industry?

- Ss4(d) Regulator's reliance on overseas regulators work

We strongly support both the principle to have a regulator that engages internationally and recognises the work of trusted overseas regulators (ss4(b)), and the provision (ss207) that the regulator may rely on reports, assessments, decisions, or information of recognised authorities (such as overseas regulators), to make decisions.

We trust that this will increase efficiency and timeliness of decisions, build on and improve Medsafe's current abbreviated approval processes, and provide a foundation for the regulator to engage in work-sharing programmes with overseas regulators. This approach should be applied to all product applications, and major changes including but not limited to new and extended indications, line extensions, new strengths etc.

We provide detailed comment on this in our response to question B28.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Medicines New Zealand submits that a definition that a “person” is either a body corporate or an individual should be added. This is particularly relevant to sections such as ss30; 42; 44; 48, 52 and 83(2)(a)(i), where it is not always an individual who imports, supplies or advertises a product. We also note that in some sections, requirements have been set for a “person”, when it may be clearer to readers to differentiate requirements according to whether the person is a body corporate or an individual. For example, see our response to definition ss47 and ss48, and our response to question B22.

• Ss27 meaning of clinical trial

Medicines New Zealand strongly recommends that the meaning of clinical trial (and associated terms and phrases) follow international definitions, including the WHO's definitions and accepted ICH Good Clinical Practice (GCP) terminology.

• Ss28(3) meaning of compound and ss32(2) Meaning of manufacture, for medicines

Ss28(3) and ss32(2) indicate that “compounding or dispensing a medicine is part of manufacturing the medicine”.

Please provide further explanation for this as compounding or dispensing by a pharmacist or health care practitioner would not normally be considered as part of the manufacture of a medicine by the sponsor, who has already released the product to market, and cannot be responsible for the actions of practitioners.

Please also refer to our comments on ss31.

• Ss30 meaning of import

The scope of persons who are importers under ss30 is very wide. Ss30(2)(a) indicates that this includes “a person who does the physical activity of importing the product”.

We are concerned that this definition is broader than the definition of an importer under the Customs and Excise Act 2018, and that this may pass unreasonable responsibility and liability to a broader range of persons than the Medicines Act does, such as freight operators.

We question the rationale for this broad definition.

• Ss31 meaning of manufacture, manufacturer, and responsible manufacturer

We recommend alignment with international norms for the definition of manufacture.

The wording in the Bill suggests that as well as the sites of production, testing, sterilising, labelling, packaging and release of the product, also any subcontracted sites involved in these activities would be considered manufacturers.

Please explain why the relevant considerations for determining a ‘responsible manufacturer’ for a medicine or an AMI differ substantially to that for a medical device or type-4 product (ss31(4) vs ss31(5)). For medical devices or type-4 products, it is noted in ss31(5)(a) that a person may be a ‘responsible manufacturer’ “whether or not they personally undertake the manufacturer of the product”. Whereas for a medicine or AMI such a clause is not included. We infer that this difference may have been made to account for the differing inherent characteristics of the different products and their manufacturing, but we do not believe this is necessary and we recommend that the considerations for the different product types are aligned.

We suggest that the same approach that is given for medical devices and type-4 products should be applied to medicines and AMIs.

Our reasoning is that for multinational pharmaceutical companies, the parent company (international headquarters) of the New Zealand sponsor, is often best placed, and best suited to be the ‘responsible manufacturer’ for a medicine or AMI. The international headquarters may not personally undertake the manufacture of a product, but they will have oversight of the full process and be responsible for the overall quality assurance and quality control in relation to the manufacture of the product(ss31(4)(b)). Additionally, its name or trademark would be attached to the medicine (ss31(4)(c)).

In many cases, a standard practice for the pharmaceutical industry is for the parent company to hold the agreements with the many parties involved in manufacture of a medicine. The New Zealand sponsor is less likely to hold these agreements directly. Therefore, the parent company would often be in the best position to assist with and supply of required manufacturing information back to the local New Zealand sponsor as and when required. The consideration that “a person may be a ‘responsible manufacturer’ whether or not they personally undertake the manufacturer of the product” should feature for all product types (medical devices and type-4 products AND medicines and AMIs).

We seek confirmation from the Ministry of Health that the parent company (international headquarters) of the local New Zealand sponsor could be nominated as the ‘responsible manufacturer’.

We also ask that the Ministry take consideration of companies that are “outsourced” sponsors because there is no New Zealand affiliate of the parent company. In these cases, the New Zealand sponsor is usually procured by the parent company via an Australian or regional affiliate and the New Zealand sponsor does not hold any contracts directly with manufacturers. Please confirm whether an Australian or regional affiliate could be nominated as the ‘responsible manufacturer’.

We stress that the Ministry must consider current company models and practices for New Zealand. The presence of multinational pharmaceutical companies in New Zealand is small compared to other territories and many functions are outsourced to other countries. Regardless, Medicines New Zealand’s member companies ensure that they have the correct processes and controls in place for the New Zealand market. The ‘responsible manufacturer’ and contractual relationship requirements need to be more clearly explained for local affiliates, subsidiaries and outsourced companies who are sponsors of medicines in New Zealand.

Please also refer to our response to question B13 for further comment regarding the contractual relationship requirements.

• Ss36 meaning of pharmacy business and pharmacy activity

Ss36(3)(c) defines that a pharmacy business can supply medicines and medical devices by wholesale supply in circumstances permitted by regulations, and that this is a pharmacy activity.

Paragraph 68 of the consultation document says:

"we intended to develop regulations to allow pharmacists to supply to other health practitioners, in the types of situations that currently occur under practitioner supply orders. We are also considering allowing a pharmacist to supply a medicine to a nearby pharmacy that is out of stock of the medicine requested by the patient".

We strongly recommend that if a pharmacy is permitted to supply by wholesale, they must meet the requirements of a wholesaler as per Part 4 of the New Zealand Code of GMP, Wholesaling of Medicines and Medical Devices (i.e. facility suitability, stock control, temperature control and monitoring, invoicing, traceability of sales for purposes of recall), and they must attain a wholesale licence for such an activity.

Additionally, allowing such an activity within a pharmacy licence rather than a separate wholesale licence may cause difficulties for suppliers to distinguish between customer types for the purposes of monitoring excessive or aberrant ordering patterns.

- Ss47 fit and proper person and Ss48 meaning of senior manager

Ss47 defines the test of whether a person (e.g. "person A") is a 'fit and proper' person.

Ss47(2) states that as well as "person A", others are subject to the 'fit and proper' person test:

- (i) each person "who is or has been a senior manager of person A"; and
- (ii) each person "of whom person A is or has been a senior manager".

There is no differentiation given for whether person A is an individual or a company and this makes this requirement quite broad in its reach to different parties. It also does not give any consideration to the point in time when Person A was at a particular company, or in a particular role.

As an example, the way the Bill has been drafted, if Person A is an individual then the regulator would need to consider:

- (i) any company of which the person is or has ever been a director, CE, CFO, or similar; and
- (ii) any partnership or business where Person A has been a partner, or equivalent of a partner or director. It may also consider;
- (iii) any individuals that are currently or have ever been a "senior manager" of Person A, at any of the companies Person A has worked at.

As another example, if Person A is a Company ("Company A"), then:

- (i) any individual that is currently, or has ever been, a director, CE, CFO or similar of Company A; and
- (ii) any company that is able to exert significant influence over the management or administration of Company A.

We recommend that there be two definitions to differentiate between individual and company sponsors/licensees. The way it is currently written is unclear and confusing. We also suggest that there be a time limit or timeframe given in the senior manager definition. As it stands, it appears to be unreasonably wide-reaching for the 'fit and proper' person test.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

- Ss51 product approval required to import or supply medicine, medical device, or type-4 products

Medicines New Zealand supports the requirement to have a product approval, approval exemption or an authorisation in order to import or supply a medicine, medical device or type-4 product.

- Ss52 sponsor's consent required to import approved product

We support the prohibition of parallel importation.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

- Ss53 Authorisation required for controlled activity

As stated in answer to question B2, we ask for the rationale behind including compounding and dispensing in the definition of manufacturing a medicine (ss28(3) and ss32(2)).

This decision appears to create additional uncertainty in ss53(2)(a) where it is stated that manufacturing a therapeutic product is a controlled activity. The qualifier "(which, for medicines includes compounding and dispensing)" had to be added in brackets to state that compounding and dispensing is also a controlled activity. For clarity, we would suggest these activities are separated from the definition of manufacture instead and that they are listed separately as controlled activities in ss53.

- Ss55 Persons in supply chain must comply with regulations

The list of activities persons in the supply chain must comply with is very broad (ss55), and encompasses activities related to manufacturing of therapeutic products (packaging and labelling), supply (storage, transport, disposal and tracing/recall) and clinical practice (monitoring of conduct in relation to a supply order or special clinical needs supply authority). The regulations need to specifically apply requirements to different groups of persons in the supply chain, in light of the

wide range of supply chain activities defined in s44(1).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

- Ss76 patient or carer importing medicine for personal use and ss77 Patient or carer importing medical device for personal use

It is noted that a patient is permitted to import certain medicines/devices without authorisation of the sponsor, provided that the medicine/device has been obtained legally and does not exceed a supply limit.

There is a concern from a pharmacovigilance perspective that this may complicate the identification of a product belonging to a sponsor, and the sponsor's obligations relating to the imported product. It is further noted that ss119 describes that if someone imports a product without the sponsor's permission, ss116-ss118 (Obligations of Sponsors) do not apply so this may be a moot point.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

- Ss71-75

We agree with the authorisations created in ss71-75.

- ss78 Authorisation for unapproved product stock in supply chain

Medicines New Zealand strongly supports the authorisation created in ss78.

The ability of the regulator to issue a 'use of current stock' notice is seen as an improvement on the current norm; where sponsors typically need to wait until date of last product expiry in the market before de-registering a product.

We suggest that a 'use of current stock' notice could also be utilised in situations where a major change to a product has been made (and approved) and an amount of the original/unchanged product is still present in the market. This would allow a sponsor to 'transfer' a product's approval, TT50 number, and entry in the regulator's register to the changed product, and if any of the unchanged product was present in the market, it could be used. We believe this would be an opportune scenario to issue a 'use of current stock' notice.

- ss79 regulations may grant authorisation

We support the intent of ss79 to allow for more tailored authorisations for specific circumstances (paragraph 91 of consultation document).

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

- ss82 meaning of advertisement and related terms

Medicines New Zealand notes that ss82(1) defines an advertisement for a therapeutic product as "communication made to the public or a section of the public for the purpose of promoting the product."

We believe a definition of 'promote' is required in the Bill to make clear the difference between promoting (advertising) and providing education.

As a separate point, we ask that the Ministry of Health consider advertising at international conferences in New Zealand.

There are often products or indications that are approved in other countries such as Australia, that companies wish to advertise to international health care professionals at these events. These products/indications are regularly approved in other countries, but not in New Zealand due to restrictions on public reimbursement of medicines. This is a common scenario particularly for Australasian conferences and scientific meetings of Australasian royal colleges, where significant proportion of total attendees are Australian-residing health care professionals. Under the Medicines Act, it is prohibited to advertise these in New Zealand and our reading of ss83(1)(a), is that this prohibition would continue under the TPB. It is common in other countries to permit this, provided there is a statement that the product/indication is not approved in the host country.

We suggest a permit system could be utilised to enable this activity in New Zealand, set conditions/requirements, and provide suitable regulatory oversight. A permit could authorise a company to advertise to international health care professionals at an international conference for products/indications that are not approved in New Zealand. We ask that the Ministry of Health consider a permit system (or similar) to provide a limited exception to ss83(1)(a) for the activity described above. This could assist international investment in these conferences, and long-term sustainability for hosting scientific conferences in New Zealand. We suggest further discussing this suggestion with industry and conference organisers.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

- Ss97 Criteria for sponsor of approved product

ss97(c) states that a contractual relationship is required between the sponsor and the 'responsible manufacturer'. While the rationale for this requirement is reasonable – to ensure the regulator can use the sponsor as a contact person when manufacturing information is required, or urgent safety issues arise. However, we are concerned regarding the ability for New Zealand sponsors to meet be able to meet this requirement.

Some local sponsors who are part of multinational pharmaceutical companies would not ordinarily hold individual agreements with each of the many manufacturing sites. It is often standard practice for these agreements to be held by the parent company (international headquarters) and for there to be an agreement between the local affiliate/subsidiary and the parent company. For companies that are "outsourced" sponsors because there is no New Zealand affiliate of the parent company, the New Zealand sponsor is usually procured by the parent company via an Australian or regional affiliate and there are no contracts directly with manufacturers.

The requirements of this contractual relationship should be more clearly defined for local affiliates/subsidiaries and outsourced companies who are sponsors of medicines. As in our response to ss31, we stress that the regulator must consider current company models and practices for New Zealand when developing the criteria of the contractual relationship in rules. Subsidiary relationships and off-shore headquarters need to be given due consideration in this context.

Our understanding from the reading of the definition of a 'responsible manufacturer' (ss31(3)) and in particular the considerations 31(4)(b) and (c) "who is responsible for the overall quality assurance and quality control in relation to the manufacture of the product"; and "if the product is, or is intended to be, released into the supply chain, whose name or trademark the product is, or is to be, supplied under.", is that the parent company (international headquarters) of the local New Zealand sponsor could be nominated as the 'responsible manufacturer'. The parent company will hold agreements with the many parties involved in manufacture of a medicine, and their affiliates/subsidiaries report back to them. Therefore, the parent company (international headquarters) is often in the best position to assist with and supply any required information back to the local New Zealand sponsor as and when required.

Please also confirm whether an Australian or regional affiliate could be nominated as the 'responsible manufacturer' for "outsourced" sponsors. Refer back to our comments on ss31 in question B2 for further detail.

As a separate point, the TPB proposes that the responsible person (called the sponsor) is responsible for all aspects of the product, extending from the manufacture, application, approval, importation and supply through to the supply channel. This wording relating to the "responsible person (called the sponsor)" is in the consultation document, but it seems at odds with the wording in the draft Bill, where the responsible person is named on the licence, but is not necessarily the sponsor.

The sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. While the sponsor will be responsible for post marketing safety activities and investigation of quality issues, the sponsor cannot be held accountable for all activities after the product has left their control. There is responsibility that resides with wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine. Please also refer to comments on question B2 Ss32(2).

• Ss98 Content of approval

Please refer to comments on the responsible manufacturer ss31.

It is not clear whether only the address of the place of the responsible manufacturer would be required to be included in the approval, or given the broad definition of manufacturer in s31, that it will be required to list an extensive array of sites directly and indirectly involved in product manufacture.

• Ss99 Scope of approval

Please refer to comments on ss100 and ss101 below.

• Ss100 Major changes results in new product

We do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposed process described in paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued.

Furthermore, it was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019, that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors.

PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine.

We understand that the intent of the approach is to ensure different versions of the same product (i.e the original product vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not believe the practicality of the major changes process has been considered in the Bill and we strongly recommend further consultation is conducted with industry on this matter.

A solution would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the regulator's register can be replaced by the changed product. This type of approach is used by the TGA, referred to as TGA Grouping.

For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s78)." We believe a major change to a product would be an appropriate reason to issue a 'use of current stock' notice. We suggest this is also discussed further with pharmacists and prescribers.

In cases where the sponsor did wish to have both versions of the product approved and marketed concurrently, they could nominate to receive a new approval and TT50 number for the changed product.

- ss101 Sponsor must notify regulator of certain minor changes

Medicines New Zealand supports the management of changes to products based on a framework of risk-based assessment of minor variations. This is particularly important by allowing certain types of minor changes that are low risk and do not impact the quality, safety or efficacy of medicines to be notified to the regulator rather than requiring formal assessment and approval.

We recommend a post-approval lifecycle framework for quality changes/applications that aligns with the aggregation of changes for the EU and Australia to reduce submission burden for sponsors, and a framework that establishes activity-based timelines for changes that do require evaluation.

Paragraph 259 of the consultation document explains that minor changes would likely be notified by a consolidated six-monthly or annual update. This would need to align with the timelines for the EU and Australia as mentioned above. There may need to be some flexibility in the scheme to still allow companies to notify certain changes as they arise, such as those that do not meet the threshold of minor changes. We recommend that the industry is further consulted on this aspect before the details are set in regulations or rules.

- Ss102 Change of sponsor

We support the ability to change a sponsor (transfer an approval) as set out in ss102. However, we ask that the Ministry of Health note that the current requirement set out in ss102(2) is not aligned with other countries.

In most jurisdictions, including Australia, a change of sponsor is considered a commercial decision and needs only to be notified to the regulator. We wish to further discuss the intent behind ss102(2). As one example, we would consider that the new sponsor having a prior history of product approvals with the regulator would be sufficient to satisfy the regulator that they meet the criteria in ss97.

- ss103 – Duration of approval

Medicines New Zealand agrees with the proposal for product approvals to generally not have expiry dates, meaning that approvals are perpetual until the sponsor or regulator cancels the approval.

This is aligned with current practice of the TGA in Australia.

Under the Medicines Act, product approvals lapse after five years if there has been no regulatory activity or no commercial supply of the product. This has often created uncertainty regarding the status of the product approval. There does not seem to be any compelling reasons to assign a standard expiry date on approvals. Medicines New Zealand would expect that if there were situations or certain products where a "maximum duration for the approval", would be applicable, this would be specified in regulations along with any related conditions (ss103(2)(b)).

- Ss104 Approval lapses on death, bankruptcy, or insolvency of sponsor

Please provide rationale for why a product approval would automatically lapse in these situations (death, bankruptcy, or insolvency), yet a licence or permit would be transferred to an executor of the person's estate, the Official Assignee, or to the liquidator, receiver etc (ss151).

The reasons for lapsing an approval, and the disparity between approvals vs licences, are not clear to us and we could not find an explanation in the consultation document. Please also refer to our response to B22 ss151.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

- ss105 – ss107 Conditions on approval

Medicines New Zealand agrees that the regulator should have the right to impose or vary conditions on an approval. We support that the sponsor is given opportunity to comment.

- ss108 – ss112 Cancellation of approval

Medicines New Zealand agrees that the regulator should have the right to cancel an approval based on the grounds cited in ss108. We agree that the sponsor is given opportunity to comment.

- Suspension of Approvals

Medicines New Zealand notes that product approvals can be cancelled (ss108 – ss112), but not suspended.

We submit that the ability to suspend an approval should be maintained. It gives flexibility to resolve a temporary issue before an approval is resumed and lifting a

suspension of an approval offers a more reasonable timeframe and cost than if an approval were cancelled and a new application was submitted.

We note that the Therapeutic Goods Administration in Australia have added the ability to suspend an approval. It was clarified at the Ministry of Health sector forums, that the mechanism to suspend a product approval exists through adding conditions on an approval (ss 105-107), which can be done on request of the sponsor or by the regulator after giving the sponsor opportunity to comment. For the reasons stated above, we believe a suspension mechanism is pragmatic. We seek confirmation that such a mechanism exists through ss105-ss107.

- ss113 Therapeutic products register

Medicines New Zealand agrees with the proposal to develop a Therapeutic Products Register (ss113) which contains a copy of the latest prescribing information and consumer medicine information for approved products.

There are several points we seek clarification on.

It is unclear whether the practice of assigning a registration number to the product (i.e. TT50 number) will continue under the new regulatory scheme.

It is unclear whether only the address of the place of the responsible manufacturer would need to be included in the approval or if it will be required to list an extensive array of sites directly and indirectly involved in product manufacture, given the broad definition of manufacturer in ss31.

Medicines New Zealand agrees that all applications submitted to the regulator and all approved products should be made publicly available on a product register which is routinely maintained by the regulator to ensure currency and accuracy. This practice is consistent with how other jurisdictions have embraced or improved transparency over recent years. However, we do not agree that all declined or withdrawn applications should be made public as the sponsor should be given the opportunity to decide whether the non-approval recommendation from the regulator is made public.

For example, other jurisdictions (like Australia and the EU) have specific evaluation milestones, and if a negative recommendation is received after a particular milestone, irrespective of whether the sponsor withdraws the application, the outcome becomes public.

On the flip side, if a sponsor withdraws the application prior to a specified milestone, the withdrawal/rejection is not made public.

In New Zealand, following receipt of a negative decision on the application, the sponsor should also have the opportunity to voluntarily withdraw the application (consistent with other jurisdictions), without having this included or made public on the Therapeutic Products Register. This is particularly important when the regulator and sponsor disagree on the regulator's reasons for rejecting/not approving an application.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

- ss114 – ss115 – Subpart 2 Approval-exempt products

Medicines New Zealand's understanding is that the regulator needs to have a sponsor (even for products that do not require an approval) so that they can contact someone in the event of any issue with the product.

The sections regarding approval-exempt products (ss114-ss15) are unclear, and we have several questions regarding them:

- (i) For a class of approval-exempt products, who would be liable for product quality/safety?
- (ii) If no one opts to sponsor a potential approval-exempt product, will the Crown or other entity be the sponsor?
- (iii) What is the process for the Crown to become a sponsor of a product?
- (iv) Would approval-exempt products be included on the proposed Therapeutic Products Register?

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

- ss116-118 – Subpart 3 Obligations of sponsors

The TPB proposes that the sponsor is responsible for all aspects of the product, extending from the manufacture, application, approval, importation, through to the supply channel. The scope of responsibility of sponsors appears to have widened. The sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of quality issues, the sponsor cannot be held accountable for all activities after the product has left their control. There is responsibility that resides with the wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine. This section of the TPB seems to duplicate the intent of ss55, which places obligations on persons in the supply chain, who may not all be sponsors. The obligations should be limited to activities that those in the supply chain are licenced/authorised to perform.

Additionally, these sections discuss the requirements for compliance with obligations and the penalties that apply to breaches. Details are lacking on what sponsor obligations for pharmacovigilance are tied to the penalties outlined in ss118(1) and ss118(2). While we agree that sponsors should be accountable for complying with obligations, we think it would be unreasonable if the entirety of Guideline Part 8: pharmacovigilance and applicable device regulations were to form the legislation.

For context, in Australia only the following pharmacovigilance requirements are legislative requirements:

- (i) reporting of ICSRs;
- (ii) reporting of SSIs;

- (iii) notification of the pharmacovigilance contact person; and
- (iv) archiving of records.

We recommend that the industry is consulted with in relation to the specific requirements. Requirements should be aligned to those of comparable regulators.

- ss119

Medicines New Zealand is in agreement that the sponsor is not responsible for approved products imported without the sponsor's consent.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

- ss120 -122 – Subpart 4 Protection of active ingredient information about innovative medicines

We do not support the continuation of five years regulatory data protection (ss 102-104) for innovative medicines from the Medicines Act 1981. Maintaining a regulatory data protection period of five years is at odds with the vision to future-proof medicines legislation.

Maintaining regulatory data protection at five years does not align with a regulatory scheme that "reflects international norms and is designed to be responsive to the challenges of emerging technologies" (page iii of the consultation document). In fact, it is at odds with the positions of many of New Zealand's trading partners. Most OECD countries have extended data protection terms for biologics up to 8-12 years to encourage investment in these important new medicines. While patents protect innovative small molecule pharmaceuticals, often biologics rely on regulatory data protection as an important form of IP protection.

New Zealand's current and proposed five-year regulatory data protection period, although consistent with Australia, lags behind many other territories like the EU. The EU, a territory New Zealand is presently negotiating a trade deal with, provides eight years of regulatory data protection plus two additional years of market exclusivity (and a potential for a further one-year extension). New Zealand's position on data protection does not appear to support New Zealand's trade and economic objectives. For a consistent approach on regulatory data protection, that reflects international norms, New Zealand should move to align with the EU and others.

Fellow CPTPP signatory countries, Canada and Japan, have also extended data protection periods for biologics to encourage investment in these important new medicines. These actions had no material impact on the total cost of medicines portfolios to the respective Governments. [1]

- a. In 2006 Canada changed its regulations and increased regulatory data protection terms from zero years to eight years, consistent with the EU. Rather than leading to an increase in costs to the system – the trends shows that spend on medicines, as a percentage of total health budget decreased from 18.3% in 2006 to 17.6% in 2016.
- b. Japan increased regulatory data protection in 2007, to eight years. Expenditure on medicines since the increase have been in line with growth in health care spending as a percentage of GDP. Pharmaceutical spend decreased in 2010 - a year when health care spending increased. Furthermore, as a percentage of total health costs the pharmaceutical expenditure actually dropped from 20% to 18.8% from 2007 to 2014 respectively.

The proposal to maintain New Zealand's regulatory data protection at five years is also inconsistent with the regulatory data protection for "innovative agricultural compounds" which was increased from five to 10 years through the Agricultural Compounds and Veterinary Medicines Amendment Act 2016.

Lastly, the proposal does not account for the lengthy period in New Zealand between product approval and reimbursement by PHARMAC and it does not preclude entry by a generic company using their own clinical data.

As a separate comment, the use of the term active moiety in the draft TPB appears to allow for the protected period to apply in the event of significant modifications of an active ingredient that serve to alter characteristics of the active ingredient (such as formulation of a complex salt that results in significantly altered pharmacokinetic properties).

Reference:

[1] OECD.Stat (2017). Health Expenditure and financing database.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

- Ss123 What licence may authorise

Medicines New Zealand agrees with the principle in ss123.

- Ss124 Content of Licence

Ss124(1)(e) indicates that a licence will list the therapeutic products it covers.

Does this imply that all products will be named individually?

As product registrations are constantly changed, and it is indicated in ss137 that licences remain in force for three years, consideration needs to be given to the time and cost of varying licences due to changes in products during each three-year period.

While we support the ability to have one licence to cover a range of activities involved in the running of a clinical trial. It is important that requirements and obligations are clear in subordinate legislation including whether it is the sponsor of the clinical trial or the investigators that seek the licence.

- Ss127 Grant of Licence

Medicines New Zealand agrees with requirements of ss127.

Ss127(3) explains that if the regulator is not satisfied that the criteria [of the licence] will be met, the regulator must refuse to grant a licence. We agree with this, provided that if the regulator is not satisfied, that the applicant has been provided with an opportunity to comment or an opportunity to provide further information at the request of the regulator in order to meet the criteria.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

- Ss128 Criteria for granting licence

Ss128(1)(g) explains that a clinical trial, requires either ethics approval, or certification from a relevant ethics approval entity that an approval is not required.

Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current clinical trial approval process, concern remains that the licence cannot be issued until the ethics approval is granted and what impact this may have on timelines.

The primary advantage to conducting clinical trials in New Zealand is the efficiency of the regulatory system. On the other hand, there are several significant disadvantages, including a high uncertainty of future public reimbursement of innovative medicines. The 2010 Parliamentary Inquiry into clinical trials found that "to remain competitive New Zealand must have a regulatory scheme as good as, or better than, other comparable countries" [1]. As a result of the inquiry, improvements were made which included setting and meeting prompt timeframes for scientific and ethics evaluations [2]. For these reasons we would be concerned if the new regulatory system did not continue to meet the recommendations of the 2010 Parliamentary Inquiry.

Please set out how the regulator will guarantee that the current efficiency and timeframes of the clinical trial approval process will be maintained. Please also explain how the new regulatory system will work efficiently alongside local approval processes by DHBs.

As a further point, we seek further information on the process for certifying that ethics approval is not required (ss128(1)(g)).

It is unclear if applications that do not require ethics approval will have the same quick timelines as is currently the norm. It is imperative that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g observational trials, clinical audits). We suggest that appropriate rules and/or guidance are created so it is clear which types of trials do not meet the threshold for ethics review, and that there is an efficient process in place for certifying that a trial does not require ethics approval.

- Ss129 Criteria for licensee

We agree with the criteria in ss129.

- Ss130 Criteria for responsible persons

Currently, Medsafe will allow an overseas person to be listed on a licence provided there is a minimum of one New Zealand resident on the licence. The overseas person is usually a senior staff member (e.g a Regulatory or Quality manager) of the company where there is no resource in New Zealand. This situation should continue to be permitted under the TPB. The number of employees of pharmaceutical companies in New Zealand is small, with many functions such as regulatory often based out of Australia or another country. We submit that the drafting of the TPB must accept this commercial reality, noting that companies presently have appropriate controls in place to meet requirements. Furthermore, where a licensee is a body corporate, consideration should also be given to how they will demonstrate meeting the criteria for being a responsible person.

References:

[1] New Zealand Parliament (2011). Inquiry into improving New Zealand's environment to support innovation through clinical trials. Retrieved from: https://www.parliament.nz/en/document/00SCHE_MediaRelease20110608_1

[2] New Zealand Parliament (2011). Inquiry into improving New Zealand's environment to support innovation through clinical trials. Report of the Health Committee. Retrieved from: https://www.parliament.nz/resource/en-nz/49DBSCH_SCR5154_1/19f143ece9bbafc1f5970397e5d92a582e003faa

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

- Ss131 What permit may authorise

ss131(1)(a) states that a permit can authorise a person to import a product without the sponsors consent.

Is it correct to assume that the criteria for importing an approved product without the sponsor's consent will be outlined and specified in regulations?

We submit that this is an activity that needs to have very tight restrictions and controls on it. If this is not the case this would appear at odds with the policy intent of ss52 which is to prohibit parallel importation of therapeutic products.

- Ss132 Content of permit

We agree with the specifications listed in ss132.

- Ss133 Effect of permit

We agree with the requirements listed in ss133.

- Ss134 Grant of permit

We agree with the requirements listed in ss134.

- Ss134(3)

As for granting a licence we agree, provided that if the regulator is not satisfied that criteria will be met, that the applicant is provided with an opportunity to comment/opportunity to provide further information at the request of the regulator in order to meet criteria.

- Ss135 Criteria for granting permit

Again, as in ss131 we submit that the granting of a permit needs to have very tight restrictions and controls on it. We support the explicit statement in ss135(b) that granting a permit must be "necessary or desirable in order to promote the purpose of the Act; and is consistent with the principles set out in section 4." Of particular importance to granting a permit would be ss4(a) "the likely benefits of therapeutics products should outweigh the likely risks associated with them". We seek further information on the intended situations where a permit would be authorised.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

- Ss136 Regulator may split application

We have some concern regarding ss136.

Specifically, ss136(2) gives the regulator discretion to assess the application together, or as discrete applications.

We are concerned by the potential for inefficiencies to arise in the evaluation process that slow down application processing times. We seek further information on this aspect.

We suggest that the process for splitting applications is explained clearly in guidance material, and that guidance material stipulates what types of applications would be likely to be split. There needs to be a clear policy in place by the regulator, so there is a shared expectation of types of applications the regulator should and should not split, and so that applicants may be able to prepare ahead of time an appropriate application/s so that it is processed as efficiently as possible.

- Ss137 Duration

Ss137 indicates that a licence remains in force for a maximum of three years.

We agree that the increase from one-year licences under the Medicines Act, to licences of up to three years under the TPB is an improvement. However, a three-year licence duration for clinical trials is potentially unworkable.

Many clinical trial activities continue well beyond three years, some for over 20 years. As an example, clinical trials measuring overall survival after an earlier intervention may require more than five years of follow-up of participants. If a clinical trial involves children, follow-up may be for 20 years, until the youngest eligible child turns 16. For reasons of practicality, we submit that the duration of licences for clinical trials should be based on the expected duration of the trial, as identified in the trial's protocol.

Clinical trials are currently not regulated via licences and are unlike the activities that currently require a licence like pharmacy and wholesale. The proposed one size fits all approach is problematic. Further consideration, and specific engagement with the research sector is required to pragmatically regulate clinical trials under a licencing system.

We suggest a similar approach to that proposed for conditional product approvals as in ss105-107 could be taken, where product approvals do not generally have a maximum duration, but a duration could be set as a condition.

If this approach to licences was taken, standard maximum durations for licences like pharmacy and wholesale could be specified in conditions set in rules, whereas a duration of a specific clinical trial could be set at the time of the licence application, based on the trial's protocol, or a date could be set for when further information is required for the trial licence to be continued.

Our reading is that the mechanism for this approach to licences exists in ss139-141 but cannot be utilised because a maximum licence duration has been set in ss137 (i.e. ss137 appears to contravene ss139-ss141).

We reiterate that a three-year licence duration is impractical for clinical trials, and we recommend specific feedback is sought from the research sector on optimal mechanisms to maintain safe operation and delivery of clinical trials over varying time periods (rather than the proposed three-yearly tick box approach).

- Ss138 Conditions
We agree with ss138.

- Ss139 Regulator may impose conditions and ss140 Variation

We seek further information on what changes will require a variation of a licence.

For instance, for a clinical trial licence will a change in the pharmacy or compounder of the medicine require a licence variation?

For all licences, would a staff change require a variation, or would the licence stipulate the job roles under the licence rather than a named person?

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

- Ss151 Death, bankruptcy, or insolvency of licensee or permit holder

ss151 details that if the licensee or permit holder dies, the licence or permit is transferred to the executor or administrator of the estate, who has to notify the regulator of the event within five working days.

We question the practicality of this process.

We have been advised that an executor/administrator of an estate would often not be appointed within five working days of a death, let alone be in a position where they fully understand the assets within the estate and the action required to notify the regulator. It is therefore requested that a longer notification period be applied. We suggest 15 working days (21 calendar days) would be more appropriate.

Furthermore, it is unclear what the consequence will be if the executor of the estate fails to notify the regulator within five working days.

We note that the regulator would have the discretion to cancel the licence but would be required to give the licensee opportunity to comment, except in specific circumstances (ss144).

We are concerned that the licensee death or failure to notify the death within five working days will result in a business continuity issue or the licence may lapse. There would be ethical and operational issues if a clinical trial had to be suspended as a result.

Additionally, this clause would not necessarily be applicable for licensees or permit holders who are body corporates. We do not believe this one size fits all approach is practical.

If the intent is that it is applicable to certain classes of controlled activities that are typically conducted by individuals (e.g pharmacy), the TPB could be more explicit about this. For instance, the corresponding clause for product approvals (ss104) distinguishes between a product sponsor who is an individual, and a product sponsor that is an entity.

Paragraph 147 of the consultation document states that:

“...if a licensee or permit holder wishes to sell the business to which the licence or permit relates, the purchaser of the business must obtain their own licence or permit before they take over the business.”

This is quite a different position to that taken for product approvals (ss102) which will mean in the event of corporate mergers and acquisitions, a business may acquire the product approvals, but not the licence/permit(s) to import the product(s).

We believe more consideration of this aspect needs to occur with further consultation with industry. The transfer of licenses or permits to another person/party needs to be a seamless process to ensure continuous supply of medicines in New Zealand.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

- Ss158 Responsible person must comply with regulations

Ss158 requires the responsible person to comply with the requirements, in relation to the competency of workers in the licensee's business.

At this stage it is unclear what the competencies are or how the responsible person is realistically able to comply with this requirement. Further clarification on this is sought.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

- Ss160 Regulator to monitor safety

Ss160 allows the regulator to 'perform monitoring', with respect to safety monitoring. This would introduce the ability for the regulator to conduct regulatory inspections.

We do not object to the inclusion of this provision, however the introduction of the power would require further vetting through industry consultation prior to implementation.

- Ss168 – ss171

Clarification is sought on whether “person” in theses clauses relating to Directions orders and Product Prohibition orders extends to the sponsor or an individual only?

- Ss178 Making regulatory order

Ss178(2)(c)(i): mentions the “person who distributed the advertisement”. Clarification is sought whether “person” in this case also means the sponsor of the product being advertised. The definition of person in the TPB is currently unclear.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator’s investigative powers (ss 183-196).:

Under the Bill, investigative powers will be cross-referenced to the investigative powers under the Search and Surveillance Act 2012 ss183, 185, 188, 191, 192). The powers that are granted under the Search and Surveillance Act 2012 are those used across a large section of New Zealand legislation that require investigative powers. Therefore, we consider the amendment to bring the Bill under the remit of the Search and Surveillance Act 2012 brings it into line with what is generally the standard set of investigative powers in New Zealand.

It would be important to clarify the potential tension between:

- (i) a prohibition on shipping overseas any products that are subject to a prohibition order (ss170(2)(f)); and
- (ii) an ability for therapeutic products that are seized by the regulator/border security to be returned to the country of origin if the regulator requires it (ss194).

In order to relieve this tension, we presume that this right to return products to a country of origin would be exercised by the regulator only where the product does not pose significant risk of death or harm. If this is not the intent, we are concerned that therapeutic goods that would otherwise be subject to a prohibited product order and therefore not able to be returned to their country of origin would be treated differently if seized at the border rather than if they were released to the sponsor (either erroneously or as they were subsequently found to have concerns).

Additionally, the consultation slide deck includes the following:

The Bill links to the Search and Surveillance Act 2012 to provide the regulator with investigative powers. The regulator would have the following powers of entry:

- entry and search without a warrant (for routine monitoring & where there are concerns of non-compliance)
- entry and search with a search warrant (including dwelling houses & Marae)
- the right to inspect therapeutic products being imported.

The TGA can do this in the situation of a ‘for cause inspection’, however this power seems a little excessive for ‘routine monitoring’, unless of course this means that access cannot be prevented, in which case the powers we believe are similar. As a general comment, industry would need to be consulted in relation to the specific requirements. These should also be fairly aligned to other comparable agency requirements.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

- Ss197-199 Subpart 3 – Offences relating to regulator

In contrast to the Medicines Act 1981, there are different tiers of offences, depending on whether there is knowledge and/or recklessness as to whether the Bill is breached (i.e. while it is a strict liability offence, a more stringent penalty will be applicable where the contravention of the obligation was reckless, and an even more stringent one where the convention was done with knowledge). It will be a defence for any prosecution of an offence under the Bill if the defendant took “all reasonable steps to ensure contravention was not committed” (ss243). On that basis, it is considered that this provides adequate grounds to protect against unfair prosecution under ss197-199. Please also refer to our responses to questions B29-B31 relating to enforcement.

Subpart 4: Review of regulator’s decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator’s decisions (ss 200-204):

- ss200 Application for review of Regulator’s decision

Medicines New Zealand submits that the timeframe of 30 working days given for a sponsor/applicant to apply for review of the regulator’s decision, with supporting data/justification is insufficient.

Many sponsors have global headquarters overseas preparing data to support the review, and, therefore, consultation and agreement with overseas colleagues is required prior to submission of the application. Depending on the magnitude of the issue being applied for review, a timeframe of 30 working days does not allow enough time for appropriate consultation within companies plus the preparation of the application which details the grounds for the request of the review.

A more appropriate timeframe to submit an application for review with supporting data and justification would be 60 working days (ie approximately three calendar months). This timeframe is aligned with other regulators such as the Australian Therapeutic Goods Administration (TGA). We suggest that applicants could

submit a provisional response within 30 working days indicating their intent to apply for a review of the decision, and a complete response within 60 working days that details supporting data and justification. This suggested process would provide a sufficient timeframe for applicants to prepare their application for review, while providing sufficient lead time for the regulator to prepare the review panel.

Furthermore, we wish to clarify that in order for the applicant to respond to the regulator's decision, and apply for a review within the suggested timeframes, the regulator must provide their reasons for the decision at the time of notifying the person (as in ss208(b)(i)), rather than only advising the person that they are entitled to ask for a statement of reasons for the decision (as in ss208(b)(ii)).

- **Ss201 Regulator to convene review panel**

Medicines New Zealand agrees with the proposal of a merits review process of regulator decisions (specified in Schedule 2). We support the use of a convened review panel for this process, in replacement of the current review process under the Medicines Act which is conducted by a standing committee with a set membership. We agree that this will provide flexibility by allowing the membership of the review panel to be chosen based on the relevance of their expertise to the subject matter of each particular review.

We support the proposal to appoint three people (including a lawyer) who do not have a conflict of interest and who have not previously been involved in the decision. We welcome the proposal as we believe it will facilitate independent and unbiased review. Additionally, appointing subject-matter experts, people with appropriate knowledge, skills and experience, for the reviewable decision, is critical in ensuring there is a fair and equitable review of decisions.

As a separate comment, we ask the Ministry to provide evidence that the regulator will be able to convene a panel of appropriate, impartial subject-matter experts within a reasonable timeframe. We have concern that this will be difficult to achieve for highly specialist areas.

How will the regulator secure relevant experts from within New Zealand (or from overseas)? e.g. for medical devices decisions.

Furthermore, we note that there are no timeframes specified in the TPB for convening a review panel which we consider unacceptable. Please refer to our further comment on ss203 below.

- **Ss202 Procedure on review**

We support the requirements specified in ss202(2) that the review panel must act independently and in accordance with the principles of natural justice. We support the specific reference made to the review panel meeting the principles of natural justice. This is important to state outright in the TPB, because there is minimal administrative detail provided in the Bill, in general, to otherwise provide assurance of a fair and transparent process being followed. This specific mention in ss202, ensures that the review panel is accountable to act fairly and in line with natural justice.

For similar reasons, we believe the same standard should be set for the regulator's decisions. We therefore submit that reference to the rules of natural justice should also be made in both the purpose and principles of the TPB (ss3 and ss4). To give effect to the principles of natural justice, it should also be defined in the interpretations section. Please refer to our response to question B1 for further information.

- **Ss203 Decision on review**

There are no timeframes given for the review panel's process. Ss201, ss202 and ss203 do not specify any timeframe for convening the review panel, completing the review and notifying the applicant of the outcome, or even progress of the panel.

Medicines New Zealand requests that a timeframe equivalent to that suggested for review applicants in ss200 (i.e 30 or 60 working days), is specified in the TPB for review panel activity. It is prudent for each party, the regulator and sponsor/applicant, to be held accountable to act within pragmatic timeframes, thus facilitating timely review of decisions. Specific timeframes for the review process, for both the regulator and the sponsor/applicant, should be stated in the TPB to ensure a reasonable and efficient process is maintained, and applications are not unreasonably delayed. Businesses need a level of certainty within which to operate and maintain source of supply. New Zealand, as a small country far away from major manufacturing centres, needs to be cognisant of supply chain processes.

We have concern regarding the lack of specified timeframes in particular for reviews of decisions relating to refusals to revoke or vary regulatory orders. With no timeframes given for convening the review panel or that review panel providing a decision, the sponsor may be required to comply with the regulatory order (that they are seeking a review of), while waiting for the review panel to convene. The benefit of seeking a review will be lost if timeframes mean that the sponsor has already complied with the regulatory order (e.g conducting a recall).

We ask that:

- changes are made to the Bill that provide timeframes for the review panel's activities (refer to details in our response above);
- there be an ability to request a panel to sit in urgency. For example, when a sponsor applies for a review of a decision to refuse to revoke a recall order because there is insufficient evidence that a recall is required. The applicant/sponsor would act to provide their application and supporting data/rationale under urgency. Where such a request is made, will the regulator commit to acting under urgency? and
- if a decision is not upheld (i.e. the panel recommends a different decision be made), what steps will be taken by the regulator to compensate for any loss of supply, or the loss of product confidence of consumers, healthcare practitioners and manufacturers that has occurred?

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

- Ss207 Regulator may rely on recognised authorities

The draft TPB (ss207) states that the regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. Medicines New Zealand agrees with this proposal, which is both logical and efficient, and consistent with current practice for abbreviated submissions, as well as international regulatory practices (eg TGA). Applications that are submitted to the regulator utilising evaluation reports from other recognised regulatory authorities must be accompanied by reduced evaluation timeframes and fees.

Additionally, the scope of the application types should include not only new chemical/biological entities, but also new indications, line extensions, and other major changes to increase efficiencies. The types of applications that are eligible should be clearly defined in the regulations to avoid uncertainty and confusion.

The evaluation timeframes should be made transparent to the sponsor, with predictable milestones at specified timeframes, to allow for greater predictability in overall approval timeframes. Clear and transparent timelines are paramount in being able to monitor progress, which is lacking under the current regulatory system. The consultation document only refers to targeted timeframes at this stage which provides no change from the current situation. In order to meet the principle of timely availability of therapeutic products (ss4(b)(ii)), the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance. There is no detail given in the TPB or in the consultation document regarding how this will be enacted.

We are seeking assurance that this principle in the TPB will keep the regulator accountable to making decisions in a timely manner.

We also seek assurance that there will be appropriate accountability measures both within the regulator and external to the regulator to ensure appropriate timeliness is a lasting feature of the new scheme. In addition to the principle in the Bill, we suggest that maximum evaluation timeframes are stipulated in regulations.

- Ss209 Sharing of information with regulatory agencies, etc

The Bill states that confidential information that is shared with an overseas regulator or organisation should have its confidentiality maintained, but it is noted that for example, the Customs and Excise Act 2018 provides for stronger maintenance of confidentiality.

This is achieved with a requirement that either there is an obligation to have a written agreement with the relevant entity to which the information is disclosed, or only disclosing the information subject to conditions that state the use that the authority may make of that information. It is also noted that the rationale for the difference is likely to be on the basis that the information disclosed under the Customs and Excise Act 2018 is presumed to be more likely to be personal information;

- (i) It is suggested that "confidential information" needs to be defined, particularly given the reports that might be required to be made available to the regulator under the Bill and the regulations;
- (ii) if a decision is being reviewed, that decision should only be shared with the overseas regulator/organisation if it is accompanied by a note that the decision is subject to review to ensure that a precedent is not set when it is subsequently not followed in New Zealand; and
- (iii) it is suggested that this right to disclose information to third parties should be subject to the protection period for protected active ingredient information that is addressed in ss120-122.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Medicines New Zealand supports the proposed sections (ss 223-232) covering enforceable undertakings and a court's ability to grant injunctions. The ability to offer 'enforceable undertakings' provides useful, constructive flexibility to address alleged non-compliance, rather than the regulator going straight to formal court-based enforcement.

It is noted that if the regulator accepts an undertaking, it must make publicly available the undertaking, its reasons for accepting it, any variations and notification of an undertaking ceasing to be in force (ss224). This could cause concern, as it makes an alleged contravention public in a situation where there has been no admission of guilt by the relevant party. This position seems to be relatively consistent with recent legislation, particularly legislation that is aimed at maintaining the public's health and safety (for example, under the Health and Safety at Work Act 2015, an enforceable undertaking is not considered to be an admission of guilt, but must be published on the Internet site maintained by the regulator under that Act). Therefore, it does not appear to be out of line with powers granted to regulators recently under New Zealand legislation and is commensurate with the overall objective of the new Bill.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

- Ss233 – Penalties for Offences

We request that the Ministry of Health provide their rationale for the proposed penalty amounts, and the information used to decide on these amounts.

While we agree that the penalties for most offences under the Medicines Act 1981 are inappropriately low, we are concerned by the significant proposed increase to the penalties. Compared to similar modern legislation (Food Act 2016, Agricultural Compounds and Veterinary Medicines Act 1997, Hazardous Substances and New Organisms Act 1996, Biosecurity Act 1993), the penalties proposed by the TPB are very high. The prison sentences are at the higher end of the spectrum, and it seems that the TPB imposes the highest fines out of the comparable modern legislation for both individuals and for companies. We seek rationale for these proposed penalty amounts, and that the Ministry of Health provide the information that was taken into consideration when calculating these.

We also request that the Ministry of Health provide evidence that the penalties are at the appropriate level, and that they will be applied proportionately to given

breaches, not punitively.

There must be policies to ensure responses to non-compliance are commensurate to the seriousness of the breach, and they are utilised to protect personal and community health as per the purpose of the TPB (ss3), not as a punitive tool.

- Ss237 – Order to pay Regulator's expenses of mitigating risk harm

We submit that for the definition of "caused harm or a risk of harm" in ss237(3), the definition that conduct that indirectly "causes harm" (ss237(3)(i)) is a low threshold for paying the regulator's expenses.

It is requested that this be qualified – as like ss237(3)(ii), (iii) and (iv) which are given the word(s) "significant(ly)". We suggest wording such as "causes material harm" or "causes harm that is not insignificant" which would be on the basis of reasonableness.

- Subpart 4 – Attribution of liability and defences

Conduct of senior managers, workers and agents within the scope of that person's actual or apparent authority is attributed upwards to the relevant entity (ss239). As a reciprocal measure, if a body corporate contravenes the Bill then this will be attributed down to its senior managers (ss242). The Bill defines "senior managers" to include people such as directors, chief financial officers and chief executives (ss48). This is not an approach that appears to be taken consistently across New Zealand legislation and appears to be a rather stringent standard.

- Defences

We do seek further information on some aspects. It is noted that Band A offences relate to offences that have a real potential to cause harm (paragraph 198 of the consultation document).

Should there be a defence that there was no real potential to cause harm by the conduct?

The penalty (up to \$300,000) appears high for a strict liability offence.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

Medicines New Zealand supports the proposed sections (ss 249–ss255) covering infringement offences and the related penalties and processes. This is considered to not be out-of-line with recent New Zealand legislation which is following this two-tier infringement process, including the Food Act 2014 and the Financial Markets Conducts Act 2013.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

- Ss256 Costs to be recovered and ss257 Regulations about fees and charges

ss256 and ss257 indicate that the intention is for cost recovery by way of fees or charges specified in the regulations, and that the regulator must review the methods and levels of cost recovery every 3 years.

Although Medicines New Zealand is not opposed to a cost recovery model, this would require greater transparency by the regulator regarding evaluation timeframes, which would need to be monitored to ensure predictability for the sponsor.

For continuity of business operations for sponsors, the regulator should set fair and reasonable evaluation timeframes. This aspect is currently missing from the draft TPB and is requested to be included. Clear and transparent timelines are paramount to being able to monitor progress, which is lacking under the current regulatory system. Previous experience of consultation and implementation of cost recovery levels in 2018 by Medsafe [1] highlighted poor transparency and communication regarding fee setting and reporting, as well as a lack of consideration of business operations such as budget setting [2]. As a result of consultation feedback from industry regarding the poor timing and communication of the increases to fees, Medsafe postponed their proposed implementation date of the increases [3].

Furthermore, the new regulatory environment should be open and pragmatic, and not cause undue delay to products coming to New Zealand. There is no reference to evaluation timeframes in the TPB. The only reference made in the accompanying consultation says that 'The regulator would be expected to set performance targets and to report against them', which provides no change from the current situation.

In order to meet the Bill's principle of timely availability of therapeutic products (ss4(b)(ii)), the scheme needs to establish transparent and meaningful timeframe setting and reporting of the regulator's performance. There is no detail given in the TPB or in the consultation document regarding how this will be enacted. We seek assurance that this principle in the TPB will keep the regulator accountable to making decisions in a timely manner. We further seek assurance that there will be appropriate accountability measures both within the regulator and external to the regulator to ensure appropriateness is a lasting feature of the new scheme. In addition to the principle in the Bill, we suggest that maximum evaluation timeframes are stipulated in regulations.

Furthermore, with the tightening of unapproved supply, plus a high likelihood of increased fees, the regulator should look at having an orphan designation/application pathway with associated reduction in fees for rare diseases.

With New Zealand's very small population there may be a handful of patients treated each year and for many products in this space it will not be commercially viable to register these in New Zealand. If there is some kind of fee waiver in place this would give the regulator more control over what is being supplied in New

Zealand in these kinds of circumstances. This would facilitate regulated access to medicines for those persons with rare conditions who are more vulnerable to risks of unregulated supply and would help redress this issue.

- Ss267 Consultation

We support the approach of making the Bill principles-based and having operational details of the scheme in subordinate legislative instruments. We agree with the rationale that this will enable efficiencies in regulation and give flexibility for regulation to be maintained, to change over time to meet future needs and keep up to date with international practice.

However, we wish to emphasise that this approach to the drafting of the TPB and consultation on the TPB creates a high level of uncertainty for stakeholders. There is a level of information asymmetry present, where stakeholders know significantly less about the intended operation of the new regulatory scheme, than the Ministry of Health. This has created difficulty for stakeholders providing feedback on the exposure draft of the TPB who do not have access to the full information.

To alleviate this problem, we strongly recommend to the Ministry of Health that they have a much higher level of targeted, quality engagement with stakeholders during the drafting and consultation phases of the subordinate legislative instruments. The Ministry of Health has admitted they have not engaged sufficiently with some sector groups (e.g cell and tissue sector) prior to this consultation on the exposure draft of the TPB. To rectify this, the Ministry of Health should commit to forming working groups of sector groups affected by the TPB to facilitate drafting of regulations that are workable and fit-for-purpose. Medicines New Zealand has noted interest from individuals in the prescription medicines industry who would be qualified and prepared to participate in a medicines sector working group. We strongly recommend a consultation that provides sufficient time and opportunity for stakeholders to comment. We recommend formation and engagement with a medicines industry working group to provide insight and advice on the development of practical regulations.

- Subpart 4 - Relationships with other Acts

ss270 discusses the relationship with Hazardous Substances and New Organisms Act (HSNO) 1996. If, as proposed, New Zealand adopts the EU definition of cell and tissue therapeutic products, the EU definition of engineered cells as genetically modified organisms would also bring the product into the purview of HSNO.

It is discussed in the consultation document that the interface between the TPB and HSNO scheme has not been drafted.

We suggest that if the product is intended to be a therapeutic product that the legislation be written so that the TPB is superior to that of HSNO. Similarly, for the interface between the TPB and the Human Tissue Act 2008 (ss 271).

References:

- [1] Medsafe (2018) Proposed Changes to fees payable under the Medicines Regulations 1984. Retrieved from:
<https://www.medsafe.govt.nz/consultations/FeesReview2018.asp>
- [2] Medicines New Zealand (2018) Response to Medsafe Fees Review 2018. Retrieved from:
https://www.medicinesnz.co.nz/fileadmin/user_upload/Submissions/Medicines-NZ-Fee-Changes-Submission-on-letterhead-signed2018.pdf
- [3] Medsafe (2018) Proposed Changes to Fees Payable under the Medicines Regulations 1982: Outcome of Consultation. Retrieved from:
<https://www.medsafe.govt.nz/consultations/Fees%20Review%202018/Outcome%20Fees%20Review%202018.asp>

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

- Schedule 2 – Reviewable decisions

Medicines New Zealand agrees with the list of decisions reviewable by the applicant or sponsor which are listed in Schedule 2 (Items 1 to 6) of the draft TPB.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

As in response to Question B13, we understand that the approach to major changes to products is to ensure that different versions of the same product (i.e original products vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposed process described in C1, paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued. It was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019, that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors.

PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding

applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We do not believe the practicality of the major changes processes has been considered in the Bill.

A solution would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the regulator's register can be replaced by the changed product. This type of approach is used by the TGA - TGA Grouping. For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s 78)." We believe this would be an opportune scenario to issue a "use of current stock" notice. We recommend that this solution is further discussed with pharmacists and practitioners.

In cases where the sponsor did wish to continue to have both versions of the product approved, they could nominate to receive a new approval and TT50 number for the changed product.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

We agree in principle with the categorisation system for medicines. We agree that having numbered categories (1,2,3,4) will be more future-proof than the current system of naming the medicine classification (Prescription, Pharmacist, Pharmacy and General Sale). We do note that the numbers for categorisation have been proposed as 1 (referring to current Prescription medicines) and 4 (referring to current General Sale medicines). This is the inverse to the numbering system used by the TGA. It was stated at the Medicines forum on 18 March 2019 that the medicine category would not need to be put on labels so there would not be an issue arising from harmonizing labels for Australia and New Zealand.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

The transition provides a 3-12-month period for applications for approvals and licences.

Due to the widened scope of the scheme for example to cover additional products (e.g medical devices) and activities (e.g clinical trials for registered medicines), there will be a large volume of applications received. We are concerned by the potential backlog created by this influx of applications, the length of time until normal operations resume and the impact of this on routine applications such as CMNs and new medicine applications.

We are concerned that this will create significant capacity and capability issues for the regulator.

We are seeking assurance that the regulator will be adequately resourced during this transition period and once normal operation resume.

• Transitional Arrangements

We have some concern regarding the transitional arrangements (Schedule 1) and seek further information.

We note that the policy intent is to allow the new regulator to efficiently deal with pending matters as soon as possible. We acknowledge the arrangements that will provide temporary approvals, licences and permits to applicants.

Our concern is that there will be a very large volume of applications made within 3-12 months from the commencement date, and that this will create a large backlog of work for the regulator.

We are concerned of the impact this backlog will have on the processing of new applications, and changes to medicines.

- What plans have been made to ensure the efficient processing of the large volume of applications?
- How will it be ensured that the regulator is sufficiently resourced to process the applications made in the transition period after the commencement date, as well as during normal business?
- What provisions does the regulator have for ensuring capacity and resources, including immediate access to qualified experts for evaluations?
- How long is it expected to take for the regulator to complete the transition? (i.e to replace all temporary approvals, licences and permits with permanent equivalents)

We note in the consultation document that:

"the new scheme would give the regulator greater flexibility to establish a number of approval pathways... for example, products with a long approval history in one or more recognised overseas jurisdictions... We envisage this flexibility would also be likely to encourage sponsors of many unapproved medicines currently supplied under section 29 of the Medicines Act 1981 to seek approval for those products."

We support the suggested approval pathway for products with a long approval history in one or more recognised overseas jurisdictions and the general flexibility intended to facilitate a range of product approvals.

While we support this new approach to section 29 medicines, we understand that there are approximately 400-500 products currently supplied via section 29. We understand the intention for these medicines is they will either be available to patients via the Special Clinical Needs Supply Authority scheme, or they will first need to receive a product approval under the new scheme.

Our concern is that receiving these approvals will take a long time considering the number of medicines and device approvals that will be submitted, and the number of licence applications that will be received during the transition period. This would have an impact on clinicians and patients.

We do not see any specific transitional arrangements being provided for the section 29 medicines and we seek further information on this. We note on page 93 of the consultation document that:

"As a wholesaler, you would only be able to import an unapproved product if your licence specifically authorised this (s 51(1)(b)). In most cases, the import would be requested by a pharmacist or health practitioner prescriber because a doctor had issued a SCNSA. For some medicines, however, it may be necessary for the wholesaler to maintain a small stockpile of the product, so it is available for immediate release once a SCNSA has been issued. If so, the licence would authorise such stockpiling. This approach might be used, for example, for medicines that must be available urgently."

Will the transitional arrangements allow a wholesaler to apply for a temporary licence to continue the import of medicines currently supplied by the section 29 of the Medicines Act? We expect there will be a number of medicines (e.g. anaesthetics) which will need to be stockpiled and have continuous import until they receive a product approval, or they are requested via the SCNSA scheme.

Question C4 - Please provide any comments on the approach to post-market controls.:

We agree in principle, but industry would need to be consulted in relation to the specific requirements. What is lacking here in terms of the detail is what requirements would be enforced in relation to risk management. The addition of requirements such as PBRER and RMP reporting perhaps should only be considered for higher risk molecules.

Medicines New Zealand would continue to welcome a continued pragmatic approach, particularly with regard to RMP ie to accept EU RMP rather than introducing country-specific requirements. More information on the monitoring system (ss160) and any potential costs to industry, will be awaited with interest when the draft regulations are issued for comment. Please also refer to our response to question B16.

Lastly, we seek clarification on whether the TPB requires the sponsor's contact for dealing with pharmacovigilance matters and reporting to the regulator to be a New Zealand resident. Currently this person can be based overseas as long as they are contactable during New Zealand business hours. This is a common practice for industry.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Please refer to our response to Question B2.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

Medicines New Zealand supports the intent of the new hawker scheme which would enable licensees to have secure online access to its database to enable them to maintain an up-to-date record of their own mobile staff and their territories and products. This approach will improve efficiencies for both the regulator and companies.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Medicines New Zealand supports the ability to have one licence to cover a range of activities involved in the running of a clinical trial. It is important that requirements and obligations are clear in subordinate legislation including:

- whether it is the sponsor of the trial or the investigators that seek the license
- license duration - three years is too short for some clinical trial activities. Would it be possible for a clinical trial license to be granted for longer rather than relying on extensions?

Clarity around requirements of when a licence can cease is also requested (i.e. is the licence required during treatment phase only or until all activities in the clinical trial have completed and clinical site is closed, or until the completion and reporting of the trial?)

Please take into account that a study can complete in New Zealand but continue in other countries.

Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current clinical trial approval process concern remains that the licence cannot be issued until the ethics approval is granted and what impact this may have on timelines.

As a further point, it is unclear if applications that do not require ethics approval will have the same quick timelines as those currently. It is imperative that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g. observational trials, clinical audits).

Please refer to our response to questions B18-B22 for further comment.

It is also requested to align the clinical trial terminology with international terminology and definitions (i.e. ICH Good Clinical Practice (GCP) definitions), in order to avoid confusion both locally and internationally.

We have additional comments on some specific aspects:

- Exporting biological samples (blood/serum) and tissues

We couldn't find reference to provisions for the export of samples or tissues derived from clinical trials (e.g. for testing, storage). We seek assurance that sensible provisions are in place, such as an authorisation to do so as part of approval of clinical trials.

- "The regulator also has the power to monitor trials and audit Clinical trials sites." (paragraph 422 of the consultation document)

This is currently being proposed by the TGA under consultation. A major concern is how outcomes of such activity are reported to ensure data quality reputation (which is currently high) remains intact.

We seek further information/detail about the intentions.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

For ongoing trials which currently do not require approval under the Medicines Act, but will under the draft Bill, it is not practical in all circumstances for the principal investigator to apply for a temporary licence to carry on the activity.

This should be changed to reflect either the 'proposed licence holder' or sponsor of the study.

It is requested that this clinical trial terminology is aligned with international terminology and definitions.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Medicines New Zealand supports the provision in the Bill for supply of an unapproved product via a Special Clinical Needs Supply Authority (SCNSA)(ss64). It is important that requirements for supply via this mechanism are clear in the regulations, including:

- Responsibilities for Adverse Event reporting
- Requirements for notifying local sponsor of supply
- Provisions for a cross-over period should an unapproved medicine supplied under a SCNSA become approved
- Under what circumstances wholesalers are able to have on hand a small stockpile of unapproved medicines ("urgently needed" needs to be defined, as does "small")
- Measures of control of products imported by "buyers' clubs" and/or healthcare professionals bulk importing unapproved medicines.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

1.1 Medicines New Zealand welcomes the fact that the status quo regarding direct-to-consumer advertising (DTCA) of prescription medicines is maintained under the TPB, and we note the enhanced range of enforcement options and higher penalties that would be available for advertising breaches.

1.2 While Medicines New Zealand is supportive of the advertising requirements proposed in the TPB, our view is that the regulator's range of enforcement tools (i.e. penalties, infringement fines, and advertising remediation orders) will rarely be required for advertising of prescription medicines. Our view is grounded on existing and historic data and experiences of all parties within the current government regulation, co-regulation and self-regulation environment. All of which has provided stringent pre-publication control on the content and quality of DTCA, and remediation if required.

1.3 DTCA by the prescription medicines industry is currently well-regulated from both a government regulation (see paragraphs 1.5 - 1.7 below), and an independent co-regulation perspective by the Therapeutic Advertising Pre-vetting System (TAPS) in conjunction with input from Medsafe (see paragraphs 1.4 and 1.8 below). The prescription medicines industry via the Medicines New Zealand Code of Practice, and the Advertising Standards Authority (ASA) via the Advertising Standards Code and Therapeutic and Health Advertising Code add a further level of self-regulation (see paragraphs 1.9 and 1.10 below).

1.4 The current independent review process, via TAPS, of advertisements for prescription medicines ensures that promotional claims are accurate and substantiated by quality references, and that all information is consistent with the Data Sheet and Consumer Medicine Information documents, both of which are approved by Medsafe. These are tools to facilitate the protection of consumer and community health. In addition, TAPS has regular contact and discussion with Medsafe to ensure that advertising is compliant with the relevant legislation.

1.5 New Zealand has strong and effective legal requirements that control the marketing and advertising of prescription medicines. Relevant existing statutes include the Medicines Act 1981 (which will be superseded by the proposed legislation), the Commerce Act 1986, the Fair Trading Act 1986, the Misuse of Drugs Act 1975, the Consumer Guarantees Act 1994, and the Privacy Act 1993.

1.6 The Medicines Act 1981, and the proposed legislation, establishes the basic legal guidelines for DTCA of therapeutic products, devices and services. The Medicines Regulations 1984 lay down more detailed requirements regarding the inclusion of statements in medicines advertising about authorised uses, appropriate precautions and contraindications. It is certain that the future regulations, yet to be generated under the proposed legislation, will also make clear the requirements, thus protecting personal and community health.

1.7 The Commerce Act 1986 establishes the legal framework for fair competition and the environment within which prescription medicine advertisers have to do business. The Fair Trading Act 1986 legislates against unfair and misleading advertising. The other Acts mentioned previously (see paragraph 1.5 above) also have bearing on how pharmaceutical companies market and sell prescription medicines.

1.8 While therapeutic products, due to their nature, do require a reasonable level of government regulation, independent co-regulation also brings public policy or "good government" advantages. This is true both in adopting and in enforcing standards and protecting public and community safety around promotion. For example, over 10 years ago, after safety concerns over Vioxx (a Cox-2 inhibitor) were raised, the New Zealand pharmaceutical industry agreed to immediately remove all Cox-2 inhibitor advertising after discussions and consultations with TAPS, the ASA and Medsafe. This is a good example of where both self- and co-regulation work together with the Government's regulation system.

1.9 Additionally, the industry self-regulation via the Medicines New Zealand Code of Practice sets the industry standard for marketing of prescription medicines and associated promotional activities. It defines and ensures high standards of conduct that match those required by law. Acceptance and observance of the Code is a condition of membership and companies must comply with both the letter and spirit of the Code. Breaches of the Code around DTCA are determined by an independent Code of Practice Standing Committee that can impose sanctions ranging from the suspension of the advertisement or marketing practice to a fine of \$80,000.

1.10 The ASA's Therapeutic and Health Advertising Code also requires advertisers to comply with the Medicines New Zealand Code of Practice and as such captures any non-Medicines New Zealand pharmaceutical companies.

1.11 The evidence that all forms of current regulation highlighted above are effective for DTCA is seen in the extremely low number of complaints made to ASA for prescription medicines advertising. It is noted that complaints to the ASA can include aspects of consumer safety, lack of clarity and false or misleading statements. Interestingly, over the past 7-year period out of a total 5446 complaints received only 19 (0.45%) were regarding prescription medicines and only two of those complaints were upheld as bona fide issues requiring remediation, which were actioned by the advertiser. [See MNZ Supporting Document #1].

1.12 In conclusion, while we are supportive of continued government regulation and enforcement of DTCA for prescription medicines, we note that this should not be in lieu of the continued mechanisms already established independent of the regulator. We further note that all regulatory systems together will continue to maintain the quality and content of all prescription medicine DTCA to ensure that both the purpose and principles of the proposed legislation are upheld and followed.

List of supporting documents (supplied by email):

#1: ASA summary of complaints

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Summary of views on permitted continuation of DTCA of prescription medicines

1.1 Medicines New Zealand's strongly held view is that regulated direct-to-consumer advertising (DTCA) of prescription medicines should continue to be permitted.

1.2 We note that the purpose of the TPB described in ss3 is to "...protect personal and community health". Therefore, in order to ban DTCA a large body of empirical evidence must be delivered to indicate that the current practice of DTCA in some way breaches that purpose. There is, however, no significant robust evidence to indicate that the personal and community health is at risk (see paragraphs 3.1-3.6), and so we believe that the well-regulated DTCA of prescription medicines should remain in force given all the benefits it provides (see paragraphs 4.1-4.7)

1.3 We note that empirical New Zealand-based evidence overwhelmingly concludes that regulated DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. It does not create any personal or community health issues (see paragraphs 4.1-4.7).

1.4 All prescription medicines advertised by DTCA are registered with Medsafe (the current regulator). Medsafe reviews the scientific dossiers and confirms the safety and efficacy of the medicines. This means that all prescription medicines advertised by DTCA are regulator-registered medicines and adhere to a core principle of the proposed regulation - that the "likely benefits of the therapeutic products should outweigh the likely risks associated with them". Therefore, this set of prescription medicines not only meet this principle but also meet the purpose of the proposed legislation of assuring public safety by regulator oversight.

1.5 Furthermore, in comparison to the vast quantity of un-regulated health information available on the internet, DTCA of prescription medicines comprises only a small percentage of advertising readily available to patients. The focus of any regulation it seems should not be on banning the already well-regulated DTCA of prescription medicines, but on the un-regulated internet sites and activities which represent a clear risk to both personal and community health (see paragraphs 2.1 to 2.6).

1.6 It is clear that interest groups on either side of the DTCA debate hold their own views, yet data and analysis of studies and surveys on consumers (who are the audience and focus for DTCA) seem to have no major concerns with the practice and indeed express concern for if the practice of DTCA were to be banned (see paragraphs 6.1). No major issues have been highlighted in a range of studies and surveys (see paragraphs 6.2-6.3)

Reasons for our views on the maintenance of DTCA of prescription medicines in the proposed legislation are further outlined in the proceeding sections.

2. Health care information and protection of personal and community health (public safety)

2.1 There is a rapidly-increasing amount of healthcare information directed at consumers via the internet that promotes, in our view, unsubstantiated therapeutic claims for all sorts of health conditions. The term “Health” is the second most searched term on Google [1]. Over 3.4 million New Zealanders access the internet across the week [2], with 87% of these New Zealanders searching for health information online [3]. WebMD, an overseas medical advice website, obtains more than 300,000 unique visitors from New Zealand each month [2]. It would, therefore, seem that the internet is a considerably bigger source of health information, than the regulated prescription medicines advertising internet sites and DTCA in standard media channels.

2.2 The level of regulated DTCA for prescription medicines is often overstated by critics and is only a very small component of the total advertising undertaken in New Zealand. By way of example, in 2017 it was shown that only 33 prescription medicines were advertised by DTCA in New Zealand. Only six of these medicines were advertised on television. The total of 33 medicines included two clinical trials advertisements, compared with a total of over 200 DTC advertisements for health supplements and over-the-counter medicines [4]. Advertising expenditure estimates indicate that DTCA of prescription medicines represented only 0.2-0.3% of total spending in New Zealand per year between the three most recent year periods of 2016 to 2018 [4]. In all cases the prescription medicines advertised in New Zealand were approved by the regulator from a safety and efficacy perspective and the advertisements had undergone independent assessment by the Therapeutic Advertising Pre-vetting Service (TAPS) to confirm compliance with the Medicines Act (1981), Medicines Regulations (1984), Medsafe Guidelines, Advertising Standards Authority and Medicines New Zealand Codes [5].

2.3 Irrespective of the source of the therapeutic product information, in the interests of public safety the questions that regulators must answer include:

- (i) Are these therapeutic claims genuine?;
- (ii) Is the therapy safe and effective?;
- (iii) Is the advertising socially responsible? and;
- (iv) Are there systems in place to ask these questions and control advertising accordingly?

Clearly DTCA of prescription medicines already falls under the domain of a range of regulatory instruments and mechanisms to protect public safety (refer to our response to consultation question C52) and so answers these questions. Our contention is that a far bigger public safety risk is that of the unregulated health information on internet sites and this we feel is a risk both now and into the future. The proposed legislation and regulator therefore need to contend with this in regard to public safety on both the matters of the internet and “Dr Google”.

2.4 In comparison to the unregulated internet, in the case of prescription medicines, regulatory approval is and will continue to be required by the regulator (Medsafe) before any product can be marketed in this country. This approval is given on the basis of scientifically-proven therapeutic value (efficacy), rigorously-tested safety standards (safety) and audited, consistent high quality of manufacture (quality) [6]. Thus, the regulator aids in protection of the public safety in the case of prescription medicines and that includes the small subset that have DTCA activities associated with them.

2.5 Aside from Medsafe's evaluation and approval processes, the public's and community's safety are ultimately protected by the fact that prescription medicines cannot be directly obtained by the consumer within this country without first obtaining a prescription from a registered medical practitioner (GP, specialist) or another approved prescriber. Thus, another mechanism is in place as regards providing public safety around DTC-advertised prescription medicines.

2.6 Prescription and over-the-counter medicines are regulated by Medsafe in New Zealand and have been determined to have acceptable risk-benefit profiles based on robust clinical trial evidence [6]. Health supplements on the other hand, do not need to go through this regulatory process prior to marketing and do not need to have proven therapeutic benefits [7]. In recent cases, these supplements have even been shown to cause harm. Arthrem, a natural health supplement marketed to relieve joint pain and stiffness with TV advertisements starring New Zealand athletes was found to cause liver toxicity in at least 14 reported patients [8]. Had a similar regulatory regime including DTCA standards and regulations been in place for health supplements, it is likely that this public health issue could have been avoided.

3. There is a lack of evidence of clear public health safety risk or other issues as justification to limit or ban DTCA of prescription medicines

3.1 Any justification to limit or remove DTCA as a form of communication must be rationally connected to a public health objective and the limitation must be proportional to that objective. To outlaw DTCA would therefore require a case to be made that its removal is necessary to achieve a public health safety objective i.e. that there is clear evidence of harm arising from DTCA.

3.2 Critics contend that DTCA harms the doctor-patient relationship, gives rise to inappropriate prescribing, provides mis-information, highlights benefits over risks, and can negatively impact the pharmaceutical budget [9, 10]. However, the vast majority of the references and citations used are to US studies or examples and not to New Zealand data or its evidence base, therefore, making bona fide links to the proposed issues around DTCA activities in this country hard to justify. A critique of the issues and critical review of the data provided, including rebuttal, is provided below in the proceeding paragraphs 3.3 to 3.6.

3.3 Doctor-patient relationships: New Zealanders enjoy one of the best doctor-patient relationships in the Commonwealth. From surveys conducted by The Commonwealth Fund, over the past decades we rank in the top three out of 11 comparative countries [11, 12]. Logic would dictate that if DTCA causes adverse effects on the doctor-patient relationship that we would occupy the lowest ranking, yet, we do not. Furthermore, New Zealand analyses found that the majority of consumers consider that DTCA has no effect on their relationship with their doctor, and a proportion (16%) felt it could actually improve the relationship [13, 14]. The clear conclusion of the work was that the majority of patients neither asked for, nor received, a prescription as a result of DTCA, and it also showed that many doctors responded to requests with alternative treatments or lifestyle advice instead [14].

3.4 Inappropriate Prescribing: Likewise, there is no New Zealand empirical evidence that DTCA gives rise to inappropriate prescribing in New Zealand. On critical analysis, the one paper citing this as an issue provides no specific New Zealand references/citations at all, but rather reference to US studies and a tacit admission that “...No similar research has been conducted in New Zealand...” [15]. New Zealand is different in the way that DTCA is conducted and regulated so the finding of no linkage to inappropriate prescribing comes as no surprise. The final treatment decision lies with the doctor who is professionally accountable for the prescribing decision, and as noted by others in the New Zealand context, often it is not the DTCA medicine that is prescribed, which further negates any

suggestion of overprescribing of such medicines [13, 14].

3.5 Fiscal impact of DTCA: In New Zealand fiscal impact of DTCA would only be an issue requiring further examination if there was evidence that DTCA was creating 'budget blow-outs' or diverting money from other health services. PHARMAC operates a discrete budget which has never been overspent in its 25-year history. PHARMAC employs a range of supply and demand side strategies, including tendering, Special Authority requirements, reference pricing and bundling that very effectively manage volume and expenditure. Furthermore, an NZIER analysis shows that the level of expenditure by PHARMAC had actually decreased in real terms (a 0.3% decrease), over the most recent 11-year (2006/7-2017/18) fiscal period [16]. This information confirms that DTCA has not caused fiscal impacts, 'budget blow-outs' or diversion of funds.

3.6 Mis-information and benefits over risks. Given the requirements of the independent TAPS pre-vetting and approvals process and the internal processes required by the companies including full legal and scientific review (see both paragraph 4.7 and Supporting Document #2), it is difficult to see how statements on mis-information and overselling benefits to risks are justified. Indeed, the Ministry of Health itself reported back in 2001 that the TAPS system had contributed to an improvement in the provision of balanced and factual risk information in advertisements [17]. This requirement for pre-vetting and approval and the fact that TAPS will engage with Medsafe to clarify perspectives on DTCA for specific products helps indicate that no mis-information or 'oversell' of benefits over risk occurs. No robust evidence of mis-information in New Zealand DTCA has been put forward, and there are no New Zealand studies or reports indicating this is the case. One study raised the issue that the quality of scientific evidence provided in advertisements of prescription medicines was poor and thus risks were downplayed [18]. However, the paper focused on advertisements directed at healthcare professionals not consumers/patients i.e. not DTCA. Its use alone and in conjunction with US data to make comment on DTCA in a New Zealand context, is flawed. Furthermore, there was a significant methodological issue in this study. The study required that any advertisement that made reference to clinical studies other than the Cochrane 'gold standard' of an independently-funded (i.e. non-industry funded) double-blind randomized clinical trial was considered poor quality. In other words, any clinical trials funded by pharmaceutical companies even if published in scientific peer-reviewed papers was considered of low quality by the authors. Ironically the same clinical data cited in the advertisements have been reviewed by Medsafe prior to approval for the registration of the medicines in the first instance. This makes the claims of the authors even more concerning as regards their perspectives on the robustness of the regulator's processes.

4. Justifications for maintaining DTCA of prescription medicines

Analyses of the case against continued DTCA of prescription medicines shows that in most cases no New Zealand data or studies have been undertaken that justify the purported issues or that the referenced studies have flaws leading to issues with conclusions drawn. What the body of empirical New Zealand data tends to highlight are a number of positive attributes of well-regulated prescription medicines DTCA.

4.1 There are multiple benefits of DTCA in New Zealand of prescription medicines including increased health awareness [13, 19, 20]; Patients encouraged to act on undiagnosed or poorly managed conditions. [19-22]; Patients feeling better about medicines when they have initiated discussion and been involved in decision-making [20, 21, 23], and; Improved treatment adherence [21, 23].

4.2 The body of New Zealand research that has been conducted on patients' and doctors' attitudes to DTCA where no bias has occurred in study design also shows positive features of DTCA. Of 632 New Zealand patients surveyed, 91% felt DTCA helps make them aware of new medicines and 67% felt it gives them enough information to decide whether to discuss a medicine with their doctor [13]. A total of 270 New Zealand GPs surveyed agreed the advertisements help make patients aware of new medicines and creates an opportunity to talk to patients about various treatment options [19]. From another survey of 1300 patients, 8.5% said they had been spurred by an advertisement to visit their doctor about a medical condition they had not discussed before and a further 8.3% were spurred to discuss a previously diagnosed condition [21].

4.3 Surveyed New Zealand patients who had spoken to their doctor about an advertised medicine, felt the DTCA had helped them communicate with their doctors [21]. An in-depth interview of GPs noted that that DTCA helps get patients 'in the door' and helps them open up the discussion about their health issues [22].

4.4 GPs, nurses and pharmacists interviewed in 2017, expressed similar views: that DTCA helps patients take notice of their health and helps them start conversations about their health conditions (conditions that may otherwise go untreated or under-treated) [20]. It also presents doctors an opportunity to screen for related health conditions [19].

4.5 A collaborative doctor-patient relationship with two-way communication allows patients to take a more active role in their health management and has several knock-on effects. Patients have higher satisfaction with their medical care and treatment, better expectations of their health outcomes, more confidence in their ability to adhere to treatment, resulting in overall higher adherence and better health outcomes [23].

4.6 Interestingly, from the three surveys of New Zealand doctors, undue pressure to prescribe advertised medicines was not found and surveyed GPs said they treat a DTCA query as an ordinary part of a visit [19, 20, 22]. DTCA does not lead to inappropriate prescribing. A related survey showed that the reasons that surveyed patients received a different medicine to the advertised one was that the medicine was not right for them, the medicine had side effects, or there was a cheaper medicine available [21]. The conclusion is that DTCA does not affect the doctor's independence or increase pressure to prescribe, it just gets patients in the door.

4.7 Unlike the abundance of other online information patients freely access, New Zealand DTCA of prescription medicines is strictly regulated. DTCA is designed to meet local requirements whereas patients often access websites from countries that don't meet New Zealand regulations. Companies in New Zealand scrutinise any advertisements during development and undertake extensive scientific, legal, patient safety and medical review. Advertisements in development are subject to rigorous internal and external review (See MNZ Supporting Document #2). All claims must be able to be substantiated and have references available on request. Again, as explained in answer to question C52, all online and mainstream DTCA are independently assessed for compliance with New Zealand laws, regulations and industry codes by TAPS. Most importantly, without this independent review by TAPS, the media in New Zealand will not run the DTCA campaign [27].

4.8 We understand the New Zealand Bill of Rights Act (1990), allows and provides for the right of freedom of expression. Medicines New Zealand, therefore, seeks clarification from the Ministry of Health on why a narrow restriction on banning of DTCA on prescription medicines DTCA vis-a-vis over-the-counter

medicines and medical devices is being proposed.

5. Promotion of prescription medicines overseas to consumers

5.1 The assertion often made by anti-DTCA groups that the US and New Zealand are the only industrialised countries to have DTCA is not strictly true. While both New Zealand and the US are the only countries that allow DTCA of branded prescription medicines, what is often not mentioned by critics of DTCA is that there are numerous other countries worldwide that allow DTCA of prescription medicines in one form or another [24-26]. For example, Canada and South Africa permit consumer reminder advertisements – which let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims [27,28]. Countries in the EU and some in Asia allow prescription vaccine advertisements including promotional claims [24-26]. France allows advertisements for vaccines and for prescription quit smoking aids [29]. All of these countries, plus many others such as Australia, also allow disease-awareness or “help-seeking” advertisements: industry-sponsored messages that encourage viewers to see their doctors about a specific health concern, without including individual product names [30].

5.2 Clearly these countries and their health systems and regulators must see a public health benefit to these various types of advertisements, having either maintained these laws following legislative reviews or relaxed the laws to allow some DTCA [24, 26]. This is irrespective of whether that public health benefit is through raising awareness of tools available to quit smoking, through counteracting dangerous anti-vaccination campaigns or through encouraging patients to speak with their doctors about health concerns.

5.3 As an example of the benefits, South Korea relaxed its laws in 2008 to allow DTCA of prescription medicines for contagious diseases. The first DTCA campaign aired in 2009 for a rotavirus vaccine [24]. Since these advertisements aired, awareness of the virus increased from 12% in 2007 to 82% by 2009 [24]; The number of children infected with rotavirus reduced by 50% and the number of hospitalisation days halved [31]. The direct and indirect costs from the disease decreased from NZ\$26 million to \$14 million, saving \$12 million in health costs [31]. Thus, the South Korean experience highlights that DTCA of prescription medicines encouraged patients to seek earlier intervention for a treatable condition, and averted costly hospital admissions.

6. Patients and community views on DTCA in New Zealand

6.1 A body of previous research has indicated both people and the wider community do find benefits from advertising of prescription medicines including: improved awareness and information, and an ability for patients to discuss treatment options and their conditions with their doctors/GPs [13, 19, 21]. Interestingly, two recent studies countered this around so-called ‘at risk’ individuals’ behavioural responses to information in prescription medicine DTCA. However, the authors admitted limitations of the study design including the use of only four “yes/no” questions on DTCA and that causal relationships/inferences could not be made “due to nature of the data”. The design also showed that it was self-reported data and so “...might not reflect individuals’ actual behavioural responses” [32, 33]. At best, the studies refer to responses as “perceived behavioural responses”. Furthermore, the reports are based on a 2013 survey of 2057 people in which only 11.4% (235 respondents) answered yes to a question on whether they had asked their physician for a prescription after seeing a DTCA advertisement. This means that 88.6% (1822 respondents) did not seek out a prescription at all. Most interestingly, more ‘at risk’ individual respondents (15.9%, 327 respondents) responded that they had asked their physician for information, rather than asked for a prescription, indicating that perceived behaviours are driven towards gaining more information rather than a prescription for a specific medicine [32, 33]. Both papers also incorrectly state that DTCA of prescription medicines is only self-regulated in New Zealand. This is clearly incorrect too.

6.2 In contrast, a more recent and more detailed survey was undertaken by Perceptive Inc as part of a larger omnibus survey of 1,082 consumers to investigate where consumers obtained their information and awareness on medicines (both over-the-counter and prescription medicines) [34]. The results showed that New Zealanders awareness of over-the-counter and prescription medicines are largely gained from Google/internet searches, and family and friends (a total of 75% of respondents). Of the various channels 44% of total respondents had awareness of advertisements for prescription medicines, and 27% of total consumers used this as an opportunity to discuss health and well-being with their doctor. The majority of these discussions with their doctor (54%) were focused on the condition, ailment or problem, not the product. This is similar to the levels in other surveys findings [21]. Interestingly, 52% of total consumers surveyed found DTCA for prescription medicines helpful, while 75% of the total 1,082 respondents noted that they would be concerned if prescription advertising was banned in New Zealand, with 53% being extremely concerned if a ban occurred [34]. This finding that consumers own views are heavily weighted towards retaining DTCA of prescriptions medicines [34], is again in alignment with the positive attributes consumers ascribe to DTCA from an information perspective given in earlier work [13, 21].

7. Concluding remarks on DTCA

7.0 In conclusion, the prescription medicines industry believes that the continuation of DTCA on prescription medicines is justified given the body of robust empirical evidence. Any decision made to stop DTCA must be shown to achieve a significant public health objective. To do this a clear case must be made of actual and robust evidenced risks that far outweighs the evidence on benefits that DTCA provides in a New Zealand context.

List of supporting documents (supplied by email):

#1: ASA summary of complaints

#2: Medicines NZ Process for DTCA

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• Final Concluding Remarks

We thank you for the opportunity to provide feedback on the Exposure Draft of the Therapeutic Products Bill.
We welcome the opportunity to present to the select committee on this matter.

We are available to meet and discuss with officials to clarify any of the comments made in this submission and we also welcome the opportunity to comment on any further revisions made to the Bill.

Response ID ANON-DPZ8-G4ZR-D

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 15:55:10

Submitter profile

What is your name?

Name:

Roula Roboris

What is your email address?

Email:

What is your organisation?

Organisation:

GlaxoSmithKline New Zealand

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

Other (please comment)

If you selected 'Other' please comment;:

Pharmaceutical company

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

GlaxoSmithKline New Zealand (GSK NZ) welcomes the invitation to make a submission to the Ministry of Health on the draft Therapeutic Products Bill ('Bill') and supports the general design of the regulatory scheme. GSK NZ notes that the Bill provides enhancements and is aligned with other international jurisdictions, which will assist in ensuring the regulatory scheme is fit for purpose and future-proof, thus benefiting New Zealand health consumers. Also, GSK NZ looks forward to further involvement in consultation opportunities in the implementation of the operational details of the scheme in the subsequent subordinate legislative instruments

GSK NZ agrees with the purpose and principles of the Bill (ss 3 and 4). Specifically, we support:

- A risk-based approach in the regulation of therapeutic products dependent on the type and nature of the product, encompassing the whole of the product lifecycle (pre-and post-marketing), this will ensure we have a fit for purpose and future-proof regulatory scheme. GSK NZ supports having different product registration pathways dependent on risk, unmet medical need, effectiveness and safety of current standards of care (e.g. priority, conditional, abbreviated etc);
- Timely availability of therapeutic products to New Zealand health consumers. To achieve this, the regulatory scheme will have to establish transparent and meaningful evaluation timeframes and reporting of the Regulator's performance. To this end, GSK NZ recommends maximum evaluation timeframes be included in the Regulations, this will also help in achieving greater predictability and certainty in approval timeframes for Sponsors, which is lacking under the current

system.

- Administration of the Act carried in an open and transparent manner.
- Co-operation with overseas regulators, compliance with international obligations, and alignment with international standards and practice where applicable. GSK NZ recommends that the existing abbreviated evaluation pathway is expanded to allow additional major application types to be evaluated under this pathway (e.g. new indications, line extensions, new strengths). This will reduce regulatory burden and costs, thus facilitating quicker access to therapeutic products.

It would be helpful for the understanding of roles if PHARMAC is actively dialoguing with Medsafe in the registration of products, depending on urgency, unmet clinical need and other priorities. GSK NZ would propose in the intent of full transparency that this is captured in guidelines/regulations.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

s31 – Definition of ‘responsible manufacturer’

GSK NZ seeks clarity that the ‘responsible manufacturer’ in relation to quality assurance and quality control can be the parent company of the Sponsor. The parent company is generally the entity with oversight of the processes to ensure quality in the manufacture of the product and is the most appropriate party.

Relatedly, GSK NZ queries the purpose of requiring the Sponsor to have a contractual relationship with the ‘responsible manufacturer’ if the ‘responsible manufacturer’ is the parent company. Such intercompany arrangements can be created, however, given the relationship between the NZ Sponsor entity and its parent company, GSK submits that there should be an exception to this requirement where the Sponsor and the responsible manufacturer are part of the same corporate group.

ss47 and 48 – Definition of senior manager

Ss47(2) states that in addition to “person A”, others are subject to the ‘fit and proper’ person test - each person “who is or has been a senior manager of person A”, or each person “of whom person A is or has been a senior manager”. This definition is also extremely broad in that it captures persons who have been senior managers in the past. For example, based on the current drafting, if Person A is a company, then the Regulator would need to consider all individuals who is or has ever been a ‘senior manager’ and then all the companies that any current or past ‘senior manager’ of Person A has been engaged by. This appears to cast a very wide group of people who would need to be considered for the ‘fit and proper’ person test and we would question the objective or utility of having the Regulator assess such a wide group of people. GSK NZ therefore recommends the text ‘has been’ is removed from the Bill.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

GSK NZ agrees with the product approval requirements for importing or supplying medicines, medical devices or type-4 products.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

s55 details the activities that a person in the supply chain must comply with, which is very broad and covers activities from manufacture, through to supply, and clinical practice. GSK NZ recommends that the Regulations contain greater granularity on the different persons within the supply chain who will be held responsible for these specific activities.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners’ staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

GSK NZ notes that a patient is permitted to import certain medicines / devices without authorisation of the Sponsor provided that the medicine / device has been obtained legally and does not exceed a supply limit. There are no objections to the inclusion of these requirements. From a pharmacovigilance perspective this

may complicate the identification of a product belonging to a Sponsor and the Sponsor's obligations relating to this imported product. It's further noted that, s119 describes that if someone imports a product without the Sponsor's permission sections s116-S118 [Obligations of Sponsors] do not apply, so perhaps this is immaterial.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

GSK NZ does not support the new provision for the Regulator to issue a 'use of current stock' notice (s78). The new provision would allow a product licence to be cancelled even though stock may still be available in the supply chain, thus allowing wholesalers, health retailers, health practitioners, and patients to continue to sell and use the product. Under the current system, the Sponsor will cancel the product licence only once the last batch in market has expired. How the new provision will work in practice without compromising patient safety is not clearly understood. For example, low volume products and those products with a long shelf life may continue to be available in the market for many years after the licence has been cancelled by the Sponsor. Consideration should therefore be given in defining the Sponsor's obligations with respect to disseminating new safety information for the cancelled product. Since there is no licence in place, how would the New Zealand Data Sheet and/or Consumer Medicine Information for the product be updated and made available to healthcare professionals and consumers. GSK NZ recommends that the Regulator consider issuing a 'discontinuation notice' to notify New Zealand healthcare professionals and consumers that a product has been discontinued from the market.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

GSK NZ submits that the definition of 'advertisement' in section 82(1) be clarified to refer to communications made with the purposes of inducing the purchase, sale, supply and/or use of a specific medicine or similar. The distinction between disease awareness and educational activities and promotion should be clear in the legislation.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

S97 – Criteria for Sponsor of approved product

The Bill proposes that the responsible person (called the Sponsor) is responsible for all aspects of the product, extending from the manufacture, application, approval, importation and supply through to the supply channel. This wording is provided in the consultation document, but differs to the wording in the Bill, where the responsible person is named on the licence (but is not necessarily the Sponsor). Of concern, the scope of responsibility of Sponsors appears to have widened. The Sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst it is recognised that there are specific activities, such as post-marketing pharmacovigilance activities and investigation of quality issues and complaints, which are part of the Sponsor obligations after the product has left their control, the Sponsor cannot be held accountable for other activities after the product has left their control. For example, there is responsibility which resides with the wholesalers and pharmacists in the supply chain with regard to correct storage and handling of medicines.

s100 – Major changes results in new product

GSK NZ does not support major changes to an existing product resulting in a new product. The Ministry of Health clarified at the Medicines forum held on 18 March 2019 that for a major change, a new TT-50 number would be issued for the product and a new entry for the product placed on the proposed Therapeutics Product Register. GSK NZ recommends that consideration be given to adopting a similar approach to the Australian TGA, where changes can be grouped under the same registration number, unless the product is considered to be a separate and distinct good. The proposal to issue a new TT-50 for major changes is seen as problematic given the downstream impact on PHARMAC funding applications which make reference to the unique TT-50 identifier.

s101 – Sponsor must notify Regulator of certain minor changes

GSK NZ supports the management of minor changes to an approved product based on a framework of risk-based assessment of minor variations. This is particularly important in allowing certain types of minor changes that are low risk and do not impact the quality, safety or efficacy of medicines to be notified to the Regulator rather than requiring formal assessment prior to approval. A post-approval lifecycle framework for quality changes/applications aligned with that in the EU and Australia that reduces the submission burden for industry and establishes activity based timelines for evaluation is recommended. GSK NZ recommend further consultation with Sponsors is undertaken for minor notifications to establish the timeframes within which the notification must occur.

s103 – Duration of approval

GSK NZ agrees with the proposal for product licence approvals not to have expiry dates, thus licences are perpetual until such time that the Sponsor or Regulator considers cancelling the licence. This is aligned with current Australian TGA practice. Under the current New Zealand regulatory system where product licences lapse after 5 years if there has been no regulatory activity or no commercial supply of the product, there is often confusion on the status of the licence. There does not seem to be any compelling reasons to assign an expiry date on the licence.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

s105 – 107 – Conditions on approval

GSK NZ agrees that the Regulator should have the right to impose conditions on approval, and that the Sponsor is given the opportunity to comment prior to enforcement of the conditions.

s108 – 112 – Cancellation of approval

GSK NZ agrees that the Regulator should have the right to cancel an approval based on the grounds cited in s108, and that the Sponsor is given the opportunity to comment prior to any action been taken.

s113 – Therapeutic products register

GSK NZ agrees in principle with the proposal to develop a Therapeutic Products Register which contains a copy of the latest prescribing information and consumer medicine information for approved products. GSK NZ recommends that the prescribing information and consumer medicine information is hidden on the proposed register unless the product is supplied (which is consistent with the approach taken by the TGA). It is unclear whether the practice of assigning a registration number to the product (i.e. TT-50 number) will continue under the new regulatory scheme and what other level of detail will be contained within the register.

GSK NZ agrees that, all applications submitted to the Regulator and all approved products, should be made publicly available, on a product register, which is routinely maintained by the Regulator to ensure currency and accuracy. This practice is consistent with how other jurisdictions have embraced or improved transparency over recent years. However, we do not agree that all declined or withdrawn applications should be made public as the Sponsor should be given the opportunity to decide whether the non-approval recommendation from the Regulator is made public. For example, other international jurisdictions (like Australia and EU) have specific evaluation milestones, and if a negative recommendation is received after a particular milestone, irrespective of whether the Sponsor withdraws the application, the outcome becomes public. Alternatively, if a Sponsor withdraws the application prior to a specified milestone, the withdrawal/rejection is not made public. Therefore, in New Zealand, following receipt of a negative decision at a pre-defined milestone on the application, the Sponsor should have the opportunity to voluntarily withdraw the application (consistent with other jurisdictions), without having this included or made public on the Therapeutic Products Register. This is particularly important when the Regulator and Sponsor disagree on the Regulator's reasons for rejecting/not approving an application.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

GSK NZ requests further clarity be provided on the intent and requirement for 'approval-exempt' products as these sections in the Bill are unclear. GSK NZ recommends that the Regulator consider developing a list of approval-exempt products to avoid having to obtain an approval/licence for such products. Additionally, GSK NZ seeks clarity on whether the approval-exempt products are intended to be included in the proposed Therapeutic Products Register and what level of detail will be made publicly available.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

GSK NZ supports the introduction of a new tiered offence structure for offences.

GSK NZ agrees in principle with the greater enforcement powers proposed for the Regulator, which includes enforceable undertakings and injunctions; issuing infringement notices; and also tiered criminal offences. Although increasing the risk to all Sponsors of non-compliance, the purpose of these greater powers is to ultimately protect patients, and therefore are considered acceptable subject to confirmation of the Regulator's enforcement policy which will provide clarity on the scope of the enforcement powers.

These sections discuss the requirements for compliance with obligation and the penalties that apply to breaches. However, details are lacking on what Sponsor obligations in relation to pharmacovigilance are tied to the penalties outlined in ss116(1) and ss116(2).

Whilst GSK NZ agree that Sponsors should be accountable for complying with applicable obligations, we think it would be unreasonable if the entirety of the current New Zealand Guideline Part 8: Pharmacovigilance / applicable device regulations form part of the legislation.

For context, in Australia only the following pharmacovigilance requirements are legislative requirements:

- Reporting of ICSRs
- Reporting of SSIs
- Notification of the pharmacovigilance contact person
- Archiving of records.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

Both New Zealand and Australia lag behind with 5 years of data exclusivity. There is opportunity to align with international jurisdictions, such as Canada (8 years) and the EU (8 years). Also, the current 5 year data exclusivity provision does not account for the lengthy period between product approval and reimbursement by PHARMAC and also does not preclude entry by a generic company using their own clinical data. Accordingly, GSK NZ submits that a longer period of data

exclusivity be considered to enhance support for launches of innovative medicines in New Zealand.

The Bill does not appear to allow for a 5 year data protection period for combination medicines (containing 1 or more active moieties) where 1 of the active moieties has previously been approved by the Regulator. GSK NZ requests that the Bill be revised to include a 2 year data protection extension for combination medicines. GSK NZ notes that there is a 1 year extension period in the EU if there is a significant indication change.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

GSK NZ agrees with the sections covering the scope, content, effect and granting of licences. This includes the new provision for clinical trials to be authorised via a licence. Please refer to GSK NZ's response to C16 pertaining to clinical trials for further comments.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Please refer to GSK NZ's response to C16 pertaining to clinical trials.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

GSK NZ supports the Regulator to 'perform monitoring' (s160), with respect to safety monitoring. It is noted that this would introduce the ability for Medsafe to conduct regulatory inspections. We do not object to the inclusion of this provision, however, we would propose taking the opportunity to review through industry consultation prior to implementation of such power.

GSK NZ notes that the Ministry of Health's consultation slide deck for the Information forum held on 11 February 2019 includes the following:

The Bill links to the Search and Surveillance Act 2012 to provide the Regulator with investigative powers. The Regulator would have the following powers of entry:

- entry and search without a warrant (for routine monitoring & where there are concerns of non-compliance)
- entry and search with a search warrant (including dwelling houses & Marae)
- the right to inspect therapeutic products being imported.

We understand that the TGA can do this in the situation of a 'for cause inspection', however this power seems a little excessive for 'routine monitoring', unless of course this means that access cannot be prevented, in which case the powers we believe are similar. Please can the Ministry of Health comment on this.

Overall, GSK NZ agrees in principle, however we recommend the Ministry of Health consult with Sponsors in relation to the specific requirements. Additionally, in keeping with international harmonisation, we request these requirements are fairly aligned to other comparable agency requirements.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

GSK NZ agrees with the proposal to have the Regulator's decisions in relation to product approvals, licences and permits reviewed through a merits review process instead of the current process of utilising an independent standing committee with set membership.

The proposal to appoint 3 people (including a lawyer) who have not previously been involved in the decision will allow for an independent and unbiased review which is welcomed. Additionally, appointing subject-matter experts, people with appropriate knowledge, skills and experience, for the reviewable decision, is critical in ensuring there is a fair and equitable review of decisions.

However, the proposed timeframe of 30 working days, in which the Sponsor/Applicant is required to submit their application with supporting data/justifications for review of the Regulator's decision, is not considered to be sufficient. Many Sponsors have global headquarters overseas preparing the data to support the review, and therefore consultation and agreement with overseas colleagues is required prior to submission of the application to the Regulator. Depending on the magnitude of the issue being reviewed, a 30 working day timeframe does not allow for the appropriate consultation to take place and prepare the application detailing the grounds for review. A more appropriate timeframe would be 60 working days (i.e. approximately 3 calendar months). This timeframe is aligned with other Regulators, such as the Australian TGA.

The Bill (s203) does not specify the review timeframes for convening the review panel or the review timeframe for the review panel to provide a decision. GSK NZ requests that a timeframe of 30 working days is included in the Bill for this activity. It is prudent for each party, Regulator or Sponsor, to be held accountable to meet their applicable timeframes, thus allowing for timely review of decisions. GSK NZ recommends specific timelines should be included in the Bill for both the Regulator and Sponsor/Applicant to ensure each party is held accountable to meeting their obligations in the process.

Additionally, we would expect that the initial decision is withheld (and not made public) until such time that the review panel provide a decision.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

The Bill (s207) states that the Regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. GSK NZ agrees with this proposal, which is both logical and efficient, and consistent with current practice for abbreviated submissions, as well as international regulatory practices (e.g. TGA). We suggest that applications that are submitted to the Regulator utilising evaluation reports from other recognised regulatory authorities could be accompanied by reduced evaluation time and fees to reflect efficiencies in doing so. Additionally, the scope of the application types could include not only new chemical/biological entities, but also new indications, line extensions, and other major updates. The types of applications that are eligible could be clearly defined in the Regulations to avoid uncertainty and confusion. If the evaluation timeframes were transparent to the Sponsor, with predictable milestones at specified timeframes this would allow for greater predictability in overall approval timeframes. Clear and transparent timelines are paramount in being able to monitor progress, which currently is not addressed in the regulatory system. GSK NZ recommends maximum evaluation timeframes for each different application type be stipulated in the Regulations.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

GSK NZ supports the introduction of provisions relating to enforceable undertakings and the court's power to grant injunctions. This is an appropriate enforcement tool which has been successfully adopted by other regulators to address alleged contraventions, rather than regulators having to devote substantial resources in seeking remedies and declarations from the courts.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

The proposed penalty amounts in the Bill are at the higher range compared to other similar legislation. GSK NZ is supportive of increasing penalties compared to the Medicines Act 1981 which were low. However, GSK NZ seeks that the Ministry of Health considers the penalties in light of comparable legislative regimes in New Zealand.

The definition of "caused harm or a risk of harm" in ss237(3), includes conduct that indirectly "causes harm". This is a low threshold for paying the Regulator's expenses. GSK NZ requests that this be qualified – in a similar way as the term is qualified in ss237(3)(ii), (iii) and (iv) which are given the word(s) "significant(ly)". We suggest wording such as "causes material harm" or "causes harm that is not insignificant" would be more reasonable in the context.

GSK NZ also queries the automatic attribution of liability from the company to senior managers (definition has previously been mentioned). GSK NZ notes that there is a defence of reasonable steps and lack of knowledge. However, this reverse onus of proof may be difficult to discharge for a senior manager in the circumstances. GSK NZ submits that it would be more reasonable to attribute liability to senior managers who are knowingly involved in the contravention.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

GSK NZ supports a cost recovery model for fees and charges (reviewable every 3 years) under the new regulatory scheme. However, in return greater transparency and predictability in evaluation timelines is requested. It is noted that the Bill refers to targeted timeframes which is regrettably unchanged from the current system. Timely availability of medicines is a key principle of the Bill, and we therefore request that the Regulator be held accountable to deliver on evaluations and report on their performance in a timely manner. GSK NZ recommends maximum evaluation timeframes for each different application type be stipulated in the Regulations to provide more certainty.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

GSK NZ agrees with the list of decisions reviewable by the Applicant, Sponsor, Licensee or permit holder, which are listed in Schedule 2 of the Bill.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

GSK NZ acknowledges that the contents of the Bill are at a high level and is grateful that the Regulator has held information sessions to allow exchange of information between the Regulator, Sponsors and various impacted sectors. It is understood that the accompanying Regulations will contain the necessary granularity for implementation. GSK NZ therefore requests that Sponsors and other stakeholders are consulted for the other subordinate legislative instruments (i.e. Regulations) which will contain the operational implementation details of the Bill.

GSK NZ notes that the Bill does not specify any particular provisions for managing medicine shortages and seeks clarity on how the Regulator intends to manage supply shortages in New Zealand. Particularly in the context of New Zealand being a tender driven market where often a single Sponsor is the sole supplier of the particular medicine.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Please refer to GSK NZ's response to B13 pertaining to major changes to products resulting in new products.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

GSK NZ agrees in principle to the new numbered medicine classification system (i.e. 1, 2, 3 and 4) to replace the current system of naming the medicine classification. However, it is noted that it is the inverse of the Australian TGA medicine classification system, and therefore in the spirit of harmonisation, and in keeping with the numbered medical device classification, where lower risk medicines/devices commence from number 1, 2 etc, GSK NZ recommends the numbered categories are reversed as follows:

- Category 1 (general-sale)
- Category 2 (pharmacy)
- Category 3 (pharmacist)
- Category 4 (prescription)

GSK NZ notes that the consultation documents lack detail on whether this category would now be required to be included on the medicine packaging. The

Ministry of Health did however confirm at the Medicines forum held on 18 March 2019, that the medicine category would not be required on the packaging. GSK NZ requests that the labelling requirements remain unchanged and the medicine category continue not to be required on the packaging. Its inclusion on the packaging would make it prohibitive for Sponsors to continue with the current practice of supplying shared AU/NZ medicine packs in New Zealand.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

GSK NZ supports the transitional provisions for licences and product approvals. However, GSK NZ seeks assurance from the Regulator that they will be able to manage and process the influx of new applications/licences received from Sponsors (for products newly regulated under the scheme) and continue to process in a timely and efficient manner the routine 'business as usual' applications without any severe impact to the Sponsor or New Zealand health consumer.

It would be an unfortunate negative outcome if the proposed changes to the regulatory scheme result in unexpected or unnecessary delays in the availability of medicines to New Zealand health consumers. Additionally, it is optimal to all parties concerned that Sponsors are given sufficient time and education to operate within the new regulatory scheme.

Question C4 - Please provide any comments on the approach to post-market controls.:

GSK NZ agrees in principle that Sponsors have obligations in relation to post-market monitoring, reporting and risk management for their products, however requests that Sponsors are further consulted in developing the specific requirements which will form part of the Regulations. Currently, the Bill lacks detail on the requirements that would be enforced in relation to risk management, and it is hoped that a pragmatic approach be taken in implementing this in New Zealand. For example, the addition of requirements such as PBRER and RMP reporting perhaps should only be considered for higher risk prescription medicines as opposed to all registered prescription medicines

GSK NZ requests clarification on whether the Sponsor contact for dealing with pharmacovigilance matters and reporting to Medsafe will be required to be a New Zealand resident under the new regulatory scheme. Currently, this person can be based overseas provided they are contactable during New Zealand business hours, and GSK NZ is in favour of retaining this, as many Sponsors manage their pharmacovigilance activities from Australia for both countries (Australia and New Zealand).

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Please refer to GSK NZ's response to B2.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

GSK NZ supports the regulation of medical devices under the new regulatory scheme comprising both pre- and post- market controls across the lifecycle of the device. GSK NZ acknowledges that the current regulation of medical devices is not well developed in New Zealand. We propose that changes should be aligned to international medical device requirements to harmonise the requirements in New Zealand to those required in the EU and Australia. This is particularly important in the context of companies supplying shared AU/NZ medical device packs in New Zealand.

Furthermore, GSK NZ supports the implementation of a globally harmonised unique device identifier (IUD) for selected (high risk medical) devices to enhance their traceability and identification in the supply chain. However, GSK NZ does not support IUD for lower risk medical devices (i.e. Class 1) considering there is low potential for these to cause harm. A risk-based approach should be taken in implementing IUD across medical devices.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

GSK NZ supports the ability to have one licence to cover a range of activities involved in the running of a clinical trial. However, further detail surrounding the licencing arrangements is important, so as to help understand impact on the clinical trials environment. For example, it was unclear whether the Sponsor of the trial, or the investigator, are expected to seek the licence, and what is planned for the licence term. GSK NZ seek clarity on whether it is intended that the licence be issued per study, or if it would be granted for a specified period (e.g. 2 years) and therefore cover all clinical trials conducted in that period. We feel that a licence duration of 2 years would be too short as many studies take much longer, especially when they are endpoint driven and it can take some years to achieve certain endpoints. The need for regular licence renewals/extensions across multiple clinical trials may introduce a level of complexity that adds an unacceptable burden on investigators and Sponsors, especially in circumstances where resource is already limited. It would be preferable to have a licensing arrangement that covers Sponsors/investigators for all trials conducted in, say, a five-year period, requiring a single periodic renewal.

Licence cost is also an important consideration, especially if it is intended that licences are issued on a trial-by-trial basis and require frequent renewal – Sponsors may hold numerous licences for numerous trials, all requiring regular renewal, with an associated cost. This approach may be considered too costly for Sponsors to consider conducting trials in New Zealand. GSK NZ's preference is to contain licences to individual Sponsors/investigators and have them remain valid for a longer period.

Although reassurance was provided at the Ministry of Health's Information forum that the Regulator will maintain the efficiencies seen in the current clinical trial approval process, concerns remain that licences will not be issued until ethics approval is granted. This could mean an extension to the existing start-up timelines for New Zealand sites. Rapid study start-up (including ethics approval) is of critical importance in clinical trials. As Sponsors continue to look for execution strategies that mitigate the risk of overshooting planned timelines, introducing a licensing scheme that is insensitive to efficient study approval, may have a net effect of fewer studies allocated to New Zealand sites. Thus, the introduction of a novel licensing scheme should be pragmatic and give due consideration to approval timings, ensuring the length of the approval process is not inadvertently (or intentionally) extended beyond the current timeframe.

In terms of the importation of Investigational Medicinal Product (IMP), it was unclear if this activity was covered by the licence, approved as part of each trial approval or regulated separately. Relating to start-up timings, it is imperative that new processes such as licence applications, do not add delays to the import of clinical trial material, and it is vital that Sponsors/Investigators are able to confidently maintain IMP supply to study volunteers throughout the duration of a trial.

GSK NZ did not find any reference in the Bill to provisions for the export of samples or tissues derived from clinical trial participants. GSK NZ recommends that sensible, practical provisions should be implemented here, such as considering the trial approval as a permit to export.

Finally, it is noted that the Regulator has the power to monitor trials and audit clinical trial sites. There is little detail on this process in the Bill or consultation paper. This is currently being proposed by the TGA under consultation. A major concern is how outcomes of such activity is reported to ensure that data quality reputation in Australia (which is currently high) remains intact. The same considerations apply to New Zealand which also has a high data quality reputation.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

GSK NZ supports the modified process for accessing unapproved therapeutic goods via a Special Clinical Needs Supply Authority (SCNSA).

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

GSK NZ is supportive of continued government and industry regulation around DTCA which includes disease awareness campaigns for prescription medicines.

GSK NZ believes the benefits for consumers of Direct To Consumer Advertising (DTCA) and disease awareness campaigns far outweigh the alleged negatives. For nearly 40 years – since the Medicines Act 1981 – New Zealand has been participating in DTCA of prescribed medicines. During this time, advertising communications have been highly-regulated to ensure that mis-information is not communicated through DTCA. Accountability measures such as regulatory approval via the Therapeutic Advertising Pre-vetting System (TAPs), government, and Medsafe ensure that patients are provided with factual and clear communication.

GSK NZ recognise that the purpose of the proposed legislation is to ‘... protect personal and community health’, and believe that DTCA further enhances this purpose. Regulated DTCA of prescription medicines helps build health awareness amongst consumers and allows them to take a proactive role in the management of their health. Further, patients often feel better about medicines when they have initiated the discussion and are involved in the process.

Given that healthcare professionals (HCP’s) are increasingly concerned about time savings during daily consultations, increased awareness and understanding from the patient is important during patients’ visit to their HCP. DTCA allows for the patients to have a more-informed, productive conversation that could result in a more valuable consultation and quicker understanding from the patient.

Importantly, DTCA from an immunisation and public health perspective can be a valuable vehicle to educate the public regarding the National Immunisation Schedule, facilitate public health responses to current or emerging threats (e.g. pertussis, influenza, meningococcal disease) and to direct patients to appropriate sources that have greater capacity to deliver educational content, including complete risk-benefit information.

DTCA of prescription medicines comprises only a small percentage of advertising. Considering the abundance of unregulated information on the internet readily available to patients, banning the regulated and controlled DTCA of prescription medicines will not result in any time saved for doctors during consultations – saving time appears to be one of the main reasons for vocal doctors’ call to ban DTCA. As mentioned above, continuing DTCA done responsibly not only reinforces patients’ rights to find out about treatment options, but also enables them to readily access that information and take a more proactive approach in their health - all with the professional guidance of their HCP.

C10 Advertising sector

Question C52

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reinforces patients' rights to find out about treatment options, but also enables them to readily access that information and take a more proactive approach in their health - all with the professional guidance of their HCP.

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Leonie Lander

What is your email address?

Email:

What is your organisation?

Organisation:

Athena Marketing Research

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

Market Research Professional

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Submission

Therapeutic Products Consultation

Prepared by Leonie Lander
Director
Athena Marketing Research

18 April 2019

1. Introduction

Leonie Lander
Director
Athena Marketing Research

My credentials to make a submission

The discussion which follows is based on my experience working with consumers in the health sector over four decades.

I graduated with a BA in Psychology from the University of Auckland in 1974 and have been involved in the market research industry since then. I established my Athena Marketing Research consultancy in 1996.

I have conducted both qualitative and quantitative research in the health sector in order to understand how consumers make their health decisions and the role of advertising in those decisions. My client list has included:

- organisations within the health sector
 - o The Nutrition Foundation
 - o Heart Foundation
 - o Cancer Society of NZ (Sun Safe, Development of Quitline)
- pharmaceutical companies (prescription and OTC brands)
- advertising agencies with pharmaceutical clients

I have also been involved in studies with GP's and specialists about how they react to marketing and advertising to medical professionals as well as to consumers.

I received a Gold Award from Market Research NZ for developing an understanding of Direct to Consumer Advertising for Therapeutic Medications, including the use of a masthead communal magazine styles such as the Family Health Diary TV, Print and Website media.

My professional career includes;

- A member of the Advisory Board Manukau Business School for 15 years and as a guest lecturer there in advertising and qualitative research.
- A guest lecturer in Qualitative Research at Auckland University and at Massey University for consumer response to packaging
- Specific conference presentations included
 - o A presentation to a Nutrition conference on youth nutrition
 - o A Medical School professional development lecture on the impact of consumer advertising for a course for nurse practitioners and for GP's.
 - o A presentation on the 'Qualitative Aspect of Patient Care' at the February 2017 Conference of 'Optimising Patient Experience Through Digital Innovation' attended by DHB's, Medical professionals and Health NGO's

2. In summary

This document addresses C53 in the Consultation Document for the proposed Therapeutic Products Regulatory Scheme 2019:

C53: "Do you have a view on whether direct to consumer advertising of prescription medicines should be continued to be permitted? What are your reasons for your view?"

I believe that New Zealanders have the right to be active participants in the health decisions which affect them, their family and their community and this is only possible when they have unfettered access to relevant information.

I am supportive of direct to consumer advertising of prescription medicines (DTCA) in New Zealand. The current regulatory environment allows advertisements to be pre-vetted, monitored and removed should there be any concerns re the accuracy of the information. It has proved to be both practical and cost-effective to date. I believe the current status should be protected as it provides an appropriate regulatory environment and one which encourages compliance.

The experience of DTC advertising of prescription medicines over more than a decade demonstrates that it has provided valued information to consumers and has not been abused by marketers therefore there is no reason to change the status quo by tightening access to DTCA of prescription medicine information, least of all in a retrograde manner. DTCA of prescription medicines have also been adopted by the Ministry of Health for state funded public health campaigns as well as used by Pharmaceutical companies, further indicating the perceived effectiveness of this channel among health consumers.

3. Consumers have a right to all relevant prescription medicine information

DTCA of prescription medicines should have the same requirements under Consumer Law as any other category or product. There should be no less access for consumers to information about prescription medicines than any other consumer purchase category, and in fact it can be argued that consumers facing a health condition should have even more right to any relevant information as they have the most to lose if information, and therefore their options, are limited.

Freedom of access to health information cannot be restricted in order to limit potential economic consequences. Trade-offs may need to be made by the community but those decisions should first be made in an environment in which all have access to the breadth of information available. A DTCA of a prescription

medicine is not intended to provide all that breadth of information but signals that it is one aspect of the breadth of information available and from where and whom it can be accessed in more detail. It can stimulate further enquiry.

The dissemination of health information should not be limited to those who have an agenda to focus on cost vs. a more holistic viewpoint. Health, from a consumer perspective, can be more emotive than that of a medical professional or Ministry viewpoint. For the individual it involves well-being and quality of existence, and even life or not life but less concerned about what cost-benefit to the community overall. While a funding model may compare the cost-benefit of treating different people and conditions, for the individual there is no such calculation. It is their one and only life and they want it in its entirety for as long as it is of value to them. At an individual level, they may be prepared to revise personal priorities, even trade quantity for quality of life, but a central funding model is unlikely to do so.

If a medical practitioner feels intimidated by a knowledgeable and active rather than passive client, they will need to reconsider their role and skills. With or without DTCA of prescription medicines, the Internet, books, TV documentaries, support groups and word of mouth will ensure that the population will continue to become more knowledgeable and active in managing their health. This assertiveness should be welcomed as an informed and motivated consumer will be more compliant and whatever treatment programme adopted will be more effective. This could overall lower costs rather than increase them.

4. Access to credible information channels

It is preferable that relevant prescription medicine information is provided within an environment which can be vetted and there is a process in which an advertisement and the product are judged to be credible. The greater risk within the internet dominant and peer to peer information channels which have emerged since the last review (2004) is that there is minimal oversight of how and where internet advertised products are presented, hence the potential impact of 'fake news and opinion'.

Further restricting a controlled channel which has allowed New Zealand health consumers access to information about medications, treatment options and even state funded health promotions could prove to be counter-productive. It is preferable that there are credible sources of the information they seek. All DTCA of prescription medicines are subject to consumer law as to accuracy of information and requirements specific to this category.

The proposed 2019 Regulatory Scheme provides standards for those products advertising within an environment which can be monitored and prosecuted within New Zealand jurisdiction. Marketers, advertisers and consumers are familiar with the platform and have developed trust in it. The challenge in the internet age is that much of the therapeutic medicine information is circulating globally where different rules apply, is fluid and once circulating is difficult to close-down, and least of all facilitate prosecution of offenders.

5. Personal vs. Community funding or prescription medicines

Currently access to medications and the funding of them is as much a political and economic issue as one related to any personal therapeutic health benefits and the ability of New Zealanders to access from a range of appropriate treatments.

New Zealanders need to be able to decide their priorities for access to medications personally, for their family and for their community. They need timely and appropriate information and advice to make those decisions. If a medication is not fully funded for the wider community, they should at least be aware of their options and to choose private funding of a medication if it is a preferable option for them. The fact that not all in the community can afford a non-fully funded medication should not limit at least access to information about the prescription medication.

Currently consumer access to a relevant treatment can be limited because the consumer does not know that what they are experiencing could be treated and/or, if they are currently receiving treatment, that another treatment option is available which may be more relevant to them. DTCA of prescription medicines can at least create awareness and vocabulary with which to start a dialogue with a health professional.

An information model in which a consumer can only access product or brand information through their registered health professional can limit their health choices. They 'do not know what they don't know' or, even if they are currently receiving treatment, may be conditioned to believe that what they are currently prescribed is the best available for them. They would be dependent on their GP to actively elicit their current health concerns from some systematic check-list (Warrant of Fitness style), inform them of the current options available and help them choose the appropriate level of treatment for them. In a typical 10 – 15 minute appointment, there is little opportunity for a health professional to educate a patient and provide detailed options to choose from. The result is that education about health and treatment options is increasingly from an online portal when the patient returns home, if they have not already searched on their symptoms before visiting a professional.

While some GPs are proactive and may review their clients holistically on a regular basis, most appointments are for acute visits or the treatment of an established chronic condition, with little opportunity to uncover or discuss other issues. Discussion of health in its broadest sense, which includes both quality and quantity of life issues, can be sacrificed for the immediate medical need.

6. Health information is no longer the sole domain of the familiar family doctor

Building up a rapport and knowledge base about their health can be further compromised by the increase of accessing after hours and group practices in which the patient may not develop a trusting relationship with a specific health professional who knows them well. Prescribing by nurse practitioners and pharmacists can also impact on the range of information given by health professionals consulted.

The current high levels of common diseases such as heart disease, asthma and diabetes and sub-optimum compliance amongst even regular visitors to GPs would suggest that reliance on the GP to initiate discussion of a potential condition and maximise treatment options is not occurring routinely. Many conditions go

un-treated or under-treated with disastrous consequences for the individual and the community. Better informed individuals are empowered to seek appropriate advice and treatment and allows them to revisit information and share it with family as need be which can increase understanding and effectiveness.

7. DTCA of prescribed medications can facilitate conversation with a health professional

Viewed from the consumer perspective, when a consumer mentions a specific medication they have seen or heard in DTCA of prescription medicines it can act as a shortcut to start the dialogue. Most health consumers are not familiar with medical terminology or anatomy and do not want to embarrass themselves by using the wrong terms or mispronunciation of them. To start the conversation with a brand name of a medication may be their easy and safer opening line which a competent medical practitioner can then use as a qualitative tool to discover the reason for that request and then discuss relevant options with them.

There can be a conflict of interest between a health provider environment which is charged with limiting the cost of treatment and the escalation of health services on the national economy, and the priorities of their clients who want to be able to enjoy the health benefits appropriate medications and treatment could provide them. A medical professional charged on the one hand with controlling prescribing and treatment costs is less likely to initiate a discussion with a client about treatment options which are likely to counter those objectives. While the medical profession may see medical conditions in terms of the cost benefit to the country and within their practice, clients are reacting at a personal level. They want to believe they have the access to the best health options available for them and their family.

Currently the amount of information provided by a health professional about therapeutic treatment options offered to a client can be limited with little discussion of treatment or medication options, little more than dispensing information provided to refer to at home and little or no warning of side-effects or contra-indications to watch for. Even prescription information may be phrased in such a way that it is not well understood. Information from the manufacturer may provide little accessible relevant information, and then hidden within micro-small print and written in legalese and scientific and medical terminology, unfamiliar to many patients.

The role of many of the DTCA prescription medication campaigns aim to demystify, provide an introductory language and common terms of reference to be used in a subsequent professional consultation.

8. The future medical environment

Like most Western countries, New Zealand is faced with an ageing population and one which is expected to live longer than any generation previously. The demand for health services is increasing faster than the ability for governments to fund it, so prescription medicines, surgery and other treatments are being funded by individuals through their 'discretionary' spend. They may be prepared to forego the new car, overseas holiday or downsize their home for a medication which will allow them to continue to take part in their chosen life-style, employment or extend their life expectancy. These may be regarded by the Ministry as 'life-style' or 'quality of life' health choices but from the consumer perspective it is about their quality or quantity of life and allows them to make a valid choice about the importance of their health vs. other options for their or community expenditure.

The decline in the birth rate requires that the 'baby boomer' population will need to work until their late 60's or 70's. Many so called 'life-style' conditions which may not impact significantly on mortality rates will impact on the quality of life of this cohort in the years ahead. Conditions such as arthritis and incontinence may be conveniently considered to be the normal diseases of ageing, but they can severely impact on employment and quality of life. It is highly unlikely that those suffering from many under-treated health conditions will be able to maintain optimal levels of employment or quality of life. If some of these quality of life diseases go under-treated they can also impact on quantity of life if the result is that consumers become house-bound, are reluctant to exercise or eat inappropriately because of compounding health issues.

If health consumers are having to pay or co-pay for their health needs and make trade-offs as to their relative importance vs other demands on their finances, it is only fair that they have access to all information relevant to their decision making.

At the other end of the age spectrum, youth are internet savvy and turn to it and their peers for information and advice, albeit not from the traditional medical perspective. They are open to alternative options and followers of perceived opinion leaders. There is little ability to curtail these online health platforms so it is critical that there is also a visible and relevant health communication for them where and when they feel the need to access it. The rising level of mental health issues and youth suicide (as well as among other age groups) requires their heightened awareness of relevant and available therapeutic options and an easy vocabulary by which to start the dialogue with health professionals.

The rise of Internet communities, Blogs, Opinion Leaders and such will mean that those with an interest or a need will continue to seek information about health conditions, products or brands, whether advertised through traditional media or a health professional or not. It may be possible to control and make accountable the mainstream media, but viral media will prove much more difficult. It is already providing a medium for 'fake-news' with negative impacts on, e.g. immunisation rates, water fluoridation and uptake of unsubstantiated natural health claims. With much of internet advertising, peer communications and website management emanating from off-shore, it is difficult to eliminate non regulated information, therefore it is important that credible local health information relevant to the New Zealand context can reach its target audience in a timely manner.

DTCA of prescription medication also has a positive side. Within a short time of becoming aware of a health condition affecting themselves or their family many people are now online seeking more information and products or brands relevant to their needs and treatment. Some GPs will tell of clients arriving with pages from Internet sites already printed out or describing and advertisement they have seen resulting in a more informed discussion around treatment options and a more motivated and compliant client.

The Internet is now the first step for some consumers the 'health professional' they consult most often. This resource is likely to increase exponentially. Having a DTCA prescription medication protocol which can help consumers navigate their health options from vetted information about locally available products can help counter potential misinformation and should be embraced.

The sheer number of health-related websites means prohibiting access related to proprietary medications is not feasible. Suppression of information from the

Internet is associated with the most repressive political regimes. It is not an option for New Zealand.

9. Health consumers share their experiences

Relevance of DTCA of prescription medicines can be shown to increase with age and experience of health issues themselves and/or among family and friends.

Interest in health advertising increases as consumers experience more health challenges, either themselves or among those close to them. Few have reached their middle years unscathed by a serious illness or death by someone close to them. Health advertising is less often of interest to the young when their level of health is higher.

Consumers respond to health advertising depending on their degree of interest in a particular subject which will vary by their age group, gender, life-stage or situation when it is most relevant. That it is not of interest to all or to even a majority in some cases does not mean that it is not highly relevant to those with some direct or indirect need at a particular point in time. Once there is a need the demand for information is strong and better accessed through a credible and responsible platform than be found in the deepest pages of the internet.

Many individuals play a health information facilitator role within their family and community. Health information is conductive. It is passed from one to another, with most health education happening informally. Individuals are aware of the health concerns of their immediate family, neighbours, workmates and it is normal for people to discuss health conditions and treatment options. DTCA of prescription medicines, and the topics and brands covered by it, are discussed within a wider community than is possible to achieve in a one to one relationship with a health provider. The power of DTCA of prescription medicine and health category advertising is that information is blended with personal experience (direct or indirect) and therefore becomes more relevant and memorable. It helps to de-mystify health conditions, brings them into the open and in doing so can facilitate an individual seeking help.

With current privacy laws it is difficult for a family member to find out or influence the doctor-patient relationship, but they may still be impacted by the treatment offered, or not even made available. At least if the extended circle is more aware of medical conditions and treatment options then they are more able to discuss options and ensure appropriate care for those in their circle. Again, this will be increasingly important in the future to the ageing population and their carers as senior health care and those with chronic conditions will be managed in the community and among family as hospital and rest-home facilities will be under pressure.

The rise of support groups and specific societies related to health conditions is also an indication of how those with a similar need congregate with others who can support them in their quest for information and solutions. Again, the dissemination of their information can include 'viral' strands and not limited by any laws related to DTCA of prescription medicine.

10. Is DTCA of prescription medicine a help or a hindrance?

The fact that an advertisement is branded does not diminish interest over a generic discussion of a condition. Consumers know that someone is 'paying for the advertisement' and understand that there is still a medical practitioner acting as gate-keeper to prescription medicines and who can recommend what course of action, if any, is required.

The majority of New Zealanders see their primary health professional at least annually, and with advancing years the frequency of doing so increases as does the likelihood of having a medical condition which requires a prescription up-date. Given the current frequency of going to a GP, and that unless they have a Community Services Card, most of the cost of a visit and prescription is still met by the consumer, it is more likely that consumers would wait to discuss a non acute condition at their next visit. The implication of this is that the increased cost of GP visits as a result of a specific DTC campaign is likely to be low. A decision should not be made that DTC should be restricted in case it resulted in over-loaded surgeries. In fact, a case can be made that DTC advertising may get at risk groups into a surgery who may not have gone otherwise. Once they are there the GP can check blood-pressure, weight, heart lungs, diabetes profile and so on and the visit may then have uncovered a significant health issue in a timely manner.

If health professionals are more concerned about 'aggressive patients' demanding specific DTC advertised brands and feel unable to resist such pressures they should take appropriate re-training as they would also be at risk of being susceptible to 'aggressive patient' demands for such things as sickness benefits or prescription drugs.

11. Conclusion

DTCA of prescription medicine cannot create a health condition, but it can help reduce the inertia surrounding seeking a solution and enables the health consumer to become more active and motivated.

A DTCA for a prescription medicine is only a signal that more information is available and from whom or where it can be sourced. An advertisement cannot be the definitive detailed document but can facilitate dialogue. Discussion of the health condition and treatment options can contribute to compliance and effectiveness. Optimum health outcomes arise when the patient (consumer) and health professional collaborate on gaining knowledge, experience and understand the motivations for and barriers to a successful outcome. Partnership and an open dialogue are key for both parties.

The health consumer of a DTCA for a prescription medicine is still reliant on the opinion of the health professional they consult who determines the type and brand of the prescription medication, if any.

If DTCA of prescription medicine is closed off as a source of information to NZ health consumers, but one which has proved it can be controlled, monitored, and penalised if relevant, it is likely to be replaced by more 'viral' paths which cannot be.

DTCA of prescription medicine is just one of the strands empowering the patient to be active in managing and maximising their own health.

Response ID ANON-DPZ8-G48M-6

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:10:46

Submitter profile

What is your name?

Name:

Calvin Chen

What is your email address?

Email:

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Dispensing - I don't totally agree with this defintion . I believe the current meaning is better.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

It should be ok for pharmacies to transfer medicines between each other . It helps with patients being able to get their medications.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Ok in emergencies and small quantities.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

All dispensing should be from a pharmacy.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

In emergencies

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Agree

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Pharmacist owned businesses will provide better health outcomes for their community vs profit focused multi-nationals that don't care .

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

A few years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Yes

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
Ok between pharmacies or health professionals on occasions

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No . Need an independent check.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No . Practitioners are in a room and can't see what is happening .

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Response ID ANON-DPZ8-G4ZQ-C

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:15:12

Submitter profile

What is your name?

Name:
Charlie Stratton

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Bay of Plenty DHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Clinical Trials Unit

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Not Answered

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

The process for granting licences needs to ensure that no additional burden is added for those clinicians acting as co-ordinating investigators on multicentre clinical trials. Many trials are run through public institutions and clinicians are taking on duties related to trials in addition to their primary standard of care responsibilities.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

The suggested term of 3 years would be to short for many clinical trials, which can often run for in advance of 5 years. A requirement for re-application after 3 years would add unnecessary work. Consideration should be given to allowing licences to run for the planned duration of a trial.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Ensuring an efficient approval system will be important as the current approval process for trials is one of New Zealand's strengths when it comes to securing access to international multi-centre trials.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

If a clinical trial has already been approved under current process, is there sufficient justification for re-approval of the trial under the circumstances described in the draft consultation document?

Response ID ANON-DPZ8-G4D7-V

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 16:18:56

Submitter profile

What is your name?

Name:

Ian Napier

What is your email address?

Email:

What is your organisation?

Organisation:

Merck Sharp & Dohme (Australia) Pty Limited

Submitter Profile (tick all that apply)

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

MSD supports the purpose and principles of the draft Bill. MSD agrees that the regulation of therapeutic products should be risk-proportionate and the administration of the Bill/Act should be open and transparent and that it should be aligned to international standards and practice.

MSD considers the intention for risk-proportionate regulation (ss4(b)(i)) for different kinds of products and activities to be tailored to align with their risk-profiles appropriate.

MSD supports the intention of having flexible product approval pathways which are tailored to the risk profile of the product and the inclusion of conditional approvals. The inclusion of provisions for co-operation with overseas regulators will provide an enhanced framework for pre- and post-market review and monitoring.

MSD agrees that the draft Bill will in principle ensure the timely availability (ss4(b)(ii)) of therapeutic products in New Zealand. However, MSD consider it appropriate to include legislated timeframes (maximum) for evaluation/decision with regards to a marketing application in agreement with the TGA. Having mandated timelines will ensure both the regulator and sponsors are held accountable to ensuring timely availability of therapeutic products.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

As outlined below, the definition of compounding, dispensing, manufacturing, administering, and, supply, are somewhat confusing and could be refined.

Compounding; is to produce a permitted quantity of a medicine for a patient (ss28). Compounding is manufacturing (ss32).

Dispensing; is to bring a medicine to a state ready for supply (ss29). Dispensing is manufacturing (ss32).

But, preparing for immediate administration and preparing for administration according to manufacturer's product information is not manufacturing, it is administration (ss26).

Administering is a supply chain (controlled) activity ss 44(1)(iii) and requires a licence.

Supply is to supply the therapeutic product to another person (but is not administering) (ss42).

MSD considers that any definition of compounding/ dispensing must be worded such that preparing for administration as outlined in ss 26 is not taken to be compounding and therefore cannot be used as a vehicle to producing unapproved therapeutic goods for commercial gains.

MSD considers it appropriate that the definition of a clinical trial (ss27) should follow international definition (e.g. WHO).

MSD are concerned that the definition of persons who are importers (ss30) may be too broad and that such a definition could unfairly pass liability to a much wider range of persons involved in the supply chain than anticipated.

MSD does not consider it appropriate for a pharmacy licence to permit wholesale activity. If a pharmacy is permitted to supply by wholesale, MSD strongly recommend that the pharmacy must meet the requirements of a wholesaler as per Part 4 of the New Zealand Code of GMP, Wholesaling of Medicines and Medical Devices, and that a separate wholesale licence/permit is obtained for such an activity.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

MSD supports the need for product approval, approval exemption, or alternate authorisation to import or supply a medicine, medical device or type-4 product as outlined in the draft Bill (ss51) and further supports the provision to prohibit parallel importation (ss52).

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

MSD agrees in principle to the provisions within the Bill to regulate supply chain activities, but, would need to review the subordinate legislation to determine whether the proposed regulatory framework was appropriate.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

MSD agrees with the aims of the Bill to prevent parallel importation and ensure therapeutic goods imported/ supplied in New Zealand constitute approved or approval exempt products. MSD also accept that situations will arise wherein patients or carers will need to import for personal use and that the Bill provides provisions to enable this without compromising patient safety.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

The draft Bill does not explicitly detail how product approvals will be managed with respect to 'major' product changes which result in 'new' therapeutic products, therefore the need for and management of 'unapproved' product stock in the supply chain through 'use of current stock' notices is unclear. It is assumed that the 'use of current stock' notice would allow continued supply of pre-change stock but whether this has any impact to other regulatory activities and where in the supply chain this would be effective is unknown.

MSD agrees in principle to the inclusion of ss79, regulations may grant authorisations.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

In the context of advertising, MSD consider it appropriate to include a definition of 'promotion' such that it can be clearly differentiated from 'education'.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

According to ss31(3), the responsible manufacturer of a therapeutic product is the person who is in fact primarily responsible for the manufacture of the product.

This could be interpreted in a number of different ways, as, for many large multi-national Sponsors, the manufacture of any given product involves a multitude of manufacturing sites performing discrete, defined steps. MSD would interpret the responsible manufacturer to be the site primarily responsible for product release as defined in subpart (4)(b):

(4) In determining who is the responsible manufacturer of a medicine or an AMI, the following are relevant considerations: (a) who transforms the starting materials into the final product: (b) who is responsible for overall quality assurance and quality control in relation to the manufacture of the product: (c) if the product is, or is intended to be, released into the supply chain, whose name or trade mark the product is, or is to be, supplied under.

However, in agreement with subpart (4)(c), the responsible manufacturer could also be the product Sponsor. It is unclear which is the most correct interpretation.

Furthermore, in subsection 97(c):

(c) if they are not the responsible manufacturer of the product, they have a contractual relationship with the responsible manufacturer that meets the criteria specified in the rules.

Therefore, compliance with subsection 97(c) would depend on the interpretation of subsection 31 and the definition of responsible manufacturer.

Generally, a Sponsor would hold contractual relationship with the parent company, which in turn, would hold contractual relationships with the manufacturers of the product. Hence, further clarification of the definition of responsible manufacturer would be required.

Also, whilst the sponsor will be responsible for post marketing safety activities, investigation of Quality Issues and involved in product recalls, the Sponsor cannot be held accountable for all activities in the supply chain once product has left their control. There is also responsibility that resides with the wholesalers, distributors, and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine.

Regarding ss100 – Major changes results in new product, MSD understands that the approach to major changes to products is to ensure that pre- and post-change product can be distinguished within the New Zealand market. However, MSD do not agree with the proposed requirement that "major changes result in a new product" (ss100), or the proposed process described in C1, paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued. It was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019, that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors. For example, PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We do not believe the practicality of the major changes processes has been considered in the Bill.

One solution would be to allow sponsors to nominate to replace the approval of the current product with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product. This type of approach is used by the TGA. For cases where an amount of the pre-change product is still present in the market, this could be regulated by a permit/licence/exemption, e.g. 'use of current stock' notice.

Alternatively, in cases where the sponsor did wish to continue to have both versions of the product approved, they could nominate to receive a new approval and TT50 number for the changed product.

MSD supports a two+ tiered system of notification of changes to approved products (ss100, 101) wherein minor changes could be notified to the regulator within set reporting timeframes (e.g. within 6 months, or as annual reports). However, MSD also consider it appropriate to allow for flexibility in reporting including notification for minor changes on an ad-hoc basis.

Regarding duration of product approval (ss103), MSD agrees that there should not be a defined expiry or limit on the duration of approval, particularly compared to the current scheme wherein a product which has not seen regulatory activity for the last 5 years is automatically considered a candidate for an 'approval lapsed' regulatory status. For exceptional circumstances, MSD envisages a duration of approval could be managed as a condition of approval if and when appropriate.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

MSD agrees that the regulator should have the right to impose conditions on approval where appropriate, and that the sponsor would have the opportunity to

comment.

MSD also agree that the regulator should have the right to cancel an approval based on the grounds in ss108, and that the Sponsor should have the opportunity to comment.

Regarding a therapeutic products register (ss113), MSD considers it appropriate that a regulator maintains a register containing the latest prescribing and consumer information for approved products and that this register be publicly accessible. MSD also support the notion that a database of all applications submitted to the regulator should be 'published' and available publicly. Such activities improve transparency and are aligned with similar practices internationally.

However, MSD do not agree that 'all' declined or withdrawn applications should be made public as the Sponsor should be given the opportunity to decide whether the outcome should become public. The proposed regulatory scheme does not include specific milestones akin the TGA Category 1 prescription medicines pathway wherein an application can be withdrawn prior to a decision by the regulator. Therefore in New Zealand, the Sponsor should have the opportunity to voluntarily withdraw an application without this being made public.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

MSD support the notion of approval exempt products, but seek further clarification of the practical implications, for example, who would be liable for product safety/quality? If the Crown is the sponsor, what mechanism would be required to trigger sponsorship by the Crown? Would approval exempt products be included on the proposed therapeutic products register?

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Please see response to B13.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

MSD do not support the continuation of 5 years of regulatory data protection for innovative medicines and instead seek to lengthen the period of data protection to align with international standards, e.g. 8 years for the EU and Canada. Maintenance of the 5 year data protection period is also inconsistent with the Agricultural Compounds and Veterinary Medicines Amendment Act 2016 which increased the data protection period from 5 to 10 years for innovative veterinary medicines.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

MSD agree in principle with the intent of the draft Bill with regards to licencing and permits. MSD would like clarification on the content of the licence and whether the list of therapeutic products covered by the licence will need to be updated for each new product? Will a 'major' product change require the licence to be updated? What would be the time/cost associated with updating a licence?

It is also unclear how the licencing of clinical trials will be managed and whether the maximum duration of licences for clinical trials will be appropriate.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

MSD supports the need to regulate clinical trial activities and agree in principle to the use of licences for that purpose. MSD do however have concerns that the efficiencies seen in the current clinical trial approval process, may be impacted by the need for a licence and the delay between the granting of Ethics approval and generation of a licence. MSD are concerned that this may impact on study start-up timelines and competitiveness to attract clinical trials globally.

Furthermore, for trials where it is deemed ethics committee approval is not required, it is unclear how this would impact on the need for a licence.

Concerning ss130, MSD consider the criteria of responsible persons to be at odds with the logistical operation of most multi-national sponsors. Currently, an overseas person can be listed on a licence as long as a New Zealand resident is also listed. MSD would expect this situation should continue as the commercial reality of the New Zealand market precludes a full complement of the functional responsibilities being physically present in New Zealand.

MSD would additionally recommend clarity in regard to compounding when used in clinical trial setting e.g. if a product is being compounded by a vendor that is contracted by a trial site (not sponsor) how does the license scheme work? Does the compounder fall under their own license obligations?

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Regarding licencing of clinical trials, MSD would recommend clarity to be provided on whether a Clinical Trial could include a prohibited product and would also need a licence.

MSD would recommend clarity to be provided on whether an update to the licence is required if the pharmacy and compounder changes for the clinical trial. If they specify persons and activities – if staff changes have is this updated or will it be a role at the facility?

MSD would recommend clarity to be provided on the requirements for import for Clinical trials from Australia – is there any exemption?

Subpart 3: Provisions applying to licences and permits (ss 136–151)**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

MSD agrees that a licencing system for clinical trials fits well within the principals of the draft Bill, we think further consideration is needed when legislating clinical trials under a licencing system. We agree with the move from granting 1-year licences to licences of up to 3 years. However, a 3-year licence is unlikely to be adequate given the protracted duration of many late-phase clinical trials.

MSD further seeks information on what changes will require a variation of a licence. For instance, for a clinical trial licence will a change in the pharmacy or compounder of the medicine require a licence variation? For all licences, would a staff change require a variation, or would the licence stipulate the job roles under the licence rather than a named person?

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B8 Part 6 of the Bill: Regulator**Subpart 1: Regulatory powers and functions(ss 160–182)****Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

Subpart 2: Investigative powers (ss 183–196)**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)**Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

MSD agrees in principal with the provision of a vehicle in which to have regulators decisions reviewed by an independent panel of subject-matter experts, convened as required. However, MSD are concerned that the proposed timeframe for submitting an application (30 days) is unduly short and request that this be extended to, for example, 60 working days. Likewise, the timeframe for convening the panel, and the time for the panel to reach a decision, should be legislated and be of a similar duration.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

MSD are not opposed to a cost-recovery model but do however believe that this would require greater transparency by the regulator of evaluation timeframes. Predictability of evaluation timeframes is currently missing from the Medicines Act as well as the draft Bill. MSD consider it imperative that evaluation timeframes be legislated to enable predictability and accountability by the regulator. Mechanisms to ensure that appropriate accountability measures are in place should feature in the revised legislation or subordinate legislation.

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Please see response to B13

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

MSD agrees with the approach for the categorisation of medicines, i.e. numbered categories. MSD does however request for the purposes of harmonisation between Australian and New Zealand territories that the numbering order be reversed.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

MSD supports the notion of a single licence to cover a range of activities involved in conducting a clinical trial. MSD seek clarification on the timeliness of regulatory/licence approval and ethics approval. MSD note that extended timeframes for either process will impact on the efficiencies for trial setup and execution, potentially limiting the number and type of trials conducted in New Zealand.

With reference to paragraph 415 of the consultation document: "The new scheme would take a risk-based approach to licensing so that greater scrutiny would be given to applications to trial novel products being used for the first time in humans and high-risk products..." MSD seek clarity on what additional/greater 'scrutiny' pertains to and how it is envisaged this would be implemented.

Regarding paragraph 419 of the consultation document and the creation of a publicly accessible register of licences for trials, MSD seek clarification on the details of the public data and whether such data adds to that over and above prominent clinical trials registers, e.g. clinicaltrials.gov.

Regarding the performance targets outlined in paragraph 420 of the consultation document, MSD seek details regarding the implications for these targets and what value these targets would have if not legislated.

MSD would recommend clarity to be provided on the details regarding the monitoring and auditing / inspection of clinical trials (paragraph 422). Operationally what documents are required from Site, Ethics Committee, Sponsor, CRO etc and what involvement in the audits and if limited to site or could be at other locations eg Ethics Committee, Sponsor, CRO. MSD would recommend the site notify the sponsor of the audit and findings which would impact the study and any corrective and preventative actions. MSD would recommend the findings to be kept anonymous and not publicly identifiable for the site, study and sponsor / CRO.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

MSD strongly supports the need to regulate personal and parallel importation to ensure all patients receive appropriate, safe, and efficacious medicines (or medical devices). MSD supports Special Clinical Needs Supply Authority provisions in the Bill, but ask that subordinate legislation clearly defines the roles and responsibilities of importers and suppliers with respect to liability, AE reporting, requirements for notifying a Sponsor, circumstances around wholesaling and stockpiling, and, measures to control bulk import by HCPs and other interested parties.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

MSD note that the draft version of the bill allows for the continuance of Direct to Consumer Advertising (DTCA). We are opposed to any alteration to the Bill to remove this based on the following view-point.

DTCA plays several important roles. It informs healthcare consumers of their options, increases awareness and knowledge of disease states and provides a reliable source of online information. There are several specific circumstances when these factors are particularly relevant:

1. Unfunded medications. The discussion of whether a consumer can afford an unfunded medication is acknowledged as an uncomfortable and time-consuming issue for many Doctors. DTCA is a valuable mechanism by which consumers become aware of unfunded options and can therefore pro-actively raise these during a consultation. In our experience, many HCPs support this aspect of DTCA as it enables the consultation to focus on whether the medication is a good choice for the patient rather than whether they can afford it.
2. Newly available treatments without an established treatment pathway (see Zostavax case-study below)
3. Therapeutic areas with a high degree of apathy (eg asthma control)

We believe that the recent inclusion of Zostavax on the National Immunisation Programme (NIP) provides a useful framework to enlarge on point two above. Zostavax was listed on the NIP for people aged 65-80 for two years, after which funding is restricted to a single age cohort of 65 years.

Adult vaccination is challenging because unlike childhood vaccinations, there are no established time points in primary care for the HCP to proactively discuss vaccination with the patient. Hence, without an active request by a consumer, patients are less likely to be offered their free vaccination.

Whilst the Ministry of Health and IMAC undertook a Health Care Professional education campaign on shingles vaccination, they did not engage in a public awareness campaign nor were Primary Care set any vaccination targets. In this context, DTCA encouraged patients to actively seek vaccination – without which, it is our view, that uptake would have been very low resulting in many patients missing the two-year funding window.

From a more general perspective, DTCA of prescription medicines is highly regulated and forms a credible, New Zealand specific source of information. In addition, much advertising focuses on a therapeutic area rather than a specific product, often because under Pharmac's RFP or Tender system, only one product is reimbursed within a category. In addition, direct product comparisons are banned under the MNZ code of practice, so consumers cannot be not 'sold' the benefits of one product versus another.

DTCA in New Zealand facilitates consumer access to factual and balanced information about therapeutic products. The advertisement development and review process ensures any promotional claims are accurate and substantiated, and in agreement with the medicine's regulatory approval. DTCA helps enable patients to have an informed discussion with their Doctor about the best treatment for them. In all cases, the Doctor retains the final decision.

MSD requests the opportunity for a verbal presentation.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

See response to C52

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G48V-F

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 16:31:41

Submitter profile

What is your name?

Name:

Jeanie Walls & Pasquale Gargiulo

What is your email address?

Email:

What is your organisation?

Organisation:

Pfizer New Zealand Pty Limited

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medical devices, Medicines, Active ingredients

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Pfizer supports the general design of the new Regulatory scheme for therapeutic products and understand the need for the bill to be less prescriptive than the current Medicines Act.

The support of Pfizer is contingent on a willingness by the Ministry of Health and Medsafe to engage in genuine consultation with the Pharmaceutical sector during the drafting and finalising of the regulations and rules.

All comments below should be read with the assumption that this expectation will be fulfilled.

Pfizer supports the purpose and principle of the bill as outlined in ss3 and ss4:

- The likely benefits of therapeutic products should outweigh the likely risks associated with them.
- Regulation of therapeutic products should-
- be proportionate to the risks posed by the products; and
- support the timely availability of therapeutic products.
- The administration of this Act should be carried on in an open and transparent manner.
- There should be co-operation with overseas Regulators, compliance with international obligations, and, if appropriate, alignment with international standards

and practice.

Pfizer also fully supports the timely availability of therapeutic products and open and transparent administration of the Act. Pfizer would welcome more predictable and transparent target Regulatory timelines and fair decision making whilst maintaining flexibility in overall Regulatory processes.

Pfizer supports the inclusion of a Type-4 product as a reserve term to future proof the legislation.

Risk-proportionate regulation is fully supported by Pfizer. Pfizer agrees that Regulatory requirements and pathways should be varied, flexible and tailored according to different classes of products according to risk.

Pfizer encourages the open and transparent reporting of standard Regulatory performance metrics.

Pfizer strongly encourages alignment with international standards and practices where ever possible particularly given the specific uniqueness of the New Zealand market i.e. small and often sole supply. Co-operation and work sharing with overseas Regulators whilst maintaining sovereignty is strongly supported by Pfizer including the expansion of the abbreviated approval process to extend past New Medicine Applications.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Pfizer does not support the use of the term Active Medicinal Ingredients, nor the abbreviation AMI. Pfizer requests the globally accepted term Active Pharmaceutical Ingredient and its abbreviation, API, be used.

Pfizer suggests the World Health Organization (WHO) definition for a clinical trial is used in the Act i.e. 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.'

Fit and proper person (ss47)

Pfizer requests clarification as to which grounds would lead to a belief that "person A" is likely in the future to contravene a provision of the ACT as set out in ss47(1)c. The current definition seems to allow for a person's future actions to be presumed by the new Regulatory authority and acted on. This is not possible with any sense of certainty.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Pfizer supports the inclusion of the requirement to gain Sponsors consent prior to the importation of approved product into NZ.

Pfizer supports section ss52 of the Act as a way to prevent parallel importation of medicines, medical devices or type 4 products into NZ.

In addition, Pfizer believes that this requirement should be extended to any product that has been submitted to the Regulator. It is usual for a new medicine application to take 12 months or more for approval. Once submitted to the Regulator, the sponsor assumes responsibility for that product in NZ. The wording suggested in the bill creates a loophole whereby a person can import, even after a sponsor has submitted an application to the authority. This loophole should be closed.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Pfizer supports the requirement for the issuing of a licence, permit and/or provision before controlled activities can take place.

This support is contingent on any issuing timeline and fee being proportional to the risk involved with the controlled activity.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Authorisations for pharmacists is outside of the business scope of Pfizer.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Authorisations for pharmacy workers is outside of the business scope of Pfizer.

Question B7 - Please provide any comments on the authorisations for health practitioners :

Pfizer supports the implementation of special clinical needs supply authority (SCNSA) route for allowing health practitioners to gain access to and administer

unapproved medicines to patients under their care.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (ss 65).:

Authorisations for health practitioners' staff is outside of the business scope of Pfizer.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Authorisations for veterinarians is outside of the business scope of Pfizer.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

The Ministry of Health is proposing a change to current practice that will protect consumers from counterfeited or adulterated medicines. Pfizer supports this change.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Pfizer supports the certainty that these authorisations will provide to the classification of a medicine.

Pfizer views the provisions under ss78 as an improvement on the existing system. Use of current stock notices will allow stock that is already in the supply chain but has been subsequently varied and hence is unapproved to continue to be on the market providing the product is not a risk to anyone. Will a ss78 use of current stock notice be a standard part of an issued approvals for varied products such as new manufacturing sites in order to use "in trade" stock from the previously approved manufacturer?

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Pfizer supports the continued permission of advertising of all medicines, with the exception of controlled drugs, to consumers (DTCA). DTCA is performed in a responsible manner by Pfizer. Pfizer ensures all advertisements are balanced and do not contain misleading information through both internal checks, via the Medical department, and external checks through the Therapeutic Advertising Pre-vetting Service (TAPS).

There are multiple benefits of DTCA, including:

- Increased health awareness.
- Patients encouraged to act on undiagnosed or poorly managed conditions.
- Patients feel better about medicines when they have initiated discussion and been involved in decision-making.
- Improved treatment adherence.

Pfizer believes that a strong Regulator with the powers envisaged in section 83, in combination with the powers in sections 166 and 167, will ensure the benefits derived from DTCA are achieved. A strong Regulator, in combination with the Therapeutic Advertising Pre-vetting Service (TAPS), will also enhance the confidence of the public and healthcare professionals that any advertising is accurate, fair, balanced and in the best interests of the New Zealand public.

It is important to note that any ban on DTCA would not include advertisements that originate on web-sites hosted on servers based overseas. Thus, any NZ ban on DTCA, would only be a ban on balanced, fair and truthful advertising. It would not ban mis-leading, reckless or false advertising that New Zealanders may be exposed to when searching for information on the internet.

DTCA is allowed by many countries, not just New Zealand and the USA. Canada and South Africa permit reminder ads – ads that let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims. Countries in the EU and some in Asia allow prescription vaccine ads including promotional claims. As well as vaccine ads, France allows ads for prescription quit smoking aids.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Pfizer supports the broad terms used in this section of the Bill. These sections are written expecting all details to be in the regulations and rules. Pfizer looks forward to genuine and comprehensive consultation with industry regarding the regulations and rules, as described in our first feedback comment.

Pfizer supports the use of overseas Regulators reports and assessments to allow for Regulatory efficiencies. We acknowledge the need for New Zealand to make its own decisions about products on its own market.

Pfizer supports the intention for minor changes to require notification only.

Pfizer does not support the intention that a product that has undergone a change that is major would become a new product. This would mean that a product would become a new product multiple times throughout its life cycle. We believe that a new product designation for all major changes adds Regulatory complexity without any benefit to the Regulator, the sponsor, the healthcare professional or the patient. For some major changes it makes sense for example an entirely new formulation or new dose form. For others for example a new population or new indication it makes more sense to adopt an approach closer to that of the TGAs where the changed product replaces the current product (see Therapeutic Goods Order no. 1).

Pfizer supports the clarification of responsibility for products on the New Zealand market. However, there needs to be a clear delineation of what responsibilities end when the product is no longer under the sponsors control. E.g. After delivery of a cold chain product to a retail pharmacy, the sponsor can no longer be responsible for cold chain storage because it is out of their control.

Pfizer agrees in principle to the circumstances whereby an approval would no longer be considered in force. However, Pfizer does not wish for a "renewal" system or a "lapse" system (as currently exists in NZ) if there is no activity within a period of time. Expiry dates on certain exemptions or licences may be appropriate for example labelling exemptions, GP licences etc in which case the duration of the approval would be assessed on a case by case basis.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Pfizer agrees the Regulator should have the ability to impose conditions on approval.

Depending on the conditions imposed it may not be possible to comply with a condition of an approval on and from the date the condition is imposed for example provision of results from a registry that is ongoing. It is agreed that should the Regulator wish to vary an approval by imposing, varying or removing a condition of approval, that the Regulator provides the sponsor the opportunity to comment.

Pfizer agrees the Regulator should have the ability to cancel approvals on the grounds for cancellation. It is imperative the Sponsor is provided the opportunity to comment prior to any issuance of a cancellation notice. Pfizer is concerned that the suspension (as opposed to cancellation) of approvals is no longer an avenue available to the Regulator. It is stated that the avenue to suspend has product approvals been removed to avoid legal uncertainty about the status of stock that is already in the supply chain and that for cancelled approvals that do not relate to safety that the Regulator could issue "Use of current stock" notices. It is not clear why "Use of current stock" notices could not be applied to suspended approvals as well. Pfizer believes the option of suspending an approval should be reinstated so that complex issues that may require extensive negotiation between the Regulator and sponsor can be conducted without the need to cancel the approval, whilst at the same time protecting public health. Pfizer notes the option to suspend a licence and / or permit still remains an option for the Regulator.

Pfizer supports an improved publicly available product register.

Pfizer supports certain information being made available to the public such as applications submitted to the Regulator and products approved however Pfizer does not agree that all information should be made publicly available. Specifically, withdrawn applications should not be made public unless the sponsor agrees to this.

The sponsor and Regulator may have very divergent views on the application/product and the sponsor should be given the opportunity to withdraw without public and /or competitor scrutiny.

Pfizer supports publicly available information held by the Regulator being easily accessible.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Pfizer agrees with the intent of approval – exempt products.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Pfizer supports the clarification of responsibility for products on the New Zealand market. However, Pfizer does not agree with the requirement that the sponsor is responsible for the product throughout the supply chain. There needs to be a clear delineation of what responsibilities end when the product is no longer under the sponsor's control. For example, after delivery of a cold chain product to a retail pharmacy, the sponsor can no longer be responsible for cold chain storage because it is out of their control.

Pfizer supports the principle that anyone importing medicines into NZ should comply with the obligations of a sponsor described in this legislation. Pfizer also agrees that the sponsor will not be responsible or obliged to adhere to these sections of the Act should a product be imported without the sponsor's consent.

Pfizer does not agree with someone being authorised to import a product without the sponsor's consent unless covered under ss 52(1)(c) and not having sponsor obligations apply to the importer.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

One of the guiding principles of the Therapeutics Product Bill is transparency. However, Pfizer is concerned that there is potential for information that Pfizer considers confidential, to be released by the Regulator. Of note is the lack of reference to the Official Information Act 1982. Pfizer is concerned that the wording in clauses 120 to 122 do not go far enough to protect its commercially sensitive information. The interpretation of active moiety (portion of the active ingredient responsible for the effect) in the draft TPB appears to allow for the protected period to apply in the event of modifications of an active ingredient that serve to alter characteristics of the active ingredient (such as formulation of a complex salt that results in significantly altered pharmacokinetic properties). For example, the active moiety for any beta-lactam antibiotic, could be considered the beta-lactam moiety. Under the definition in clause 120, innovative medicine application, part (b), it could be interpreted that every beta-lactam antibiotic submitted to the Regulator after benzylpenicillin would not be classified as an innovative medicine application and therefore no active ingredient information would be protected.

Pfizer understands that the Bill proposes no change to the current 5 years of data protection provided to innovative medicines by the Trade-Related Aspects of the Intellectual Property Rights agreement (TRIPS).

While Pfizer has been informed that changes to this timeframe are out of scope for this consultation, Pfizer would like to register its disappointment that the opportunity to increase the 5-year protected period has not been taken. Maintaining a Regulatory data protection period of 5 years is inconsistent with the

increase to Regulatory data protection for innovative veterinary medicines from 5 to 10 years made through the Agricultural Compounds and Veterinary Medicines Amendment Act 2016. Whilst 5 years is in line with Australia, it is not in keeping with other contemporary Regulators such as Health Canada (8 years) and EMA (8 years) who have all have lengthened their protected period in recognition of the resources expended and the risks taken when developing a new medicine.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Pfizer supports the issuing of a single licence to authorise activities that require licencing. However, the Regulatory authority should consider that this will mean almost every licence is unique. The production and granting of non-standard licences may increase the resources required compared with those currently assigned.

Therefore, our support is contingent on any issuing timeline and fee being proportional to the risk involved with the activity.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Pfizer agrees with the criteria for granting licences with the exception of those criteria applying to the granting of clinical trial licences. Currently, ethics committee approval and the clinical trial application are submitted in parallel. If this were to happen sequentially Pfizer requests that the process will not delay the start up times for clinical trials in NZ.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Pfizer does not support the import or supply of any approved a medicine, medical device, or type-4 product without the sponsor's consent (ss 131) Pfizer seeks clarity for which situations a permit would be granted under section 134 for a product to be imported with the sponsor's consent (other than the Crown).

Pfizer supports the requirement for the issuing of a permit before any clinical trial is conducted.

Our support is contingent on any issuing timeline and fee being proportional to the evaluation resources required and the risk involved with conducting the clinical trial.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Pfizer supports the introduction of risk based licencing periods i.e. the introduction of a 3-year maximum period for licences and 2 year maximum for permits.

Pfizer recommends the introduce a minimum licencing period of 1 year. Any activity that requires permission of less than 12 months should be covered by a permit and therefore a 1 year minimum for licences is appropriate.

Pfizer disagrees with the lack of a process for renewing licences. The renewal of licences via a simple risk-based process can save both Regulatory and sponsor resources.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

In the event that a licensee or permit holder dies, section 151 provides only a 5 working day period for the Regulator to be notified. Pfizer believes that this period is too short because an executor or administrator is not usually appointed within a 5 working day period. Pfizer suggests the notification period be increased to at least 20 working days.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

No Pfizer specific comment.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

Pfizer supports the introduction of an active and comprehensive post-market monitoring programme to collect information about the safety and quality of medicines and medical devices after they have been approved.

Pfizer notes that Clause 161 (5) does not allow for proceedings to be brought against the Regulator in respect to statements made under this section. Pfizer understands the need for this protection for the Regulator. However, Pfizer believes that there should be an obligation on the Regulator to provide the sponsor or person in the supply chain an opportunity to comment and an obligation on the Regulator to publish a correction, no less widely than the original statement, if the original statement is proved to be incorrect. Pfizer believes that this should apply irrespective of whether the information proving the statement to be incorrect, was held by the Regulator at the time the statement was issued. This would allow for information discovered at any stage in the future to update the Regulators position statement.

Pfizer wishes to point out that to ensure that both NZ and international reporting requirements are met, it is essential that there is no importation or supply of any approved medicine, medical device, or type-4 product without the sponsor's consent.

Pfizer supports the continuation of the advertising of therapeutic products, including DTCA and supports advertising remediation orders. Pfizer believes that a strong Regulator with the powers envisaged in sections 166 and 167, in combination with the powers in section 83, will enhance the confidence of the public and healthcare professionals in any advertising.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

No Pfizer specific comment.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

No Pfizer specific comment.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Pfizer welcomes an avenue for review of the Regulator's decisions and considers Schedule 2 Reviewable decisions to be comprehensive. Pfizer does consider the timeframe of 30 working days in which to make an application to the Regulator for review of a decision, insufficient time. Pfizer suggests this be increased to 60 working days.

Pfizer notes a review period is not set for the review panel to convene, evaluate the review application and make a decision. Pfizer considers this essential for the timely review of decisions. Reasonable timeframes are required so all parties, both sponsors and Regulator have certainty in the review process.

Pfizer agrees that there should be a fee paid if an application for review of the

Regulator's decision is submitted. We also agree that if the challenge is unsuccessful, the application review fee should be forfeited. However, if the review panel sets aside the original decision, we believe the application review fee should be returned to the applicant. The applicant has already paid the required evaluation fee to have the Regulatory authority evaluate its application. If the fee is not returned, the applicant has in effect paid twice for one evaluation.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

Pfizer supports and agrees with the proposal that the Regulator may rely on reports or assessments made by recognised authorities (ss207) to enable efficiencies. This is consistent with current practice for abbreviated submissions, as well as international Regulatory practices. It is expected that applications relying on recognised authorities must be accompanied by reduced evaluation time and fees. Additionally, the scope of the application types should include widened to include all types of major application such as new chemical/biological entities, new indications, line extensions, new dosage forms and other major changes. The types of applications that are eligible should be clearly defined in the Regulations to avoid uncertainty and confusion. The targeted evaluation timeframes should be made transparent to the Sponsor, with predictable timelines to allow for greater predictability in overall approval timeframes. Clear and transparent predicted timelines are paramount in being able to monitor progress.

Pfizer is concerned about the effects of clause 209 as currently expressed. While the Bill states that confidential information that is shared with an overseas Regulator or organisation should have its confidentiality maintained, it is noted that for example, the Customs and Excise Act 2018 provides for stronger maintenance of confidentiality through a requirement that either an obligation to have a written agreement with the relevant entity to which the information is disclosed, or only disclosing it subject to conditions stating the use that the authority may make of that information. However, it is also noted that the rationale for the difference is likely to be on the basis that the information disclosed under the Customs and Excise Act 2018 is presumed to be more likely to be personal information;

- "confidential information" needs to be defined, particularly given the reports that might be required to be made available to the Regulator under the Bill and the regulations;
- if a decision is being reviewed, that decision should only be shared with the overseas Regulator / organisation if it is accompanied by a note that the decision is

- subject to review for the purposes of transparency; and
- the right to disclose information to organisations should be subject to the protection period for protected active ingredient information that is addressed in ss120-122.
 - The term overseas organisations is extremely broad and Pfizer believes this should be removed from the Bill. Alternatively, a reference to a list of overseas organisations listed in the therapeutic products regulations would more accurately define this term.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

No Pfizer specific comment.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Pfizer supports the introduction of a new tiered structure for offences. However, Pfizer believes any penalties should be commensurate with the offence. Pfizer notes the penalties proposed in the draft bill are very high. Justification for these high penalties is requested.

Clause 244 does not allow the defence of "reasonable excuse" for sponsors. Pfizer questions why this defence is disallowed

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

No Pfizer specific comment.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Pfizer is concerned by the apparent overlap between the Therapeutic Products Bill and the Hazardous Substances and New Organisms Act (HSNO). The current wording, subject to interpretation, could mean that every therapeutic good is also a hazardous substance. E.g. 10% povidone iodine in 70% alcohol. This product is a therapeutic good because it is used, as a skin disinfectant. It would also be captured by HSNO because of its flammability.

Pfizer requests that the Therapeutic Products Bill specifically exclude therapeutic products from being classified as a hazardous substance and thereby not subject to the HSNO Act.

Our request would maintain the status quo where only new organisms are required to comply with both Acts.

Pfizer supports a complete review of the Misuse of Drugs Act 1975. It has several linkages with medicines regulation as some controlled drugs are used therapeutically. Minor changes are insufficient, and a complete review is the only way to improve alignment between the two Regulatory schemes.

Pfizer supports the principle of transparent consultation in relation to proposed changes in regulation. This helps to ensure there aren't unintended consequences and stakeholders are aware in advance of the changes.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

No Pfizer specific comment.

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:
No Pfizer specific comment.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:
Pfizer agrees with the list of reviewable decisions in Schedule 2 and agrees with who may apply for review.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
No Pfizer specific comment.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:
No Pfizer specific comment.

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
Pfizer does not support the issuing of a new approval after approval of a major change to an already approved medicine. This adds increasing Regulatory complexity and would result in multiple versions of an approved product.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
Pfizer would like to see the categorisation of medicines be aligned with the Australian scheduling numbering system. i.e. General sale medicine (category 1); Pharmacy medicine (category 2); Pharmacist only medicine (category 3); and Prescription only medicine (category 4).

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
Pfizer seeks assurance that a sufficient time period and Regulator resource will be afforded to the transitioning existing medicine approvals to ensure a backlog of applications does not occur and routine applications and activities are not impacted. A 2 year transition period is considered the minimum.
Pfizer does not support the imposition of transitional evaluation fees. At the time the application was made, the requirements of the Medicines Act 1981 applied. Any application made under the Medicines Act 1981 must comply with this Act; be considered with respect to this Act and granted consent or not for distribution under this Act.
Transitional fees may result in delays in the evaluation timeline to allow for additional fees to be collected. Also, during the time between the new Act gaining royal assent and the opening of the new Regulatory authority, it is expected the Regulator will have significant transition activities to complete. It is reasonable to expect that this will increase evaluation timelines. Pfizer would therefore be subject to slower evaluation timelines and additional fees.

Question C4 - Please provide any comments on the approach to post-market controls.:
Pfizer supports the establishment of explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. Pfizer's support is subject to these obligations being aligned with international norms.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
All comments on this topic are made in parts A and B.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
All comments on this topic are made in parts A and B.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:
Pfizer supports harmonization with international standards wherever possible.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
All comments on this topic are made in parts A and B.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
All comments on this topic are made in parts A and B.

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
All comments on this topic are made in parts A and B.

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
All comments on this topic are made in parts A and B.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

All comments on this topic are made in parts A and B.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

All comments on this topic are made in parts A and B.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Pfizer encourages harmonisation with regulatory model developed by the Global Harmonisation Taskforce (GHTF) and the International Medical device Regulators Forum.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Pfizer encourages harmonisation with regulatory model developed by the Global Harmonisation Taskforce (GHTF) and the International Medical device Regulators Forum.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Pfizer encourages harmonisation with regulatory model developed by the Global Harmonisation Taskforce (GHTF) and the International Medical device Regulators Forum.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:
No Pfizer comment. Pfizer encourages harmonisation with regulatory model developed by the Global Harmonisation Taskforce (GHTF) and the International Medical device Regulators Forum.

Question C4 - Please provide any comments on the approach to post-market controls.:

All comments on this topic are made in parts A and B.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

All comments on this topic are made in parts A and B.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

All comments on this topic are made in parts A and B.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

All comments on this topic are made in parts A and B.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Pfizer supports the ability to have one licence to cover a range of activities involved in the running of a clinical trial. It is important that requirements and obligations are clear in subordinate legislation including:

- whether it is the sponsor of the trial or the investigators that seek the license
- license duration - 3 years is too short for some clinical trials. Pfizer suggests longer clinical trial licenses are granted rather than relying on extensions. Clarity around requirements of when a licence can cease is also requested ie. is the licence required during treatment phase only or until all activities in the clinical trial have completed and clinical site is closed, or until the completion and reporting of the trial.
- although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current Clinical Trial approval process concern remains that the licence cannot be issued until the Ethics approval is granted.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

No comment.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pfizer supports the supply of unapproved product via a Special Clinical Needs Supply Authority.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

No comments

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

All comments on this topic are made in parts A and B.

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

No comments.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No comments.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

No comments.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

No comments

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No comments

Question C25 - Are there ways in which Option 1 could be improved?:

No comments

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

No comments

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

No comments

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

No comments

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

No comments

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

No comments

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

No comments

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

No comments

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No comments

Question C34 - Are there ways in which Option 2 could be improved?:

No comments

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No comments

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

No comments

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No comments

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

No comments

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

No comments

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

All comments made above

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

No comments

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

No comments

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

No comments

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

No comments

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

No comments

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Agreed.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Agreed.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Agreed.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

No comments

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

No comments

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No comments

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No comments

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No comments

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Pfizer supports the continued permission of advertising of all medicines, with the exception of controlled drugs, to consumers (DTCA). DTCA is performed in a responsible manner by Pfizer. We go to extraordinary lengths to ensure that our advertisements are balanced and do not contain misleading information. This includes both internal checks, through our Medical department, and external checks through the Therapeutic Advertising Pre-vetting Service (TAPS).

There are multiple benefits of DTCA, including:

- Increased health awareness.
- Patients encouraged to act on undiagnosed or poorly managed conditions.
- Patients feel better about medicines when they have initiated discussion and been involved in decision-making.
- Improved treatment adherence.

Pfizer believes that a strong Regulator with the powers envisaged in section 83, in combination with the powers in sections 166 and 167, will ensure the benefits derived from DTCA are achieved. A strong Regulator, in combination with the Therapeutic Advertising Pre-vetting Service (TAPS), will also enhance the confidence of the public and healthcare professionals that any advertising is accurate, fair, balanced and in the best interests of Kiwi's.

It is important to note that any ban on DTCA would not include advertisements that originate on web-sites hosted on servers based overseas. Thus, any NZ ban on DTCA, would only be a ban on balanced, fair and truthful advertising. It would not ban mis-leading, reckless or false advertising that New Zealanders may be exposed to when searching for information on the internet.

DTCA is allowed by many countries, not just New Zealand and the USA. Canada and South Africa permit reminder ads – ads that let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims. Countries in the EU and some in Asia allow prescription vaccine ads including promotional claims. As well as vaccine ads, France allows ads for prescription quit smoking aids too.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

No comments

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

No comments

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Pfizer supports the continued permission of advertising of all medicines, with the exception of controlled drugs, to consumers (DTCA). DTCA is performed in a responsible manner by Pfizer. We go to extraordinary lengths to ensure that our advertisements are balanced and do not contain misleading information. This includes both internal checks, through our Medical department, and external checks through the Therapeutic Advertising Pre-vetting Service (TAPS).

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- Patients feel better about medicines when they have initiated discussion and been involved in decision-making.
- Improved treatment adherence.

Pfizer believes that a strong Regulator with the powers envisaged in section 83, in combination with the powers in sections 166 and 167, will ensure the benefits derived from DTCA are achieved. A strong Regulator, in combination with the Therapeutic Advertising Pre-vetting Service (TAPS), will also enhance the confidence of the public and healthcare professionals that any advertising is accurate, fair, balanced and in the best interests of Kiwi's.

It is important to note that any ban on DTCA would not include advertisements that originate on web-sites hosted on servers based overseas. Thus, any NZ ban on DTCA, would only be a ban on balanced, fair and truthful advertising. It would not ban mis-leading, reckless or false advertising that New Zealanders may be exposed to when searching for information on the internet.

DTCA is allowed by many countries, not just New Zealand and the USA. Canada and South Africa permit reminder ads – ads that let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims. Countries in the EU and some in Asia allow prescription vaccine ads including promotional claims. As well as vaccine ads, France allows ads for prescription quit smoking aids too.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

All comments on this topic are made in parts A and B.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

All comments on this topic are made in parts A and B.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

All comments on this topic are made in parts A and B.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

All comments on this topic are made in parts A and B.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

No comment

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

No comment

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

No comment

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

No comment

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

No comment

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No comment

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No comment

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

No comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

No comment

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Pfizer supports robust therapeutic product regulation for all New Zealanders throughout their lives.

Response ID ANON-DPZ8-G4FS-T

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:34:06

Submitter profile

What is your name?

Name:
Terri Kong

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Pharmaceutical Solutions Ltd

Submitter Profile (tick all that apply)

Medical devices, Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Medical devices

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

We support the purpose and principles of the bill.

There should be appropriate provisions to ensure the review and approvals of clinical trial applications can be maintained or improved on its current performance.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

We strongly encourage that the definitions especially those around product classification such as medicine/medical device/IVDs, as well as 'therapeutic purpose' etc should be aligned internationally. This will greatly facilitate with harmonisation of our work with our global partners and do not unnecessarily increase regulatory burden to produce additional evidence or application documents.

For product categorisation (section f), we would like to propose harmonisation with Australia in terms of the category numbers assigned to prescription medicine (S4), pharmacist only (S3), pharmacy (S2) etc.

We do not see the purpose or value of using the term 'Active Medicinal Ingredient (AMI)' (section 9), when the term Active Pharmaceutical Ingredient (API) is widely used and acknowledged internationally.

We also seek clarification on Section 44 (1)(b). Does this imply, for example, a company (e.g. product sponsor) acting solely as importer does not require a licence/permit. However the company requires a third-party licensed wholesaler to wholesale and distribute on his behalf?

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

We will not be commenting on this section.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

We will not be commenting on this section.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

We will not be commenting on this section.

Question B7 - Please provide any comments on the authorisations for health practitioners :

We will not be commenting on this section.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

We will not be commenting on this section.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

We will not be commenting on this section.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

We will not be commenting on this section.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

We will not be commenting on this section.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

We will not be commenting on this section.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

With regards to 97(c) whereby the sponsor needs to have contractual agreement with the 'responsible manufacturer' - we would like confirmation that this is applicable for product approvals only, and not in other scenarios such as clinical trials. This is because local sponsors of trials usually have contracts with the global sponsor with regards to all aspects of the trial, and not the 'responsible manufacturer' of the investigational product.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

We will not be commenting on this section.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

We will not be commenting on this section.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

We will not be commenting on this section.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

We will not be commenting on this section.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

We will not be commenting on this section.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

For Clinical Trials, will the responsible persons only cover persons within the licensee' organisation, or also the responsible persons at the clinical trial sites (e.g. investigator's, sub-investigators, study coordinator etc)?

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

We seek further clarification on Section 135(c) - permit that authorises a person to conduct a clinical trial. If permits are for shorter term and/or urgent use, we would like examples on how a permit will work in a clinical trial setting? Would it mean trials of shorter duration and/or urgent start-up can apply for a permit, and in lieu of a clinical trial licence?

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

We will not be commenting on this section.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

We seek clarification on whether the rules for transfer of licences (and permits) also apply to licence to conduct clinical trials? If there is a change of local sponsor (i.e.licencee) of a clinical trial that is not due to circumstances in Section 151, will a new licence need to be applied for by the new licensee, if investigators and other aspects of the trial remain the same?

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

We will not be commenting on this section.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B24

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

If trials on approved therapeutic products also need approval, there should be some exemptions, for example trials of an approved therapeutic product within the approved indication(s) should not be required to have an approval by the Regulator. Example are post-market pharmaco-economic study and post-marketing surveillance studies.

Also, an abbreviated review application and at a lower fee for trials on approved therapeutic products should be considered.

As the ethics approval needs to be in place prior to issuance of the licence by the Regulator, we need reassurance that the timeline for issuing the licence following ethics approval will not be compromised by this additional step. We propose to have a statutory timeline between time of ethics approval and licence issuance, or there should be a system in place where the licence can be automatically issued as soon as both Regulator and Ethics have granted their approvals.

We seek clarification on the following (and needs to be clarified in the bill/regis):

- is the licensee the same meaning as the current 'local sponsor'
- who can be the licensee of a clinical trial - local CRO, local pharma company, investigators?
- who can/shall be the fit-and-proper person - is it just the person within the licensee organisation? Does it also include the investigators (and sub-investigator, study coordinator, pharmacist etc) of every site registered to the licence?

Regulator does not need to seek advise from HRC, but instead have flexibility to seek expert advice. We welcome the proposal to have the Regulator to seek expert advise where required for novel therapeutic products. However, the current setting has the HRC dedicated to reviewing the scientific soundness of clinical trial applications. The new Regulator should therefore also have a (scientific) team dedicated to review clinical trials, so as not to compromise the current 45-days review period.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

We generally agree with the transitional arrangements, provided no additional documentation is required to be submitted when applying for the licence.

Also, we seek clarification on Section 35(2) and (3)(a). Under (2) it states 'person who made the application under Section 30(2) of MA 1981 must apply', which in most instance is a local CRO or local pharma. And under (3)(a) it states 'the licence authorises the investigators to conduct the trial ...'. Should this read 'authorises the applicant/licensee' instead of just investigators?

Similarly for Section 36 on existing unapproved clinical trials, it states the principal investigator must apply for the licence. We propose to provide provision that a local CRO be allowed to apply for the temporary licence.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

Response ID ANON-DPZ8-G48R-B

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:45:46

Submitter profile

What is your name?

Name:

Peter Lim

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Green Cross Health

Submitter Profile (tick all that apply)

Consumer

Medicines

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Neutral

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

N/A

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Dispensing includes the preparation of the medicine, advice about its use, and clinical checks and is at the heart of a pharmacists' contribution to primary health care. The dispensing process is just more than packing medicines into a bag and giving out to a consumer; the consumer needs more than that from a pharmacist.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

This is positive for patient safety by ensuring that medicines, medical devices or type-4 products supplied in New Zealand are exactly as labelled and will allow timely responses in the event of a product recall.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

The ability for pharmacists to supply an emergency supply of a medicine to a patient should be maintained. This happens on a regular basis that consumers find very beneficial.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

This allows for pharmacists to supply, without a wholesale license, to other pharmacists.

This supports patients' timely access to medicines and should reduce wastage, particularly with high-cost medicines. Wastage is already a big issue in New Zealand due to poor medicines adherence from patients despite pharmacists' efforts.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

It would be ideal for pharmacy technicians to vaccinate, provided that they have undergone through adequate training equivalent to a nurse and a pharmacist.

Question B7 - Please provide any comments on the authorisations for health practitioners :

Five years of training, and obligations for continuing education, are considered necessary to ensure medicine efficacy, patient safety, and to prevent misuse, overuse, and abuse. Pharmacists are bound by a Code of Ethics that, when it comes to medicine supply, is more stringent than that which applies to other health practitioners.

Pharmacists are the medicines experts for every step of the supply process from storage, transportation, potential for misuse, interactions with other medicines, reporting of harm, and creating systems enabling patient follow-up and product recalls. All pharmacy activity is subject to strict regulations and unannounced inspection audit about every aspect of medicines handling.

If health professionals were regulated to supply Category 3 medicines, they would need to have made the capital and other investments necessary to meet the above requirements, and have their staff supervised by a pharmacist.

To increase access to medicines we would support increased prescribing rights, allowing other health practitioners to prescribe the required medication within their scope of practice. This has the benefit of the patient then being able to access a funded medicine.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

The ability for a health practitioner to supervise their staff to supply these medications under direct supervision is limited due to consultations generally occurring behind closed doors.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

N/A

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Support this - patients should have access to medicines that they are unable to obtain in NZ, provided that it is not a controlled substance in NZ.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94..:

Response ID ANON-DPZ8-G48W-G

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 16:48:54

Submitter profile

What is your name?

Name:

Andrew Collins

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

School of Optometry and Vision Science, The University of Auckland

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Optometrist

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

University - training provider for registerable degree, Bachelor of Optometry

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

no comments

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

no comment

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

no comment

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

no comment

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

no comment

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

no comment

Question B7 - Please provide any comments on the authorisations for health practitioners :

By intending to restrict the issuing of special clinical needs supply authorities for medicines that do not have a product approval in New Zealand (Therapeutic Products Regulatory Scheme consultation document item 75b, p22) to medical practitioners only, the proposal has the unintended consequence of restricting existing prescribing practice by optometrists, as authorised prescribers, and creating additional barriers, both financial and procedural, to the provision of evidence-based healthcare by optometrists. In particular, the described intention would place a significant limitation on the ability of optometrists to provide medical control of myopia progression and its associated ocular health issues.

Optometrists, as authorised prescribers under the Medicines Act 1981, and following a growing body of evidence(1,2) are prescribing atropine eye drops for the control of myopia (short-sight) progression. While the refractive error of myopia can be corrected with spectacle lenses to provide clear vision, the aim of the therapeutic management of myopia progression with atropine is to minimise the risk of developing ocular health problems (maculopathy, retinal detachment, glaucoma) in later life(2).

Atropine 1% is an approved topical ophthalmic medicine, usually used to induce mydriasis (pupil dilation) and cycloplegia (accommodation relaxation). It has been shown to also reduce the progression of myopia(1). However, when used for myopia control at the commercially available and approved 1% concentration these effects are unwanted side effects, and unnecessary for the myopia control effect(1). There is considerable evidence from clinical trials that "low dose atropine" (e.g. at concentrations between 0.01% - 0.5%) is an important new tool in myopia control(1). For optometry it is becoming best practice to inform patients (and/or patients' parents) of the availability of this treatment(2), and prescribe as necessary. However, to achieve best control of myopia progression, it may be necessary to modify the atropine dose concentration over time, in order to manage the side effects and taper the dose to prevent potential rebound effects which are concentration-dependent(1,2).

As only atropine 1% is available as an approved medicine currently, prescribing the lower dose atropine concentrations requires compounding and off-label prescribing, both of which would result in the "low dose atropine" being categorised as an "unapproved product" under the draft bill.

As part of the undergraduate optometry program, and at professional optometric continuing education conferences, we have been recommending that practitioners offer myopia control, including the compounding of "low dose atropine", as an option to parents of children with myopia as standard clinical practice, and this practice is becoming well established in optometric practice.

Section 62 Health practitioners: unapproved products states that;

"For the purposes of sections 51 and 53, a health practitioner may carry on a controlled activity referred to in section 61(1) to (5) in relation to an unapproved medicine if—

- (a) they would be authorised by section 61 to do so if the medicine were an approved medicine; and
- (b) either—
 - (i) there is a complying special clinical needs supply authority for the patient for that medicine; or
 - (ii) the medicine,—
 - (A) in the case of supplying, administering, or dispensing, was lawfully compounded for the patient; or
 - (B) in the case of prescribing, will be compounded for the patient."

Therefore section 62 allows a health practitioner (optometrist in this submission example) to prescribe an unapproved medicine (which includes medicines compounded for approved medicines) if there is a complying special clinical needs supply authority (SCNSA) for the patient.

Section 64 addresses the issuing of SCNSAs for unapproved medicines by health practitioners, if under section 64(1)(b)(i) "for a medicine, the practitioner is a health practitioner prescriber for the unapproved medicine;"

Therefore the bill does provide a mechanism by which optometrists, as health practitioners, would be able to continue to prescribe "low dose" compounded atropine as an unapproved medicine by issuing a SCNSA for the medicine and patient.

However, as noted above, the Therapeutic Products Regulatory Scheme consultation document item 75 (p22) states the intention (not described in the bill) to create two main types of (SCNSA) authorisations as follows:

- a. "the off-label use of medicines that have been approved in New Zealand – our intention is to authorise all health practitioner prescribers to issue a SCNSA for off-label use"
- b. "medicines that do not have a product approval in New Zealand – our intention is to continue to limit the ability to issue a SCNSA for these products to *medical* practitioners" [*my emphasis]

While the "off-label" use of atropine 1% to treat myopia progression would likely fall under the type (a) authorisation above, and then be available to an optometrist as a health practitioner to issue a SCNSA, the compounding required to produce the recommended "low dose" atropine, would shift the authorisation to type (b) where the issuing of a SCNSA would require the examination and approval by a medical practitioner. As optometrists could be considered the primary care practitioners most likely to have the knowledge and experience of the use of atropine in the eye, and in its "low dose" forms for myopia control, this

requirement seems to create unnecessary barriers, both financial and procedural, to the provision of evidence-based healthcare by optometrists.

We propose that the issuing of SCNSA for medicines that do not have a product approval in New Zealand should not be limited to medical practitioners, primarily it appears on the basis of simply reproducing the effect of Section 29 of the existing medicines Act 1981, but that the issuing of such SCNSA should be available to all health practitioners through an appropriate regulatory regime, possibly managed by the appropriate regulatory authority, as is reflected in the overall objectives of the bill.

References

1. Wildsoet CF, Chia A, Cho P, et al. IMI – Interventions for Controlling Myopia Onset and Progression Report. Invest Ophthalmol Vis Sci. 2019;60:M106–M131. <https://doi.org/10.1167/iovs.18-25958>
2. Gifford KL, Richdale K, Kang P, et al. IMI – Clinical Management Guidelines Report. Invest Ophthalmol Vis Sci. 2019;60:M184–M203. <https://doi.org/10.1167/iovs.18-25977>

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

no comment

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

no comment

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

no comment

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

no comment

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

no comment

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

no comment

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

no comment

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

no comment

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

no comment

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:
no comment

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:
no comment

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
no comment

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:
no comment

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:
no comment

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:
no comment

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:
no comment

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:
no comment

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:
no comment

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):
no comment

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

no comment

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

no comment

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

no comment

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

no comment

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

no comment

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

no comment

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

no comment

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

no comment

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

no comment

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
no comment

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:
no comment

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
no comment

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
no comment

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
no comment

Question C4 - Please provide any comments on the approach to post-market controls.:
no comment

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
no comment

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
no comment

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:
no comment

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
no comment

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
no comment

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
no comment

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
no comment

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
no comment

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:
no comment

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:
no comment

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

no comment

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

no comment

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

no comment

Question C4 - Please provide any comments on the approach to post-market controls.:

no comment

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

no comment

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

no comment

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

no comment

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

no comment

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

no comment

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

no comment

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

no comment

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

no comment

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

no comment

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

no comment

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

no comment

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

no comment

Question C25 - Are there ways in which Option 1 could be improved?:

no comment

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

no comment

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

no comment

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

no comment

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

no comment

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

no comment

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

no comment

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

no comment

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

no comment

Question C34 - Are there ways in which Option 2 could be improved?:

no comment

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

no comment

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

no comment

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

no comment

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

no comment

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

no comment

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply

authority, a pharmacy, or a wholesaler?:

no comment

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

no comment

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

no comment

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

no comment

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

no comment

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

no comment

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

no comment

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

see response to Question B7

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

see response to Question B7

Question C48 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Question C49 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

no comment

Question C50 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

no comment

Health practitioners (non-prescribers)

Question C51 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

no comment

Question C52 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

no comment

Question C53 - Please provide any comments on the advertising requirements and enforcement tools.:

no comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

no comment

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

no comment

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

no comment

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

no comment

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

See response to Question B7

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

See response to Question B7

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

no comment

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

no comment

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

no comment

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

no comment

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

no comment

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

no comment

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

no comment

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

no comment

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

no comment

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

no comment

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

no comment

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

no comment

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G468-F

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 16:51:50

Submitter profile

What is your name?

Name:

Bridget Seque

What is your email address?

Email:

What is your organisation?

Organisation:

Weleda (New Zealand) Ltd.

Submitter Profile (tick all that apply)

Medicines, Active ingredients

Medicines, Active ingredients

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Weleda agrees with the purpose and principles of the Bill and the clearly defined regulatory framework proposed for therapeutic products. It supports the objectives of the regulatory scheme outlined in the Consultation paper at point 7.

What will be critical to the success of the Scheme will be in how those principles are applied to the development of the regulations, rules and notices, and how they are interpreted and applied in practice when the Scheme is operational.

Proposal: Weleda proposes that guidelines be developed to help guide the regulator in the application of those principles, including a code of conduct, so that the individual regulator can be supported in their interpretation and application of the regulatory scheme.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

- Section 15 Meaning of therapeutic purpose, (1) The following are therapeutic purposes: ... , (g) supporting or sustaining human life:

At 49.c., the Consultation document states that “therapeutic purpose (s 15): This is in line with international definitions”.

Unfortunately, the Consultation document does not include references to the international definitions used so it was not possible to check the source of the definitions. We note that the statement at 15(1)(g) is not included in the Australian Therapeutic Goods Administration definition of ‘therapeutic use’.

Our understanding from the Ministry of Health’s Medicine Forum is that this statement may be specific to the use of medical devices, but it may also apply to other therapeutic goods. References to this statement have subsequently been found in the U.S Food & Drug Administration (FDA) Code of Federal Regulations, Title 21, Chapter 1, Subchapter H – Medical Devices, Sec. 860.3 Definitions, and in other sources such the World Health Organization (WHO), ‘Medical Device – Full Definition’.

- FDA: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=860.3>

- WHO: https://www.who.int/medical_devices/full_definition/en/

The lack of context could leave room for misinterpretation by some people, for example, food supports and sustains human life.

Proposal: Given the general nature of the statement at 15(1)(g) and possible misinterpretation, Weleda proposes that the ‘meaning’ of the statement be included in Section 14 Interpretation with an explanation of its intended application.

• NATURAL HEALTH PRODUCTS

Section 16 Meaning of therapeutic product, ...

(3) However, a product that would otherwise be a therapeutic product under subsection (1)(a) is not a therapeutic product if it is a natural health product.

[Note for consultation draft: The government is considering options for the regulation of natural health products and intends to exclude them from the Bill.

However, the definition of natural health product and the exact mechanism by which they will be excluded from the Bill are yet to be determined. Exclusion from the definition of therapeutic product, as provided by subsection (3), is one of the options being considered.]

Under point (3) of Section 16 Meaning of therapeutic product, it is proposed to exclude natural health products (NHPs) that are “(1)(a) intended for use in, on, or in relation to humans for a therapeutic purpose” from the ‘therapeutic product’ definition and from regulation under the Draft Therapeutic Products Bill (TP Bill).

Weleda is concerned about the intention to exclude natural health products (NHPs), which are a diverse range of products, from regulation under the TP Bill.

Under the proposed TP Bill definitions of ‘therapeutic purpose’ and ‘therapeutic product’, and in the absence of the exclusion, NHPs would be classified as therapeutic products and are already classified as therapeutic products in a number of other countries. NHPs encompass the range of risk, from low to medium/higher risk products. Presumably the proposal is not intended to exclude medium to higher risk NHPs from the TP Bill, which means that a definition would be required for lower risk NHPs. Trying to develop a definition of lower risk NHPs in an attempt to exclude them from the TP Bill compromises any chance for a meaningful definition. The proposal is likely to split NHPs into two groups, lower risk NHPs and medium/higher risk NHPs, leading to inconsistent and disjointed regulation for the whole group of NHPs.

There have been numerous attempts over many years to implement legislation in NZ for NHPs, including under the proposed Australia New Zealand Therapeutic Products Agency and a number of attempts to implement separate NZ NHP specific legislation, i.e. the Natural Health Products Bill. To date these attempts to regulate NHPs in NZ have failed. Medicines, foods and cosmetics are regulated in NZ providing certainty for the consumer that those products are safe to consume and/or use. Overwhelmingly the public also wants and needs access to safe, effective NHPs. (Industry also wants appropriate regulation for their products so that they can proceed with confidence in the regulatory environment, and in their investment in production and sale of NHPs.) This failure to implement appropriate legislation for NHPs means that the NZ public continue to be at risk from unregulated and potentially unsafe NHPs, and industry continually faces an uncertain regulatory environment. There have been a significant number of reported cases of harm to consumers from some NHPs, but lack of legislation for NHPs compromises the ability for appropriate action to be taken. It is time to take action and implement legislation that will ensure safe, effective NHPs for consumers.

Weleda’s understanding is that the approach to try and implement a separate NHP Bill in NZ was taken as a means to address some NHP stakeholder concerns about the potential impact of ‘medicine’ style legislation on NHPs and to engage the diverse group of NHP stakeholders in an effort to achieve appropriate legislation. The current proposal to exempt NHPs from the TP Bill is consistent with this previous intent to implement a separate NHP Bill in NZ, but the proposal highlights the complexity of the proposed exemption and definition of NHPs. Weleda believes it is time to step back and take a fresh look at the proposed legislation, and reconsider the options and the risks.

The fundamental defining criteria for NHPs (and for a potential definition) is that they are based on naturally occurring substances (parameters to be defined in legislation), and they are used in humans for therapeutic purposes, including to maintain and restore good health. NHPs encompass a wide range of diverse products – herbal, traditional, homoeopathic, dietary supplements. They are used for a variety of therapeutic purposes, including the maintenance and promotion of health and wellness, through to the relief of symptoms and conditions. They span a wide spectrum of risk, from low risk to medium/higher risk, depending on ingredients, concentration, dosage form, product claims, etc. The same NHP ingredient may be used for health maintenance, but in a different concentration or dosage form may be used for the relief of symptoms and conditions. They may be presented not only in oral or topical dosage forms, but also in sterile dosage forms, such as eyedrops.

Regulating the whole group of NHPs together would ensure that a wholistic and integrated approach could be taken to managing the risks and requirements appropriately, rather than trying to regulate lower risk and medium/higher risk NHPs as two separate groups under two different sets of legislation. The TP Bill incorporates the flexibility to develop risk appropriate product approval pathways as well as product approval-exemptions where product approval is not required due to the product’s “nature or risk profile”. These mechanisms allow for other regulatory controls to be applied, where necessary, to manage risks such as safety and quality. It is also interesting to note that at section 15, the Bill includes in the definition of ‘Meaning of therapeutic purpose’, the clause (g) ‘supporting or sustaining human life’. Although possibly intended for other purposes, this section also encompasses the ‘maintenance and promotion of health and wellness’ aspect of NHPs.

In addition, including NHPs under the TP Bill would mean that other general legislative requirements such as advertising, labelling, etc. would apply to NHPs, with amendments for NHPs where necessary, without the need for those requirements to be covered again in separate NHP legislation.

Weleda Proposals

Proposal 1: Include natural health products in the Therapeutic Product Bill

- Weleda proposes that natural health products should not be excluded from the ‘therapeutic product’ definition and that they should be included in and regulated by the Therapeutic Products Bill.

- Including NHPs in the TP Bill would provide the structure for the development of NHP legislative requirements, along with appropriate timelines and transition,

whilst enabling the management of any significant NHP safety issues during the development phase.

Proposal 2: Natural health product definition

- Weleda proposes that the natural health product definition should include wording to the effect that these products are based on naturally occurring substances (parameters such as to be defined in legislation), may be used in traditional modalities and are used in humans for therapeutic purposes, including to maintain and restore good health.
- The aim of the definition should be to define the fundamental nature of NHPs, and should not include additional criteria that limit the NHP definition to a particular risk level. Criteria and management of risk should be covered in other parts of the legislation, as is done for general medicines.
- Weleda would welcome the opportunity, and may be contacted, to contribute to the development of a draft natural health product definition.

Proposal 3: Development of natural health product regulations and rules

- The development of draft regulations and rules cover a wide range of regulatory requirements. There would be specific requirements for NHPs. Weleda would welcome the opportunity, and may be contacted, to contribute to that development.
- Regulation for NHPs should consider the following specific requirements:
 - Classification of NHPs according to risk, including parameters that cover ingredient risk, dosage form risk and product claims;
 - Development of risk-based criteria to manage requirements for the different risk groups, including development of appropriate approval pathways and identifying NHPs suitable for product approval-exemptions and possible exemption from other types of regulations and rules;
 - Database for the registration of low to medium risk NHPs;
 - A good manufacturing practice code for low to medium risk NHPs;
 - Permitted NHP substance schedules.

• Section 24 Meanings of approved product, approval-exempt product, and unapproved product

Approved products: Weleda supports the meaning of approved product and the intent for obtaining product approval, outlined in point 250 of the Consultation paper "that the new scheme would give the regulator greater flexibility to establish a number of approval pathways". As outlined in the paper, this could allow greater recognition of overseas regulators and be "tailored to suit, for example, products with a long approval history in one or more recognised overseas jurisdictions", including that "the data requirements, time to regulatory approval and fee structure could be tailored to suit different circumstances".

Approval-exempt products: Weleda supports the meaning and development of this new mechanism which, as outlined in the Consultation paper, allows the regulator to decide that approval is not required due to the product's "nature or risk profile". As described in the Consultation paper under Subpart 2:

Approval-exempt products, this mechanism can be used for products with characteristics that mean their safety, efficacy and quality could more appropriately be regulated through a different regulatory control, such as a manufacturing licence.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

None

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

None

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

None

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

None

Question B7 - Please provide any comments on the authorisations for health practitioners :

None

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

None

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

None

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

None

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

None

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

None

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Approved products: Weleda supports the intent for obtaining product approval, outlined in point 250 of the Consultation paper “that the new scheme would give the regulator greater flexibility to establish a number of approval pathways”. As outlined in the paper, this could allow greater recognition of overseas regulators and be “tailored to suit, for example, products with a long approval history in one or more recognised overseas jurisdictions”, including that “the data requirements, time to regulatory approval and fee structure could be tailored to suit different circumstances”.

- Weleda expects that the fee structure for these types of product approvals would reflect the reduced workload associated with reliance on the approvals of other regulators.
- In point 108, the consultation paper highlights that under section 95(c), other criteria will be specified in the rules setting out the requirements for different kinds of products. As mentioned in the paper, there will be consultation on the development of these criteria with stakeholders.
- Request: Weleda would welcome the opportunity, and may be contacted, to contribute to the development of the criteria that will be specified in the rules for the requirements for different kinds of products.

Approval-exempt products: Weleda supports the development of this new mechanism which, as outlined in the Consultation paper, allows the regulator to decide that approval is not required due to the product’s “nature or risk profile”. As described in the Consultation paper under Subpart 2: Approval-exempt products, this mechanism can be used for products with characteristics that mean their safety, efficacy and quality could more appropriately be regulated through a different regulatory control, such as a manufacturing licence.

Proposal: Weleda proposes that the flexibility of the ‘approval pathways’ and the ‘approval-exempt’ pathway are mechanisms which could be considered for low risk NHP products that may be categorised as therapeutic products due to sterility or substance. For example, the ‘approval-exempt’ pathway could be applied in many cases as potential risks are well controlled by the regulatory controls applied via good manufacturing practice.

- Request: Weleda would welcome the opportunity, and may be contacted, to contribute to the development of the types of pathways and criteria that will be considered for different kinds of products.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

None

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Approval-exempt products: Weleda supports the development of this new mechanism which, as outlined in the Consultation paper, allows the regulator to decide that approval is not required due to the product’s “nature or risk profile”. As described in the Consultation paper under Subpart 2: Approval-exempt products, this mechanism can be used for products with characteristics that mean their safety, efficacy and quality could more appropriately be regulated through a different regulatory control, such as a manufacturing licence.

Proposal: Weleda proposes that the flexibility of the ‘approval pathways’ and the ‘approval-exempt’ pathway are mechanisms which could be considered for low risk NHP products that may be categorised as therapeutic products due to sterility or substance. For example, the ‘approval-exempt’ pathway could be applied in many cases as potential risks are well controlled by the regulatory controls applied via good manufacturing practice.

- Request: Weleda would welcome the opportunity, and may be contacted, to contribute to the development of the types of pathways and criteria that will be considered for different kinds of products.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

None

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

None

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

None

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

None

Subpart 2: Permits (ss 131–135)**Question B20**

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

None

Subpart 3: Provisions applying to licences and permits (ss 136–151)**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

None

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

None

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

None

B8 Part 6 of the Bill: Regulator**Subpart 1: Regulatory powers and functions(ss 160–182)****Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

None

Subpart 2: Investigative powers (ss 183–196)**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196).:

None

Subpart 3: Offences relating to regulator(ss 197–199)**Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

None

Subpart 4: Review of regulator's decisions (ss 200–204)**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

None

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

Weleda supports the intention of the Bill, in particular Section 207, to allow the Regulator to recognise and base its decisions on reports, assessments and decisions for therapeutic products approved by other recognised regulatory authorities. As mentioned in the Consultation paper this is “intended to assist the efficiency of this regulatory scheme” and presumably should help mitigate both the regulatory burden and costs for the regulator and industry.

Proposal: Whilst the regulator would not be bound by the decision of the other authority, Weleda proposes that when the Regulator is considering how far to go in evaluating overseas data for a product, that this decision be “proportionate to the risks posed by the product”. For example, where an overseas regulator has approved a change to manufacturing sections of a dossier of a low risk product, it is suggested that the NZ Regulator should be able to recognise that approval without further costly evaluations. Presumably criteria and guidance on this process would be outlined in regulations and rules.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

None

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

None

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

None

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Regarding cost recovery, Weleda supports the intention of the Bill, in particular Section 207, to allow the Regulator to recognise and base its decisions on reports, assessments and decisions for therapeutic products approved by other recognised regulatory authorities. As mentioned in the Consultation paper this is “intended to assist the efficiency of this regulatory scheme” and presumably should help mitigate both the regulatory burden and costs for the regulator and industry.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

None

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

None

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

None

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

None

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

None

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

None

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

None

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.: In the Bill under Schedule 1, Part 1, 1(1) Subpart 1 – product approvals, it states that “existing consents, and consents granted by the Regulator after commencement under this Part, will generally become approvals under this Act, but subject to new rules (for example, about cancellation, additional conditions after 2 years, and sponsor obligations)”. There is no information regarding the statement “additional conditions after 2 years”, so the meaning and potential impact of this point is unclear. Further clarification of this point is required.

Question C4 - Please provide any comments on the approach to post-market controls.: None

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.: None

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.: None

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?: None

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).: None

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.: None

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.: None

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.: None

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.: None

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.: None

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Yes. Whilst these products are not intended for a therapeutic purpose, they are being applied in some way to the human body and have the potential to cause harm if there is no regulation applied to them.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

None

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

None

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

None

Question C4 - Please provide any comments on the approach to post-market controls.:

None

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

None

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

None

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

None

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

None

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

None

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

None

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

None

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

None

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

None

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

None

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

None

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

Option 2 is supported because:

- It is a simpler, therapeutic focused option.
- It focuses on the pharmacy operations and pharmacist control of the quality systems.
- It allows the Regulator to properly direct its efforts towards ensuring pharmacies have transparent, evidence-based systems that support patient safety.
- There is no Regulator involvement required to review the business or financial set-up, i.e. no requirement to review detailed business documents, which helps to reduce costs and compliance requirements.
- The business and financial set-up of pharmacy operations should sit outside a therapeutic products regulatory system.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

None

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Direct-to-consumer advertising of prescription medicines is supported as it enables increased consumer knowledge and involvement in their own health decisions. Supply is still controlled by the practitioner who must make the final clinical decision on the suitability of a prescription medicine for that patient.

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Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:54:05

Submitter profile

What is your name?

Name:

Sanjoy Nand

What is your email address?

Email:

What is your organisation?

Organisation:

National DHB Directors of Allied Health Scientific and Technical

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Combined DHBs Directors of Allied Health Scientific and Technical

Other health practitioner (please comment)

If you select 'Other', please comment below::

We are the DHB Executive Professional Leaders that represent the Allied Health Scientific and Technical workforce in DHBs

If you selected 'Other' please comment::

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

The purpose and principles are appropriate

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

The definitions are detailed in the body of the Bill with references made in the definition section - this makes it difficult to follow in the bill as one has to constantly refer to the various part of the Bill. It could be made easier if the definitions were provided in the definitions part. In addition the definition of "manufacture" is confusing. We note later in the consultation the view on the description of "manufacture" is requested.

The definitions of software used with devices has not be clearly outlined - it is difficult to determine what would be in scope and what wont. Under the proposed definitions how do the drafters see medical devices and their software applying to the legislation? Is it the drafter's intention that said software also falls under the Bill? We understand that while software is purchased usually the programming of said software (e.g. drug libraries) is by local decision support information (for example that dabigatran cannot be given in patients with GFR < 30 ml/min). While software regulation (as part of therapeutic products legislation) has some merit, this needs to be done at a very high level so as not to inadvertently limit the market, but enough to enable the regulator oversight of intra-operability both nationally and internationally. Hence, the DHB supports very high level regulation or perhaps some rules in this space, For example:

- Reputable software suppliers

- Medicines terminology follows NZULM
- Diseases terminology follows Snomed
- Systems communication uses HL7

However, we would not wish to see regulation that requires, for example, an ED physician to involve the regulator should they wish to programme a new infusion rate for N acetyl cysteine. In any case, further clarification is required (likely as part of subsequent regulations) to ensure the scope of what is considered under the definition of therapeutic product as pertains to devices, their software and local data to ensure this is unambiguous.

There is a wide range of software used in the hospital systems eg medicines information systems, software used to make clinical decisions such as by dieticians, software used with infusion devices to improve safety and monitoring software - eg software used with devices such as a holter monitor

Bulk Fluids

Currently bulk fluids do not fall under the Medicines Act which enables direct ward delivery of these (bulky) products from suppliers. DHBs do not wish to see any changes to definitions that would undermine current systems and require bulk fluids to be supplied or dispensed by a licenced pharmacy.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

The requirement for approvals for medicines is appropriate in principle, however, our experience would suggest that there are many medicines supplied in New Zealand that are not registered by the suppliers because of market constraints. These are vital to patient care and often these medicines are available overseas eg low volume products (currently used under and procured via Section 29). The ability of hospitals to procure this through their existing supply chains for stock (ie without a prescription being issued before procurement) is critical to timely patient care. In the acute stage, it is not practical to wait for a prescription to be issued prior to procuring as most of these medicines may take days to weeks to arrive in the country. In addition, while the principle of approval of medical devices is good, this will limit ability of patients to procure medical devices that they may currently have access to that may not necessarily be available in the NZ market. This limits consumer choice. It is critical that some medical devices are registered, however, the definition of medical device includes almost everything that a patient may use to support them. For example a consumer may be able to procure a blood pressure monitor for home monitoring cheaply in the international market and many of these would be of reasonable quality. The same may apply to equipment that may be used by patients to support activities of daily living. The off label use of medicines requiring a SCNSA could increase administration burden. It is unclear how compliance would be assessed? In addition the recommended processes such as permits to authorise the importation of unapproved products to deal with situations where an approved equivalent is out of stock could result in delays in access to critical products. There needs to be a rapid assessment and approval process for this.

In Radiation Oncology there is widespread use of internally manufactured personalised medical devices- often manufactured for specific patients. These include lead and cerrobend shielding (both covered with a lacquer spray) to create individualised beams of radiation to treat shallow cancers (such as skin cancer). The use of this shielding ensures the patient does not receive unnecessary dose to normal tissue and critical organs. This service also manufactures phantoms used for quality assurance, to ensure certain types of patients receive the correct dose in a safe manner. These are only manufactured when there is no suitable product on the commercial market. Is this covered in the exemptions and if not how does the provisions in bill deal with such items?

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

It is difficult to comment on this without regulations, however, the general overarching principles are appropriate.

Section 53 (2) (c) (i) defines the supply of a category 1 medicine (prescription medicine) as a controlled activity. Section 54 further defines that such supply can only be made in accordance with a complying prescription (or as authorised by license or permit).

The use of medicines in the hospital setting requires a provision in the legislation to supply category 1 medicines without a complying prescription, that is, against an inpatient order (medication chart)

There is a lack of clarity currently over how hospital pharmacies would comply with legislation in this area. Typically, inpatient orders are viewed as "orders to administer" rather than 'prescriptions', and currently category 1 medicines are dispensed against these 'orders'. The Therapeutics Bill needs to make a clear provision to enable a hospital pharmacy to supply all categories of approved and unapproved medicines against an inpatient-order. DHBs also require a legislative basis for verbal orders which are not covered in current legislation or regulations, which are essential for delivery of time critical therapies and care. The Bill also does not provide any consideration for supply of medicines used for ward stock; this is a key system for medicine distribution and access in a hospital setting

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

These are reasonable. We would like to see authorisations to undertake controlled activities including those within the definition of "conducting a pharmacy business" able to be undertaken outside of the physical pharmacy premises (i.e. other than at the place "specified in the pharmacy licence" as per subsection 3). We would foresee this would enable DHBs to undertake activities such as bedside or point-of-care medicines supply (using mobile labellers for example) without having to send prescriptions back to a licensed pharmacy premises for dispensing.

This could also prove very beneficial in some of our hub and spoke services (for example regional oncology services) whereby we have infusion centres located around the regions. It would enable to pharmacy staff to visit those centres and undertake appropriate controlled activities on site without having to send prescriptions back to the main hospital pharmacy.

We understand the current legislation prevents such activities being undertaken by pharmacy staff and only allows these activities to be undertaken by Authorised Prescribers. We believe that allowing these activities to be undertaken (outside of the pharmacy premises) by pharmacy staff will improve the quality, standard and oversight of such services.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

These are largely reasonable. There needs to be consideration provided for pharmacy technicians who can check dispensed prescriptions within the regulations. The Pharmacy workforce is evolving so consideration must be given to enable innovative models for service provision, particularly for supply and distribution and pharmacy workers are a relevant and capable workforce to provide supply and distribution services.

The draft bill proposes that a pharmacy worker may only carry out controlled activities (other than the non-wholesale supply of category three medicines) when under the direct supervision of a pharmacist (ss60).

Additionally, ss159 stipulates that pharmacy activities are unauthorised if carried out when a pharmacist is not present at the place or vehicle.

The DHB proposes there are other, more effective mechanisms by which the quality and standard of services can be ensured other than by direct supervision.

The DHB would like to see a provision that allows pharmacy activities to be undertaken without direct supervision (with the pharmacist still retaining responsibility for those processes, products and services). We would foresee this would enable:

- a future where prescriptions (having been clinically screened by a pharmacist)

are dispensed, checked and released by a purely PACT-led pharmacy technician team

(releasing the pharmacist from the dispensary to fulfil clinical roles).

The Therapeutics Bill in its current format would preclude hospitals from adopting this type of service model for example, weekend work where pharmacy technicians could undertake medicine re-packing (with the pharmacist checking it off on Monday)

, cleaning isolators, setting out consumables and medicines and compounding medicines for a pharmacist to check when they come in (in-process checks are already performed by validated Pharmacy Technicians in our DHB)

We propose that robust process oversight along with staff training are examples of

alternative tools (other than direct supervision) which could effectively ensure the quality of the service, the security of the premises, and the safe and secure storage of medicines. For example a clear process for quarantine and release would ensure a pharmacist retains control of that pharmacy activity

In addition access to the clinical and professional advice of a pharmacist by pharmacy workers performing these activities (a stated goal of this provision) could be achieved by many other mechanisms other than direct supervision (for instance telephone, video link, chat, technology etc.)

We advocate for broadened requirements to allow pharmacists to provide clinical advice or oversight of pharmacy activities remotely.

Question B7 - Please provide any comments on the authorisations for health practitioners :

These are appropriate and the allowance for category 3 medicines supply is supported. However clarity needs to be provided for example does this mean a nurse should be able to provide ibuprofen for pain and a physiotherapist be able to provide ibuprofen. We would support nurses being able to supply some category 3 medicines if the medicines are used within the context they work eg pain relief, laxatives, topical anaesthetics, which they can under standing orders, however, it would be reasonable for registered nurses to supply some category 3 medicines without needing to operate under a standing order. The legislation should encourage and enable equity within health professionals where deemed appropriate and safe.

Radiation therapists are another practitioner type that may provide certain category 3 medicines.

Dieticians are another group of health practitioners that currently prescribe a range of medicines, including some prescription medicines. The Bill would need to provide enough transitional time for the regulators under HPCA act to enable the prescribing scope to be included in their governance processes.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

We understand the drafter had a clear view that this clause imparted a very limited scope to 'their staff' which only permits the processing of such a transaction through the till or point-of-sale. We believe the intended scope of this clause requires revision for clarity as it can be widely misinterpreted as allowing the sale of category 3 medicines without the involvement of a health practitioner (which we understand was not the drafter's intent).

An important downside of the proposed approach is that it might negate the ability to have a standardised, central, electronic medicines record (including category 3 medicines) for an individual patient (assuming such a record would be more practically achieved if supply were to be limited to pharmacies).

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

These are fine, but there appears to be oversight for supply chain needs for veterinary providers. For example who are they authorised to procure medicines from; Can a pharmacy supply a medicine on a prescription for an animal cared by a veterinarian? This is not clear within the draft bill.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

From a safety perspective this is fine, however, it may limit consumer choice. This may have significant impact with medical devices, particularly for the disabled.

For medicines - There are several drivers which may lead to patients choosing to personally import medicines. These include:

- Not having the means or motivation to get a valid prescription (there are adequate provisions in the legislation to control for this activity)
- No authorised (registered) medicine available in New Zealand (for which the unapproved route would be used)
- Lack of funding, whereby the patient exercises personal choice to procure a medicine at a lower cost from abroad.

Lack of funding results in New Zealanders not always having access to the breadth of funded treatment options available in e.g. Australasia and Europe. Under the proposed legislation some patients will be able to get on a plane, travel internationally, obtain a valid prescription and supply of medicine in that country, and return to New Zealand with a specified amount of that (category 1) medicine (ss76, luggage conditions). Whereas other patients, who either cannot afford or are not fit enough for international travel, would be prohibited from importing that same prescription medicine to New Zealand (even if they hold a valid New Zealand prescription). We are unsure how this distinction supports the drafter's stated objective to:

- a. Ensure the quality of medicines
- b. Reduce the chance of misappropriation or
- c. Balance personal freedom with consumer protection

As such we would like to understand why category 1 medicines are currently missing from the delivery conditions in section 76?

There are many specialised services where patients choose to obtain category 1 (prescription medicines) from abroad. Some examples are:

- HIV patients who use personal importation to access pre-exposure prophylaxis medicines
- Cancer patients who use personal importation to obtain unfunded, registered, medicines more affordably from abroad

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

These are appropriate. The rules around vending machines may need to be considered for current vending machines for condoms. We note that in the responses to our questions, the intent is that condom vending machines are excluded; it would be good to specify exclusions in the instruments that will be developed.

Subpart 4: Other offences (ss 81–94)**Question B12****Please provide any comments on the offences created in sections 81–94.:**

These are largely appropriate. Clarity needs to be provided around the definition on advertising particularly for situations where best practice messages or safety concerns may result in communications that promote one product over the other eg. bulletins from HQSC or BPAC. Additionally health providers may also provide communications that sometimes result in choosing one product over the other - eg choosing wisely campaigns.

We also like to provide our view over the concept around who can hold interest in a pharmacy business. We do not support the view that pharmacist prescribers should not hold interests in a pharmacy. The pharmacist prescriber role is not a core activity that pharmacists do, it is a tool used by a subset of pharmacists to improve patient care. For pharmacist prescribers, we consider that there would always be a medical practitioner involved in the care of patients, as diagnosis is not within the scope of the pharmacist prescriber, hence there is unlikely any negative impact of pharmacist prescriber on conflicts of interest or ability to be impartial, if having interests in a pharmacy. Restricting this for pharmacist prescribers would have a negative impact on the ability of pharmacists to work in better ways to improve timely patient care and also restrict access to medicines.

B6 Part 4 of the Bill: Product approval**Subpart 1: Approval of products (ss 94–113)****Question B13****Please provide any comments on the sections covering product approval requirements (ss 94–104).:**

These are appropriate.

Question B14**Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:**

These are appropriate.

Subpart 2: Approval-exempt products (ss 114–115)**Question B15****Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:**

These are appropriate.

Subpart 3: Obligations of sponsors (ss 116–119)**Question B16****Please provide any comments on the sections covering sponsor obligations (ss 116–119).:**

We support this as this would improve accountability and safety.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)**Question B17****Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:**

It is unclear what information is withheld. It would appear from the explanation presented that it relates to a product patents. However, as the regulator is required to publish all products that have been approved and declined, how would this be implemented? Are there particular elements of that information that would be withheld? If a medicine is approved then you would expect that the information relating to the active ingredient ie what it is, is available, as such information will be required for the safe use of that medicine. Some clarity on intent of this would be useful.

B7 Part 5 of the Bill: Licences and permits**Subpart 1: Licences (ss 123–130)****Question B18****Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:**

This is largely appropriate. The ability of a company to perform activities in behalf for a licenced company would be an enabler, however, it is unclear what checks and balances would be in place to ensure that the subcontractor is operating using reasonable standards.

Regarding clinical trials, we would support the concept of licences, however, would suggest the cost of these be minimal as for many trials and organisations that do research may not have commercial funding and operate with small budgets, as such, this requirement may lead to a reduction in innovation due to the costs of licences. It should be noted that most clinical trials would work within international standards of practice (GCP) which are industry standards, so what would be

rationale for a requirement for a local licence. That may be something that is considered around the licence approval process.

In addition, would medicines dispensed for clinical trials from a pharmacy require a separate licence for pharmacy to undertake supply for clinical trial? We suggest that the pharmacy licence should be sufficient to allow such supply ie. no separate licence is required by pharmacies to supply clinical trial medicines.

Hospitals also require a provision in the legislation to be able to continue to supply all categories of medicines (including unapproved medicines) as part of ward and clinic imprests (which may be offsite or mobile). The drafting seems to preclude this in its current form.

Looking strategically at future medicine supply models, one concept is that

of a regionally-provided operational supply model allowing medicines to be supplied from a central location and then transported across the region. We query if there is enough flexibility and scope in the proposed legislation to allow such service models from a licensing perspective.

Hospitals that operate a retail pharmacy would like to see a provision in the legislation to enable DHB retail pharmacies (which are often 'satellite' or 'off-site') to (wholesale) supply all categories of medicine for the purpose of administration pursuant to an inpatient order or imprest supply. For the avoidance of doubt, in this scenario the inpatient order (i.e. drug chart) would not fulfil regulatory prescription requirements.

In addition hospitals would like retail pharmacies to be able to dispense all categories of medicine for individual patients pursuant to an inpatient order.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

These are appropriate. There are 2 considerations however, in large institutions the senior person such as a CEO may not be the appropriate person to be the holder of a licence. It may be more appropriate that a person with operations responsibilities closer to where the work done that requires a licence is, is the person who holds the licence. This we believe would better align with the intent of "fit and proper". What would happen if the person on the licence is under investigation? – The impact of this on the ability to continue delivering a service needs to be considered? We support the concept that a pharmacy to be majority owned and effectively controlled by a pharmacist.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

These are appropriate and we support this.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

These are appropriate.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

While the intent of transfer of licences and permits is great, there may be issues with implementation, for example, in DHBs, a pharmacy licence is issued to the pharmacy manager or senior manager and these individuals may change with short notice periods. In addition, the new person may not have entered into an employment agreement in time for a new licence to be issued. Some clarity and allowance needs to be available for transition periods.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

While these are largely reasonable, they pose restrictions in modern and evolving pharmacy practice. The impact of law that a pharmacist is always present when a pharmacy premise is open is currently overly restrictive, including interpretations of the law when designing pharmacy premises such as consultation rooms, particularly in the context of our health strategy which promotes integrated ways of working. We would like to see allowances that allow premises to remain open for activities during tea breaks and lunch breaks where licences require compliance with supply of category 1-3 medicines without having to lock parts of the pharmacy. Similar restrictions don't apply in medical practices where a practice may be open without a doctor. The current rules and the proposed bill also does not enable the changing nature of pharmacy and medicines supply options and the people involved in the supply process. For example, a pharmacist could be working in an integrated care clinic providing supervision to a pharmacy that operates within that medical clinic - ie the pharmacist may be involved in the providing services that ensure appropriate medicines are prescribed, but the actual dispensing and checking is led by checking pharmacy technicians. Pharmacy and Pharmacist's Medicines supply could be indirectly supervised eg. the pharmacist consults in a consulting room next to the pharmacy or in a clinic setting, but does not have to be in the pharmacy itself for the supply to occur.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

We support this. We suggest that the issues covered in S172-176 needs to have good operational mechanisms to enable health providers to work safely in the

context of health information privacy obligations .

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

We think these are largely legal instruments; we do not have the expertise required to comment on this is, however, the principles seem reasonable

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

These are appropriate.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

These are appropriate for approvals of products. The review of decisions, licences and permits however, may be an onerous process, particularly if the decision is to be challenged in the Court setting. This may have consequences on costs of licences and may become a barrier to challenging a decision. Perhaps greater thought needs to be given about the reviews of decisions for licences and consideration to separating large commercial licence processes from those required for small businesses or state sector organisations.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

This seems reasonable.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

These seem reasonable. We support the notion of enforceable undertakings and providing opportunity to improve.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

These seem reasonable.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

The concept is reasonable.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Elements within this are reasonable approaches. The cost of approvals needs to be carefully considered and may need to take a tiered approach so as to allow less commonly used items in the market to remain accessible ie costs could become a barrier for niche products as well as result increased costs to consumers.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

We support this as this will make it easier for a wider range of health practitioners to be considered for prescribing scope.

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

These are reasonable.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

These are reasonable. However, there may be a need to consider review requested by third parties, for example a professional body may want a review of a particular product or medicine due to safety concerns.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

These we understand are broad areas that would be detailed in the instruments. There would need to be consultation when these instruments are developed. As a specific point, the regulations may need to differentiate between a prescription for dispensing versus an order for administration that currently exists legislation to allow for the unique needs of prescribing in the acute hospital setting.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

We are unable to confirm whether everything that interfaces with Medicines Act is covered. However, the TPB may need to consider interaction with Civil Defence and Emergency Management Act 2002, Privacy Act 1993, the Radiation Safety legislation and the new legislation on Social Work.

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

A process for minor and major changes is welcomed. However, for medicines the regulations may need to consider how changes such as label changes and product packaging is classified – they may need to be classed as major, as changes in labels and packaging can have a significant impact on safety for example look alike labels and packages.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Category 1-4 medicines: We suggest consideration is given to alignment with the TGA categorisation of medicines. There is much potential for confusion with the proposed numbers as they work in opposite to the numbering convention in the TGA (i.e. a TGA category 4 medicine would be a NZ regulator category 1 medicine as proposed).

We support the idea to future proof a 'fourth' category of as yet undefined technologies

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Seeking approvals for patients on unapproved medicines supplied via Section 29 within a 3 month period would create a huge burden on the health system. A grand parented approach should be considered. The need to reissue a standing order for an existing standing order within 12 months will also create a significant burden on the system, given that many standing orders may have longer expiry dates and having all renewed in the 12 month timeline could be burdensome. For medical devices the 6 month period before licenses are required for medical devices may also be too short for the range of devices that the Bill covers. This would seem like an unrealistic timeframe for the regulatory body to work to. A longer period such as 12 months may be more achievable for device licences. The transition timeframes across the various activities needs to be carefully considered. They appear to be very short and unrealistic given the scale of products and providers that the transition will apply to.

Question C4 - Please provide any comments on the approach to post-market controls.:

Currently pharmacovigilance reporting is voluntary. A robust national system would be required as well as consideration given to the implementation of such activity. A significant change process is required for this to occur, particularly around provider reporting. There is also additional administration burden. This is a good thing to achieve, however, organisations can't be left on their own to manage this change. It may be that this is enforced via the HPCA act to enable providers to be responsive to the intent of this change.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

We are pleased to see some recognition of the various activities that are associated in the product life cycle. It still remains unclear whether a contractor who may not be a pharmacist or pharmacy could still compound and what type of licence would be required for this. Additionally would a hospital pharmacy require a separate licence to pack down products for use on wards as stock. We would recommend the pharmacy licence is an all-inclusive approval for potential activities that may be conducted by a pharmacy.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

This is reasonable and is a good step toward ensuring quality and safety of work associated with "hawking".

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Yes

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

No additional comments

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

We do not have the expertise to comment on this, however it would be important to ensure alignment with the legislation that covers cells and tissues.

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

The same challenges around implementation as for pharmacovigilance may apply, however causal relationship in the case of tissues and cells may be more difficult to establish than for medicines

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

These are reasonable

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

These are clear for tissues and cells

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

These are appropriate.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

While in principle this would be a useful thing to do, the scope could be large and may not be the best use of state sector resources.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

The ability to import approved medical devices from overseas without sponsor approval. This may have an impact on consumers being able to procure devices competitively.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

As above

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

These are appropriate.

Question C4 - Please provide any comments on the approach to post-market controls.:

As above

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

The approach is reasonable. Timeframes would be considered reasonable

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

With respect to therapeutic products being medical devices, the definition of manufacturing is clear. Is it then, the intention of Bill to also include activities such as sterilisation of surgical equipment (reusable instruments and devices)? It also appears that the licence to manufacture is to capture information on the manufacturer and not whether the product they manufacture meets a standard, which then raises the question around what benefit would this requirement provide to the user or the sector.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

The approach is reasonable. Timeframes would be considered reasonable.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

This approach is appropriate. Would each trial have to have a separate licence for each site? What would be the costs of obtaining such a licence? There could be significant number of existing trials and the transition period of 12 months may be not be enough for the regulator to issue licences. Please refer to earlier comments on approvals for clinical trials as well.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

As per Question C16

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

This would be appropriate as long as consumers are still able to access medicines without additional costs.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

As per comments provided earlier to this question.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

As per comments provided earlier to this question.

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

The supply and distribution activities do not necessarily require pharmacist skills and therefore distribution models should not be determined by the pharmacist being physically present at the point of supply. The supply and distribution must ensure safety and not determine how the pharmacist works within the supply and distribution system. Supply via robotics and other supply chain mechanism could be enabled, particularly, if access to pharmaceuticals is to be improved.

Technological solutions for supply such as robotics offer significant safety and remove the human factors involved in errors. As such the new legislation should consider enabling this and not restricting supply models by sticking with old or current approaches.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Yes, the requirement of a pharmacist to directly supervise supply activity is impacting innovation particularly when the pharmacist doesn't necessarily have to be physically present in the dispensary to provide the expertise. Technicians for example can competently run a pharmacy supply service, with direction from a pharmacist - eg a pharmacist could be working alongside a GP or a doctor to optimise the medicines and check the prescription details, which can then be supplied via robotics or technicians.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Dispensing and supply functions could be done by a wider range of health professionals as long as their has been pharmacist oversight on prescription appropriateness, for example, it should be acceptable for nurses to supply medicines in circumstance where supply is needed to cover a period before a patient can source supply from their own pharmacy, for example, overnight from an emergency department for initial doses of antibiotics and pain relief.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

The entry of commercial entities as in Option 2 may result in a focus on profits over the importance on standards of quality care and outcomes. Pharmacists may better influence the different models of operation that would enable ways of working that promote practice innovation and improve patient outcomes.

As an additional comment, hospitals that operate retail pharmacies require retention of the (current) ability for an organisation (e.g. the DHBs) to own pharmacies. Moving forward this ownership should not be restricted to the hospital site but allow unrestricted ability for DHB hospitals to own a pharmacy at any geographical

location necessary in order to provide services to DHB patients. For example, a hospital may wish to own a pharmacy linked with an infusion centre based off site).

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Benefits -Professional practice interests driving models of care - enabler for integrating care within multi disciplinary team setting .

Risks - Limited capacity as the availability of pharmacies would be constrained by pharmacists availability and willingness to operate in certain areas - so may impact access, although, this could be enabled by innovative business design eg online services etc

Question C25 - Are there ways in which Option 1 could be improved?:

Practice audits as part of licencing that would require licences to demonstrate patient and professional interest over commercial interests. For example independent pharmacist auditors.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Responsibility that supply, compounding and distribution of Prescription and Pharmacist Only medicines is done as per standard set out by regulations. How the service is designed should not be dictated by the legislation. For example - the licensee may decide not to have a pharmacist involved in the physical supply , but in the decision making on the choice of a product.

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

It does not matter, it could be either or both.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Is there any evidence around what is the optimal number of pharmacies that a pharmacist owns or has interest in and how this impacts on ability to provide appropriate governance. If so then this should be informed by evidence rather and selecting a number or relying in what was the intent of old legislation.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

If the limit were to be retained then, each pharmacist should be able to be afforded 5 - so if there were 2 pharmacists jointly sharing they could run 10.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

No

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

We would suggest grand parenting current licence holders and introducing the new rules for any new licences rather than transition.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Be able to continue. There also needs to be some allowance for situations such as death of a pharmacist owner - perhaps a transition period.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Benefits - competition in the market and possibly improved access

Risks - Commercial interest over professional and patient centred

Question C34 - Are there ways in which Option 2 could be improved?:

Could be through independent governance - for example a regulatory board - however this would be a significant undertaking.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Unlikely as there will always be a conflict of interest between employment and the need to perform in a commercial context vs professional interests.

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes most definitely - all circumstances for which a pharmacist is trained or skilled - most technical elements of a pharmacy activity are now successfully completed by technicians.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No - for all the reasons listed in the consultation.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

It could also be used for public health measures, managing communicable disease epidemics.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

We support this allowance. However, consistency of permissions should be achieved by the Bill - for example, a pharmacy licence would require a pharmacist to be present in the pharmacy for a category 3 medicine to be supplied yet, a retail only licence would not require a pharmacist presence. The risk to the consumer would be same so why would one enable supply without pharmacist and the other require a pharmacist to supervise.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

As per response provided earlier

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes, in all hospital settings and others settings where acute care delivery requires medicines to be available immediately. It may also be useful for improving costs and reducing labour costs - however, adequate standards must be in place to ensure safety of product compounded.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Supply to veterinarians, ambulance services, private hospital clinics, NZMAT, Search and Rescue bases.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

For devices - The change may result in an increase in administrative burden. Processes would need to be relatively simple and responses must be timely. It is unclear whether products already approved would need every retailer to reapply for approval before being able to import.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

This is appropriate.

A specific comment from our dietetic colleagues is that prescribing is included as a component of a Dietitians Scope of Practice - Under this proposed change would the Dietitians Board need to update the Scope of Practice to explicitly include prescribing practices of dietitians?

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Yes

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

It is appropriate to include standing orders in the Bill.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

While the intent is reasonable, this will result in significant burden on health practitioners. Off label use of medicines is common in many areas and parts of the patient population eg paediatrics. The off label use of medicines could take a different approach eg a list of medicines which are considered controversial may need approval - others shouldn't.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

a) No - others who have the authority to prescribe should be able to as well if the patient is being cared by them.

b) They should be able to apply for this in the first instance.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

As provided previously

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Already covered in wholesale supply questions.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Dependant on the type of medical device. If we are talking about therapy equipment then potentially yes. If we are talking about items that need to be implanted, possibly not.

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Yes - Do not foresee any risks on safety so long as their professional scopes ensure competency.

Has the potential result in restricted choice of product for the patient eg the health practitioner may offer only what they hold in stock.

Benefits would be improving access to medicines.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Yes as long as it is done under exact direction.

Benefits - enabling the health practitioner to devote their time on patient care and decision making rather than transactions.

Risks - may not have the competency to answer any questions.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

These are appropriate.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

No - the information presented in DTCA is often out of individual context and often results in medicine seeking behaviours without appropriate assessment of options. This puts pressure on prescribers.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

The approach is reasonable.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

As per previous response

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

As per previous response

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

As per previous response to this question.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

As per previous response to this question.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

As per previous response to this question.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Yes, there will be individual circumstances and a permit should be able to look at the merits of such application. For example where a personal import would be a more affordable option than going through a pharmacy. A prescription and SCNSA would still apply. The other would be ineligible patients who may be able to seek supply of medicines from their country of origin, if visiting.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

As per previous response to this question.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

As per previous response to this question.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

As per previous response to this question.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

As per previous response to this question.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

As per previous response to this question.

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

As per previous response to this question.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

As per previous response to this question.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

As per previous response to this question.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

As per previous response to this question.

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

As per previous response to this question.

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Ability for consumers to access medical devices or products that assist with disability must not be made harder with any new changes, particularly if they are classed low risk items. Affordability for the disabled community is a significant challenge so being able to access products (not medicines) that are fit for purpose is important to maintaining choice and control for disabled people. The Bill must take into consideration the impact on disabled people and value the principles within the NZ Disability Strategy.

Response ID ANON-DPZ8-G418-A

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:55:34

Submitter profile

What is your name?

Name:

Sally Zhu

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Pharmacy

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

-

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Neutral

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

I do not agree with allowing other professions to dispense medications. As a pharmacist who had trained for 5 years it is not right that other professions are allowed to dispense without extensive educations and training in this field. I believe that the risks outweigh the benefits and that dispensing should be left with pharmacists to ensure best practice and safety to public. I also do not believe it is right for pharmacy licensing to be deregulated. Pharmacists being forced to work under purely business minded people jeopardises our morals and code of ethics as we will feel pressured to just sell and dispense products with the

intention to generate money instead of for the good of the public. Yes pharmacists will still be required to supervise the pharmacy but the pressure to perform sales wise from higher up will impact the way we work and we will have to obey if we want to keep our jobs. This is utterly wrong and should not be allowed.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Yes it is a good idea to allow pharmacies to supply without requiring a wholesale license as this minimises wastage of Medicines

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

I believe it is good to allow health practitioners to prescribe medications relevant to their scope of practice but dispensing of the medications should be left to pharmacists.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Pharmacy licenses should only be granted to pharmacists and should be left as is! It is a terrible idea to let non-pharmacy business owners obtain licenses as there will be a conflict of interest whereby the pressure for a pharmacist to sell to generate business income vs for the good of the patient becomes unbalanced and pharmacists will be breaching code of ethics for fear of losing their jobs.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

I think pharmacies should be able to supply medicines to other pharmacies without a manufacturing license. I also believe a pharmacy should be able to operate outside of a brick and mortar building especially in terms of emergency situations

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I believe that it is in the best interest of the public that pharmacy ownership remains with pharmacists. Pharmacists are obliged to adhere to the code of ethics and have a standard of professional service and care that is likely to be jeopardised under open ownership.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Benefits of option 1 are that best practice is adhered to and a high level of service and care is extended to the public as pharmacists are held accountable for our actions. Under open ownership, the owner is not risking loss of pharmacist practising license so is able to pressurise pharmacists into doing things that may not align with our morals and ethics.

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

I believe prescribers should not be allowed to take a financial interest in pharmacies.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes this makes time management easier

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Response ID ANON-DPZ8-G48F-Y

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 16:58:42

Submitter profile

What is your name?

Name:

David Menkes

What is your email address?

Email:

What is your organisation?

Organisation:

University of Auckland Medical School and Waikato DHB

Submitter Profile (tick all that apply)

Consumer

Professional body (eg, Colleges, Pharmaceutical Society etc), District Health Board (DHB)

If you select DHB, please state service area:

Wa kato

Medical practitioner (excluding Surgeons)

If you select 'Other', please comment below;:

Medicines (other than cells and tissues)

Other (please comment)

If you selected 'Other' please comment;:

pharmacologist

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:
generally sound

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:
rather wordy, but coherent

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:
no comment

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:
no comment

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

yes

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

coherent, but detail needed

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

latitude required for medical prescribers, with a minimum of necessary documentation

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

agree

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

agree

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

tricky. needs to be audited.

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Quite simply, advertising of prescription medicines should be banned, and thus advertising requirements and enforcement tools would apply only to therapeutic products available without a prescription. In the latter case, there should still be a monitoring of advertising content, to ensure that the material is truthful, not misleading, and includes a reasonable balance of intended benefits and possible harms.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Direct to consumer advertising (DTCA) of prescription medicines should be banned. There are multiple reasons for this view:

1. DTCA effectively stimulates demand for certain medicines, and in some situations this is undoubtedly useful. However, the evidence indicates that the net harms of DTCA far outweigh its occasional benefits (Every-Palmer S, Duggal R, Menkes DB. Direct to consumer advertising of prescription medication in New Zealand. NZ Medical Journal 2014; 127: 102-110).
2. A particular harm caused by DTCA is distortion of the doctor-patient relationship. This is why a variety of professional bodies, including the NZ Council of Medical Colleges (CMC), have consistently opposed the continuation of DTCA. Consumers (unbeholden to industry) are likewise skeptical of DTCA and emphasize the importance of protecting the doctor-patient relationship (Menkes DB, Rostron S, Ware K, Sokratov A, Duggal R. Service user perspectives on direct-to-consumer advertising (DTCA). Australian and New Zealand Journal of Psychiatry 2014; 48 [suppl 1]:110).
3. Attempts to regulate DTCA have consistently failed to ensure that advertising material contains reasonable, balanced information (Lexchin J, Menkes DB. Can Direct-to-Consumer Advertising of Prescription Drugs Be Effectively Regulated? New Zealand Medical Journal (2019, in press).

As a final point, I would emphasise that consumers do need a reliable and accessible source of medicines information. In my view, New Zealand should develop a platform for providing this information online, with input from relevant professional bodies.

Response ID ANON-DPZ8-G481-A

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 16:59:24

Submitter profile

What is your name?

Name:

Gareth Frew

What is your email address?

Email:

What is your organisation?

Organisation:

NA

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

New Zealand

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

The new legislation needs to allow pharmacists to supply more than 72 hours of medicine without a prescription in the event of an emergency.

Allowing pharmacists to supply 7 days minimum but ideally 30 days would be preferable, as was enabled following the CHCH and Kaikoura earthquakes.

Allowing pharmacists to provide these medicines with PHARMAC funding would also be desirable.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

A more permissive approach to licensing and pharmacy service provision is needed going forward especially in the context of responding to an emergency.

Scenarios that need to be enabled are dispensing from a novel facility e.g. a CBAC/ flu center. This could be treated as either offsite dispensing by a pharmacy that already has a license or through a pharmacy permit to provide one specific pharmacy activity ie dispensing.

There also needs to be increased flexibility for pharmacies that must relocate in the event their usual premises is deemed unsafe/unsatisfactory. The bill needs to enable multiple options such as two pharmacies temporarily sharing a building or a pharmacy relocating to a container or other premises that might not meet all the usual licensing requirements.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

I support provision to include the concept of a permit where it is in the public interest to allow service provision to either continue or be established in circumstances where the requirements of a license are unable to be met e.g. as part of an emergency response.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

I would like to see dispensing from novel facilities enabled particularly as part of an emergency response.

Supply of Cat 3 medicines by other health practitioners e.g. physios is not desirable. There is a risk of increased harm when these medicines are supplied by people with no or little information about the patients other health conditions or prescribed medicines. There is also ambiguity about how these medicines might be supplied in practice e.g. would a person need to have a consultation with e.g. a physio each time they wished to purchase an NSAID or could they simply speak to the receptionist.

In the rural context it would be good to see sale of pharmacist only medicines enabled. E.g through enabling consultations to take place via a video conference with a pharmacist located offsite.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

The requirement for a pharmacist to be physically present at all times is outdated and is a barrier to collaboration, particularly in remote rural areas.

Allowing the pharmacist to provide clinical advice and over site remotely would be desirable. An example could be a sole charge rural pharmacist leaves the pharmacy to attend a clinical meeting at a local medical center. for the duration of the meeting the pharmacist is offsite but is contactable and thus can remotely provide clinical guidance to consumers presenting at the pharmacy.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No.

The current legislation acts as a disincentive for pharmacists to become prescribes, as prescriptions written by them cannot be dispensed at a pharmacy they own.

A community pharmacist with the ability to prescribe could be a useful addition to a general practice team, particularly in the area of repeat prescriptions.

The risks associated with prescribes holding an interest in pharmacies are offset by the relatively low mark ups on drugs in 2019 compared with 1981.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Yes where a pharmacy has to relocate following unforeseen circumstances. Enabling the pharmacy to continue providing medicine to their community is a desirable outcome.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Regarding the special clinical needs supply authority for off label medicines use. Putting a requirement for a tick box or similar is likely to increase the work for

both prescribers and community pharmacists, who will have to follow up with prescribers when they don't tick the box. It appears the proposal will increase the bureaucracy without improving patient safety.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

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Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 17:18:49

Submitter profile

What is your name?

Name:

Fleur Winslade

What is your email address?

Email:

What is your organisation?

Organisation:

Terumo Australia Pty Ltd

Submitter Profile (tick all that apply)

Medical devices

Medical devices

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

Terumo Australia supports the purpose and principles of the Bill and, the need for co-operation with overseas regulators. It is essential to align devices (both import and export) and avoid costly duplication of conformity assessment and delayed availability of devices in New Zealand.

Specific evidence and documentation, issued by specific overseas regulators and assessment bodies, should be considered by the New Zealand Regulator to support medical device approval to supply in NZ:

- Australian Therapeutic Goods Administration (TGA)
- Certificates issued by Notified Bodies designated by the medical device regulators of European member states, under the current three Directives on Active Implantable Medical Devices (AIMD), Medical Devices (MDD) as well as In Vitro Diagnostic Devices (IVDD) To be replaced by the Medical Device Regulations (MDR) and In Vitro Diagnostics Regulations (IVDR)
- Decisions of the United States Food and Drug Administration (FDA)
- Approvals and licences issued by Health Canada

- Pre-market approvals from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA) or Registered Certified Body (RCB), whatever is applicable)
- Certificates and reports issued under the Medical Device Single Audit Program (MDSAP).
- ISO 13485:20016 and ISO 9001:2015

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

s21 meaning of a medical device - Definition needs to completely align with the harmonised global definition

Regardless of the definitions enacted the regulator needs to maintain flexibility to recognise different classifications from different jurisdictions in respect to products that sit on the borderline between medicines vs devices (i.e some products are treated as medical devices in some jurisdictions and medicines in others: international approvals should be leverageable in New Zealand despite these differences)

s34 Meaning of manufacture, for medical devices

The definition of “responsible manufacturer” for a medical device (Section 31(5) of the Bill) doesn’t align with the new European Medical Device Regulations (MDR): ‘manufacturer’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark. “Responsible manufacturer” is a medicine terminology. Regulatory nomenclature should have recognised international universal terminology “legal manufacturer” for medical devices

s34 (4) Remanufacture - unless endorsed by the legal/original manufacturer, any remanufacturing of a medical device must become the responsibility of that manufacturer. this needs to be clear under the regulations.

s43 Meanings of wholesale supply and non-wholesale supply

From this definition a medical device supplier could be classified as both a wholesaler and a non-wholesaler by means of supplying a device as per (2) (a) to supply to other persons and (3) supply to patients

Terumo Australia strongly disagrees with the concept of defining medical device sponsors as either wholesalers or non-wholesalers – this is more appropriate for medicines. A medical device “product approval” should allow the sponsor to conduct all supply chain activities without further regulatory requirements.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

s52 Sponsor’s consent required to import an approved product

(1) (b) import the product without the written consent of the sponsor

Terumo Australia does not agree that there can only be one sponsor however all Sponsors should maintain evidence of direct relationship with the manufacturer, especially where there are multiple importers/ Sponsors of the identical product from the same manufacturer. It is then imperative that each sponsor maintain supply chain records of distribution related to their approval.

1(c) are authorized by a licence, permit, or provision of subpart 3 of Part 3 to import the product without the sponsor’s consent.

Terumo Australia completely disagrees with this provision. Importing without the consent of the sponsor bypasses that sponsor who is still held responsible for that device being in the NZ market. The sponsor cannot be held responsible for actions of another importer unless there is a written agreement between the parties allowing use of the sponsors approval.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

s55 Persons in supply chain must comply with regulations. (1) (d)

This has more relevance to medicines than medical devices and will need some detail as to the extent of complying with this requirement for medical device suppliers. Any on-supplier in the supply chain must have obligations for traceability of that medical device. Wholesalers must hold equal responsibility for traceability for the device as the sponsor if that wholesaler on-supplies or provides to a patient

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

no comment as a medical device sponsor

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

no comment as a medical device sponsor

Question B7 - Please provide any comments on the authorisations for health practitioners :

no comment as a medical device sponsor

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

no comment as a medical device sponsor

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

To avoid confusion, it would be better to refer to the customer of the veterinarian as an "animal" rather than a "patient"

s68 Veterinarians: wholesale supply (a) the regulations permit the device to be supplied

Devices approved for humans aren't always approved for animal use. As soon as you decide to use a therapeutic product on an animal it inherently becomes a non-therapeutic product. And, if it is approved or approval exempt, it automatically becomes unapproved. The veterinarian takes the risk associated with use of the product post market. Sponsors cannot be held responsible for the use of their approved products in veterinary animal health.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

no comment

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

no comment related to medicines

s75 Manufacturer of custom-made devices

Custom-made devices need to be defined according to IMDRF definitions. This definition should be included in the Bill

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

s82 Meaning of advertisement and related terms - This should state that it excludes Healthcare Professionals

s87 Notifying Regulator of suspicion of tampering (2) (b) the therapeutic product does not yet exist - This statement needs better clarification with examples

s92 Misleading information in records - A "required record"? This should be defined in regulations

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

s95 Criteria for product approval

Products manufactured in New Zealand that are only intended for supply in overseas markets would still require a product approval. This requirement should only attract a simplified pathway that meets the regulations of the importing country

s96 Product standards (1) The rules may specify standards for therapeutic products

As medical devices will be approved in New Zealand recognizing international regulatory authorities pre-market approvals, no standards should be mandated in legislation for medical devices approved in New Zealand

Terumo Australia supports adoption of international standards for medical devices in New Zealand realizing that the NZ market for medical devices is very small, i.e., it represents approximately 3% of the global market. Referencing or mandating compliance with national-only standards in regulations would be counterproductive and would hinder patient access to state-of-the art medical devices. Manufacturers need to take into consideration the feasibility of supplying medical devices in small markets at an increased cost and effort, when there is no added value to patient safety. We recommend that no unique Australia/New Zealand standards or requirements are implemented and that acceptance of international harmonized requirements be accepted such as for labelling

s98 Content of approval (e) name of the responsible manufacturer and the address of each place at which it manufactures the product

This requirement is more suited to manufacture of medicines than medical devices. Devices may be subcontract manufactured at various sites controlled by the legal manufacturer - it is recommended to use harmonized terminology for manufacturer. This requirement is not necessary for medical devices as evidence of conformity assessment would be provided that proves the device has been assessed and a comparable regulator or notified body.

s99 Scope of approval

Approval must be harmonized around international accepted models. A family of devices is not one single product. approvals must not be for an individual product but allow for families or kinds of approvals

s100 Major changes result in a new product

Assuming that most medical devices marketed in New Zealand would be imported and holding an approval by a recognized authority, it is expected that design changes and changes to the manufacturer's quality management system will be managed by the regulatory authority who issued the approval in accordance with their own guidelines. The New Zealand Regulator should only receive notification in relation to elements that make up the content of approval, Section 98, and these notifications should not result in a new product approval.

s101 (2) Minor changes - Refer to comments above

s102 Change of Sponsor. There must be an option for transfer of approvals to another sponsor. Devices or parts of business are sold to other companies and cancelling an approval for such a device would be unreasonable

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

s104 Approval lapses on deaths, bankruptcy, or insolvency of sponsor - approvals should. be able to be transferred to another sponsor in this event. The approval lapses on death, bankruptcy or insolvency of sponsor could result in critical device shortage. This clause needs to be re-thought in relation to medical devices.

s108 Grounds to cancel approval (a) the quality, safety, or efficacy or performance of the product for the purposes for which it is used is unacceptable should read "becomes unacceptable"

There is no process to suspend a product, only cancel. This means that the Sponsor may have a problem that needs fixing and can be fixed and then the Sponsor can continue supply. If the product approval is cancelled the Sponsor would need to apply again to the Regulator for product approval and this would result in more cost with new approval numbers and time to supply market again

s112 Effect of cancellation.

It needs to be clear that the approval for the sponsor to is cancelled and therefore cannot import/supply/export any further devices. Devices already in the supply chain were imported/supplied under a valid approval at that time and therefore cancellation of the approval should not impact this device. On-suppliers (wholesalers) must have obligations to trace all product

s113 Therapeutic products register

- (2) (b) therapeutic products that the Regulator has refused to approve
- (c) therapeutic products for which an approval application has been made

Both the above clauses would be considered breaches of commercially sensitive information if published on a public website. Terumo Australia disagrees with both clauses (b) and (c) as not being acceptable.

(6) The Regulator must make the register publicly available

The Regulator should only publish those parts of the register that are not commercially sensitive and suggest that there is a public and non-public section of the register

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Approval exempt products should be defined in the regulations

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

s116 (1)(c) Sponsor of approved product must ensure compliance with approval

the sponsor can only legal enforce compliance within the sponsors company. It is not clear what the definition of "other person" is - does this mean within the legal control of the company/sponsor or external to the company/sponsor. The sponsor is not responsible for how the device is used once it is supplied nor responsible for those companies that on-supply (wholesale)

s117 Sponsor must ensure compliance with product standards

Standards are detailed technical specifications that are voluntary in nature. They are issued by organizations competent in the standardization area and aim to reflect the current state of technology. International standards must be accepted over country specific standards (AS/NZS). Terumo Australia does not support mandating standards in law

s118 (1)

(e) tracing and recall of, or other market actions in relation to, the product

the sponsor is respons ble for tracing to the first customer they supply to. If this is a wholesale customer then that wholesaler is responsible for traceability to whomever they on-supply to. The sponsor should not be held responsible for any actions of an on-supplier/wholesaler

s119 Sponsor not responsible for approved products imported without consent

This should include and extend to, products imported for personal use and approval
exempt products.

Further, the Bill should clearly state that any entity that imports without the consent of the Sponsor is required to assume all the responsibilities that would otherwise be required to be met by the Sponsor, It is not adequate to rely upon the Regulator to add these responsibilities to the licence or permit as conditions. importation without consent of the sponsor should be treated as an offense

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

no comment as a medical device sponsor

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

This section applies to medicines only. Medical devices should not be covered by licenses.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Medical devices should not be covered by licenses.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

s131 What permits may authorise (1)(a) import or supply a medicine, medical device, or Type-4 product without it being approved or import an approved product without sponsor's consent

Terumo Australia has concerns with an approved product being imported into NZ without our knowledge as the sponsor. The Sponsor should not be responsible for product imported without consent. It is not the responsibility of the sponsor to record the product information/lot numbers of this product as traceability is the responsibility of the importer and they would carry all obligations for that product. It must be an offense to import without the consent of the sponsor who is seen as the responsible entity for the product within NZ

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Medical devices should not be covered by licenses.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Medical devices should not be covered by licenses.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

Terumo Australia rejects licences for medical devices and cannot ensure healthcare professionals/ practitioners have authority and resources. This is more reflective of medicine requirements. This bill is designed to ensure safety and efficacy of therapeutic products and not to regulate the practice of healthcare professionals. Therefore sponsors/importers/licencees or any other term used to describe someone responsible for the medical device should not be responsible for ensuring healthcare professionals are authorized/resourced.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

We support the focus of the Regulator on an active and comprehensive post-market monitoring programmes to collect information about the safety, quality and performance of medical devices after they have been approved. Any process and requirements must be aligned with current international practice and reflect the same language and interpretation of criteria.

s161 Public safety announcements

There needs to be a requirement for consultation about such public safety announcements before they're made – the Regulator should not be able to unilaterally make such statements about such things without consultation and dialogue with the Sponsor

s162 Recall order

There must be consultation / dialogue before a recall order is made. There also needs to be a mechanism, as there is now, for sponsors to initiate a recall action in consultation with the Regulator. A recall order should only be made in a situation where a sponsor is not willing undertake such an action under their own initiative and, after the appropriate dialogue, the Regulator has formed the view a recall is still needed.

no comment related to medicines clauses

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

s185 Regulator may require information (1)(b) in relation to a specified relevant document

Suggest inserting a time frame of 20 working days to enable the sponsor to source any documentation required by the Regulator. International regulatory best practice does not require the sponsor to hold all information but have access to obtain the information

s186 Testing of samples for investigative purposes

The regulator should be responsible for obtaining testing if they require this at their expense.

s187 Laboratories and analysts

If a New Zealand laboratory will be the mandated testing facility how will international manufacturers transfer the test methods to them and how will the New Zealand testing laboratory know they'll appropriately validate those methods. For some products there'll also be very specific equipment needed to do the tests; sometimes this equipment may be custom made for a specific device.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

s200 Application for review of Regulator's decisions

Schedule 2 specified who's able to apply for a review. This should include: "...a person whose interests are affected by an initial decision..."

Schedule 2 also specified what decisions are reviewable but does not include approvals. Addressing both comments above allows competitors (or even "affected" individuals of the public) to apply to have a decision reviewed.

(2)(a) The timeframe should be started from when the applicant has become aware of the decision not when the decision is made, and 90 working days would be more appropriate than 60 working days

(2)(c) there should not be a fee for this review

s202 Procedure on review

There should be a mandated timeframe within which the review panel reaches a decision. The review panel should also be required to form its decision having a view to the Purpose and Principles of the Bill.

s203 Decision on review (2) the review panel must notify the applicant and Regulator of its decision

There should be a time frame identified from application to review and to the panel's decision and suggest 60 working days

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

s208 Notice and reasons for decision by Regulator

(5)(b) there should be a time specified not just a "reasonable" timeframe

s209 Sharing of information with regulatory agencies (4) The Regulator must not give information to an overseas organisation unless satisfied that appropriate protections will be in place

The whole of this section should be limited to overseas agencies the Regulator has a formal agreement with that specifically protects confidential and private data. Sharing, either way, should not be possible without such an agreement.

s210 Power of Regulator to act on requests of overseas regulators, etc

This section should be limited to only formal agreements the Regulator has other international regulators

s212 Regulator may request further information, site access, etc

(1)(b) This should only relate to medicines and not medical devices as we should be aiming for 100% reliance on an overseas approval unless the regulator has the capacity to provide their own conformity assessments

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

s232 Regulator may accept undertakings

If the Sponsor has let the Regulator know someone is acting in contravention to the Bill and that action is causing the Sponsor's organisation financial or reputational harm and the Regulator doesn't take enforcement action, the Sponsor's organisation should be able to seek an injunction to stop the person conducting the action regardless of any other remedies that may be available to the Sponsor's organisation under other New Zealand legislation

Suggest delete 232(6)

The 'and' at the end of 239 (3) (a) should be 'or'

The 'and' at the end of 242 (3) (a) should be 'or'

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

no comments

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

no comments

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

A regulatory scheme must be limited to efficiency costs only. The industry should not be expected to fund the establishment of the Regulator nor the initial operational cost during the transition period.

The Regulator should be accountable for timeframes for product approval and non-performance

s272 Relationship with Misuse of Drugs Act

The Misuse of Drugs Act should not apply at all to a therapeutic product approved under this Bill where the controlled drug cannot be used as a controlled drug (e.g. the amount included is too small or it's impractical to extract it in sufficient quantities for it to be used as a controlled drug).

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

no comments

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

no comments

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

no comments

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
no comments

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:
no comments

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
no comment

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
no comment

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
no comment

Question C4 - Please provide any comments on the approach to post-market controls.:
no comment

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
no comments

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
no comments as a medical device sponsor

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:
no comments

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
no comments

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
no comments

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
no comments

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
no comments

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
no comments

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:
no comments

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

non therapeutic products may need to be regulated under separate legislation and not the therapeutic products bill

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

no

It is essential that the proposed Therapeutic Products Bill supports the growing momentum for global harmonisation of medical device regulations, and this includes recognition of other international regulators approvals as determined by the New Zealand Regulator. This must also look at other jurisdictions than the EU, also including acceptance of MDSAP country participants

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Terumo Australia does not agree that there is a need to create a 'new' product approval for changes to devices. There should be more allowance for variations to current approvals. The changed device is not supplied until regulatory approval is obtained (if applicable). Track and trace is achieved through batch/serial records and UDI moving forward.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

We do not see the need to restrict supply is the device is approved

Question C4 - Please provide any comments on the approach to post-market controls.:

Terumo Australia supports the industry associations view - The Medical Technology Industry proposes the provision of annual reports for 3 consecutive years from the date of registration for high risk and implantable devices. No annual report on low-medium risk medical devices, unless requested by the Regulator if post-market audit is conducted.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Terumo Australia supports the MTANZ position

This requirement for both suppliers and the Regulator would exceed the resources available for most suppliers who would have thousands of devices to apply for licences within the 6-month period and at the same time submit applications for product approvals. It is not indicated how the licence will be "automatically" issued? It may be possible for some form of licence to be generated based on existing WAND entries, however, this will be impossible for IVD medical devices that do not currently appear in WAND.

The intent of this policy does not show any benefit in the short term and logically would be impossible to achieve. The Medical Technology Industry totally rejects the need to issue licences to continue supply of devices to the New Zealand market at commencement of the Therapeutic Products Bill. Rather, there should be a specific form of medical device application under the new regulatory framework for products legally supplied to the New Zealand market at the date of commencement. This form of application should require the Sponsor to declare that the medical devices covered by the application were legally supplied at the date of commencement.

The Medical Technology Industry needs a 3-year transition period from the commencement date of the scheme for devices, currently being lawfully supplied in NZ, to apply for a product approval to continue supply with no temporary licence required to be issued by the Regulator.

The Medical Technology Industry suggests as an incentive to encourage early product approval applications, there be a sliding scale of fees charged with no annual fees charged during the transition period of 3 years.

- First year fee free
- Second year 50% fee charged
- Third year 75% fee charged
- All new product approval applications during that transition period of 3 years would attract full fees.

There is the potential for PHARMAC and/or other tender/contract bodies having to be notified of each issued licence (for current devices on market and then again temporary licence before approval) and again once product is approved. The Medical Technology Industry sees no added benefit for the triplicate process and will only cause considerable waste of resources, not only for the industry, but also for those entries that have a requirement to be updated in relation to changing registration details.

The Regulator must demonstrate that the electronic platform being established for product approval applications is proven and reliable before the transition period begins.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

this must align with international GHTF/IMDRF definitions

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

see response in C14

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

not comments

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

no comments

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:
no comment

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:
no comment

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:
see response to C14

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
no comments as a medical device sponsor

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
no comments as a medical device sponsor

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
no comments as a medical device sponsor

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:
no comments as a medical device sponsor

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
no comments as a medical device sponsor

Question C25 - Are there ways in which Option 1 could be improved?:
no comments as a medical device sponsor

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
no comments as a medical device sponsor

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:
no comments as a medical device sponsor

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:
no comments as a medical device sponsor

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
no comments as a medical device sponsor

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
no comments as a medical device sponsor

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
no comments as a medical device sponsor

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

no comments as a medical device sponsor

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

no comments as a medical device sponsor

Question C34 - Are there ways in which Option 2 could be improved?:

no comments as a medical device sponsor

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

no comments as a medical device sponsor

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

no comments as a medical device sponsor

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

no comments as a medical device sponsor

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

no comments as a medical device sponsor

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

no comments as a medical device sponsor

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comments as a medical device sponsor

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

no comments as a medical device sponsor

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

no comments as a medical device sponsor

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

no comments as a medical device sponsor

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

no comments as a medical device sponsor

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

no comments as a medical device sponsor

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

We do not support off label use of any therapeutic product as a sponsor

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

no comments as a medical device sponsor

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comments as a medical device sponsor

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

no comments as a medical device sponsor

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

no comments as a medical device sponsor

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

no comments as a medical device sponsor

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

no comments as a medical device sponsor

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Advertising to healthcare professionals (and associated support roles) should not be regulated.

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

direct to consumer advertising must be regulated

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

Medical devices are currently supplied into NZ by the sponsor (WAND notification holder). The sponsor supplies the device to customers which may include hospital, clinic, pharmacy, wholesaler/distributor who intends to on-supply. Some of these wholesalers/distributors supply into the human medical supply chain while others are vet related. Any medical device being supplied regardless of the industry (human or vet) use should be obligated to ensure that they maintain supply chain records and are held responsible for reporting complaints and actions related to recalls. Once the sponsor initially supplies the device (to the first customer) their responsibility for traceability is completed. If the "first" customer chooses to on-supply in any capacity and in any industry they must be held responsible for supply chain related matters regards of the industry they supply to (human or vet) even though the device is no longer a therapeutic product if not for human use.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

previously answered

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

previously answered

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

we do not support off label use or promotion of any therapeutic product as a sponsor

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

no comment

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comment

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

no

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

no comments as a medical device sponsor

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

no comments as a medical device sponsor

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

no comments as a medical device sponsor

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

no comments as a medical device sponsor

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

no comments as a medical device sponsor

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

no comments as a medical device sponsor

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

no comments as a medical device sponsor

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

previously answered

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

previously answered

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

previously answered

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

no comment

Response ID ANON-DPZ8-G4U1-7

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 17:20:50

Submitter profile

What is your name?

Name:

David Tsui

What is your email address?

Email:

What is your organisation?

Organisation:

Shire New Zealand Limited, now part of Takeda

Submitter Profile (tick all that apply)

Industry body

Medicines

Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Next steps after the consultation

Executive summary

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).::

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).::

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).::

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).::

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

We do not support the inclusion of therapeutic products that the Regulator has refused to approve in the Therapeutic Products Register (s113(2)(b)). Such information is not included in a similar database, the Australian Register of Therapeutic Good (ARTG), managed by the TGA in Australia. Information pertains to refusal of approval can be made available to the public by other means. The Therapeutic Goods Register should be set up as a database of all products approved for use in New Zealand rather than an archive of approval and refusal decisions.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

We believe the TPB should extend the period of data protection to more closely align with those adopted in major overseas countries such as the USA (5 to 8 years), EU (8 years*), Sweden (10 years), Canada (8 years), Switzerland (10 years).

(* European Union has a system allowing a maximum of up to 11 years comprising 8 years of data exclusivity, 2 years of market exclusivity and potentially 1 additional year of market exclusivity based on approval of a significant new indication)

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

The Executive Summary of the TPB consultation document states one of the objectives of the new regulatory scheme is:

- Ensures high-quality, robust and accountable decision-making

The Executive Summary also states two of the measures that will be put in place to achieve the stated objectives are (to establish):

- regulatory requirements that are consistent with international approaches and effectively administered
- a regulator that can exercise regulatory powers effectively, is accountable, and can engage internationally and recognize work done by trusted overseas regulators.

Despite the emphasis on accountability stated in the Executive Summary of the TPB consultation document on the part of the Regulator in making decisions and exercising power, there is no provision in ss205 to 222, either as a part of the Bill or by referring to regulations, requiring the Regulator to make approval (or non-approval) decision within a specified length of time to ensure timely access to new therapeutic products by patients. Time-bound regulatory decision making an important feature recognised by overseas jurisdictions and this practice is underpinned by legislative instruments governing the operation of the TGA, US FDA, and EMA. In order to meet the accountability objective, the TPB should include a provision requiring the New Zealand Regulator to make time-bound approval (or non-approval) decisions within an interval that is commensurate with the effort that is needed to assess an application and comparable to the best practice of overseas regulators.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

With Topic 1 - Matters that may be considered in regulations, and under the subheading 'Interpretation', there should be the addition of the critical matter of orphan drug and rare disease.

Developing legal definitions for terms such as "orphan drugs" and "rare disease" is pivotal to setting up legal frameworks to protect the well-being of the rare disease community. While the lack of a legislative framework could still achieve some operative success, only the law can confer enforceable protection uniformly across the country, thus avoiding abrupt policy changes or postcode lottery situations (Orphanet Journal of Rare Disease 2014;9:137). Like many overseas developed countries (including those in the APAC region like Australia, Japan, Taiwan, South Korea, Singapore), the definition for orphan drug and rare disease should be included in the regulations so the Regulator can proceed to develop an appropriate decision pathway for orphan drugs.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We support provisions in the TPB to allow direct-to-consumer advertising (DTCA) of prescription medicines. In addition to complying with applicable laws that

have provisions covering prescription medicines, Shire New Zealand Limited (now part of Takeda) is a member of Medicines New Zealand and abide by its Code of Conduct in promoting prescription medicines. Currently, all advertisements of prescription medicines are scrutinized for compliance by an independent body the Therapeutic Advertising Pre-vetting System (TAPS) that we envisage will continue to play a role under the new regulatory regimen. We are not aware of any significant public safety/health concern attributable to DTCA operating in the country. The ability to communicate important health information and treatment options responsibly should be retained under the TPB

Response ID ANON-DPZ8-G41K-W

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 17:28:25

Submitter profile

What is your name?

Name:

Fen Ni Wong

What is your email address?

Email:

What is your organisation?

Organisation:

Independent Pharmacist

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Neutral

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Chapter C: What the new scheme would mean for different sectors and health practitioner groups

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

"retail-only licences' to continue. This type of licence allows a store to supply pharmacy medicines without meeting the standard pharmacy requirements (ie, requiring a pharmacist to be present)." - No, I do not agree with this. If it is categorized as a Pharmacy/Pharmacist Only medicine it needs to have a Pharmacist present to facilitate supply to a consumer.

Does the pharmacist need to physically be there? Possible not - with the improvement of technology, having a Pharmacist available via Skype/video chat/virtually to see if the product is suitable for this consumer could be an option.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Current pharmacy licensing requirements do create barriers when limiting pharmacy services to be delivered from a set physical location.

Mobile services or those services allowing pharmacists to take their services and pharmacy activity outside of their fixed premises is really innovative and would improve access to consumers.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Innovation in pharmacy will come with technology, but this needs to have pharmacists present either physically or virtually to ensure that professional, ethical, legal obligations are upheld.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

A pharmacist who owns and has effective control over a pharmacy will have to abide by legal and most importantly, professional and ethical standards and obligations.

Open ownership may not take these professional and ethical obligations into consideration and there will be a focus on profit rather than positive patient outcomes.

I would like to see the 5 pharmacy limit scaled back to 3 pharmacies as this is a more manageable number that has better oversight and control. Also, owners must be required to work minimum amount of specified hours per year in their pharmacies to ensure they are upholding their effective control responsibilities - employing responsible persons to share the role in quality audits and improvements can occur; but ultimately, if a pharmacist is to own a pharmacy, a requirement should be that the owner is actually aware and experiences how their pharmacy staff members are carrying out pharmacy activities.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Benefits: Pharmacy Owners are more accountable for the provision of quality services consumers are accessing. Often there is a disconnect with the owner and the employees employed to run the pharmacy. If you want to own a pharmacy, you have to have a hand in running it and ensuring that your staff meet and deliver pharmacy services at a specified standard.

Risks: Pharmacy owners who have more than 2 pharmacies and who do not actively work in their pharmacies will continue to have a hands off approach to the running of their businesses. They hold no accountability for errors made or for inadequate systems taking place.

"A potential risk associated with this approach is that it limits the potential for commercial investment and competition, which could reduce opportunities for greater economies of scale and investment in technology and subsequent innovation"

- possibly a risk as investment partners often want to see a financial return which would could lead to pharmacy activities breaching ethical and professional standards.

Question C25 - Are there ways in which Option 1 could be improved?:

More restrictions, a robust enforceable system.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

The pharmacist owner must work a certain amount of hours at their pharmacies in order for effective control.

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Yes - they should all equally show effective control.

Responsibilities can be shared but not separated amongst the owners.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Absolutely! Scale back to 3 if possible.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Evidence of hours worked at each.

Evidence of internal audits and quality improvement systems.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

About 5-10 years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Investors looking at financial gain without the responsibilities and legal ramifications placed on Pharmacists.

Not having patient-centric care, moving towards more revenue/cost cutting practices that endanger the public/consumers.

Question C34 - Are there ways in which Option 2 could be improved?:

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No!

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes - it could be applied to a few

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Restricting prescribers from taking a financial interest in pharmacy is still required.

Having prescribers having any potential to financially gain (double dipping from charging consumers for their time/services, to getting money again from prescribing/recommending products and getting a cut/commission) needs to be limited.

Currently there are prescribers who have circumnavigated this by appointing family members who are not prescribers to hold shares in pharmacy.

Has this negatively impacted the consumers? Consumers from these prescribers who hold some form of financial investment, come out with prescriptions for 4-6 items, where half these items is not necessary and often not asked for by the consumer.

These prescribers do not know about how pharmacy is reimbursed and think that a high script number leads to higher pharmacy profits. Not the case.

Any situation where a prescriber has the risk to manipulate/control pharmacy activity for personal/financial gain is inappropriate.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Yes - much needed during times of emergency.

Some cases apart from natural disasters would be e.g. if a vehicle had plowed into the pharmacy premises/the building had caught fire/the building was flooded and the premises would need significant time to renovate - working from a container or temporary premises.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Retail-only licences - e.g. Airports?

Who would be accountable if a product sold caused the consumer significant harm?

Who could be prosecuted?

Should have a pharmacist available - not physically if required, but virtually when needed.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Either a pharmacy or a wholesaler could be asked and could fulfill this.

Had heard a pharmacist set up a supply chain for a medicine that was delisted from NZ, contacted a pharmaceutical compounding company to set up manufacture and supply and still successfully going till present.

Did the pharmacist get remunerated for this service - no. Our time is never reimbursed.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Response ID ANON-DPZ8-G4F2-S

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 18:01:12

Submitter profile

What is your name?

Name:

Rebekah Williams

What is your email address?

Email:

What is your organisation?

Organisation:

Philips New Zealand Commercial Ltd

Submitter Profile (tick all that apply)

Medical devices

If you select DHB, please state service area:

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:
s103 > Require clarification under what conditions would be set for s103 (2)(a) & (b) would come into effect?

s207 > Alignment with comparable overseas regulators for medical device applications.

Consideration of an inclusion for fast-track approvals which meet a certain criteria.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
s113 > for approvals that have been refused approval or are under review/pending a decision, we do not see a public benefit for this information being made available. This information may be misleading to the public, in particularly reference to product refusals which do not relate to any safety or performance issues.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

The term 'specified' product standards in particular reference to conformity assessment and evidence for product compliance to the Essential Principles, we would like to recommend in alignment with TGA the use of (unmodified) international standards at the identification and appointment of the legal manufacturer.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

In specific regards to medical devices, for major changes we recommend alignment to TGA's - Varying entries in the ARTG, where a sponsor can apply to amend an existing approval within the constraints of the variation criteria and does not require a new and separate application & subsequent approval.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:.

Question C4 - Please provide any comments on the approach to post-market controls.:.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

We kindly request the reconsideration of a 6-month transition period, due to the scale of registrations and company resourcing that would be required to complete an activity of this magnitude. Our recommendation would be a 18-24 month period with priority based on risk classification.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

The criteria and definition of what classifies as a special clinical needs supply needs to be defined for further comments to be supplied.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G483-C

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 18:13:59

Submitter profile

What is your name?

Name:
Antonia Natalia Nu'u

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Pharmacist

Submitter Profile (tick all that apply)

Pacific peoples

Pharmacy organisation

If you select DHB, please state service area:
Auckland

Pharmacist

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:
Fine

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

No comment

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

No comment

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

No comment

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

No commnet

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

No comment

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Pharmacists ownership maintains the accountability for all actions with a pharmacist. Under open ownership Pharmacists may be pressured to place profitability over ethical and clinical judgement. Also the idea that opening Pharmacy ownership would increase access is flawed in that investors are more likely to want a pharmacy in a high population area such as the big centres where there are already too many pharmacies rather than rural small communities where the need is the greatest. Finally, under option 2 a Pharmacist would still be responsible for all the workings of the Pharmacy so should an error occur or legal action is taken against the Pharmacy who bears the responsibility? The responsible Pharmacist it appears. Which means they wear all the risk whereas the "owner" can claim no responsibility. This seems to be a flawed system.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

- Pharmacists' taking responsibility for Pharmacy Activities
- The nature of pharmacy requires professional and ethical judgment. Pharmacists would be free to act according to the patients best interests not profits.
- For the future of Pharmacy - Pharmacist owners have the freedom to take students, interns and other trainees and teach them at any time. This is a great asset to our profession.

Question C25 - Are there ways in which Option 1 could be improved?:

- Clearly wording about the ownership model
- Restricting pharmacists to ownership in fewer pharmacies
- Tighter regulation over multiple pharmacy owners

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

- There involvement in the actual running of the pharmacy. They shouldn't just own and not take ownership of the day-to-day runnings of the pharmacy
- Shares in other pharmacies - maybe limit the number of pharmacies you can part own.
- Link Ownership shares with profit share = more accountability

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

They should have both. By linking these two Pharmacists must be invested both financially and professionally. Practice at a pharmacy must reflect good practice. Linking the 2 would lead to an increase in best practice as accountability would be linked with ownership.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

I think it should be reduced to 1-3. If effective control is linked to ownership then it is physically impossible to own as many pharmacies.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

There should be a limit on the number of pharmacies you can jointly share. And joint ownership should require that 1 pharmacist in the partnership has effective control of the pharmacy.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Pharmacists need to be held accountable for the pharmacies they own. Those circumventing the ownership restriction models as they stand are effectively acting as an investor or private owner and not taking ownership of their responsibilities as Pharmacists. If the rules were tightened up it would lead to pharmacist owners that are invested both financially and professionally in the business. This would improve practice as there would be more relationship building, owners would have a better understanding of the driving forces in their pharmacy and innovate to improve service. They would then directly see the financial benefits of better practice instead of "sitting on the sidelines" and dictating to staff putting them under pressure to financially drive the business.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

I'm not sure. Considering the a number of pharmacists own several pharmacies there would be a need for organisation of time etc.

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Yes.

Detailed questions relating to Option 2**Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

Risks:

1. Non-pharmacist owners prioritising profits over ethical and professional responsibility
2. Non-pharmacist owners pressuring Pharmacists to act against the best interests of the patient to "make the sale"
3. Pharmacists having all of the regulatory responsibility should an error or an issue occur and the Non-pharmacist owner not taking any responsibility.
4. Non-pharmacist owners not having any experience in the Pharmacy Sector and running a Pharmacy in a way that would not benefit the patients or the profession
5. More Pharmacies opening in the big urban centres as that would be the most profitable. Auckland already has too many pharmacies and opening ownership would only lead to more in the major cities and not in rural areas where the need is the greatest.
6. Loss of training and learning opportunities for students, interns and trainee technicians as these groups can take a lot of time and supervision which could be perceived as a loss of productivity and therefore profits. The goodwill of the Profession may be pushed aside in a profits first model.
7. Non-pharmacist owners may have access to more capital so will force other Pharmacist owned pharmacies out of the market by using loss-leaders, discount prescriptions, bully tactics to take customers.

Question C34 - Are there ways in which Option 2 could be improved?:

No.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

No. A supervisory pharmacist would be under immense pressure to please owners and satisfy regulations. This role would be extremely difficult.

Other changes to pharmacy licensing requirements**Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:**

Yes. In isolated areas where a pharmacist is not within reasonable travelling distance. There would be a need for privacy issues to be addressed and services of

an appropriate standard. Also the burden of adequate service would lie with the pharmacist so however the system is set up it must be robust enough that the pharmacist can feel confident that all patient rights have been observed and legal requirements satisfied.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Response ID ANON-DPZ8-G48X-H

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 18:26:27

Submitter profile

What is your name?

Name:

A/Prof Matthew Doogue

What is your email address?

Email:

What is your organisation?

Organisation:

University of Otago, Christchurch

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Medical practitioner (excluding Surgeons)

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Trial ethics

Other (please comment)

If you selected 'Other' please comment;:

Academic

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

I support the move from set legislative framework to a principles based legislative framework.

Regarding ss4 a) of the Bill

Please reconsider terminology - I submit that "potential harm" is more accurate than 'likely risk'.

1. The likelihood of a harm is a risk.
2. The use of the term "likely" suggests a high probability.
3. Prior to use, medicines have potential effects (beneficial and/or harmful). After use medicines have actual effects, benefits and harms (beneficial/therapeutic effects and adverse effects)
"...the potential benefits of therapeutic products should outweigh the potential harms associated with them..."

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Question C4 - Please provide any comments on the approach to post-market controls.:

I submit that the primary responsibility for pharmacovigilance should be with the regulator AND that this capacity should be strengthened.

I further submit that the Regulator be given powers to access health data for the purpose of pharmacovigilance.

Adverse drug reactions are an area of my clinical expertise and research interest.

Prior to registration the trial information is held by the sponsor worldwide and hence they are well equipped to provide the information.

In clinical use the information on outcomes accrues in the health system. This information is not specific to one product and needs to be broadly examined for pharmacovigilance.

For example some children are born with a birth defect, the cause is not known the full data related to those cases need to be examined.

For example a concern about one drug in a class is raised, patient data in all exposed patients AND controls needs to be examined.

There are potential privacy risks in sharing health data with sponsors off shore. There are potential conflicts of interest for sponsors between commercial and safety outcomes (e.g. delaying the release of adverse findings by months may have a very large financial impact on a pharmaceutical manufacturer).

Safety issues frequently apply to a class (rather than an individual product), hence a broader view is required. The data from all exposed patients should be accessible to pharmacovigilance not just the subset of information selectively reported by individual clinicians at cost of clinical time.

After patent expiry, generic manufacturers do not have the resources or expertise to carry out pharmacovigilance.

For spontaneous reports practitioners want a single point of reporting.

Large data sets allow for effective pharmacovigilance incorporating multiple variables.

I submit that pharmacovigilance is a public health activity and a core responsibility of the regulator. The regulator will require appropriate resourcing and empowerment to access data.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

Consistency across the health sector for business and professional responsibilities.

Reducing conflicts of interest between business and professional responsibilities.

Empowering professional responsibilities.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

There are some conflicts of interest between business and professional responsibilities. Separating these consistently in the health sector is desirable.

Question C25 - Are there ways in which Option 1 could be improved?:

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Separating professional and business responsibilities makes accountability clear.

Question C34 - Are there ways in which Option 2 could be improved?:

Ensuring that the professional responsibilities are sufficiently empowered.

It is anticipated that there will be some conflicts with business needs, e.g. time on patient counselling.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Not clear

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No,

Consistency across the health sector for business and professional responsibilities is desired.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

I oppose direct-to-consumer advertising of prescription medicines.

1. To align with other jurisdictions.

2. Brand name promotion causes confusion for patients and clinicians. Generic names are recommended to be used for safety reasons and brand name

promotion increases the risk of wrong drug errors. For example, Tegretol was the originator brand name for carbamazepine and I have seen it confused with tramadol.

3. The evidence does not show benefit and suggests harms.

I note that there are broad methods used which limits regulation and regulating DTCA is only one step. Transparency of spending by sponsors is one approach that could be considered to make it easier to identify marketing disguised as health professional education or consumer advocacy.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

The implications are unclear but there is a risk of high regulatory burden. Off-label use is the norm and usual practice needs to be distinguished from unusual practice. This is done by inclusion in guidelines.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

I support this.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

I support separation of business and clinical responsibilities to reduce conflicts of interest. An individual might have both roles but they could and should be separated.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G48T-D

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 19:55:08

Submitter profile

What is your name?

Name:

Geoff Williamson and Mary Allan

What is your email address?

Email:

What is your organisation?

Organisation:

Botanical Resources Limited, Thyme Heal

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

Natural Health Products Manufacturer

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Don't support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

There needs to be a clear definition of what natural products are and what is excluded first, before this bill proceeds any further. To proceed otherwise will risk excluding input from stakeholders in industry who are currently under the impression that the proposed bill does not relate to products that they use, supply or manufacture.

The bill hasn't defined the scope of Therapeutic products by default by not defining what Natural health products are, given that 'the definition of natural health product and the exact mechanism by which they will be excluded from the Bill are yet to be determined.' Hence the purpose is too broad, and too easily changed retrospectively after submissions.

It is our opinion that on this basis the bill cannot be approved as the full scope is not yet transparent until the definition of natural products and the mechanism by which they are included is transparent. By excluding but not defining natural health products and the respective mechanism by which they have excluded, the attention of those interested and concerned regarding natural health products is being deflected.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Therapeutic product - This cannot be properly defined until natural products are defined and agreed with industry

Active medicinal ingredient (AMI) - the scope of what is an active medicinal ingredient cannot be properly defined until natural products are defined and agreed with industry., otherwise natural active ingredients will be included in this without first defining them. It also doesn't indicate or determine if a synthetic version of a natural active ingredient deems the equivalent natural ingredient in or out of the scope. Furthermore there is no evident protection mechanism for the natural active ingredient being protected from being synthesised then patented and then restricted away from the natural health industry later to IP conflict from pharmaceutical lobby pressure.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B7 - Please provide any comments on the authorisations for health practitioners :

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Again the approval process pertains to what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

What is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Fine however what is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

What is considered therapeutic and what is considered natural - this needs to be defined and approved in parallel before this bill can be approved.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

What are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

What are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

What are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

What are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

What are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

The regulator's scope regarding what are considered to be 'natural products' will need to be defined and approved before this bill can progress any further.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183–196).:

Too draconian - is this New Zealand or we in Russia?

A regulator should have to prove just cause to have a search warrant and to take samples - we aren't in a military state, they must be able to prove just cause to also instruct customs. The proposed powers are far too overreaching and even beyond those of our police.

Access to a premises should be by appointment only. The party/ company being entered must be able to recover costs for any time impacts on administration or production, in the case where there has been no just cause for entry/ or where the regulator has been proven wrong, or where the party/ company has assisted the regulator at their own expense.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197–199):

Too draconian and too grey - who determines what is misleading. The regulator should have to prove beyond a reasonable doubt before being able to act.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200–204):

The cost of appeal looks too onerous and too costly for small business, and should be more accessible to them and to businesses. There shouldn't be any fees for appeal. There be an interim step and separate process without incurring a cost of the district court and legal teams. This process would mitigate the volume of individuals or small busienss having the opportunity to appeal poor decisions.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

'Who washes the washer?' There needs to be a degree of accountability and an independent ombudsman who the regulator is accountable to, that members of industry can appeal to regarding decisions made or powers exercised by the proposed regulator.

The regulator should not be able to have site access without appointment and appeal of their decisions should not be cost or time prohibitive.

The fines are over-reaching and exorbitant and must be downscaled as they appear to be aimed at big business/ large corporations and do not take the size and turnover of a company into account. The New Zealand industry is full of small to medium businesses that would not be able to absorb these penalties and continue to trade. Dangerous if they are wrongly applied.

The intent of this bill and the powers should be to penalise not to control, regulate but not destroy industry.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

The scope of conduct to which an injunction can be applied needs to be clearly defined

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

The fines are over-reaching and exorbitant and must be downscaled as they appear to be aimed at big business/ large corporations and do not take the size and turnover of a company into account. The New Zealand industry is full of small to medium businesses that would not be able to absorb these penalties and continue to trade. Dangerous if they are wrongly applied.

It appears to be one sided, and the expenses of the company should also be taken into account, particularly where the regulator is wrong in their actions or decisions, and the process of appeal should take this into account where the costs and costs associated to time of the appealing party where successful can be fully recovered.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

The fines are over-reaching and exorbitant and must be downscaled as they appear to be aimed at big business/ large corporations and do not take the size and turnover of a company into account. The New Zealand industry is full of small to medium businesses that would not be able to absorb these penalties and continue to trade. Dangerous if they are wrongly applied.

It appears to be one-sided, and the expenses of the company should also be taken into account, particularly where the regulator is wrong in their actions or decisions, and the process of appeal should take this into account where the costs and costs associated to the time of the appealing party where it can be successfully fully recovered.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

This proposal is far too punitive on industry, and will create yet another cost to operating a business within the industry. The cost of operating a business within New Zealand is already high.

The regulator should be given a budget and work within that. The headcount of the department and regulator should be capped and should reviewed transparently to minimise costs of the department.

The proposal to encourage a regulator to actively source funding and revenue from fines and fees will encourage dysfunctional departmental behaviour. This proposed recovery system is used in Australia where the result is a regulator and government authority that doesn't work well with industry and at its detriment. Instead of being constructive and supporting and guiding industry particularly small to medium businesses, the proposed bill will create and encourage a regulator and a respective department that active burdens, and penalises industry to survive and fund.

The regulator and the department should be looking to help encourage New Zealand business and industry growth, not crush it, and generate employment not mitigate it. The longer-term outcome of the proposed bill will be less New Zealand owned and operated companies, an expansion of government and more market share for large pharmaceutical multinationals.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Natural products need to be defined and excluded before this can be approved.

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

Too draconian and the proposed powers are too overreaching - entry should only be given by agreed appointment and the Regulator must be able to prove just cause for entry prior to doing so, and must apply for a search warrant.

The party/ company being entered must be able to recover costs for any time impacts on administration or production, in the case where there has been no just cause for entry/ or where the regulator has been proven wrong, or where the party/ company has assisted the regulator at their own expense.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

The applicant should be able to also apply in all cases

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

There needs to be a clear definition of what natural products are and what is excluded first, before this bill proceeds any further.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

NA

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Minor and major changes need to be more clearly defined in the act

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Natural products would need to be defined and excluded. There would need to be a transparent list of natural ingredients, products and natural actives that would be excluded from categorisation. The expert committee would need to be transparent and include representation of NZ SME industry, and not just representative of multinational pharmaceutical companies.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

NA

Question C4 - Please provide any comments on the approach to post-market controls.:

The terms and boundaries of post-market monitoring would need to be clearly defined and agreed with industry before this bill proceeds. Post-market monitoring will exclude natural products.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

The fees would need to be clearly defined and agreed with industry before this bill proceeds. The fees should be accessible not punitive, as we are only a small country of 4m people. Post-market monitoring will exclude natural products

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

There would need to be controls and protection of a business's IP, as a business would not want competitors or general industry being aware of their sales and distribution information and channels.

As part of the wholesale/ hawking process, when hawkers promote products Drs should not receive incentives to prescribe certain medicines and there should be controls on the nature of incentives provided, included in this bill.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

NA

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

There needs to be more transparency regarding what elements of the European and Australian models are being proposed. Also definition of what is considered a minor change.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

NA

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

NA

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

NA

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

NA

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

NA

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

NA

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

NA

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

NA

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

NA

Question C4 - Please provide any comments on the approach to post-market controls.:

NA

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

NA

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

NA

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

NA

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

NA

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

NA

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

It would need to be very clear to customs and staff of controlling authorities what is considered pharmaceutical and what is considered a natural product.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

As part of the wholesale/ hawking process, when hawkers promote products Drs should not receive incentives to prescribe certain medicines and there should be controls on the nature of incentives provided, included in this bill.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

NA

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

More access for natural products manufactured by New Zealand companies

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

NA

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

NA

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Restricts the ownership and control of chains by larger businesses

Question C25 - Are there ways in which Option 1 could be improved?:

NA

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

NA

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

NA

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

NA

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

NA

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

NA

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

NA

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

NA

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

NA

Question C34 - Are there ways in which Option 2 could be improved?:

NA

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

NA

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

NA

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

NA

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

NA

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

NA

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

NA

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

NA

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

NA

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

NA

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

The above proposals should not include natural health practitioners, practising Natural Health including Naturopaths and Medical Herbalists

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

NA

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

NA

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

NA

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

NA

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

NA

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

NA

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

NA

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

NA

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

NA

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

NA

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

NA

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

We are surprised that veterinarians that prescribe to animals would be included within this proposed bill. We feel veterinarians should be outside the scope of this, as they are governed by the ACVM act.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

The fines are far too punitive, and should be set as a percentage of revenue as they do in Europe not set fines. Large set fines only benefit large companies and penalise SMEs and individuals.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

NA

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

This must not apply to natural products. Natural products must be defined before this bill proceeds any further.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

This must not apply to natural products. Natural products must be defined before this bill proceeds any further.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

This must not apply to natural products. Natural products must be defined before this bill proceeds any further.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

This must not apply to natural products. Natural products must be defined before this bill proceeds any further.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

NA

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Pharmacies should be encouraged to enable a selection of NZ manufactured natural health products

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

NA

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

NA

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

NA

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

NA

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

NA

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

NA

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

NA

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

NA

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

NA

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4UR-8

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 20:47:55

Submitter profile

What is your name?

Name:

Prisca Drysdale

What is your email address?

Email:

What is your organisation?

Organisation:

Merck

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medical devices, Medicines

Medical devices, Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Medical devices

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

By omitting the administrative details from the Bill provides uncertainty on what the sponsors are agreeing to and if the objective of the Bill "ensure high quality, robust and accountable decision making", has been met.

ss4 bi Risk-proportionate regulation - Merck supports this principle

ss4bii Timely availability of therapeutic products - Merck support this principle. However, in the absence of administrative details or guidance documents that needs to be read in conjunction with the Bill, there is uncertainty around how key performance indication on transparency or the regulator's performance are met.

ss4 c - Merck supports this principle. There's uncertainty how the regulator plans to implement transparency in the process.

ss4 d - Merck supports this principle. We strongly support both the principle to have a regulator that engages internationally and recognises the work of trusted overseas regulators (ss4(b)) and the provision (ss207) that the regulator may rely on reports, assessments, decisions, or information of recognised authorities (such as overseas regulators), to make decisions. As it will increase efficiency and timeliness of decisions, build on and improve Medsafe's current abbreviated approval processes, and provide a foundation for the regulator to engage in work-sharing programmes with overseas regulators. This approach should be applied to all product applications, and major variations.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

ss27 - Meaning of clinical trial. - Merck supports this principle. However, Merck requests that Medsafe should follow international definitions and including the WHO's definitions and accepted ICH GCP terminology.

ss28 (3) meaning of compound and ss32(2) meaning of manufacturer, for medicines. Further clarification is required as the compounding or dispensing of the medicines will likely occur outside the responsibility of the sponsor and after the sale of the medicine.

ss31 meaning of manufacture, manufacturer and responsible manufacturer. This definition will need to be aligned with international definitions of manufacturer. Sponsors of multinational companies may not be the manufacturer of the product but rather is an administrative entity within NZ. The company headquarters, as most often the case would be the 'responsible' manufacturer. Further clarification is required whether the parent company can be the responsible manufacturer. Additionally the definitions should be aligned and consistently applied to the 4 product categories.

ss47 fit and proper person and ss 48 meaning of senior management. Further clarification/expansion of the definition is required individuals and company sponsors/ licensees.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

No additional comment

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

ss53 Authorisation required for controlled activity.

Please see response as per B2.

Merck suggest compounding and dispensing are separated from the definition of manufacturer.

ss55 Persons in supply chain must comply with regulations. Supply chain encompasses a wide range of activities, maintenance of stock levels, manufacturing and release for supply etc. The regulations need to be more specific when applying to the different activities within the supply chain process.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

No additional comment

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

No additional comment

Question B7 - Please provide any comments on the authorisations for health practitioners :

No additional comment

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

No additional comment

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

No additional comment

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

No additional comment

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

No additional comment

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

ss 83 meaning of advertisement and related terms.

Merck notes the definition of "advertisement" need to be further expanded to say " Any statement , pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods. The Bill will need to include the definition of "promote".

Additionally consideration needs to be made when International HCPs attend International conferences held in NZ, where the Therapeutic Good is approved internationally but not approved in NZ. The regulations should provide further guidance what kinds of activities and information would be considered promoting off -label and what would be informative educational content.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

ss97 Criteria for sponsor of approved product

The requirement for a contractual relationship between sponsors and manufacturers needs further clarification. Generally multinational companies are most likely to have contractual agreements with the manufacturers rather than the sponsors who solely distributes that product within NZ. Would a contractual relationship between the local affiliate of the parent company be sufficient to meet this principle?

ss100 Major changes results in new product.

Merck does not agree with this principle or the proposed process described in paragraph 262 of the consultation document which states that "once the application [for the major change] was approved, a new approval document would be issued. It was stated by Ministry of Health representatives at the Medicines sector forum on 18 March 2019, that the changed product would be given a separate entry on the regulator's public register to the original product, and a separate identifying number (TT50 entry).

This approach creates significant practical issues for sponsors.

PHARMAC funding applications are identified by their TT50 number. The proposed scheme would mean companies would need to update their funding applications each time a major change was made to any of their products. This would add an additional level of administrative burden to both companies and to PHARMAC, especially for applications for funding through the tendering process, where multiple companies will be applying for sole-supply of a medicine. We understand that the intent of the approach is to ensure different versions of the same product (i.e the original product vs the original product with a major change) can be distinguished within the New Zealand market. However, we do not believe the practicality of the major changes processes has been considered in the Bill and we strongly recommend further consultation is conducted with industry on this matter.

A solution would be to allow sponsors to nominate to replace the approval of the current product, with the changed product so that the existing TT50 number, approval, and entry in the Regulator's register can be replaced by the changed product. This type of approach is used by the TGA, referred to as TGA Grouping. For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a notice. For example, we note that in paragraph 271 of the consultation document that "If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s78)." We believe a major change to a product would be an appropriate reason to issue a "use of current stock" notice. We suggest this is also discussed further with pharmacists and prescribers.

In cases where the sponsor did wish to have both versions of the product approved and marketed, they could nominate to receive a new approval and TT50 number for the changed product.

ss102 Change of sponsor. Merck supports this principle. However Merck requests that this principle aligns with other major international Health Authorities and that it would be acceptable to Medsafe that sponsorship transfers to a new sponsor with prior history of product approvals.

ss104 Approval lapses on death, bankruptcy or insolvency of sponsor. Justification is required why product approval will automatically lapse in these situation when insolvency would be transferred to an executor etc.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

ss108- ss112 Cancellation of approval.

Suspension of approvals.

The Bill should provide the flexibility of a suspended approval rather than cancellation. This gives an opportunity for the sponsors to resolve any issues prior to cancellation. Lifting a suspension of an approved product is far more resourceful (time and costs) than to resubmit a product via a new application.

ss113 Therapeutic products register. Merck supports this principle. However, this principle needs to align with international Health Authorities with the aim of improving transparency. Merck suggests that this principle should mirror the TGA.

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:
ss114 - ss115 subpart 2 Approval of exempt products.

The sections regarding approval-exempt products (ss114-ss15) are unclear, and we have several questions regarding them:

- (i) For a class of approval-exempt products, who would be liable for product quality/safety?
- (ii) If no one opts to sponsor a potential approval-exempt product, will the Crown or other entity be the sponsor?
- (iii) What is the process for the Crown to become a sponsor of a product?
- (iv) Would approval-exempt products be included on the proposed Therapeutic Products Register?

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

ss116-118 – Subpart 3 Obligations of sponsors

The TPB proposes that the sponsor is responsible for all aspects of the product, extending from the manufacture, application, approval, importation, through to the supply channel. The scope of responsibility of sponsors appears to have widened. The sponsor should, rightly, be responsible for activities associated with product registration, manufacture up until product supply to third parties, such as wholesalers and pharmacies. Whilst the sponsor will be responsible for post marketing safety activities and investigation of quality issues, the sponsor cannot be held accountable for all activities after the product has left their control. There is responsibility that resides with the wholesalers and pharmacists in the supply chain, particularly with regard to the correct storage and handling of the medicine. This section of the TPB seems to duplicate the intent of ss55, which places obligations on persons in the supply chain, who may not all be sponsors. The obligations should be limited to activities that those in the supply chain are licenced/authorised to perform.

Additionally, these sections discuss the requirements for compliance with obligations and the penalties that apply to breaches. Details are lacking on what sponsor obligations for pharmacovigilance are tied to the penalties outlined in ss118(1) and ss118(2). While we agree that sponsors should be accountable for complying with obligations, we think it would be unreasonable if the entirety of Guideline Part 8: pharmacovigilance and applicable device regulations were to form the legislation.

For context, in Australia only the following pharmacovigilance requirements are legislative requirements:

- (i) reporting of ICSRs;
- (ii) reporting of SSIs;
- (iii) notification of the pharmacovigilance contact person; and
- (iv) archiving of records.

We recommend that the industry is consulted with in relation to the specific requirements. Requirements should be aligned to other those of comparable regulators.

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

ss120 -122 – Subpart 4 Protection of active ingredient information about innovative medicines

Merck does not support the continuation of 5 years of regulatory data protection (ss 102-104) for innovative medicines from the Medicines Act 1981. Maintaining a regulatory data protection period of 5 years is not aligned with most OECD countries (8-12 years)and at odds with the vision to future-proof medicines legislation.

EU countries, Japan, and Canada have a minimum of 8 years data protection plus an additional 2 years extension.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Ss124 Content of Licence

ss124(1)(e) indicates that a licence will list the therapeutic products covered by the licence. Does this imply that all products will be named individually? As product registrations are constantly changed, and it is indicated in ss137 that licences remain in force for 3 years, consideration needs to be given to the time and cost of varying licences due to changes in products during each 3-year period.

While we support the ability to have one licence to cover a range of activities involved in the running of a clinical trial. It is important that requirements and obligations are clear in subordinate legislation including whether it is the sponsor of the clinical trial or the investigators that seek the license.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Ss128 Criteria for granting licence

Ss128(1)(g) explains that for a clinical trial licence either requires ethics approval, or certification from a relevant ethics approval entity that an approval is not

required.

Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current clinical trial approval process, concern remains that the licence cannot be issued until the ethics approval is granted and what impact this may have on timelines. The primary advantage to conducting clinical trials in New Zealand is the efficiency of the regulatory system. On the other hand, there are several significant disadvantages, including a high uncertainty of future public reimbursement of innovative medicines. The 2010 Parliamentary Inquiry into clinical trials found that "to remain competitive New Zealand must have a regulatory scheme as good as, or better than, other comparable countries" [1]. As a result of the inquiry, improvements were made which included setting and meeting prompt timeframes for scientific and ethics evaluations [2]. For these reasons we would be concerned if the new regulatory system did not continue to meet the recommendations of the 2010 Parliamentary Inquiry. Please set out how the regulator will guarantee that the current efficiency and timeframes of the clinical trial approval process will be maintained. Please also explain how the new regulatory system will work efficiently alongside local approval processes by DHBs.

As a further point, we seek further information on the process for certifying that ethics approval is not required (ss128(1)(g)). It is unclear if applications that do not require ethics approval will have the same quick timelines as is currently the norm. It is imperative that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g observational trials, clinical audits). We suggest that appropriate rules and/or guidance are created so it is clear which types of trials do not meet the threshold for ethics review, and that there is an efficient process in place for certifying that a trial does not require ethics approval.

Ss130 Criteria for responsible persons

Currently, Medsafe will allow an overseas person to be listed on a licence provided there is a minimum of one New Zealand resident on the licence. The overseas person is usually a senior staff member (e.g a Regulatory or Quality manager) of the company where there is no resource for that company in New Zealand. This situation should continue to be permitted under the TPB. The number of employees in New Zealand of pharmaceutical companies is small, with many functions such as regulatory often based out of Australia or another country overseas. We submit that the drafting of the TPB must accept this commercial reality, noting that companies have appropriate controls in place to meet requirements. Furthermore, where a licensee is a body corporate, consideration should also be given to how they will demonstrate meeting the criteria for being a responsible person.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Ss131 What permit may authorise

ss131(1)(a) states that a permit can authorise a person to import a product without the sponsor's consent.

Is it correct to assume that the criteria for importing an approved product without the sponsor's consent will be outlined and specified in regulations?

We submit that this is an activity that needs to have very tight restrictions and controls on it. If this is not the case this would appear at odds with the policy intent of ss52 which is to prohibit parallel importation of therapeutic products.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Ss136 Regulator may split application

Merck seeks further clarification regarding this principle as it gives the regulator discretion to assess the application together, or as discrete applications. There are currently already some uncertainty around evaluation times and by splitting the application this uncertainty will be exacerbated. Further guidance is required to explain the process of splitting an application and what types of applications would be likely to be split. This process has to be mutually agreed by all parties.

Ss137 Duration

ss137 indicates that a licence remains in force for a maximum of three years. We agree that the increase from one-year licences under the Medicines Act, to licences of up to three years under the TPB is an improvement. However, a three-year licence duration for clinical trials is potentially unworkable - many clinical trial activities continue well beyond three years, some for over 20 years. As an example, clinical trials measuring overall survival after an earlier intervention may require more than 5 years of follow-up of participants. If a clinical trial involves children, follow-up may be for 20 years, until the youngest eligible child turns 16. For reasons of practicality, we submit that the duration of licences for clinical trials should be based on the expected duration of the trial, as identified in the trial's protocol.

Clinical trials are currently not regulated via licences and are unlike the activities that currently require a licence like pharmacy and wholesale. The proposed one size fits all approach is problematic. Further consideration, and specific engagement with the research sector is required to pragmatically regulate clinical trials under a licencing system.

We suggest a similar approach to that proposed for conditional product approvals could be taken as in ss105-107, where product approvals do not generally have a maximum duration, but a duration could be set as a condition. If this approach to licences was taken, standard maximum durations for licences like pharmacy and wholesale could be specified in conditions set in rules, whereas a duration of a specific clinical trial could be set at the time of the licence application, based on the trial's protocol, or a date could be set for when further information is required for the trial licence to be continued. Our reading is that the mechanism for this approach to licences exists in ss139-141 but cannot be utilised because a maximum licence duration has been set in ss137 (i.e. ss137 appears to contravene ss139-ss141).

We reiterate that a three-year licence duration is impractical for clinical trials, and we recommend specific feedback is sought from the research sector on optimal mechanisms to maintain safe operation and delivery of clinical trials over varied time periods (rather than the proposed 3-yearly tick box approach).

Ss139 Regulator may impose conditions and ss140 Variation

Further information is required to identify the activities that would warrant a change in the licence.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Ss151 Death, bankruptcy, or insolvency of licensee or permit holder

ss151 details that if the licensee or permit holder dies, that the licence or permit is transferred to the executor or administrator of the estate, who has to notify the regulator of the event within 5 working days. We question the practicality of this process. We have been advised that an executor/administrator of an estate would often not be appointed within 5 working days of a death, let alone be in a position where they fully understand the assets within the estate and the action required to notify the regulator. It is therefore requested that a longer notification period be applied. We suggest 15 working days (21 calendar days) would be more appropriate.

It is unclear what the consequence will be if the executor of the estate fails to notify the regulator within 5 working days. We note that the regulator would have the discretion to cancel the licence but would be required to give the licensee opportunity to comment, except in specific circumstances (ss144). We are concerned that the licensee death or failure to notify the death within 5 working days will result in a business continuity issue or the licence may lapse. There would be ethical and operational issues if a clinical trial had to be suspended as a result.

Furthermore, this clause would not necessarily be applicable for licensees or permit holders who are body corporates. We do not believe this one size fits all approach is practical. If the intent is that it is applicable to certain classes of controlled activities that are typically conducted by individuals (e.g pharmacy), the TPB could be more explicit about this. For instance, the corresponding clause for product approvals (ss104) distinguishes between a product sponsor who is an individual, and a product sponsor that is an entity.

Paragraph 147 of the consultation document states that "...if a licensee or permit holder wishes to sell the business to which the licence or permit relates, the purchaser of the business must obtain their own licence or permit before they take over the business." This is quite a different position to that taken for product approvals (ss102) which will mean in the event of corporate mergers and acquisitions, a business may acquire the product approvals, but not the licence/permit(s) to import the product(s). We believe more consideration of this aspect needs to occur with further consultation with industry. The transfer of licenses or permits to another person/party needs to be a seamless process to ensure continuous supply of medicines in New Zealand.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

Ss158 Responsible person must comply with regulations

Further clarification is required. What are the competencies required to meet this requirement.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

The definition of "persons" is unclear in the Bill. Is it referring to individuals, company directors, sponsors etc.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Under the Bill, investigative powers will be cross-referenced to the investigative powers under the Search and Surveillance Act 2012 ss183, 185, 188, 191, 192). The powers that are granted under the Search and Surveillance Act 2012 are those used across a large section of New Zealand legislation that require investigative powers. Therefore, we consider the amendment to bring the Bill under the remit of the Search and Surveillance Act 2012 brings it into line with what is generally the standard set of investigative powers in New Zealand.

It would be important to clarify the potential tension between:

- (i) a prohibition on shipping overseas any products that are subject to a prohibition order (ss170(2)(f)); and
- (ii) an ability for therapeutic products that are seized by the regulator/border security to be returned to the country of origin if the regulator requires it (ss194).

In order to relieve this tension, we presume that this right to return products to a country of origin would be exercised by the regulator only where the product does not pose significant risk of death or harm. If this is not the intent, we are concerned that therapeutic goods that would otherwise be subject to a prohibited product order and therefore not able to be returned to their country of origin would be treated differently if seized at the border rather than if they were released to the

sponsor (either erroneously or as they were subsequently found to have concerns).

Additionally, the consultation slide deck includes the following:

The Bill links to the Search and Surveillance Act 2012 to provide the regulator with investigative powers. The regulator would have the following powers of entry:

- entry and search without a warrant (for routine monitoring & where there are concerns of non-compliance)
- entry and search with a search warrant (including dwelling houses & Marae)
- the right to inspect therapeutic products being imported.

The TGA can do this in the situation of a 'for cause inspection', however this power seems a little excessive for 'routine monitoring', unless of course this means that access cannot be prevented, in which case the powers we believe are similar. As a general comment, industry would need to be consulted in relation to the specific requirements. These should also be fairly aligned to other comparable agency requirements.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Merck does not have any comments

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

ss200 – 204 – Subpart 4 – Review of Regulator's decision

ss200 Application for review of Regulator's decision

Merck recommends that this principle is aligned with the TGA timeframe of 60 working days (ie approximately 3 calendar months). Whereby a 30 day provisional response will be provided to Medsafe initially and a complete response within 60 working days that details supporting data and justification.

Furthermore, we wish to clarify that in order for the applicant to respond to the regulator's decision, and apply for a review within the suggested timeframes, the regulator must provide their reasons for the decision at the time of notifying the person (as in ss208(b)(i)), rather than only advising the person that they are entitled to ask for a statement of reasons for the decision (as in ss208(b)(ii)).

Ss203 Decision on review

The Bill needs to provide transparency and certainty around timelines. In the absence of specified time frames Merck believe standard TGA time frames of 30 or 60 working days review panel activity would be appropriate.

It is prudent for each party, the regulator and sponsor/applicant, to be held accountable to act within pragmatic timeframes, thus facilitating timely review of decisions. Therefore, specific timeframes for the review process, for both the Regulator and the sponsor/applicant, should be stated in the TPB to ensure a reasonable and efficient process is maintained, and applications are not unreasonably held up. Businesses need a level of surety within which to operate and maintain source of supply. New Zealand, as a small country far away from major manufacturing centres needs to be cognisant of supply chain processes.

We have concern regarding the lack of specified timeframes in particular for reviews of decisions relating to refusals to revoke or vary regulatory orders. With no timeframes given for convening the review panel or that review panel providing a decision, the sponsor may be required to comply with the regulatory order (that they are seeking a review of), while waiting for the review panel to convene. The benefit of seeking a review will be lost if timeframes mean that the sponsor has already complied with the regulatory order (e.g conducting a recall).

We ask that:

- (i) changes are made to the Bill that provide timeframes for the review panel's activities (refer to details in our response above);
- (ii) there be an ability to request a panel to sit in urgency. For example, when a sponsor applies for a review of a decision to refuse to revoke a recall order because there is insufficient evidence that a recall is required. The applicant/sponsor would act to provide their application and supporting data/rationale under urgency. Where such a request is made, will the regulator commit to acting under urgency?; and
- (iii) if a decision is not upheld (i.e. the panel recommends a different decision be made), what steps will be taken by the regulator to compensate for any loss of supply, or the loss of product confidence of consumers, healthcare practitioners and manufacturers that has occurred?

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

Ss205-ss222 Subpart 5 – Administrative matters relating to regulator

Ss207 Regulator may rely on recognised authorities

Merck agrees with this principle. However, with the increased in efficiencies, sponsors would expect decrease in costs and evaluation times. Guidance documents should provide transparency and certainty around this process. The scope should include all major application types.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Merck supports this principle

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 3 – Offences

Ss233 – Penalties for Offences

Merck is uncertain how the penalty amounts have been derived or the rationale/ evidence used to determine the amounts. Merck therefore seeks clarification.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

Merck supports this principle

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

Ss256 Costs to be recovered and ss257 Regulations about fees and charges

Merck supports the cost recovery model. However, we require increased transparency and clarity around evaluation timeframes and milestones.

We also seek assurance that there will be appropriate accountability measures both within the regulator and external to the regulator to ensure appropriate timeliness is a lasting feature of the new scheme. In addition to the principle in the Bill, we suggest that maximum evaluation timeframes are stipulated in regulations.

Furthermore, with the tightening of unapproved supply, plus a high likelihood of increased fees, the regulator should look at having an orphan designation/application pathway with associated reduction in fees for rare diseases. With New Zealand's very small population there may be a handful of patients treated each year and for many products in this space it will not be commercially viable to register these in New Zealand. If there is some kind of fee waiver in place this would give the regulator more control over what is being supplied in New Zealand in these kinds of circumstances. This would facilitate regulated access to medicines for those persons with rare conditions who are more vulnerable to risks of unregulated supply and would help redress this issue.

Ss267 Consultation

Merck supports this principle. However the approach that the Ministry has taken only to review the Bill independent of any further guidance documents has created further uncertainty.

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

Merck does not have comments

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:

Merck does not have comments

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:
Merck agrees with this principle

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
Merck does not have comments

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

Merck does not have comments

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
Merck does not agree to this principle.

As per B13.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
Merck agrees with this principle

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
Merck agrees to this principle

Question C4 - Please provide any comments on the approach to post-market controls.:
Merck agrees to this principle.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
Please refer to B2

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
Merck does not have any comments

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:
Merck does not have any comments

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
Merck does not support this principle

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
Merck does not have any comments

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
Merck does not have any comments. However the approach should be consistent across all Therapeutic Goods

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
Merck does not have any comments

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
Please see B2

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:
Merck does not have any comments

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Medical devices should be defined and regulated in accordance and aligned to International guidelines

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

There are no aspects of the global MD model that is inappropriate for NZ

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Merck supports this principle

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Merck supports this principle. However, further guidance is required on the transparency of the decision. Sponsors should have the opportunity to address the regulators concerns prior to any restriction being imposed.

Question C4 - Please provide any comments on the approach to post-market controls.:

Merck supports this principle

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Merck supports this principle. However, there is uncertainty around the expiry date of the temporary licence. Since MD are currently not regulated in NZ, the concern is that there will be a very large volume of applications made within 6 months from the commencement date, and that this will create a large backlog of work for the regulator. We are concerned of the impact this backlog will have on the processing of new applications, and whether the temporary licence will lapse during evaluation.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Merck does not have any comments

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

Merck does not have any comments

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

Merck supports this principle.

It is important that requirements and obligations are clear in subordinate legislation including:

- whether it is the sponsor of the trial or the investigators that seek the license
- license duration - 3 years is too short for some clinical trial activities. Would it be possible for a clinical trial license to be granted for longer rather than relying on extensions?

Clarity around requirements of when a licence can cease is also requested ie. is the licence required during treatment phase only or until all activities in the clinical trial have completed and clinical site is closed, or until the completion and reporting of the trial (please take into account that a study can complete in New Zealand but continue in other countries).

Although reassurance was provided at the TPB information forum that the regulator will maintain the efficiencies seen in the current clinical trial approval process concern remains that the licence cannot be issued until the ethics approval is granted and what impact this may have on timelines.

As a further point, it is unclear if applications that do not require ethics approval will have the same quick timelines as those currently. It is imperative that this process is efficient and does not create undue delay or require unnecessary bureaucracy for low risk trials (e.g. observational trials, clinical audits).

Please refer to our response to questions B18-B22 for further comment.

It is also requested to align the clinical trial terminology with international terminology and definitions (i.e. ICH GCP definitions), in order to avoid confusion both locally and internationally.

We have some additional comments on some specific aspects:

Exporting biological samples (blood/serum) and tissues

We couldn't find reference to provisions for the export of samples or tissues derived from clinical trials (e.g. for testing, storage). We seek assurance that sensible provisions are in place, such as an authorisation to do so as part of approval of clinical trials.

"The regulator also has the power to monitor trials and audit Clinical trials sites." (paragraph 422 of the consultation document)

This is currently being proposed by the TGA under consultation. A major concern is how outcomes of such activity are reported to ensure data quality reputation (which is currently high) remains intact. We seek further information/detail about the intentions.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

Schedule 1 – Transitional Arrangements

For ongoing trials which currently do not require approval under the Medicines Act, but will under the draft Bill, it is not practical in all circumstances for the principal investigator to apply for a temporary licence to carry on the activity. This should be changed to reflect either the 'proposed licence holder' or sponsor of the study. It is requested that this clinical trial terminology is aligned with international terminology and definitions.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

It is important that requirements for supply via this mechanism are clear in the regulations, including:

- Responsibilities for Adverse Event reporting
- Requirements for notifying local sponsor of supply
- Provisions for a cross-over period should an unapproved medicine supplied under a SCNSA become approved
- Under what circumstances wholesalers are able to have on hand a small stockpile of unapproved medicines ("urgently needed" needs to be defined, as does "small")
- Measures of control of products imported by "buyers' clubs" and/or healthcare professionals bulk importing unapproved medicines.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Merck does not have any comments

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

Merck does not have any additional comments

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Merck does not have any comments

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Merck does not have any comments

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Merck does not have any comments

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Merck does not have any comments

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Merck does not have any comments

Question C25 - Are there ways in which Option 1 could be improved?:

Merck does not have any comments

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Merck does not have any comments

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

Merck does not have any comments

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Merck does not have any comments

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Merck does not have any comments

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Merck does not have any comments

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Merck does not have any comments

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Merck does not have any comments

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Merck does not have any comments

Question C34 - Are there ways in which Option 2 could be improved?:

Merck does not have any comments

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Merck does not have any comments

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Merck does not have any comments

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

Merck does not have any comments

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Merck does not have any comments

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Merck does not have any comments

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Merck does not have any comments

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Merck does not have any comments

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Merck does not have any comments

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Merck does not have any comments

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Merck does not have any comments

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Merck does not have any comments

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Merck does not have any comments

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Merck does not agree with this principle.

Off-label use of an approved medicine should be made under the practitioner's medical judgement and should not impact or impede the clinical use of the medicine.

This principle is most appropriate for sponsors rather than HCPs.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Merck partially agrees with this principle.

If a sponsor is supplying the product for off-label use then a SCNSA would be required.

If a practitioner prescribes an approved product for an off-label indication independent of sponsors and based on medical need and judgement, Merck does not believe SCNSA is required for the practitioner.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Merck does not have any comments

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Merck does not have any comments

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Merck does not have any comments

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Merck does not have any comments

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Merck does not have any comments

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Merck supports this principle

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

1.1 Merck supports the continuation of DTCA.

1.2 We note that the purpose of the TPB described in ss3 is to "...protect personal and community health". Therefore, in order to ban DTCA a large body of empirical evidence must be delivered to indicate that the current practice of DTCA in some way breaches that purpose. There is, however, no significant robust evidence to indicate that the personal and community health is at risk (see paragraphs 3.1-3.6), and so we believe that the well-regulated DTCA of prescription medicines should remain in force given all the benefits it provides (see paragraphs 4.1-4.7)

1.3 We note that empirical New Zealand-based evidence overwhelmingly concludes that regulated DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. It does not create any personal or community health issues (see paragraphs 4.1-4.7).

1.4 All prescription medicines advertised by DTCA are registered with Medsafe (the current Regulator). Medsafe reviews the scientific dossiers and confirms the safety and efficacy of the medicines. This means that all prescription medicines advertised by DTCA are regulator-registered medicines and adhere to a core principle of the proposed regulation - that the "likely benefits of the therapeutic products should outweigh the likely risks associated with them". Therefore, this set of prescription medicines not only meet this principle but also meet the purpose of the proposed legislation of assuring public safety by regulator oversight.

1.5 Furthermore, in comparison to the vast quantity of un-regulated health information available on the internet, DTCA of prescription medicines comprises only a small percentage of advertising readily available to patients. The focus of any regulation it seems should not be on banning the already well-regulated DTCA of prescription medicines, but on the un-regulated internet sites and activities which represent a clear risk to both personal and community health (see paragraphs 2.1 to 2.6).

1.6 It is clear that interest groups on either side of the DTCA debate hold their own views, yet data and analysis of studies and surveys on consumers (who are the audience and focus for DTCA) seem to have no major concerns with the practice and indeed express concern for if the practice of DTCA were to be banned (see paragraphs 6.1). No major issues have been highlighted in a range of studies and surveys (see paragraphs 6.2-6.3)

Reasons for our views on the maintenance of DTCA of prescription medicines in the proposed legislation are further outlined in the proceeding sections.

2. Health care information and protection of personal and community health (public safety)

2.1 There is a rapidly-increasing amount of healthcare information directed at consumers via the internet that promotes, in our view, unsubstantiated therapeutic claims for all sorts of health conditions. The term "Health" is the second most searched term on Google [1]. Over 3.4 million New Zealanders access the internet across the week [2], with 87% of these New Zealanders searching for health information online [3]. WebMD, an overseas medical advice website, obtains more than 300,000 unique visitors from New Zealand each month [2]. It would, therefore, seem that the internet is a considerably bigger source of health information, than the regulated prescription medicines advertising internet sites and DTCA in standard media channels.

2.2 The level of regulated DTCA for prescription medicines is often overstated by critics and is only a very small component of the total advertising undertaken in New Zealand. By way of example, in 2017 it was shown that only 33 prescription medicines were advertised by DTCA in New Zealand. Only 6 of these medicines were advertised on television. The total of 33 medicines included 2 clinical trials advertisements, compared with a total of over 200 DTC advertisements for health supplements and over-the-counter medicines [4]. Advertising expenditure estimates indicate that DTCA of prescription medicines represented only 0.2-0.3% of total spending in New Zealand per year between the three most recent year periods of 2016 to 2018 [4]. In all cases the prescription medicines advertised in New Zealand were approved by the regulator from a safety and efficacy perspective and the advertisements had undergone independent assessment by the Therapeutic Advertising Pre-vetting Service (TAPS) to confirm compliance with the Medicines Act (1981), Medicines Regulations (1984), Medsafe Guidelines, Advertising Standards Authority and Medicines New Zealand Codes [5].

2.3 Irrespective of the source of the therapeutic product information, in the interests of public safety the questions that regulators must answer include:

- (i) Are these therapeutic claims genuine?;
- (ii) Is the therapy safe and effective?;
- (iii) Is the advertising socially responsible? and;
- (iv) Are there systems in place to ask these questions and control advertising accordingly?

Clearly DTCA of prescription medicines already falls under the domain of a range of regulatory instruments and mechanisms to protect public safety (refer to our response to consultation question C52) and so answers these questions. Our contention is that a far bigger public safety risk is that of the unregulated health information on internet sites and this we feel is a risk both now and into the future. The proposed legislation and regulator therefore need to contend with this in regard to public safety on both the matters of the internet and "Dr Google".

2.4 In comparison to the unregulated internet, in the case of prescription medicines, regulatory approval is and will continue to be required by the regulator (Medsafe) before any product can be marketed in this country. This approval is given on the basis of scientifically-proven therapeutic value (efficacy), rigorously-tested safety standards (safety) and audited, consistent high quality of manufacture (quality) [6]. Thus, the regulator aids in protection of the public safety in the case of prescription medicines and that includes the small subset that have DTCA activities associated with them.

2.5 Aside from Medsafe's evaluation and approval processes, the public's and community's safety are ultimately protected by the fact that prescription medicines cannot be directly obtained by the consumer within this country without first obtaining a prescription from a registered medical practitioner (GP, specialist) or another approved prescriber. Thus, another mechanism is in place as regards providing public safety around DTC-advertised prescription medicines.

2.6 Prescription and over-the-counter medicines are regulated by Medsafe in New Zealand and have been determined to have acceptable risk-benefit profiles based on robust clinical trial evidence [6]. Health supplements on the other hand, do not need to go through this regulatory process prior to marketing and do not need to have proven therapeutic benefits [7]. In recent cases, these supplements have even been shown to cause harm. Arthrem, a natural health supplement marketed to relieve joint pain and stiffness with TV advertisements starring New Zealand athletes was found to cause liver toxicity in at least 14 reported patients [8]. Had a similar regulatory regime including DTCA standards and regulations been in place for health supplements, it is likely that this public health issue could have been avoided.

3. There is a lack of evidence of clear public health safety risk or other issues as justification to limit or ban DTCA of prescription medicines

3.1 Any justification to limit or remove DTCA as a form of communication must be rationally connected to a public health objective and the limitation must be proportional to that objective. To outlaw DTCA would therefore require a case to be made that its removal is necessary to achieve a public health safety objective i.e. that there is clear evidence of harm arising from DTCA.

3.2 Critics contend that DTCA harms the doctor-patient relationship, gives rise to inappropriate prescribing, provides mis-information, highlights benefits over risks, and can negatively impact the pharmaceutical budget [9, 10]. However, the vast majority of the references and citations used are to US studies or examples and not to New Zealand data or its evidence base, therefore, making bona fide links to the proposed issues around DTCA activities in this country hard to justify. A critique of the issues and critical review of the data provided, including rebuttal, is provided below in the proceeding paragraphs 3.3 to 3.6.

3.3 Doctor-patient relationships: New Zealanders enjoy one of the best doctor-patient relationships in the Commonwealth. From surveys conducted by The Commonwealth Fund, over the past decades we rank in the top 3 out of 11 comparative countries [11, 12]. Logic would dictate that if DTCA causes adverse effects on the doctor-patient relationship that we would occupy the lowest ranking, yet, we do not. Furthermore, New Zealand analyses found that the majority of consumers consider that DTCA has no effect on their relationship with their doctor, and a proportion (16%) felt it could actually improve the relationship [13, 14]. The clear conclusion of the work was that the majority of patients neither asked for, nor received, a prescription as a result of DTCA, and it also showed that many doctors responded to requests with alternative treatments or lifestyle advice instead [14].

3.4 Inappropriate Prescribing: Likewise, there is no New Zealand empirical evidence that DTCA gives rise to inappropriate prescribing in New Zealand. On critical analysis, the one paper citing this as an issue provides no specific New Zealand references/citations at all, but rather reference to US studies and a tacit admission that "...No similar research has been conducted in New Zealand..." [15]. New Zealand is different in the way that DTCA is conducted and regulated so the finding of no linkage to inappropriate prescribing comes as no surprise. The final treatment decision lies with the doctor who is professionally accountable for the prescribing decision, and as noted by others in the New Zealand context, often it is not the DTCA medicine that is prescribed, which further negates any suggestion of overprescribing of such medicines [13, 14].

3.5 Fiscal impact of DTCA: In New Zealand fiscal impact of DTCA would only be an issue requiring further examination if there was evidence that DTCA was creating 'budget blow-outs' or diverting money from other health services. PHARMAC operates a discrete budget which has never been overspent in its 25-year history. PHARMAC employs a range of supply and demand side strategies, including tendering, Special Authority requirements, reference pricing and bundling that very effectively manage volume and expenditure. Furthermore, an NZIER analysis shows that the level of expenditure by PHARMAC had actually decreased in real terms (a 0.3% decrease), over the most recent 11-year (2006/7-2017/18) fiscal period [16]. This information confirms that DTCA has not caused fiscal impacts, 'budget blow-outs' or diversion of funds.

3.6 Mis-information and benefits over risks. Given the requirements of the independent TAPS pre-vetting and approvals process and the internal processes required by the companies including full legal and scientific review (see both paragraph 4.7 and Supporting Document #2), it is difficult to see how statements on mis-information and overselling benefits to risks are justified. Indeed, the Ministry of Health itself reported back in 2001 that the TAPS system had contributed to an improvement in the provision of balanced and factual risk information in advertisements [17]. This requirement for pre-vetting and approval and the fact that TAPS will engage with Medsafe to clarify perspectives on DTCA for specific products helps indicate that no mis-information or 'oversell' of benefits over risk occurs. No robust evidence of mis-information in New Zealand DTCA has been put forward, and there are no New Zealand studies or reports indicating this is the case. One study raised the issue that the quality of scientific evidence provided in advertisements of prescription medicines was poor and thus risks were downplayed [18]. However, the paper focused on advertisements directed at healthcare professionals not consumers/patients i.e. not DTCA. Its use alone and in conjunction with US data to make comment on DTCA in a New Zealand context, is flawed. Furthermore, there was a significant methodological issue in this study. The study required that any advertisement that made reference to clinical studies other than the Cochrane 'gold standard' of an independently-funded (i.e. non-industry funded) double-blind randomized clinical trial was considered poor quality. In other words, any clinical trials funded by pharmaceutical companies even if published in scientific peer-reviewed papers was considered of low quality by the authors. Ironically the same clinical data cited in the advertisements have been reviewed by Medsafe prior to approval for the registration of the medicines in the first instance. This makes the claims of the authors even more concerning as regards their perspectives on the robustness of the regulator's processes.

4. Justifications for maintaining DTCA of prescription medicines

Analyses of the case against continued DTCA of prescription medicines shows that in most cases no New Zealand data or studies have been undertaken that justify the purported issues or that the referenced studies have flaws leading to issues with conclusions drawn. What the body of empirical New Zealand data tends to highlight are a number of positive attributes of well-regulated prescription medicines DTCA.

4.1 There are multiple benefits of DTCA in New Zealand of prescription medicines including increased health awareness [13, 19, 20]; Patients encouraged to act on undiagnosed or poorly managed conditions. [19-22]; Patients feeling better about medicines when they have initiated discussion and been involved in decision-making [20, 21, 23], and; Improved treatment adherence [21, 23].

4.2 The body of New Zealand research that has been conducted on patients' and doctors' attitudes to DTCA where no bias has occurred in study design also shows positive features of DTCA. Of 632 New Zealand patients surveyed, 91% felt DTCA helps make them aware of new medicines and 67% felt it gives them enough information to decide whether to discuss a medicine with their doctor [13]. A total of 270 New Zealand GPs surveyed agreed the advertisements help make patients aware of new medicines and creates an opportunity to talk to patients about various treatment options [19]. From another survey of 1300 patients, 8.5% said they had been spurred by an advertisement to visit their doctor about a medical condition they had not discussed before and a further 8.3% were spurred to discuss a previously diagnosed condition [21].

4.3 Surveyed New Zealand patients who had spoken to their doctor about an advertised medicine, felt the DTCA had helped them communicate with their doctors [21]. An in-depth interview of GPs noted that that DTCA helps get patients 'in the door' and helps them open up the discussion about their health issues [22].

4.4 GPs, nurses and pharmacists interviewed in 2017, expressed similar views: that DTCA helps patients take notice of their health and helps them start conversations about their health conditions (conditions that may otherwise go untreated or under-treated) [20]. It also presents doctors an opportunity to screen for related health conditions [19].

4.5 A collaborative doctor-patient relationship with two-way communication allows patients to take a more active role in their health management and has several knock-on effects. Patients have higher satisfaction with their medical care and treatment, better expectations of their health outcomes, more confidence in their ability to adhere to treatment, resulting in overall higher adherence and better health outcomes [23].

4.6 Interestingly, from the three surveys of New Zealand doctors, undue pressure to prescribe advertised medicines was not found and surveyed GPs said they treat a DTCA query as an ordinary part of a visit [19, 20, 22]. DTCA does not lead to inappropriate prescribing. A related survey showed that the reasons that surveyed patients received a different medicine to the advertised one was that the medicine was not right for them, the medicine had side effects, or there was a cheaper medicine available [21]. The conclusion is that DTCA does not affect the doctor's independence or increase pressure to prescribe, it just gets patients in the door.

4.7 Unlike the abundance of other online information patients freely access, New Zealand DTCA of prescription medicines is strictly regulated. DTCA is designed to meet local requirements whereas patients often access websites from countries that don't meet New Zealand regulations. Companies in New Zealand scrutinise any advertisements during development and undertake extensive scientific, legal, patient safety and medical review. Advertisements in development are subject to rigorous internal and external review (See MNZ Supporting Document #2). All claims must be able to be substantiated and have references available on request. Again, as explained in answer to question C52, all online and mainstream DTCA are independently assessed for compliance with New Zealand laws, regulations and industry codes by TAPS. Most importantly, without this independent review by TAPS, the media in New Zealand will not run the DTCA campaign [27].

4.8 We understand the New Zealand Bill of Rights Act (1990), allows and provides for the right of freedom of expression. Medicines New Zealand, therefore, seeks clarification from the Ministry of Health on why a narrow restriction on banning of DTCA on prescription medicines DTCA vis-a-vis over-the-counter medicines and medical devices is being proposed.

5. Promotion of prescription medicines overseas to consumers

5.1 The assertion often made by anti-DTCA groups that the US and New Zealand are the only industrialised countries to have DTCA is not strictly true. While both New Zealand and the US are the only countries that allow DTCA of branded prescription medicines, what is often not mentioned by critics of DTCA is that there are numerous other countries worldwide that allow DTCA of prescription medicines in one form or another [24-26]. For example, Canada and South Africa permit consumer reminder advertisements – which let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims [27,28]. Countries in the EU and some in Asia allow prescription vaccine advertisements including promotional claims [24-26]. France allows advertisements for vaccines and for prescription quit smoking aids [29]. All of these countries, plus many others such as Australia, also allow disease-awareness or "help-seeking" advertisements: industry-sponsored messages that encourage viewers to see their doctors about a specific health concern, without including individual product names [30].

5.2 Clearly these countries and their health systems and regulators must see a public health benefit to these various types of advertisements, having either maintained these laws following legislative reviews or relaxed the laws to allow some DTCA [24, 26]. This is irrespective of whether that public health benefit is through raising awareness of tools available to quit smoking, through counteracting dangerous anti-vaccination campaigns or through encouraging patients to speak with their doctors about health concerns.

5.3 As an example of the benefits, South Korea relaxed its laws in 2008 to allow DTCA of prescription medicines for contagious diseases. The first DTCA campaign aired in 2009 for a rotavirus vaccine [24]. Since these advertisements aired, awareness of the virus increased from 12% in 2007 to 82% by 2009 [24]; The number of children infected with rotavirus reduced by 50% and the number of hospitalisation days halved [31]. The direct and indirect costs from the disease decreased from NZ\$26 million to \$14 million, saving \$12 million in health costs [31]. Thus, the South Korean experience highlights that DTCA of prescription medicines encouraged patients to seek earlier intervention for a treatable condition, and averted costly hospital admissions.

6. Patients and community views on DTCA in New Zealand

6.1 A body of previous research has indicated both people and the wider community do find benefits from advertising of prescription medicines including: improved awareness and information, and an ability for patients to discuss treatment options and their conditions with their doctors/GPs [13, 19, 21]. Interestingly, two recent studies countered this around so-called 'at risk' individuals' behavioural responses to information in prescription medicine DTCA. However, the authors admitted limitations of the study design including the use of only four "yes/no" questions on DTCA and that causal relationships/inferences could not be made "due to nature of the data". The design also showed that it was self-reported data and so "...might not reflect individuals' actual behavioural responses" [32, 33]. At best, the studies refer to responses as "perceived behavioural responses". Furthermore, the reports are based on a 2013 survey of 2057 people in which only 11.4% (235 respondents) answered yes to a question on whether they had asked their physician for a prescription after seeing a DTCA advertisement. This means that 88.6% (1822 respondents) did not seek out a prescription at all. Most interestingly, more 'at risk' individual respondents (15.9%, 327 respondents) responded that they had asked their physician for information, rather than asked for a prescription, indicating that perceived behaviours are driven towards gaining more information rather than a prescription for a specific medicine [32, 33]. Both papers also incorrectly state that DTCA of prescription medicines is only self-regulated in New Zealand. This is clearly incorrect too.

6.2 In contrast, a more recent and more detailed survey was undertaken by Perceptive Inc as part of a larger omnibus survey of 1,082 consumers to investigate where consumers obtained their information and awareness on medicines (both over-the-counter and prescription medicines) [34]. The results showed that New Zealanders awareness of over-the-counter and prescription medicines are largely gained from Google/internet searches, and family and friends (a total of 75% of respondents). Of the various channels 44% of total respondents had awareness of advertisements for prescription medicines, and 27% of total consumers used this as an opportunity to discuss health and well-being with their doctor. The majority of these discussions with their doctor (54%) were focused on the condition, ailment or problem, not the product. This is similar to the levels in other surveys findings [21]. Interestingly, 52% of total consumers surveyed found DTCA for prescription medicines helpful, while 75% of the total 1,082 respondents noted that they would be concerned if prescription advertising was banned in New Zealand, with 53% being extremely concerned if a ban occurred [34]. This finding that consumers own views are heavily weighted towards retaining DTCA of prescriptions medicines [34], is again in alignment with the positive attributes consumers ascribe to DTCA from an information perspective given in earlier work [13, 21].

7.0 Concluding remarks on DTCA

In conclusion, the prescription medicines industry believes that the continuation of DTCA on prescription medicines is justified given the body of robust empirical evidence. Any decision made to stop DTCA must be shown to achieve a significant public health objective. To do this a clear case must be made of actual and robust evidenced risks that far outweighs the evidence on benefits that DTCA provides in a New Zealand context.

List of supporting documents and references provided by Medicines New Zealand response.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

Merck does not have any comments

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Merck supports this principle

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

1.1 Merck supports the continuation of DTCA.

1.2 We note that the purpose of the TPB described in ss3 is to "...protect personal and community health". Therefore, in order to ban DTCA a large body of empirical evidence must be delivered to indicate that the current practice of DTCA in some way breaches that purpose. There is, however, no significant robust evidence to indicate that the personal and community health is at risk (see paragraphs 3.1-3.6), and so we believe that the well-regulated DTCA of prescription medicines should remain in force given all the benefits it provides (see paragraphs 4.1-4.7)

1.3 We note that empirical New Zealand-based evidence overwhelmingly concludes that regulated DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health. It does not create any personal or community health issues (see paragraphs 4.1-4.7).

1.4 All prescription medicines advertised by DTCA are registered with Medsafe (the current Regulator). Medsafe reviews the scientific dossiers and confirms the safety and efficacy of the medicines. This means that all prescription medicines advertised by DTCA are regulator-registered medicines and adhere to a core principle of the proposed regulation - that the "likely benefits of the therapeutic products should outweigh the likely risks associated with them". Therefore, this set of prescription medicines not only meet this principle but also meet the purpose of the proposed legislation of assuring public safety by regulator oversight.

1.5 Furthermore, in comparison to the vast quantity of un-regulated health information available on the internet, DTCA of prescription medicines comprises only a small percentage of advertising readily available to patients. The focus of any regulation it seems should not be on banning the already well-regulated DTCA of prescription medicines, but on the un-regulated internet sites and activities which represent a clear risk to both personal and community health (see paragraphs 2.1 to 2.6).

1.6 It is clear that interest groups on either side of the DTCA debate hold their own views, yet data and analysis of studies and surveys on consumers (who are the audience and focus for DTCA) seem to have no major concerns with the practice and indeed express concern for if the practice of DTCA were to be banned (see paragraphs 6.1). No major issues have been highlighted in a range of studies and surveys (see paragraphs 6.2-6.3)

Reasons for our views on the maintenance of DTCA of prescription medicines in the proposed legislation are further outlined in the proceeding sections.

2. Health care information and protection of personal and community health (public safety)

2.1 There is a rapidly-increasing amount of healthcare information directed at consumers via the internet that promotes, in our view, unsubstantiated therapeutic claims for all sorts of health conditions. The term "Health" is the second most searched term on Google [1]. Over 3.4 million New Zealanders access the internet across the week [2], with 87% of these New Zealanders searching for health information online [3]. WebMD, an overseas medical advice website, obtains more than 300,000 unique visitors from New Zealand each month [2]. It would, therefore, seem that the internet is a considerably bigger source of health information, than the regulated prescription medicines advertising internet sites and DTCA in standard media channels.

2.2 The level of regulated DTCA for prescription medicines is often overstated by critics and is only a very small component of the total advertising undertaken in New Zealand. By way of example, in 2017 it was shown that only 33 prescription medicines were advertised by DTCA in New Zealand. Only 6 of these medicines were advertised on television. The total of 33 medicines included 2 clinical trials advertisements, compared with a total of over 200 DTC advertisements for health supplements and over-the-counter medicines [4]. Advertising expenditure estimates indicate that DTCA of prescription medicines represented only 0.2-0.3% of total spending in New Zealand per year between the three most recent year periods of 2016 to 2018 [4]. In all cases the prescription medicines advertised in New Zealand were approved by the regulator from a safety and efficacy perspective and the advertisements had undergone independent assessment by the Therapeutic Advertising Pre-vetting Service (TAPS) to confirm compliance with the Medicines Act (1981), Medicines Regulations (1984), Medsafe Guidelines,

2.3 Irrespective of the source of the therapeutic product information, in the interests of public safety the questions that regulators must answer include:

- (i) Are these therapeutic claims genuine?;
- (ii) Is the therapy safe and effective?;
- (iii) Is the advertising socially responsible? and;
- (iv) Are there systems in place to ask these questions and control advertising accordingly?

Clearly DTCA of prescription medicines already falls under the domain of a range of regulatory instruments and mechanisms to protect public safety (refer to our response to consultation question C52) and so answers these questions. Our contention is that a far bigger public safety risk is that of the unregulated health information on internet sites and this we feel is a risk both now and into the future. The proposed legislation and regulator therefore need to contend with this in regard to public safety on both the matters of the internet and "Dr Google".

2.4 In comparison to the unregulated internet, in the case of prescription medicines, regulatory approval is and will continue to be required by the regulator (Medsafe) before any product can be marketed in this country. This approval is given on the basis of scientifically-proven therapeutic value (efficacy), rigorously-tested safety standards (safety) and audited, consistent high quality of manufacture (quality) [6]. Thus, the regulator aids in protection of the public safety in the case of prescription medicines and that includes the small subset that have DTCA activities associated with them.

2.5 Aside from Medsafe's evaluation and approval processes, the public's and community's safety are ultimately protected by the fact that prescription medicines cannot be directly obtained by the consumer within this country without first obtaining a prescription from a registered medical practitioner (GP, specialist) or another approved prescriber. Thus, another mechanism is in place as regards providing public safety around DTC-advertised prescription medicines.

2.6 Prescription and over-the-counter medicines are regulated by Medsafe in New Zealand and have been determined to have acceptable risk-benefit profiles based on robust clinical trial evidence [6]. Health supplements on the other hand, do not need to go through this regulatory process prior to marketing and do not need to have proven therapeutic benefits [7]. In recent cases, these supplements have even been shown to cause harm. Arthrem, a natural health supplement marketed to relieve joint pain and stiffness with TV advertisements starring New Zealand athletes was found to cause liver toxicity in at least 14 reported patients [8]. Had a similar regulatory regime including DTCA standards and regulations been in place for health supplements, it is likely that this public health issue could have been avoided.

3. There is a lack of evidence of clear public health safety risk or other issues as justification to limit or ban DTCA of prescription medicines

3.1 Any justification to limit or remove DTCA as a form of communication must be rationally connected to a public health objective and the limitation must be proportional to that objective. To outlaw DTCA would therefore require a case to be made that its removal is necessary to achieve a public health safety objective i.e. that there is clear evidence of harm arising from DTCA.

3.2 Critics contend that DTCA harms the doctor-patient relationship, gives rise to inappropriate prescribing, provides mis-information, highlights benefits over risks, and can negatively impact the pharmaceutical budget [9, 10]. However, the vast majority of the references and citations used are to US studies or examples and not to New Zealand data or its evidence base, therefore, making bona fide links to the proposed issues around DTCA activities in this country hard to justify. A critique of the issues and critical review of the data provided, including rebuttal, is provided below in the proceeding paragraphs 3.3 to 3.6.

3.3 Doctor-patient relationships: New Zealanders enjoy one of the best doctor-patient relationships in the Commonwealth. From surveys conducted by The Commonwealth Fund, over the past decades we rank in the top 3 out of 11 comparative countries [11, 12]. Logic would dictate that if DTCA causes adverse effects on the doctor-patient relationship that we would occupy the lowest ranking, yet, we do not. Furthermore, New Zealand analyses found that the majority of consumers consider that DTCA has no effect on their relationship with their doctor, and a proportion (16%) felt it could actually improve the relationship [13, 14]. The clear conclusion of the work was that the majority of patients neither asked for, nor received, a prescription as a result of DTCA, and it also showed that many doctors responded to requests with alternative treatments or lifestyle advice instead [14].

3.4 Inappropriate Prescribing: Likewise, there is no New Zealand empirical evidence that DTCA gives rise to inappropriate prescribing in New Zealand. On critical analysis, the one paper citing this as an issue provides no specific New Zealand references/citations at all, but rather reference to US studies and a tacit admission that "...No similar research has been conducted in New Zealand..." [15]. New Zealand is different in the way that DTCA is conducted and regulated so the finding of no linkage to inappropriate prescribing comes as no surprise. The final treatment decision lies with the doctor who is professionally accountable for the prescribing decision, and as noted by others in the New Zealand context, often it is not the DTCA medicine that is prescribed, which further negates any suggestion of overprescribing of such medicines [13, 14].

3.5 Fiscal impact of DTCA: In New Zealand fiscal impact of DTCA would only be an issue requiring further examination if there was evidence that DTCA was creating 'budget blow-outs' or diverting money from other health services. PHARMAC operates a discrete budget which has never been overspent in its 25-year history. PHARMAC employs a range of supply and demand side strategies, including tendering, Special Authority requirements, reference pricing and bundling that very effectively manage volume and expenditure. Furthermore, an NZIER analysis shows that the level of expenditure by PHARMAC had actually decreased in real terms (a 0.3% decrease), over the most recent 11-year (2006/7-2017/18) fiscal period [16]. This information confirms that DTCA has not caused fiscal impacts, 'budget blow-outs' or diversion of funds.

3.6 Mis-information and benefits over risks. Given the requirements of the independent TAPS pre-vetting and approvals process and the internal processes required by the companies including full legal and scientific review (see both paragraph 4.7 and Supporting Document #2), it is difficult to see how statements on mis-information and overselling benefits to risks are justified. Indeed, the Ministry of Health itself reported back in 2001 that the TAPS system had contributed to an improvement in the provision of balanced and factual risk information in advertisements [17]. This requirement for pre-vetting and approval and the fact that TAPS will engage with Medsafe to clarify perspectives on DTCA for specific products helps indicate that no mis-information or 'oversell' of benefits over risk occurs. No robust evidence of mis-information in New Zealand DTCA has been put forward, and there are no New Zealand studies or reports indicating this is the

case. One study raised the issue that the quality of scientific evidence provided in advertisements of prescription medicines was poor and thus risks were downplayed [18]. However, the paper focused on advertisements directed at healthcare professionals not consumers/patients i.e. not DTCA. Its use alone and in conjunction with US data to make comment on DTCA in a New Zealand context, is flawed. Furthermore, there was a significant methodological issue in this study. The study required that any advertisement that made reference to clinical studies other than the Cochrane ‘gold standard’ of an independently-funded (i.e. non-industry funded) double-blind randomized clinical trial was considered poor quality. In other words, any clinical trials funded by pharmaceutical companies even if published in scientific peer-reviewed papers was considered of low quality by the authors. Ironically the same clinical data cited in the advertisements have been reviewed by Medsafe prior to approval for the registration of the medicines in the first instance. This makes the claims of the authors even more concerning as regards their perspectives on the robustness of the regulator’s processes.

4. Justifications for maintaining DTCA of prescription medicines

Analyses of the case against continued DTCA of prescription medicines shows that in most cases no New Zealand data or studies have been undertaken that justify the purported issues or that the referenced studies have flaws leading to issues with conclusions drawn. What the body of empirical New Zealand data tends to highlight are a number of positive attributes of well-regulated prescription medicines DTCA.

4.1 There are multiple benefits of DTCA in New Zealand of prescription medicines including increased health awareness [13, 19, 20]; Patients encouraged to act on undiagnosed or poorly managed conditions. [19-22]; Patients feeling better about medicines when they have initiated discussion and been involved in decision-making [20, 21, 23], and; Improved treatment adherence [21, 23].

4.2 The body of New Zealand research that has been conducted on patients’ and doctors’ attitudes to DTCA where no bias has occurred in study design also shows positive features of DTCA. Of 632 New Zealand patients surveyed, 91% felt DTCA helps make them aware of new medicines and 67% felt it gives them enough information to decide whether to discuss a medicine with their doctor [13]. A total of 270 New Zealand GPs surveyed agreed the advertisements help make patients aware of new medicines and creates an opportunity to talk to patients about various treatment options [19]. From another survey of 1300 patients, 8.5% said they had been spurred by an advertisement to visit their doctor about a medical condition they had not discussed before and a further 8.3% were spurred to discuss a previously diagnosed condition [21].

4.3 Surveyed New Zealand patients who had spoken to their doctor about an advertised medicine, felt the DTCA had helped them communicate with their doctors [21]. An in-depth interview of GPs noted that that DTCA helps get patients ‘in the door’ and helps them open up the discussion about their health issues [22].

4.4 GPs, nurses and pharmacists interviewed in 2017, expressed similar views: that DTCA helps patients take notice of their health and helps them start conversations about their health conditions (conditions that may otherwise go untreated or under-treated) [20]. It also presents doctors an opportunity to screen for related health conditions [19].

4.5 A collaborative doctor-patient relationship with two-way communication allows patients to take a more active role in their health management and has several knock-on effects. Patients have higher satisfaction with their medical care and treatment, better expectations of their health outcomes, more confidence in their ability to adhere to treatment, resulting in overall higher adherence and better health outcomes [23].

4.6 Interestingly, from the three surveys of New Zealand doctors, undue pressure to prescribe advertised medicines was not found and surveyed GPs said they treat a DTCA query as an ordinary part of a visit [19, 20, 22]. DTCA does not lead to inappropriate prescribing. A related survey showed that the reasons that surveyed patients received a different medicine to the advertised one was that the medicine was not right for them, the medicine had side effects, or there was a cheaper medicine available [21]. The conclusion is that DTCA does not affect the doctor’s independence or increase pressure to prescribe, it just gets patients in the door.

4.7 Unlike the abundance of other online information patients freely access, New Zealand DTCA of prescription medicines is strictly regulated. DTCA is designed to meet local requirements whereas patients often access websites from countries that don’t meet New Zealand regulations. Companies in New Zealand scrutinise any advertisements during development and undertake extensive scientific, legal, patient safety and medical review. Advertisements in development are subject to rigorous internal and external review (See MNZ Supporting Document #2). All claims must be able to be substantiated and have references available on request. Again, as explained in answer to question C52, all online and mainstream DTCA are independently assessed for compliance with New Zealand laws, regulations and industry codes by TAPS. Most importantly, without this independent review by TAPS, the media in New Zealand will not run the DTCA campaign [27].

4.8 We understand the New Zealand Bill of Rights Act (1990), allows and provides for the right of freedom of expression. Medicines New Zealand, therefore, seeks clarification from the Ministry of Health on why a narrow restriction on banning of DTCA on prescription medicines DTCA vis-a-vis over-the-counter medicines and medical devices is being proposed.

5. Promotion of prescription medicines overseas to consumers

5.1 The assertion often made by anti-DTCA groups that the US and New Zealand are the only industrialised countries to have DTCA is not strictly true. While both New Zealand and the US are the only countries that allow DTCA of branded prescription medicines, what is often not mentioned by critics of DTCA is that there are numerous other countries worldwide that allow DTCA of prescription medicines in one form or another [24-26]. For example, Canada and South Africa permit consumer reminder advertisements – which let consumers know of the availability of prescription medicines, their names, strengths, pack sizes and prices without promotional claims [27,28]. Countries in the EU and some in Asia allow prescription vaccine advertisements including promotional claims [24-26]. France allows advertisements for vaccines and for prescription quit smoking aids [29]. All of these countries, plus many others such as Australia, also allow disease-awareness or “help-seeking” advertisements: industry-sponsored messages that encourage viewers to see their doctors about a specific health concern, without including individual product names [30].

5.2 Clearly these countries and their health systems and regulators must see a public health benefit to these various types of advertisements, having either

maintained these laws following legislative reviews or relaxed the laws to allow some DTCA [24, 26]. This is irrespective of whether that public health benefit is through raising awareness of tools available to quit smoking, through counteracting dangerous anti-vaccination campaigns or through encouraging patients to speak with their doctors about health concerns.

5.3 As an example of the benefits, South Korea relaxed its laws in 2008 to allow DTCA of prescription medicines for contagious diseases. The first DTCA campaign aired in 2009 for a rotavirus vaccine [24]. Since these advertisements aired, awareness of the virus increased from 12% in 2007 to 82% by 2009 [24]; The number of children infected with rotavirus reduced by 50% and the number of hospitalisation days halved [31]. The direct and indirect costs from the disease decreased from NZ\$26 million to \$14 million, saving \$12 million in health costs [31]. Thus, the South Korean experience highlights that DTCA of prescription medicines encouraged patients to seek earlier intervention for a treatable condition, and averted costly hospital admissions.

6. Patients and community views on DTCA in New Zealand

6.1 A body of previous research has indicated both people and the wider community do find benefits from advertising of prescription medicines including: improved awareness and information, and an ability for patients to discuss treatment options and their conditions with their doctors/GPs [13, 19, 21]. Interestingly, two recent studies countered this around so-called 'at risk' individuals' behavioural responses to information in prescription medicine DTCA. However, the authors admitted limitations of the study design including the use of only four "yes/no" questions on DTCA and that causal relationships/inferences could not be made "due to nature of the data". The design also showed that it was self-reported data and so "...might not reflect individuals' actual behavioural responses" [32, 33]. At best, the studies refer to responses as "perceived behavioural responses". Furthermore, the reports are based on a 2013 survey of 2057 people in which only 11.4% (235 respondents) answered yes to a question on whether they had asked their physician for a prescription after seeing a DTCA advertisement. This means that 88.6% (1822 respondents) did not seek out a prescription at all. Most interestingly, more 'at risk' individual respondents (15.9%, 327 respondents) responded that they had asked their physician for information, rather than asked for a prescription, indicating that perceived behaviours are driven towards gaining more information rather than a prescription for a specific medicine [32, 33]. Both papers also incorrectly state that DTCA of prescription medicines is only self-regulated in New Zealand. This is clearly incorrect too.

6.2 In contrast, a more recent and more detailed survey was undertaken by Perceptive Inc as part of a larger omnibus survey of 1,082 consumers to investigate where consumers obtained their information and awareness on medicines (both over-the-counter and prescription medicines) [34]. The results showed that New Zealanders awareness of over-the-counter and prescription medicines are largely gained from Google/internet searches, and family and friends (a total of 75% of respondents). Of the various channels 44% of total respondents had awareness of advertisements for prescription medicines, and 27% of total consumers used this as an opportunity to discuss health and well-being with their doctor. The majority of these discussions with their doctor (54%) were focused on the condition, ailment or problem, not the product. This is similar to the levels in other surveys findings [21]. Interestingly, 52% of total consumers surveyed found DTCA for prescription medicines helpful, while 75% of the total 1,082 respondents noted that they would be concerned if prescription advertising was banned in New Zealand, with 53% being extremely concerned if a ban occurred [34]. This finding that consumers own views are heavily weighted towards retaining DTCA of prescriptions medicines [34], is again in alignment with the positive attributes consumers ascribe to DTCA from an information perspective given in earlier work [13, 21].

7.0 Concluding remarks on DTCA

In conclusion, the prescription medicines industry believes that the continuation of DTCA on prescription medicines is justified given the body of robust empirical evidence. Any decision made to stop DTCA must be shown to achieve a significant public health objective. To do this a clear case must be made of actual and robust evidenced risks that far outweighs the evidence on benefits that DTCA provides in a New Zealand context.

List of supporting documents and references provided by Medicines New Zealand response.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Merck does not have any comments

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Merck does not have any comments

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Merck does not have any comments

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Merck does not have any comments

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Merck does not have any comments

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Merck does not have any comments

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Merck does not have any comments

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Merck does not have any comments

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Merck does not have any comments

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Merck does not have any comments

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Merck does not have any comments

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Merck does not have any comments

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Merck does not have any comments

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Merck does not have any comments

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Merck does not have any comments

Response ID ANON-DPZ8-G41V-8

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 20:49:30

Submitter profile

What is your name?

Name:

James Westbury

What is your email address?

Email:

What is your organisation?

Organisation:

Westbury Pharmacy

Submitter Profile (tick all that apply)

Consumer

Pharmacy organisation

If you select DHB, please state service area:

Wellington

Pharmacist

If you select 'Other', please comment below;::

If you selected 'Other' please comment;::

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially don't support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

It appears the bill is being proposed to address areas of shortcomings in the current legislation eg radioactive substances and the treatment of tissues.

Surely that these can be addressed by minor legislative changes without wholesale changes to the legislation.

I am unclear at this stage what is the compelling reason to change the profession of pharmacy for public good with no defining compelling rationale for change or benefit. All examples internationally point to changes that are proposed will damage public benefit. See Deloitte report.

Why is it believed ownership to corporate will improve patient outcomes or benefit the public.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

I am unclear why the definition has changed so significantly.

Dispense a medicine (s 29) – the definition of dispensing has changed significantly. I am concerned about this change. Why has the definition changed to just supply a medication? The process of dispensing is a complex set of processes from supply to the provision of information. It is very difficult to break down the dispensing process. It is also unclear on the rationale to change the definition ie what is the advantage of public benefit to change the definition eg what or how will the public be safer by changing the definition.

What is the compelling reason for the change? I can find no evidence to change the definition internationally.

Pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

The definition is different to current professional definitions.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

In the consultation you note allowing one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine requested by a patient. I am extremely supportive of allowing this type of supply between pharmacies. In fact this often happens in reality. This will enable a legal mechanism to do this.

This would greatly benefit patients by giving them fast access to their prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Not sure what this means

Question B7 - Please provide any comments on the authorisations for health practitioners :

I would be supportive of health practitioners supplying each other with small amounts of medicines in an emergency situation when a pharmacy is either not accessible or cannot provide the medicine in a timely manner.

The legislation needs to be framed in a way to

ensure that it does not allow the trading of stock between medical practitioners. The legislation will need to clearly define what is regarded as a small amount of medicine.

If medical practitioners want to trade or supply medications then they need to be under the same obligations as pharmacies

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

I am very concerned over the importation of any medication due to the risk of counterfeiting and/or resale of medication.

I

I would prefer if all medications are secured via a pharmacy as this will ensure that medications provided will be sourced from a valid and authentic manufacturer or wholesaler.

I would prefer that medical practitioners are not able to import medications unless they are held to the same obligations as pharmacies.

I believe that section 76 (5)(a) should be amended to only allow the personal importation of category 4 prescription medicines. Equivalent medicines to those that are available in New Zealand should be restricted in the same manner that they are here.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

I do not support or endorse the provision of any medication via a Vending machine unless it is operated and managed by a pharmacist and or that there are suitably controlled to ensure that medications are appropriate for patients eg a consultation or via a prescription.

Vending machines should also be required to be linked to the pharmacy licence of a full service pharmacy to ensure appropriate clinical oversight and provision of advice to patients.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

The granting of a license for a pharmacy should be based on needs as in the UK and Australia. The market should be managed to ensure that patients care and oversupply do not erode a sustainable service

A further question is why are Pharmacies licensed and not GP practices. What has the greater ability to cause harm? What is the value of a license?

GP practices have a greater ability to cause harm via poor infection control and or by bad management than a pharmacy.

Vending machines should only be authorized for use when patients do not have suitable access to a pharmacy or pharmacy depot. Vending machines should also be required to be linked to the pharmacy license of a full-service pharmacy to ensure appropriate clinical oversight and provision of advice to patients.

Please create an equitable license arrangement with other health care providers.

The activity of dispensing (traditional definition) should always be conducted in a traditional full service pharmacy. The separation of supply and advice need to be considered hand in hand and it is not practical and safe to be able to be separated.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

I am supportive of the introduction of permits for shorter-term and urgent situations. It will be important that the permits system is responsive enough to deal with these situations quickly.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Increasing the period that licences are valid for, from one year to up to 5 years, as this would greatly reduce compliance costs for both the sector and the licencing authority. Alternatively a system like resthome audits could be considered based on risk low risk five years high risk yearly or less

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

I do not support the transfer of a license and or permit.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

Keep consistent with current legislation

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Why does a regulator need to have more power or ability to fine than is currently defined.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

I would welcome and embrace opportunities and arrangements that promote patient health outcomes and do not compromise patient safety or the integrity of the community pharmacy distribution model. Any alternative distribution or supply model that is considered, must not undermine the integrity and safety of the current system or current levels of access to community pharmacy services for all New Zealanders.

It is important to recognise that the clinical process of dispensing a prescription medicine and advising patients on the medicines safe and effective use, is very different to the sale of a retail commodity, and that dispensing should be provided face-to-face by the pharmacist to the patient.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

The current rules and requirements do not create barriers to innovation. In fact the current monopoly by large incumbents such as Green Cross enforces the status quo. If history is looked at in business innovation always comes from small innovative and flexible players, not large corporates. Look at Xero in accounting. Small independent pharmacies are a breeding ground for innovation. They are able to move quickly.

Any licensing requirements need to establish the requirements for safe and effective provision of pharmacist services involving medicines.

Innovation will come through better models of care, funding and IT.

I believe that the advancement of technology and the community pharmacy workforce over time will lead to the development of new and innovative ways of delivering care to match the evolving needs of our communities.

The public good aspects of alternate distribution and supply arrangements must be fully considered against the risk to patient safety and any need for investment in supporting infrastructure or technology.

Larger is not always better. Currently, in local government, there is a move for localism. New Zealand has the highest level of centralization in the developed world. We need to think of decentralization.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

I believe all pharmacy supply arrangements need to be tied to a full-service pharmacy.

What may need to be considered can robots dispense remotely and how would this be enabled especially for remote or isolated communities.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I fully support pharmacist ownership of pharmacies.

Skin in the game is one of the strongest drivers for professional and health gain. A person invested both in his or her community and a health professional ensures both tangible and intangible benefits for a community.

Owner-operator pharmacists are both accountable for their decisions both professionally and personally. They are highly regarded in the community they service. This is proof b how many are involved in local politics.

Pharmacist ownership and effective control assures the public that patient care is the focus of community pharmacy.

Pharmacists are under a professional obligation to provide services and a standard of care that requires adherence to higher standards than those that may be imposed by the regulator. A non-pharmacist investor owner is more likely to focus on meeting minimum compliance standards at minimum cost which will have a negative impact on the range and scope of services the investor owner is prepared to provide.

Medicines are not a normal item of commerce and pharmacies are not like other small businesses in a free market environment.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Is the current system is not broken and what will the effect of non-pharmacists owners. In general non-pharmacist owners in the UK and internationally have not delivered improvements in care or public benefit.

Community pharmacies, under current majority pharmacist ownership requirements, are delivering many benefits to patients and the wider health sector at no cost to patients or the government.

I do not believe that corporate owners add value to pharmacy.

Many such as Countdown have commoditized pharmacy into a retail service as opposed to a professional health care provider. It is like asking a GP to work in a supermarket. It then has the impact of diminishing the value or perception of the dangers of medication and the need for advice.

I believe there are a number of pharmacies that are not operating under the current legislation as it was written eg with shareholder agreement and equity being not considered controls.

It is important how equity and control are managed in any arrangement

I do not support the continuation of supporting pharmacies that have deliberately acted outside of the act eg grandparenting clauses.

There is a risk that there could be a lower level of external investment from the dividend requirements under Option 1. This is unlikely. Pharmacies do not normally have trouble securing capital.

Any arrangement should ensure that the controlling pharmacist has control over any other investor. Care needs to be taken when this can be circumvented via a shareholder agreement such as what happens with Green Cross.

Question C25 - Are there ways in which Option 1 could be improved?:

The Bill should consider improving Option 1 by legally mandating that the owner pharmacist to have a 'veto share' so that this pharmacist is always in control of all voting rights, giving them unequivocal control of all activities, operations and governance matters related to the pharmacy. A veto share ensures effective control is in the hands of a pharmacist and replaces the need for regulating dividend requirements in proportion to shareholding. This would allow some flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters

This also needs to protect from shareholder agreements that go to circumnavigate the legislation.

It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to outvote the owner pharmacist where matters of public safety or pharmacy practice are concerned.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

All clinical activities within a community pharmacy setting that require a pharmacy licence, such as the provision of medicines (except general sales medicines).

Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

The Act needs to be clear about the definition of effective control. Effective control drives governance and operating decisions.

Effective control provisions are grounded in pharmacist owners' obligation as registered health professionals under the Code of Ethics, pharmacists are highly trained medicines experts who must put their patients' interests first, before profits or shareholder value, which are the driving motivations of any normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations. This allows for flexible ownership arrangements while strengthening the requirement for pharmacist ownership, and effective control provisions.

I believe a pharmacist should have effective control with a minimum controlling share of 51%. One pharmacist should hold this and it should not be diluted.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

I believe the current limit is sufficient as I do not believe that a pharmacist could possibly have appropriate oversight over more than this.

In addition, I believe that there should be no non-pharmacist ownership of more than 5 pharmacies.

This would simplify the governance and ensure there are no dominant players in the market

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

I believe that 1 pharmacist needs to have overall control eg 51 and 49%

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Non-pharmacist owners may leave the market reducing the value of pharmacies, therefore, reducing the cost of a pharmacy and therefore debt and therefore the cost of the service.

The financing of a pharmacy should not be construed as ownership. Non-pharmacist owners will add very little value to pharmacy nor public benefits

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

5 years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

I do not support friendly societies owning pharmacies. They were grandfathered last time and have no place in owning pharmacies.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

I am concerned that removal of majority pharmacist ownership of a community pharmacy or any pharmacy under Option 2 will be detrimental to patient access to

services, patient safety, patient health outcomes, the pharmacist's professional obligations, and the pharmacy profession generally.

Pharmacies will focus on increasing product turnover and margin rather than on consumer experience or outcomes, in a manner similar to some consumer product chains.

Option 2 would likely increase compliance costs, due to complexity around accountability conflicts, and may also cause future workforce issues due to the reduced opportunity for pharmacists to progress in their careers. Community pharmacy currently benefits from a relatively young workforce, with many attracted to the profession by the opportunity to one day own their own business.

Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. By placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Government effectively 'raises the stakes' for non-performance.

Question C34 - Are there ways in which Option 2 could be improved?:

I do not support this option. I see no benefit to the public or the profession under this model.

The Chemist Warehouse and Countdown do not add value to the profession nor the public.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

All pharmacy activities that require a pharmacy licence need to be conducted either by a pharmacist, or under the supervision of a pharmacist. I do not understand how these activities can be performed safely without the direct in person oversight by a pharmacist. We are concerned that any change in this space could lead to patient safety concerns.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

I do not support prescribers holding an interest in a pharmacy. In order to remove any conflict of interest it is essential that prescribing and dispensing remain separate.

There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:.

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

There needs to be a provision to ensure that batch compounding can still continue. Pharmacies typically compound in bulk for the compounded products that they dispense on a regular basis.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Legislative burden and cost without any real benefits to public safety that are quantified just add costs to consumers. I would strongly encourage that any framework and legislation does not increase the burden to retail and pharmacy.

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C48 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C49 - Are there situations where it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

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Submitted to Therapeutic Products Regulatory Scheme: Online Consultation

Submitted on 2019-04-18 20:50:26

Submitter profile

What is your name?

Name:

Antony Bedggood

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Private/self

Submitter Profile (tick all that apply)

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:

Surgeon

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially don't support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

As noted by the NZMA while many parts of the Bill could provide an improvement to the medicines act, in particular allowing regulation of new technology and devices. However the exclusion of complementary and alternative medicines, and the lack of regulation for direct to consumer marketing of medicines are significant issues.

It appears that details decrease, administrative layers increase, who will be responsible for providing regulatory approval is vague and potentially subject to meaningless or ineffective decisions, and compliance costs will be passed back onto suppliers and the public.

There is a significant risk that the proposed bill will result in decreased product choice in our already small market.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

- 1) Proposed requirements for control of "off label" use of medications (by registered medical practitioners) which are already approved for use in New Zealand. The draft bill indicates that a Special clinical needs supply authority (SCNA) would be required for each individual patient and every medicine used. This will include an extremely large number of commonly used medicines. Specifically it is noted that the regulatory body will be unable to determine whether the use for an individual patient is clinically justified, and that including already approved medicines is likely to increase administrative burdens or decrease the ability to provide efficient clinical care without any improvement of safety or outcome for each individual patient.
- 2) The Therapeutic products bill will also restrict the availability of new medications and technology to New Zealanders, both those for approved indications due to increased compliance costs, and the availability of what can be used off label. It is likely that our patients will be less able to access medications that are the standard of care internationally - due to our small market size.
- 3) I note that the bill appears to indicate that it will borrow the regulatory guidelines of other countries to decrease administrative work, however those environments are often quite different to NZ and will make us subject to costs and restrictions that could make the cost of healthcare increase markedly.
- 4) A further layer of restriction of approval for clinical research, which would appear to increase compliance costs and limit what research will come to New Zealand. Our patients will suffer because of this. Our research funding already lags far behind other OECD countries, if international research groups have no reason to conduct clinical trials here it could produce very significant harm to our medical system and patients.
- 5) Creation of a new system that is so broad as to include all items used in patient care, all software etc - while designed as a 'catch-all' is too nonspecific and will make compliance difficult and expensive for practitioners and hospitals or health providers to achieve. The costs also appear to be planned to pass on to consumers.
- 6) Lack of detail as to who will govern regulation, how they will make their decisions, ie the details are all missing from the intended bill.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Need more detail around design of obtaining 'product' approval so that it is not simply a commercial matter but facilitates availability of proven medicines (ie ones that may be used 'off label' now but have good evidence of benefit and lack of harm). It is a significant concern that instead of doctor being able to exercise their clinical knowledge - which should be constantly developing according to the latest evidence based practice - we will be judged by whether what we supplied was 'approved', by a system that has no medical knowledge, and no hope of being up to date.

What is more the 'approval' is liable to be significantly biased towards whatever source has been consulted, not to mention fiscal and other considerations rather than the actual patient in question. In summary, very bad medicine not to be able to tailor care to the individual patient because of regulatory systems. It also puts doctors at risk, and will change practice, limiting patient choice and possibly delivering poorer outcomes.

Parallel importation may be crucial in some situations where a medicine is not funded. Will the NZ government and Pharmac fund all new medications? Almost never according to my experience, at least 4 or 5 years after mainstream international use in many cases. Why should only the rich of New Zealand or those who will be subject to severe health poverty be given the chance to have the best health outcomes? Are you protecting commercial interests? Or the public...

If we want to apply for product approval what is it actually going to cost? The way the new bill seeks to restrict what products are approved could significantly limit what medicines are available to New Zealanders, there must be systems in place to ensure that conditions which affect only a small number of people in our country, or which have low commercial interest can get approval without costs restricting that process.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).:

These would seem similar to the current bill, with more encompassing stipulations. Who will the applications for licenses and the such be made to/controlled by? Who will be responsible for managing the multiple steps outlined in the bill in the supply chain?

How do you propose to make this a clinically relevant process? And how will you control the cost of these requirements - especially given that the model you propose will have the supplier (& therefore end-user) carrying the cost.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

The need to have an SCNSA for every different type of a medicine's use for each patient will be a major issue with far-reaching implications.

The most important being that instead of using an effective medicine 'off-label' the way off label use is regulated in the proposed bill has a good chance of causing a shift towards only using expensive, limited 'approved' medications. Especially if who controls the approvals fails to be doctors exercising evidence based medicine.

In terms of practical day to day work SCNSA is the most important part of the Bill for Ophthalmology, we use many medications off label in large volumes, specifically for the treatment of retinal disease and cataract surgery:

Bevacizumab is used intravitreally as a section 29 medicine for treatment of age-related macular degeneration, diabetic retinopathy, occlusive retinal vascular disease and a large number of other retinal diseases. Each patient will require on average 6 injections per year, and there are approximately 6000 injections undertaken in Canterbury each year.

Cataract surgery section 29 medication commonly used:

Adrenaline injected into the fluid used during surgery (every case done in New Zealand, ie >20,000 surgeries annually)

Intracameral (into the anterior chamber of the eye) injection of antibiotics, xylocaine, phenylephrine, triamcinolone - all commonly required.

Intravitreal injection of other medicines, ie antivirals, antibiotic, tissue plasminogen activator.

Who should decide which 'off-label' use is justified is an important issue (ie whether the medication is known to be effective and safe, and of benefit in each situation).

Almost all of these medications are very well researched for the indications involved. The proposed bill will shift our focus from the most efficient and effective clinical care to one of a regulator/supplier/manufacturer issue about which medications are approved for what.

The proposed Therapeutic products bill would either require each patient (& possibly each instance of it being used) to have a approval made - this would be difficult to administer in a timely fashion, and the increase administrative requirements from a system which does not play any part in clinical management would be far more likely to cause harm than prevent it. In that setting we would require the regulator to make an exception for off-label use of Bevacizumab and probably many other other medications to be used without individual SCNA, or have some means of allowing the product to be registered for the therapeutic use in New Zealand.

So- how can we be assured that this process would work and that patients would be able to be given the medication when it is needed - which is time critical for the conditions being managed? Much more detail is required as to what the process will be to provide an off label use with regulatory approval such that it is not necessary to seek for every patient.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (ss 65).:

Nurses are frequently required to prepare and administer 'off label' medications. Would a standing order ever even be possible for a SCNSA? Too few details about how your regulations will affect the efficiency of the NZ health system.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:

The proposed bill tries to be broad enough to cover everything (except health products & direct to consumer advertising), but the devil is in the detail. Reading even your simplified interpretation above shows the incredible complexity you are hinting at while simply scratching the surface. The regulatory system is liable to become enormous. How will you keep key clinical outcomes as the focus and not get lost in detail - who is going to provide the clinical advice necessary, and how will you make that unbiased?

My advice - iron out clear, clinically oriented priorities at the core of the legislation in these areas, not just vague concepts.

Subpart 4: Other offences (ss 81–94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

There are gross inconsistencies here. The proposed bill will continue to allow DTC marketing with minimal control other than 'not misleading' - this is so obviously going to result in biased and clinically unsound or unnecessary decisions being made, with increased costs to the patient and taxpayer.

And yet on the other hand you are apparently trying to 'protect' from biased prescribing by preventing a pharmacist or doctor prescribing a medication that will be supplied by a pharmacy they happen to have an interest in. This will significantly limit the ability of pharmacists to provide clinical care, increase costs and decrease availability for patients.

DTC advertising must go. Pharmacists and anyone that takes clinical responsibility should be allowed to prescribe regardless of where the medicine will be sourced from.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)**Question B17**

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

B7 Part 5 of the Bill: Licences and permits**Subpart 1: Licences (ss 123–130)****Question B18**

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Subpart 2: Permits (ss 131–135)**Question B20**

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

Subpart 3: Provisions applying to licences and permits (ss 136–151)**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

B8 Part 6 of the Bill: Regulator**Subpart 1: Regulatory powers and functions(ss 160–182)****Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

See my answer below, a heavily regulated system works well for common disease/large volumes, but will not allow us to even access medicines that are needed for rare diseases. There will be need to be dispensation for medicines needed in small numbers or even individual patients given the incredibly complex world of highly specific drugs that we are entering.

Subpart 2: Investigative powers (ss 183–196)**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183–196).:

This is huge if it will be an active - 'looking for problems' process. The Bill should stimulate that the degree of monitoring and compliance required will be specifically linked to the potential for harm, and also that systems will be easily utilised/already in place for medicines that are used in only small numbers or for clinical trials.

For example, if there were 20 children a year who would go irreversibly blind without a new agent there should be a simple to apply registration and monitoring system (ie doesn't have to be re-invented for every different instance and product), ie a system that limits the costs of meeting compliance for such instances, especially when the medications in question will usually be part of clinical trials and hence closely monitored.

The same for research, the research design itself will achieve the things you are proposing.

Otherwise being compliant will be so expensive that no innovative or niche medications will be available to our patients, NZ is already so small a market that we are likely to be overlooked if the process is expensive, complex etc

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

As stated before, New Zealand is vulnerable to loss of supply and medicines not even being offered here due to compliance costs. Some way of controlling the costs of your regulatory system have to be in place, and important medicines, ie life-saving or for children etc provisions should be in place to make sure extra costs are absorbed and suppliers not put off.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

Very short transition phase?

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

You are using too broad a definition of medical device

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

The concept of needing to actively consider if there is an approved medicine to use in the setting is good, but in situations where the approved medicine is, for example, 20 times the cost of the unapproved one which has been shown to have the same efficacy, are you actively wanting to push us towards following suit with expensive overseas health systems rather than continue off-label use which is one of NZ's little advantages? This again acknowledges that the ability for a product to have been approved is usually linked to its sponsor and thus to commercial interest.

Avastin at \$100/dose compared to \$2500 for the approved medication is the prime example.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

"The intention under the Therapeutic Products Bill is to try to minimise the use of unapproved medicines in New Zealand." this represents a massive change in how we will be able to practice medicine, you are removing the ability of doctors to use their clinical judgment to prescribe and you are giving that role and right to manufacturers and suppliers who are the ones who will pay for the cost of 'approval'.

The implications are enormous, especially in terms of cost to our country and availability of medicines.

We have an exceptionally high quality health system, your proposed bill intends to both make health so expensive that it cannot be afforded by many, and make the very quality of our healthcare pointless in the face of layers upon layers of regulation.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.: