Response ID ANON-DPZ8-G4X3-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2018-12-19 10:19:55**

Submitter profile

What is your name?

Name:
Leanne Arker

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

Consumer

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

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 support sunscreens being declared therapeutic products using regulations.
The consultation document does not explain why dietary supplements could not be declared therapeutic products. Without understanding why supplements are excluded from the proposed draft Bill, I cannot comment on whether I agree with the omission. I could be persuaded otherwise, but currently I would support dietary supplements being treated in a similar way to sunscreens.

Response ID ANON-DPZ8-G4XE-X

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2018-12-28 15:03:03**

Submitter profile

What is your name?

Name:
Dale Griffiths

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Westview Pharmacy 1994 Limited

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;:

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).:
Why when we are trying to get in step with overseas standards, are we using the term Active Medical Ingredient (AMI) when your discussion states that internationally what you are referring to is called Active Pharmaceutical Ingredient (API). If we are using new terms in this legislation, as we are, and we want to use terminology then why should we invent a new term?

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).:
I cannot see in the Bill (and this may be an oversight) an ability to export for personal use when travelling. Do users of medicines need to be exempt from the legislation to do this? I may also have put this comment in the wrong section, but you do refer to export here in the Bill.

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).:
I have concerns that the term "qualified pharmacy worker" is too loose. I presume we are discussing Intern Pharmacists, Pharmacy Technicians and those students in training to gain such qualifications as listed in the current legislation.
I suspect that by failing to fully define the current roles you are opening a door for pharmacists and pharmacy owners to exploit the lack of definition in the Bill. Perhaps the term "qualified pharmacy worker" could be clarified in the Regulations. This would permit new titles/roles to be listed as the profession develops them.

Question B7 - Please provide any comments on the authorisations for health practitioners :
The creation of a formal special clinical needs supply authority is significant and to be applauded. This provides protection to patients and other health practitioners downstream of the prescriber acting in these circumstances.
I have an issue with the phrase "special clinical needs supply authority", I suspect it will get confused with the use of "Special Authority" in the Pharmaceutical Schedule.
GPs in my experience lack familiarity with the detail fo the legislation and can have a cavalier attitude to it.
Can two more direct terms be used e.g. "Off-label Permit" and "Unapproved medicines permit" to distinguish the two instances which would trigger the need to prescribe outside the indication. How would off label prescribing be monitored? What are the consequences of a prescr ber failing to issue a "special clinical needs supply authority" and how would this SCNSA be shared with the patient and other health providers? I suspect that off label will be well handled by specialist as they are more aware of the indications than GPs who have to deal with so many more medicines. Should a patient countersign a SCNSA to acknowledge that they have been fully informed and accept any inherent risk?

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
I have concerns with the amount of supervision provided in the circumstances discussed in s65.
If another health practitioner requests a second health practitioner to supply e.g.GP asking a nurse to supply I do not see a problem.
I have seen dentists break down retail packs of pharmacy medicines and place the medicine in an envelope and have these handed out by reception staff with no labelling when the payment for the service is completed. While this is poor practice, the legislation must prevent this. There is no obligation as written to record the provision of this medicine and there will be no record on the repositories despite the medicine being provided on professional advice.

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).:
If counterfeit medicines are such a concern, why would you allow personal importation?
Despite this, category 2 medicines require the authorisation of a pharmacist, much toughened in this Bill, before a patient can access a Cat 2 medicine. Presumably this is because Cat 2 medicines and the conditions they treat if treated poorly can have serious consequences. Why then let patients have open access to these medicines? I am aware of the chronic overuse of chronic OTC NSAIDs for the treatment of gout. These patients should be referred to a GP and started on preventative therapy, if they can continue to bypass a community pharmacy then the renal damage these medicines cause will not be averted. There is no specification around the importation for "personal use or a a limit on the quantity that an individual can import

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
Does the section around Standing Orders need an addition? As a pharmacist who has worked under a Standing Order for warfarin dosing I am adjusting doses rather than supply or administer as a lay person would understand the two terms.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
S93 may need some modification to permit a company owning a whole medical centre as in a local health trust to allow all the practitioners to own a share of the practices or a community from owning a pharmacy as a trust when a pharmacy is not a viable business as a stand alone investment in rural areas.
There does need to be protection from a prescriber being financially interested in supporting a specific pharmacy because of direct ownership, as a landlord or by use of a family trust in either of the circumstances described.
Prescribers work in a private space with a patient, their decisions cannot be overheard or directly influenced by a practice owner. Pharmacy practice is mainly in

the open and given the retail environment that pharmacists work in sales targets are often a performance tool used by pharmacy owners to measure performance and influence staff behaviour.

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).:
Would hearing aids be covered or exempt?

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
The move to include post-marketing responsibilities is a positive move.

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).:
Ensuring as best as possible that anyone dealing with medicines is fit and proper is a sensible move

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).:
Eminently sensible

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).:
Under S150 and S151 can pre-approval be sought in the case of sale? If the new owner was faced with a restriction linked to the previous owner could a pre-approval process allow a prospective owner to understand any restrictions that would be placed or him or her as a new owner before the final sale and purchase went ahead?

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 concept behind these clauses are sensible, I have a couple of thoughts on the details. What timeline are you suggesting around non-response from the licencee and how will you ensure that responsible persons inform the Ministry in a confidential way? How easy would it be to change the responsible person(s) listed on a licence?

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).:
There are no timelines associated with these steps, if they follow in regulation that would make sense.
With regard to a pharmacy licence are there sufficient powers to ensure corrections are made in a timely fashion. There appears to be no powers of suspension of a licence, it may be covered elsewhere

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

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

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.:
Should there be an obligation on health professionals to report adverse reactions?

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?:
Yes - it seems very sensible to treat these products in the same way as a major trade group/source of product does

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
Would the performance targets be open to scrutiny. From a business perspective it would be useful to now how long changes should take so that supply timelines can be optimised

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.:
Sensible new change

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 comments

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?:
Sunscreen manufacturers are frequently found to be less protective than they claim. Consumers should have confidence in the SPF rating on the packaging, better regulation of these products should guarantee this.

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?:
I have concerns about a lack of access to some devices for which a sponsor would never eventuate because of the low volume of sales in NZ. As an example www.miaomiao.com sells a device which permits real time blood glucose monitoring when linked to a Freestyle Libre BG sensor.
Given that this device is only available on-line and it doesn't control an insulin pump as some other devices can or are close to doing means that the risk to the patient is no higher than failing to check their sensor is working and actually scanning the sensor by hand.
Much will depend on what is exempted and what is not.

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.:
This is a very sensible proactive move

Question C4 - Please provide any comments on the approach to post-market controls.:
Again, very sens ble

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?:
It shouldn't be limited to Category 1 medicines as discussed earlier

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?:
Hub and spoke arrangements
Pre-packing by central pharmacy of bu k medicines
Greater electronic enablement

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
Not that I know of

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
Delivery is not covered in the Bill, it may be covered in the regs. Post is a dying service, so the Regulations need to acknowledge a wider safer way of medicines delivery.

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?:
there is an increasing corporatisation of health, many GP practices are not owned by the GPs who work in them and access has become limited as longer hours and weekend work has been shunned by employee doctors. I would not like to see pharmacy become corporatised as the same would occur, with service innovation prevented and as we can already see pharmacy services being discounted and as a result diminished.
My experience is since the opening up of ownership of pharmacies the personal investment in the services they deliver has reduced except when there is an overwhelming commercial imperative to run the service. Many other pharmacies have drifted towards a lower level of service because the pharmacist opening the doors has little personal investment in the business

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
A failure to optimise the opportunities that amalgamation could create

Question C25 - Are there ways in which Option 1 could be improved?:
Tightening ownership controls as indicated is sensible, but needs to allow for family trusts being the beneficiary of the business when the licensee is a beneficiary of the trust

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
All aspects of the pharmacy's operation

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?:
I suspect that where ownership becomes too large, control is reduced. There is a lack of structure and quality oversight in a number of the pharmacy groups where a few pharmacists have come together to own a group of pharmacies.

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)?:
If you remove the number, then how do you assure that the oversight is effective. If there are large geographic distances between the pharmacies under one pharmacist then the oversight becomes difficult. This is where the licence conditions can play a part.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
There is an ability for pharmacists toward together for purchasing benefits which can be passed on to al the pharmacies involved. There should be no ability to coagulate pharmacies as has happened as this makes the who is responsible to which pharmacy difficult to oversee

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?:
2 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?:
You need to talk to the Friendly Societies, I suspect they are a dying institution given they control less pharmacies than they used to. I wouldn't support this exemption lasting more than 5 years under the new legislation.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Greater investment along with a more corporate model, lack of innovation for innovations sake and a greater emphasis on sales rather than care./ There will be less pharmacies available and less choice for patients

Question C34 - Are there ways in which Option 2 could be improved?:
No, because once the fences are taken down re-instating them is impossible.

Question C35 - Are the requirements adequate to ensure the ‘supervisory pharmacist’ would be able to effectively perform this function?:
It is very hard to protect anyone who in discharging their duties correctly can be protected from the behaviour of corporates, particularly if that corporate has a significant market share. Despite the protections in this legislation, a lack of promotion within the organisation and other barriers could result in a pharmacist being effectively punished for speaking out. Corporates are very difficult to pursue legally as the have very deep pockets and corporate behaviour when bad is hard to change.

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?:
Oversight may be a bigger challenge, clinical advice already happens remotely, by phone and other electronic methods. Advice was not part of the regulated activities under this Bill

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?:
There is an issue of prescr bers directing to a pharmacy they have an interest in. I am facing resistance in a new business from prescribers who are either the landlord or tenant of the pharmacy

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Permits may be a useful way of regulating trials of new services that involve medicines. New services that depend on advice are not regulated. It costs nothing to enable permits in the legislation even if in reality they are not used.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
Given the development of closed door internet pharmacies I should think the need for retail-only licences to be minimised. Depots may also be under threat for the same reason, but they currently have apart to play in providing access to rural 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?:
Very sens ble

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?:
If supply to a second pharmacy of pre-packed medicines from bulk is considered wholesaling them this would be a reason to permit this

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
Hopefully a greater sense of responsibility around the provision on Category 2 medicines. Will a requirement to dispense these through the pharmacy PMS be included? This will ensure that the medicine is listed on the local repository should the patient either be hospitalised or should a prescriber need to identify what was provided by the pharmacist

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

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, it is currently challenging to find prescribers who are not medical practitioners in the registers of the various regulatory bodies. Knowing who can do what is a challenge when dealing with the multitude of prescriber types now working.

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

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
This is an improvement on current practice under S29.
The terminology is confusing - see my earlier comments under Question B7
"The creation of a formal special clinical needs supply authority is significant and to be applauded. This provides protection to patients and other health practitioners downstream of the prescriber acting in these circumstances.
I have an issue with the phrase "special clinical needs supply authority", I suspect it will get confused with the use of "Special Authority" in the Pharmaceutical Schedule.
GPs in my experience lack familiarity with the detail fo the legislation and can have a cavalier attitude to it.
Can two more direct terms be used e.g. "Off-label Permit" and "Unapproved medicines permit" to distinguish the two instances which would trigger the need to prescribe outside the indication. How would off label prescribing be monitored? What are the consequences of a prescr ber failing to issue a "special clinical needs supply authority" and how would this SCNSA be shared with the patient and other health providers? I suspect that off label will be well handled by specialist as they are more aware of the indications than GPs who have to deal with so many more medicines. Should a patient countersign a SCNSA to acknowledge that they have been fully informed and accept any inherent risk?"

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?:
My only concern is if we end up with practitioners of the level of one of my UK colleagues, who is a Consultant Cardiac Pharmacist with prescribing rights. He probably knows more about the medicines available and the indications for what is available to him than many of his cardiologist colleagues. We are limiting patient choice in specialist areas back to medical practitioners, this potentially removes some future proofing around new roles that have not yet occurred in NZ. There needs to be common access to an authority once issued so that all those whose professional decisions fall from the decision are aware of the authority and the circumstance s behind it.

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?:
Very sens ble, I would like to see it extended to all medicines, in particular Category 2 medicines

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:
To cover shortfalls, or emergencies, where would this provision be used instead of a standing order?

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?:
As long as those medicines were within their scope of practice

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?:
It depends on the level of supervision and the recording involved. If poorly supervised this could be problematic

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?:
I am unsure if patients have really benefitted from DTCA. DCTA has primarily been in lifestyle medicines e.g. sildenafil and weight loss. I know prescribers have felt under pressure to prescribe on demand.
Money has been spent on driving new expensive medicines to market, particularly in asthma with LABA/ICS combinations being promoted as more effective than traditional ICS preventers. Poor control of asthma is often more about adequate adherence rather than a clinical need for a new medicine.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:
Seems sens ble. Will the period of supply be more clear under the new regulations? At present veterinarians play by different rules in terms of period of supply. As they commonly now dispense to their patients their attitude about compliance with legislation can be erratic.

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?:
I do not see a reason to continue this.
I am unsure if patients have really benefitted from DTCA. DCTA has primarily been in lifestyle medicines e.g. sildenafil and weight loss. I know prescribers have felt under pressure to prescribe on demand.
Money has been spent on driving new expensive medicines to market, particularly in asthma with LABA/ICS combinations being promoted as more effective than traditional ICS preventers. Poor control of asthma is often more about adequate adherence rather than a clinical need for a new medicine.

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?:
I don't believe that the intentions of the S29 have been routinely followed by prescribers and pharmacists, as a result patients have not always been fully informed of the situation because the situation is often complex and over recent years been related to stock shortages. The use of S29 has been compulsory and not a treatment option.

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 provision lacks the future proofing that is contained in much of the Bill. Could this ability also be extended under scopes of practice as these develop. Specialist pharmacists as they develop as a profession and play a greater role in prescribing may well be capable of initiating such treatment.

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?:
Sensible, protects everyone in the chain with the most important being the patient

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
Potentially, this could be used as a backstop, if the patient was from overseas and paying for the medicine as it was not available in NZ. This does circumvent a number of the patient safety mechanisms in existence. It should be under exceptional circumstances not a matter of a way around a SCNSA

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
Pharmacists working in an advisory role may still be in situations where they have to sort, rearrange or physically handle medicines. e.g. a rest home where they are consulting. The Bill needs to recognise that while not dispensing a pharmacist may have to handle medicines outside a pharmacy. this may be a simple as returning medicines to a pharmacy for destruction.

Hub and spoke arrangements
Pre-packing by central pharmacy of bu k medicines
Greater electronic enablement

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Delivery of medicines does not appear to be covered as it is under the current Act. Where ever this is covered, this needs to permit safe, secure delivery using current and future delivery modes. In another role I am seeing the confusion in responses from NZ Post's legal team as to what needs to be signed for and what does not as despite being the child of the Post Office, they do not see their courier service as "post"

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?:
there is an increasing corporatisation of health, many GP practices are not owned by the GPs who work in them and access has become limited as longer hours and weekend work has been shunned by employee doctors. I would not like to see pharmacy become corporatised as the same would occur, with service innovation prevented and as we can already see pharmacy services being discounted and as a result diminished.
My experience is since the opening up of ownership of pharmacies the personal investment in the services they deliver has reduced except when there is an overwhelming commercial imperative to run the service. Many other pharmacies have drifted towards a lower level of service because the pharmacist opening the doors has little personal investment in the business

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Greater coordination fo care between various providers

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Access could be restricted and more distanced from medical care. Less choice

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?:
Within their scope of practice.

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?:
Unqualified staff with no direct knowledge of what they are handling

Advertising

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

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 see the benefits of a brief advertisement that provides little but positive information about a product. It would have little bearing on what is the best medicine for the user

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?:
Probably, should consumers be protected when devices that purport to add benefit do not

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.:
Good idea

Response ID ANON-DPZ8-G4X2-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-01-21 13:49:57**

Submitter profile

What is your name?

Name:
Perry Nichols

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
SheffMed NZ Ltd

Submitter Profile (tick all that apply)

Consumer

Industry body

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;:

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).:
Depends if costs will go up and we end up paying more TAX, and as long as it does not follow the Australian TGA system

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).:
Then DHB's should have medical and Bio MEdical declared as manufacturers and should be CE certified to do any checking and changes.
Companys spend millions on CE, why are we not following there information re product, seems l ke some of this can be changed as needed

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).:
Then Surgeons should not be allowed to buy and use medical devices from conferences.

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).:
SOme of the people in Supply chain need to understand the product

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
No comment they know what they are doing

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

Question B7 - Please provide any comments on the authorisations for health practitioners :
They should not be allowed to import and use a product that is not CE or FDA approved

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
No conmment

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).:
Personal Imports, you need a web portal so the items can be checked, to see if they will be ok

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.:
People need a way to check the legal aspects of what they want to import

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).:
As long as we do not follow the Australian TGA method, which cost a fortune, and NZ could not afford this way.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
The reason why the cancellation needs to be given by people who understand the product, so more people will need to be employed

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).:
All product should be company sponsored

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
Once the product is in the supply chain, as such in a DHB, then responsibility should be with the DHB and Hospital.

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).:
depends on the ingredients in the product, and we should not be forced to use a generic product as consumers

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).:
Re sterilisation of product, New Zealand has few plants to do this, we should have developed a gamma plant in New Zealand for sterilisation.
If a company in NZ wants to sterilise a product then the company who is sterilising the product should be a licensed manufacturer and have the certificates to do this.
Then shouldn't hospitals have the same conditions as they sterilize and are basically manufacturers

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
who is going to do this? who has the skill in NZ to approve these licence, will on-site visit happen, will full test's of all equipment be carried out where the product is being sterilised ?

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).:
How much will this cost?

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).:
So this would mean operator error or incorrect end user use would need to be reported, would hospitals do this to get accurate feedback on product issues

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator’s investigative powers (ss 183-196).:
Who is going to train the regulators

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):
Sounds l ke this could become expensive if anyone one want to contest this in court

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).:
Sounds l ke this will become expensive to NZ

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).:
If these end up in Court , Big companies will be ok, they have deep pockets what about smaller companies how will they get on with this

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).:
Companies should be sent details about points in the above part 199

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).:
First, a warning should be given and someone should explain why and what improvements need to happen, then if the breach continues a fine

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).:
Whatever fee you put on this, companies will put prices up, so in the end, the Government will take more Tax to cover the cost, so in the end, we all lose out, we are a small country and can't afford the TGA prices, this could also mean companies may stop importing product due to cost

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).:
sounds fair

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).:
Only New items should be looked at

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?:

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, if you are talking Multi-Vitamins as long as these are coming from reputable dealers through appropriate sponsors l ke companies, not individuals then fine

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?:
Surgeons and Hospitals who are importing directly

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
WAND works well, why change it, also costs need to be kept down as these will be passed on.

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

Question C4 - Please provide any comments on the approach to post-market controls.:
As I have said before , will Hospitals report End user incorrect use by clinicians

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:
sounds like more cost alread

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:
401 , this should be set up by clinicians for approval and or the hospital, then have companies work with the Clinicians and DHB's/Hospitals

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:
What if companies cover both types of products

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
I would hate to think we put New Zealand behind with this, as some companies will not supply to other countries with too difficult regulations

Question C17

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

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?:
If it saves someone money then good on them, I would hate for us to get to cost like the USA, that stop people getting the medicine they need.
As long as it is from a reputable manufacturer then fine

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?:
what is wrong with the current set up?

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
as long as they are reputable and have a company set up and follow the rules

Question C22Which 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?:
If they can run multiple stores and have no problems then why not, but should have a licensed pharmacist on the shop floor of every store, through business hours

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?:
as long as they are medical Doctors and Surgeons then they should be able too

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 , should only come from a Doctor, and these need to have checks in place , as could be easy to slip a prescription to someone

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
We should not get l ke the USA and allow medicines and drugs to be promoted on TV

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?:
Should not be permitted, then the pharmaceutical companies will drive the drugs to market, which when that happens you will not be able to stop.
Drs will be bombarded with people wanting a drug because they think they have the illness, just look at the USA to this

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 should have some form of regulation if Therapeutic then some form of check needs to be in place for products, the medical mar juana and supply of along with some of these items need more care, looking at the USA and Canada they have massive problems from legalizing these items

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.:
My biggest concern is as a Taxpayer, I see this costing New Zealand a lot of money, and will become a vicious circle, of more tax and price rises that the government will have to fund to DHB's as the price will rise to them.
Companies cannot afford to carry the costs of registration and other related expenses that will come from this.
Consumers for Multivitamins will be restricted, and the price for medicines will go up.
And all of this just because we look overseas for answers doesn't mean those countries are right either

Response ID ANON-DPZ8-G4XF-Y

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-01-23 17:41:43**

Submitter profile

What is your name?

Name:
Daryl Crimmins

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

Cells and tissues, Active ingredients

If you select DHB, please state service area:

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

If you selected 'Other' please 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).:

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).:
I wish to submit that under the new therapeutic products guidelines that blood component manufacture especially biopharmaceutical medicines fractionated from plasma blood products collected and manufactured by the New Zealand Blood Service should be subject to licencing, just l ke any pharmaceuticals currently in the market. The plasma is fractionated by CSL Behring and turned into sterile injectable pharmaceuticals. The current manufacturing licencing between Medsafe and NZBS does not take into account the subsequent manipulation of this blood derived product into valuable biopharmaceuticals. Hence the request for a special licence in relation to this blood component. It should not be exempt from licencing as the government stands to lose significant regulatory income from this important biopharmaceutical source.

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).:

Response ID ANON-DPZ8-G4EP-P

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-08 23:45:23**

Submitter profile

What is your name?

Name:
Peter Shenoda

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Geraldine 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;:

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

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).:
The Medicines Act 1981 requires a pharmacy to be majority owned and effectively controlled by a pharmacist. The Government is seeking feedback on options to retain and improve the majority pharmacist ownership requirement, or to replace the pharmacist ownership requirement with other licensing requirements. See Chapter C6 for more detail and questions

Pharmacists are governed by ethical standards and use their judgment and ethics to counsel patients and guide them to the best treatment options and not the most profitable. As a pharmacist owner my duty to the patient comes first, I am not confident that other business minded people that could be potential owners would share the same values and principals. even if there is "charge pharmacist" if the person that pays the bills asks them to meet certain targets and the pharmacist is not meeting them then they are potentially jeopardizing their job.
I am concerned to see pharmacists change from top 3 most trusted health professional in New Zealand to a store clerk and being pushed to achieve profits alone.

Every pharmacist I have spoken is concerned regarding the change of ownership rules, as how it will damage the profession.
Pharmacists is the health professional seen most often in New Zealand according to the pharmacy Guild of NZ research.

Another question that we need to ask, what are we trying to achieve by changing the ownership rules?
more access? currently in New Zealand we have over 1000 pharmacies, that is 4500 for every pharmacy. Pharmacists are on the skilled immigration list as we struggle to fill enough positions.
is it better commercially to have a monoply or duoply? as that what it will end up happening in a matter of 10 years- ex; USA there is a handful of players such as CVS, Walgreens, rite aid which has been bought out and walmart an a very few independents. Every pharmacist that I speak to from the united states hate it and hate their practice to what is has become.

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):

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).:

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

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?:
I am very keen to explore new options ex; Drone delivery to homes

However pharmacists need a very basic tool that I believe the new proposed bill has missed.

We are the medicines expert, we can provide advice on how to make the most of medicines and practical solutions to reach optimal health through those medication.

for example if a vehicle; will they have medicines? if yes will the temprature be monitored, what about the amount of stock needed to actually offer an effective service. almost a bus is necessary what will happen if there is a medicine that is not in stock? how will it be secured overnight?

Pharmacists are not doctors in the sense that our primary duty is not to diagnose.

I can see that internet based pharmacies might be an option but there so many at the moment with huge growth over the last 3 to 5 years

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
I do not think medicines act was the barrier, I truly believe DHBs are the current barrier with what they will fund and what they wont.

It truly depends on where you live in New Zealand to what service you get from your pharmacy, its all dictated by DHB funding

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?:
I support option 1, as this enables pharmacists to focus on their practice and preform at the top of their scope while maintaining the patient as the number one focus (in line with the pharmacy action plan)

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;
you are likley to give your own business a 110 % instead of just working for someone else
pharmacists owners; will go over and beyond for their patients the quality of care is much better than a corporate structure.

douglas pharmaceuticals have an automation devices that been brought to the market around 3 years ago;
I believe around 40% of pharmacies currently have at least a device, this shows that you do not need huge investments to have R&D or investment in new technologies

Competition is very healthy in the NZ pharmacy market currently, so I do not believe it will diminish competition an any way

Question C25 - Are there ways in which Option 1 could be improved?:
Yes, if the compliance costs are mitigated.
This can be achieved by giving all current pharmacies a 3 year licences and within those 3 years, they are expected to alter their structure at their own cost to accommodate and be in line with the new laws.
This will give the pharmacies the time and split the workload over 3 years

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
Pharmacy activities outside medication and health should continue, as it provides more reasons for patients/customers to come in the pharmacy which can be utilized in giving them more healthcare

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 can 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)?:
The 5 pharmacy limit should continue

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
a designated pharmacist should be made responsible 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?:
This will give opportunities to younger generations of pharmacists to own their pharmacies and be more inclined to adapt and evolve new technological advances.

douglas pharmaceuticals have an automation devices that been brought to the market around 3 years ago;
I believe around 40% of pharmacies currently have at least a device, this shows that you do not need huge investments to have R&D or investment in new technologies

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
3 years transition time for any pre-existing pharmacy and any new pharmacy following the new law

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?:
This exemption should be removed after the 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: unless I am a corporation with unlimited funds there is no real benefit to the patients or profession

Risks:
1-retail pharmacy becomes corporate, with 1 or 2 players that control the whole market.
2-With corporate and big overseas business track record of shipping profits, a reduction in taxes received from pharmacies
3-Pharmacists ethical judgment may be clouded by potential incentives, since companies are after profits
4-pharmacists under-staffing, thus longer hours of access but the quality of care is diminished

Question C34 - Are there ways in which Option 2 could be improved?:
Restrict the number of new pharmacies- ex; restrict new pharmacy within 500m for urban and 1km for rural

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
unless the supervising pharmacists is there 24/7 its imposs ble for them to oversee every thing that occures in that pharmacy or how "other staff" may be given incentives

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 agree in some circumstances it my be appropriate however pharmacists not only clinical advice but they are the last check before the patients receives their medication.

I am a pharmacist and if I was to sign my name to a check a prescription, I would not feel comfortable to check the prescription remotely
it normally involves checking the tablets/medicine, strength, instructions, suitability and quantity. and often we need to communicate with the Doctor or prescriber / patient or colleagues to evaluate it.
in a clinical non-retail pharmacy setting I think remotely will work, but I do not believe it will work in a community based pharmacy that receives a couple of hundred prescriptions per day

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.:
The need for Depot could decline however the need for it in some rural places that a child can get a fever on the days the pharmacist is not there for liquid paracetamol is still very real and providing access to medication is key to better health.

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 its a means of quality control.
I believe New Zealand has had great control and barriers over the quality of medications , however these barriers are diminishing quickly with access to medication online so easily therefore ensuring the quality is there is paramount

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 simply create efficiencies within the practice

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
I dont think pharmacists should be able to supply medicines by whole sale but I think that pharmacies as they are licensed should be able to do so. which are in effective control of a pharmacist

C7 Retail sector

Question C42

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

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 C22Which 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-G4E5-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-13 10:40:17**

Submitter profile

What is your name?

Name:
Stephen Boyd

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:

Medical practitioner (excluding Surgeons)

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

If you selected 'Other' please comment;:

Next steps after the consultation

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?:
Most countries have given considerable thought to this issue and concluded that direct to consumer advertising has a net negative effect. The fact that the only other country that allows this is the US should serve as a major warning. The US health system is one of the most expensive, ineffective, inequitable, and dysfunctional in the world and in no way one that we should be attempting to emulate. It is my view that on this issue we should be aligning ourselves with countries that have more functional health systems, and hence not permit direct to consumer advertising.

Response ID ANON-DPZ8-G4EU-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-14 20:47:49**

Submitter profile

What is your name?

Name:
John Waldmann

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
N/A

Submitter Profile (tick all that apply)

Consumer, Disabled person

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?

Neutral

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 some reference a principle of ensuring that the NZ supply chain does not take advantage of the regulatory scheme to rort the consumer by overpricing products by comparison to international pharmacy prices for the sam product.
Example in point: nz supply of melatonin is bound by historical conflation with steroids, resulting in a price regime three to five times as expensive as the same bottled product available overseas, before GST. The present regime also ensures very limited range of supply via particular importers who do not always supply suitably cmpounded meleatonin (eg. Source Naturals brand which is labeled as a dietry supplement, but supplied on script.
Ensuring the regulatory scheme does not infairly benefit particular importers in principle must be good for the NZ health system.

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).:
49a. Poses problems for some disabled patients prescribed enduring medicines regimes.
For example: i am proscribed - in both cases offlabel - gabapentin, and melatonin for chronic pain (melatonin is also useful for sleep) as recomended several years ago by a DHB pain specialist. My GP may not under this new bill be able to maintain my prescriptions which have been trialed, tested and measured over several years as the best option. This process has nvolved severql pain specialists reviews, and to date has been transportable across more than 15 general practioners.
It appeas to me that the proposed changes may interupt the transportablity of a useful medicianal regime between sucessive proscribers thus adding additional unforseen costs. For instance the existng backlog for seeing DHB pain specialists has even under the present regime become harmful to consumers. Requiring further visits to confirm existing prosc bed regmes would be not useful.

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).:
Clearly, this appoach is harmful to the consumer, and the health industry generally, although the importers, and suppliers priviledged by these provisions will be able to further rort the NZ public, amd the taxpayer Public health system by continuing to supply products at prices well above the international norm. Eg. Melatonin currently supplied at three to five times the international price, more so if the specific product is funded in specific contexts by Pharmac. Note. Some recent authorisd importers supplying NZ pharmacies have supplied melatonin that is descr bed on label as a “dietry supplement”, which raises flags to the user regarding the products manufacture.

Clearly it would make sense to facilitate a healthy parallel import market amongst appropriately qualified individuals and their businesses, eg., pharmacists, some specialists, and ceritfied industrial suppliers. While allowing individuals to parallel import recognised branded products to prescription for personal use to their own risk (of counterfiet). For individuals such as myself, on enduring regimes we know when a product is not behaving as labeled, and can discuss issues with our GPs as required.

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).:
Facilitating retail pharmacy parallel import and wholesale supply would be a more useful approach, particularly in regards to supply to the aged care industry where volumes would permit such an activity to be a productive business venture due to economies of scale.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
Section 59. Should afford phamacists the opportunity to also supply wholesale, via import of products the NZ maket is not well served by present importers and manufacturers. (Such a clause may be better placed elsewhere in the bill)

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
Pharmacy authority, needs to be matched by an explicit requirement for pharmacists to take responsibilty for goving feedback and insight on the Acts, rules, and products to the Ministry, and other governing bodies. For example where the 90 day rule fails due to administrative errors (such as starting a new script, when a pre-existing script overlaps - result patient shortchanged a months supply between 3 monthly GP visits). Or xample when Pharmac special authority mechanism fails due to poorly communicated rapidly changing application documentation requirements. (happened to me two times this last decade in regards to a drug that one should not cold turkey withdraw from due to a failed authorisation process).

Question B7 - Please provide any comments on the authorisations for health practitioners :
S.75 sounds good, but would seem to conflict with supply chain provisions elsewhere in this bill, that limit the supply chain to 1st in first served supplier status, by preventing parallel import supply chain options.

Question B8 - Please provide any comments on the authorisations for health practitioners’ staff (s 65).:
As long as the long standing practical solution to hospital ward supply whereby charge nurses retrospectvely provide medications bfore seeeking Doctor authorisation enhanced. Rules should provide for mechanisms by which similar solutioms can be dveloped in a constructive fashion. I realise nurse practicioners is he prefered solution, but as yet there must be a reliance on other trained, experienced repsons ble staff, and legislative, and pragmatic protections put in place to ensure these staff can make decissions in th bst interests of their patients in good faith, based on their working knowledge of particular patients needs.

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).:
S.83 is meaningless as wholesalers are beyond the effective reach of praticioners, and the consumer. Pharmacists rely to seems on a vanishingly small number of importers / wholesalers in part because the present regime appears to confuse them, and mechanisms by which additional wholesalers, and mporters might enter the market fail to facilitate a competitive market, of well priced quality products - particularly at the therapeutic, rather than medicinal end of the spectrum. Eg. An Australian pharmaceutical chain operating in NZ sources products via third party nz importers, rather than take advantage of its Australian based supppy chain. Thus failing to provide Australian pricing bnefits to the N.z consumer. It beggers belief that products sold in Australia, even specified compounded products can not be readily supplied to NZ by a pharmacy present in both countries.

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.:
S.93. A more useful approach would be to allow health practicioner prescibers to import medicines to general supply, but proscribe (deny) authorisation to prescribe said medication to the importer or their imediate (shared business collgues). Likewise permit a business interest in a pharmacy in another town, or geographic area beyond the reach of the patients they prescibe to. (as a partner- noting a registered pharmacist must still hold primary ownership, and responsibility). And note. Would need to preclude online paharmacy.

Thus a knowledgeable, specialist or GP could import and sell a medicine to supply pharmacies. And or could hold share in retail phamacy, but could not directly or indirectly (in most instances) benefit from prescribimg decissions.
This approach has the benefit of broadening pharmacy supply chain, and retail ownership to a wider range of suitable individuals, rather than arbitrarily excludng them from investing in this area.

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).:
There is a need for provision for the poss bility of a product having more than one sponsor, thus providing for parallel import at the whlesale level. To be sure, each would need to maintain and provide suitable documentation of supply (g. Batch numbers) so that product quality issues could be identified as relevant to a particular supply chain.

Allowing for just one market supplier (sponsor) presents opportunities for sponsors to rort the retailers (pharmacists) and consumer by overinflating prices in a captured market. Evidence of this can be seen in regards to the supply of melatonin, with local prices, and products supplied being of lower quality, and substanially higher pricing than elsewhere in regulated (for quality and control) international markets. The effect has been to ensure poor supply, of in my opinion (as a user) of lower quality medicine at barely affordable prices, in part because pharmacies only stock what they can access from existing authorised wholesalers.

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).:
Requiring products to be microdot identified at point of manufacture, or wholesale supply in NZ would enable supply chain abuses, and counterfeit products to be easily identified.
Such a regime could easily applied to imported prepackaged products externally to retail packaging at border points, or wharehouse facilities, or to individual capsuls, or tablets at local or international manufacture.
Or even as part of border control/ policing efforts to pursue and prosecute abusers of private, and personal import.

This would also serve to protect the interests of holders of intellectual property rights.

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).:
See response to q. B16.

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).:
Any fees charged for compliance activities ought not be onerous.

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).:
See response to q. B16.
A mechanism ought to be allowed for by which illegal and problematic international supply chains crossing the border can be indentified. And by which the local supply chain pathways can be distiguished from perhaps legal pathways. Suggest microdots be promoted as an industry solution, and provide lgal mans by which customs and police can “adulterate” imported products by application of inert microdots, before allowing distr bution under close monitoring by relevant authorities.
This would aid in prosecution, and removal of unsuitable persons from the broader supply chain. And would ensure that products less easily enter the country in an unregaulated fashion. In some instnaces the result may be identification of a private user, acting appropriately, in which case no prosecution would result, but would still allow for misuse downstream f that individual to be identified. Eg. A consumer imports on presciption codiene, but that consumers supply is stolen, thus misusd by a third or fourth party that then suffered injury. The original source of the misused drug is then easily identied in the customs record, allowing for intervention.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
There is a need for provision for trial licencees to be required to provide health insurance cover to trial participants to cover unforseen, and forseen side effects. This unburdens the public health sector of the costs associated with trials that go wrong in individual or wider contexts. Such cover is inexpensive, and could have very significant hewlth and fnancial benefits to trial casualities.
Otherwise. The public health system becomes the sole insurer underwritimg the trial. This is not good because it places the supervisory body so to speak in a position of being a direct shareholder, and places undue emphasis on reducing risk to nil, when a more flexable approach might lead to advantageious outcomes for the most part. The result being that solutions that might then be developed after a trial with a resonable, “managed” extent of harm would not be addressed due to nreasonable regulator caution.

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?:
There is the issue of whether the notion of “approved medicine” as product refers to a branded product, class of products, or a specificied medcinal or therapeutic component of a product.
If in effect the notion of approved medicine defines a particular brand, formulation or encapsulation, or tableting then this would pose significant and untoward hardship upon those that import, on prescription for personal use.
Eg. Melatonin is suplied in NZ via a highly constrained range of dosages, formulations, and brands. (some of which are in my opion of poor quality and efficacy), and all of which are seriously overpriced, and virtually undiscoverable in the international market. Limiting consumers to these specific products neither protects the consumer, nor provides health or financial benefit, because cnsumers would, and do simply choose to fill that prescription when absolutely necesary, not when it would best benefit their health.
A more useful approach to private import would be to maintain a list of recognised dodgy suppliers / brands. So that private importers can share and have communicated to them what to avoid. It doesnt solve all the potential issues, but is inexpensive to develop, and administer, and permits / encourages better decision making by consumers. Regulators, enforcement agencies would also find such a tool useful.

At present parallel import by post serves as the only mecahnism to restrain profit hungry industrial importers, and wholesalers, from rorting the public, and to ensure an adequately diverse range of suitable medicines. Sure some supply is questionable, but no more in my limited experience than those supplied via local (legal) retailers.

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.:

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?:
On one hand his sounds very much like the creation of a highly regulated wild west health practicioner prescribing regime, on the other very hand entirely reasonable.
We do need facility by which a broader range of suitably qualified health practicioners can rubber stamp, and reissue existing Doctor presrcriptions. In part becase we have an appallingly short supply of Doctors,which is set to becme much worse.

We do also need a mechanism by which a “routine” standard script cqn become transportable between pharmacies, and refilled out of town in emergency. For Diabetics, for instance, this might nvolve a doctor, or pharmacy supplied script card that identifies the individual, the medicine and dosage and allows for issue of a weeks supply, at any time in the following year. Use of said card would then be indentifiable to the person’s GP, and regular pharmacy. This allows for said script to be updated or corrected before supply, and allows for annual changes. I know of at least one occasion where this would have ensured continuity of supply, and prevented an incident where a person confused by lack of insulin made some very life threatening decissions.

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 previously mentioned, it depends entirely on what specifically in meant by “approved medicines”, if too narrowly defined manufacturer, brand, supplier, or ingestion method, “approved” could render private importation too difficult, too expensive, or effectivel illegal.
Private importation should allow for products as defined by ones prescription to be imported, without necesitating extensive reviews of lists of approved products “sponsored” by licensed importers.
A good many products have hundreds of suitable brands and imternational suppliers, but only one, maybe two locally supplied (thus approved) products.
As long as the product meets, or at least is purchased as meeting the requirements of the prescribers script then it should be allowed to be imported unlss identified explicity by aithorities as bieng on a banned list, if merely questionable due to reported problems woth a particular brand or batch number authorities should default t notifying the private importer for example by applying a sticker to the imported product with a relevant weblink. Educate rather than create consumer problems.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
Yes. Where the NZ market is poorly served by existing market mechanisms, and approved sponsors.
Of course a monitoring regime will be required to eliminate abuses.
Certainly, it would be advantageous to have a suitably qualified health provider, and / or sponsorsupervise any such imports. Such imports should in the frst instance be allowed solely for supply on prescription, but might for instance be allowed for supply to immediate family, not just the importers own use. An example of this might be a family with a particular rare form of maleria requiring a specific drug that is not useful elsewhere in the NZ market, but is readily available elsewhere at an affordable price. In this instance the more comprehensive and expensive sponsor licensing scheme would not be wholely appropriate, or affordable.

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 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?:
Option 2 provides an opportunity for corporatisation of pharmacy supply, and would inevitably ensure that efficiency is driven to failure, and profitability for shareholders becomes the sole criteria for management decissions. (note under NZ law shareholder welfare is protected, and reified above consumer welfare and wellbeing despite other supposed legsl protections afforded the consumer).
Thus option one, despite its constraints on pharmacy owners ambitions ensures that patiients (consumer) wellbeimg is maintained, if only because it is unlikely that every pharmacy in town is owned by the same pharmacist, which then allows consumers to shop arround. Option two enables one or two national providers to corner the entire market (cf. Supermarkets).

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Undercaptialisation of the pharmacy market is the major risk.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Risk. Corporate takeovers risks consumer wellbeing, and choice, and may prioritise shareholder profits over staff, and consumer wel being.

Positive. May concievably permit better horizontal market integration, but fails utterly to solve any particular problem.

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?:
Yes they should be permitted to supply, and prescribe specified medications relevant solely to their area of expertise and practise, having recieved suitable training in the dispence of those medications.
Notification of supply, or dispnce should be required to be sent to the persons GP as routine.

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?:
With suitable safeguards, yes.

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.:
In regards to documenting product safety, a publically accessable, and contributable register would be a good thing.
Both in regard to locally suppplied products, but also privately imported products. There would need to be clear distinctions made between professional contributions and private contr butions, and explicit frameworks for identifying products by brand and batch number, and risk factor.
The present GP centered reporting system fails to ensure all issues are reported; does not address private imports; and fails to educate or inform the public.
Sure there would be teething issues, but a formal register of recalls, bans, and product issues could ensure that the public and GPs both placed less reliance on unmediated health blogs.

Response ID ANON-DPZ8-G4EV-V

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-02-21 10:17:28**

Submitter profile

What is your name?

Name:
Bronwen McNoe and Professor Tony Reeder

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Cancer Society Social and Behavioural Research Unit, Otago University

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;:
Researcher - University

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

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 Cancer Society Social and Behavioural Research Unit recommends that sunscreen be specifically listed as a therapeutic product in the Therapeutic Products Regulatory Scheme similarly to Australia where it must be listed on the Australian Register of Therapeutic Goods.[1]

Skin cancers are by far the most common cancers in New Zealand (NZ) and are estimated to account for over 80% of all new cancers diagnosed annually.[2] Skin cancers also represent a substantial cost burden on the NZ health system.[2] Exposure to excessive ultraviolet radiation is the major risk factor for skin cancer.[3] Sunscreen is one method of protection recommended by the Health Promotion Agency and commonly used by New Zealanders to reduce exposure to UVR thus potentially preventing DNA damage and development of skin cancer.[4] It is crucial that consumers can trust in the efficacy of the sunscreen product they are purchasing to provide adequate sun protection. This is not currently the case. Currently in NZ there is a wide range of sunscreens available on the market, each with different formulation and ingredients and no requirement to comply with the Standard or have their product tested.

In Australia primary sunscreens must comply with the Australian/NZ Standard (AS/NZS 2604: 2012) which includes requirements for labelling of sunscreen characteristics; UVA (broad spectrum) and UVB (Sun Protection Factor) and water resistance. Sunscreens listed on the ARTG must use pre-approved ingredients, good manufacturing practice and have low level therapeutic claims. Once the company has listed their sunscreen they must provide evidence that their product has been tested by a registered TGA laboratory and complies with the Standard. The TGA then conducts regular reviews and testing to ensure compliance of sunscreen with requirement.[1]

References

1 McRae C. Regulations of sunscreens in Australia (http://www.assc.org.au/wp-content/uploads/2018/03/McRae_Sunscreen-summit-presentation-March-2018.pdf). In: Sunscreen Summit QIMRB. Brisbane, Australia. 16 March 2018.
2 Health Promotion Agency, Melnet. New Zealand Skin Cancer Primary Prevention and Early Detection Strategy 2017 to 2022. In. Wellington. March 2017.
3 Armstrong B. How sun exposure causes skin cancer: An epidemiological perspective. In: Prevention of Skin Cancer (Hill D, Elwood JM, English DR, eds). Dordrecht: Kluwer Academic Publishers. 2004; 89-116.
4 Health Promotion Agency. https://www.hpa.org.nz/programme/skin-cancer-prevention. In. Accessed 30 January 2019.

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).:

Response ID ANON-DPZ8-G4EM-K

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-05 13:41:45**

Submitter profile

What is your name?

Name:
Mark Alison

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
NMIT

Submitter Profile (tick all that apply)

Consumer, Disabled person

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:

Nurse

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

Government agency

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 support

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 does not protect against members of the public who will circumvent the process and go "mail order' to seek a product .This can only be achieved if the citizens have access to trusted medicines that they deem fit for purpose. This is not the same as a medicinal license in the publics view.learn from Australia and the USA.Compassionate efforts should be forefront of decision making.
Keep big pharma out of the equation.We know the numbers needed to treat and its one.

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).:
ss57- needs to be extended beyond devices to organic products.An ideal role for Nurse practitioners(NP)

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 :
There is a dearth of training for medical staff around medicinal cannabis (MC).Given the Canadian experience where Doctors were not prepared and very conservative and the stock shortages after legalisation, we need to manage public expectation.The ideal professionals to be ready for this are Advanced Nurses and pharmacists.
Given the NP is a health practitioner who could provide the necessary medical knowledge to assist in rolling out MC on compassionate grounds, very quickly,it would seem prudent to equip the profession with the necessary training before law changes.This would hopefully prevent the public taking the decision to use into their own hands, with the associated risks of an unregulated system being perpetuated.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
The upskilling and knowledge for Nurses to prescr be is considerable .It will allow the Medical profession to keep their cautious approach but if we get it right,this attitude will change and soften.In the meanwhile ,gathering the evidence to publish robust, scientific, peer reviewed evidence, should give the pharmaceutical industry an opportunity to catch up.

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).:
Thats ok when you want to run a clinical trial etc. Great. However does this deal with the aged care facility where family with the Enduring power of attorney(EPOA) want to provide dad with MC sourced from home or a trusted member of the public.Again, managing public perception about gains and benefits needs to be accomodated for , otherwise people will vote with their vape.
We need Nurses/ carers to be able to manage this evolving situation.Guidelines and frameworks are needed for health professionals to operate in, that manages this aspect.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
An obvious group to grant licences to is NPs.They have got prescribing rights, they have compassion in droves and make excellent clinical decisions.As we move more and more into an iterative process of trials and publishing, the safer it will be for the public and to steer medical staff into reconsidering its role(MC)

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).:

Response ID ANON-DPZ8-G4E2-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-08 16:08:06**

Submitter profile

What is your name?

Name:
Julia Rucklidge

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
University of Canterbury

Submitter Profile (tick all that apply)

Health service provider (eg, Ambulance, M■ori or Pacific health provider etc)

If you select DHB, please state service area:

Other health practitioner (please comment)

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

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?

Neutral

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 am delighted that the Bill intends to EXCLUDE NHPs. This has proven to be a significant problem in advancing the research on NHPs in NZ as well as ensuring access to NHPs in NZ. Please make sure they do not go in! I assume this means melatonin, vitamin D, lithium, folic acid, vitamin A etc will no longer be classified as medicines? Given they are natural and nonpatentable, this would make sense to me. Also, many of these nutrients can be found in NHPs.

If these nutrients are going to continue to be classified as medicines, this is a huge problem that has been entirely overlooked in the document.

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 understand that natural health products have been left out of the definition of a therapeutic product. It will be important to ensure then that lithium, melatonin, vitamin D, etc are removed from the list 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).:
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).:
This depends on what will be classified as a medicine. Currently, melatonin is by prescription, cannot be purchased and yet is extremely expensive in NZ. In contrast in the States it can be purchased in a supermarket. Restricting importation of melatonin would seem to me overly restrictive. However, melatonin may no longer be classified as a medicine if it is viewed as an NHP.

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

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.:
As long as NHPs are not viewed as medicines then it is fine!

Question C17

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

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4EZ-Z

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-11 18:27:09**

Submitter profile

What is your name?

Name:
Cheah Soo Kiang

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Covance Inc

Submitter Profile (tick all that apply)

Industry body

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

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).:
No comments on this section

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 on this section

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 comments for 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).:
No comments for this section

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
No comments on this section

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
No comments on this section

Question B7 - Please provide any comments on the authorisations for health practitioners :
No comments on this section

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
No comments on this section

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:
No comments 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).:
No comments on this section

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
No comments on this section

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
No comments 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).:

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).:
It is stated in “141. Licences would no longer be limited to one year. The regulator would be able to issue a licence, based on an appraisal of safety concerns, up to a maximum of three years (s 137)” .

This would be a challenge for clinical trials as some clinical trials will take more than 3 years.

In this case, renewal / reapplication of the clinical trial license would be required and it's not not economical or efficient.

We would suggest that for clinical trial license its should be for the entire duration of the clinical trial instead of limiting to 3 years duration.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:
For clinical trials, sometime the trial global sponsor’s decision to change of CRO or if the CRO is being acquired by another company, it would be advisable to have flexibility in the new Act to allow the transfer of the clinical trial license rather than requiring a new application for a clinical trial license .

A lot of countries have simplified procedures for sponsor/CRO change and shorter timelines to obtain the approval / notification of the Sponsor/CRO change.

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).:

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?:
Electric tobacco heating devices should not be regulated as medical devices as they are not for therapeutic purposes.

Some tobacco companies are sponsoring clinical studies to study the health effect of "heat not burn" tobacco electric heating devices. There have been questions if these studies needs (in addition to ethics committee approvals), regulatory approvals / licences to conduct such studies.

Presently, such devices are do not needs the definition of medical devices in many countries and should also not be included as medical devices in the proposed ACT

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?:
Regarding 366 about "Licences would be used to authorise the importation and supply of unapproved products on a case-by-case basis for purposes" .

For clinical trials of medicines/pharmaceuticals, we very often supply laboratory kits/ pregnancy kits as well as ancillary medical devices such as ECG machines to the investigational sites. The laboratory kits and ancillary medical devices are not the investigational therapeutic product in the study. How would the proposed Act allows the importation of these unregistered laboratory kits and medical devices into NZ for the clinical trial. Do the Clinical trial application as well as the Clinical trial license need to specifically list the lab kits and ancillary medical devices to be used in the trials along with the investigational therapeutic products/study drugs ?

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 Act mentioned about licenses for clinical trials. We assumed these clinical trial licenses will be similar to the clinical trial approval letters issued by Medsafe currently for each clinical trial application submitted to Medsafe under the current Medicine Acts.

The Act mentioned that the Responsible person for Clinical trial licensee must meet any qualification , training and competency requirements specified in the rules . How will the regulator verify this ?

Will there be a need to have CRO and organizations conducting clinical trial in New Zealand to obtain a general "clinical trial business/activity/qualification/CRO license" in additional to the clinical trial license/ approval letter issued to the specific study/trial?

Must the sponsor specifically identify and notify the regulator in case of a change of the respons ble person ?

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:
For studies that has been issued a clinical trial approval under the Medicine Act that will stay in force for more than 12 months after the implementation of the proposed Act, instead of 12 month temporary license, we would suggest it be converted the Clinical trial Approval letter to Clinical trial License with no expiry date or for the whole remaining duration of the study in NZ. There is no benefit to resubmit the CT application dossier over all again to to the regulator as the regulatory and scientific review of the study documents and study has been conducted and the regulator would have been been kept informed of the changes/ updates of the trial via protocol amendments, IB updates and 6 monthly status reports .

For trials that did not require approval before commencement (eg, trials of medical devices or trials using approved medicines), we agree that a 12 month temporary license should be issued and application of the Clinical trial license would be reasonable for such study.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4EJ-G

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-15 10:25:05**

Submitter profile

What is your name?

Name:
David Holland

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
CMDHB

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;:

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 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).:
I have just one question.
Has the issue of faecal microbiome (as used in 'faecal transplant') been considered as to how it is viewed under the regulations.
It is now not uncommonly used and is prepared from donors (usually a family member) for instillation in to the recipient by different routes - faecal enema, colonoscopy, nasogastric slow instillation as therapy for C difficile colitis (but some practitioners may be using it for inflammatory bowel disease and even IBS
I think overseas regulatory bodies are looking at its standing eg TGA

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 refer to my comment previously re FMT

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 specific comment

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
None.
I haven't had time to review this in detail and the followingmay not apply to this proposed legislation but as a general comment..
In the antimicrobial area. I would make a plea for adequate training of pharmacists before being able to prescribe antimicrobials for 'diagnoses' such as UTI. Medical practitioners are not good at prescr bing antibiotics for these kind of conditions and opening up to wider groups needs adequate provisioning in training. Prescribing for nurses has gone over the years from requiring a Masters level of training to Diploma and now only require to do a 'course'. Quality assurance is a challenge

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).:
There is a conflict of interest between prescribing antibiotic and dispensing if there is a profit to be made from the process especially if the profit constitutes a significant proportion of an individuals remuneration

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

Response ID ANON-DPZ8-G4KH-M

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-20 21:04:54**

Submitter profile

What is your name?

Name:
Jill Masters

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
relax dental

Submitter Profile (tick all that apply)

If you select DHB, please state service area:
Wa kato

Dentist

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?

Neutral

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).:

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 C22Which 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?:
I am strongly against DTCA being allowed to continue in NZ. This type of advertising confuses and often deceives consumers.
Benefits can be played up and harms played way down, flashed up on a screen in tiny print for a second. Consumers hear what they want to hear, then they waste doctor's time by asking about particular medications they have seen on television.

Sometimes a physician would like to prescr be exercise and an improved diet, but it becomes much harder when a patient is asking for drugs that are meant to provide a quick and easy solution. DTCA is responsible for overtreatment, in cases where less medication could be otherwise indicated.

There is also the worry of advertisements citing poor quality research articles or misleading data, and most consumers would not think to check these. Some adverts, particularly on social media, have been found to include no list of adverse effects, and are therefore endangering consumers.

I believe it is acceptable for patients to do their own online research and ask doctors questions, but there is no way they should come into a consultation with an intention of receiving a medication they have decided is the right one. When they do this, the doctor's relationship with their patients suffers, and respect for the medical profession is undermined.
Advertising costs are extremely high, so the only real objective for drug companies to advertise is higher revenue, not providing useful information, or helping consumers choose. It is only about money.
A large number of newly advertised medicines are many times more expensive than ones that are already being successfully utilised, but the more expensive ones are promoted as being much more effective, when this is simply not true.

Let doctors do the prescribing, and keep drug companies in check by holding them to a much higher standard of proof for the efficacy and safety of their products, and have this research vetted by those who have the training to understand bias and conflicts of interest. Remove all pharmaceutical advertising from mainstream and social media.

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-G4KG-K

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-20 21:20:22**

Submitter profile

What is your name?

Name:
Dr Robert Weinkove

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Malaghan Institute of Medical Research

Submitter Profile (tick all that apply)

Consumer

District Health Board (DHB)

If you select DHB, please state service area:
Cancer Services

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

If you select 'Other', please comment below;:
Clinical Trial Researcher

Cells and tissues

Other (please comment)

If you selected 'Other' please comment;:
Independent Research Organisation

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 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).:
4(b)(i) regulation of therapeutic products should be "proportionate to the risks posed by the products"
- I agree with this, and would add that the risks posed by a therapeutic product must be interpreted in the context of the condition it is used to treat. For example, a higher risk level is generally considered acceptable for a product intended to treat a life-threatening disorder (such as an immunotherapy or cytotoxic chemotherapy for cancer), compared to that intended to treat a benign or cosmetic condition.

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).:

B3 Part 3
I am concerned about the impact that #51 and #52 may have on:
- Provisions for unapproved medicine use (current section 29 of the Medicines Act) - there are some conditions (typically rarer conditions) for which no medicines are approved in New Zealand, and the capacity to access these in specific circumstances is very important
- Some patients with life-threatening malignancies have been importing life-saving medicines that are not yet PHARMAC funded directly from overseas. It appears this bill intends to prevent this. This is likely to have a major adverse impact on the life expectancy of these individuals.
- Pharmaceutical company-run compassionate access schemes have provided an important way for patients to access life-saving medicines in New Zealand. In my own area, an example would be an access scheme run by Janssen for the drug ibrutinib for patients with relapsed/refractory chronic lymphocytic leukaemia. I hope these provisions will not prevent such access schemes.

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 :
#75(a): Off-label use of approved medicines should not be recorded via a special clinical needs supply authority. Off-label prescription is routine in many areas of clinical medicine, including much of paediatrics and obstetric medicine. Indeed, in some instance, PHARMAC specifically funds medicines outside their label (following clinician-led applications)- examples in own area of expertise (haematology) are rituximab for hairy cell leukaemia and for autoimmune cytopenias, and erythropoietin alfa for myelodysplasia-related anaemia. Typically, this is already recorded in PHARMAC Special Authority records. Attempting to record all off-label use will be excessively burdensome for all involved, and must be avoided.

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).:
#81 and 82: These paragraphs appear to be specifically designed to prevent personal imports of prescription medicines. There are many New Zealanders currently importing life-saving drugs for cancers, because they are not yet PHARMAC-funded in New Zealand. This will have a major impact on these individuals' life expectancy.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
#91: Another special situation to be accounted for in Section 79 is the importation or purchase of medicines for laboratory research or laboratory quality assurance activities. I work at a Medical Research Institute, and we routinely purchase small quantities of prescription medicines for use in laboratory research. In addition, clinical diagnostic labs may require small quantities of prescription medicines for quality assurance (for example, to validate and provide quality assurance assays for therapeutic drug level measurement).

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
#105: A goal of health research investment strategies in NZ has been to preserve intellectual property within New Zealand. Therefore there may be a number of health researchers nationally who conduct clinical trials of devices or pharmaceuticals for which they hold a proprietary interest in the intellectual property or the manufacturing company. It is a conflict of interest, that is reported to human ethics committees and assessed in considering approval of the clinical trial. One should be cautious that this section does not make conducting the type of translational research encouraged in NZ an offence.

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).:
#113: I am concerned about the impact of fees or regulatory burden on the approval status for infrequently used medicines. There are many older medicines (e.g. pentostatin in my own area of expertise) that are infrequently used in clinical practice because they are reserved for relatively rare conditions. If the fees or regulatory burden to maintain a license are set too high, I can imagine some sponsors withdrawing from New Zealand, requiring that any future prescription is on an unapproved medicines basis.

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).:
118(a) and (f): It is not clear to me how, outside of clinical trials, sponsors can be expected to provide thorough ongoing monitoring of clinical efficacy or of adverse effects. This reporting will rely on feedback to the manufacturer by prescribers, and will be patchy at best.

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).:
#133 (and #140): It is important that specification of license locations is not burdensome. In clinical trials, it is common for trial sites to be added and removed on numerous occasions during a study. This should not require an update to the license (it already requires notification to the Ethics Committee).

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
#135: I am concerned that the licensing requirement as written could have a chilling effect on NZ participation in international co-operative group trials, including for cancer. The draft prioritisation vehicle for health research in NZ (MoH, March 2019) specifically highlights the value of, “multi-centre trials and those that are undertaken as part of international collaborations” and notes that “funders will work to improve clinical trial networks”. Modern investigator-initiated co-operative trials in cancer often include multiple new medicines, to which participants are allocated to on the basis of disease characteristics. Often the trial sponsor is an overseas co-operative trials group and the manufacturer of some or all of the drugs involved may have no NZ presence, so the country Principal Investigator of the trial becomes the sponsor representative in NZ. Thus, this portion of the legislation may require already-burdened clinicians taking on additional roles as licensee for a number of new medicines from multiple manufacturers. I strongly recommend that any licensee requirements must be kept simple, or the Permit subpart used, and costs low (or waived), for HDEC-approved clinical trials. After all, such trials are essential to collect the key safety and efficacy data that may contribute to a future application for a medicines approval.

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).:
Might this Permit subpart offer a more appropriate regulatory framework for clinical trials involving medicines that are not yet (and indeed may never be) approved in New Zealand, and which will only be used for a special purpose (i.e. within a specific ethics committee-approved 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).:
#141: The 3 year term of licenses (and 2 year term of permits) appears too short for clinical trial purposes. The clinical trials I take part in are rarely completed within this time period, once both recruitment and follow-up periods are included. A longer license term of 5 or 10 years may be more appropriate, or at least an option for renewal.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:
#151: It seems inappropriate to transfer a license or permit to the executor or administrator in the event of the death of a licensee, as the executor or administrator is unlikely to be in a position to assume any of the responsibilities.

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).:
#154: In relation to section 160, it should be recognised that GCP-compliant clinical trials already include systems (including Data Safety Monitoring Committees, trial monitors and ethics committees) that monitor the safety of a trial intervention. It is important that this work is not unnecessarily duplicated by the new Regulator.

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).:
#209: It is very important that any fee structure draw distinction between investigator-initiated clinical trials (including international co-operative group trials) and commercial trials or applications for medicine approvals. For example, Medsafe, SCOTT and GTAC are able to provide fee waivers in such scenarios, and a similar approach should exist with the new Regulator. Charging new fees for conduct of investigator-initiated clinical trials would discourage New Zealand health research and run contrary to the aims outlined in the consultation document for the prioritisation vehicle for health research (MoH, March 2019).

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).:

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).:
2019-03-20 MoH consultation on therapeutic products draft bill
Sheila Swan, Chief Advisor, Regulatory Policy, MoH
Chris James, GM of Medsafe

Purpose and design of the bill
Ensure safety, quality, efficacy, performance of therapeutic products
Regulating manufacture, import, promotion etc

Scope and definitions
L kely benefits should outweigh likely risks
Regulation should be proportionate to the risks; and support timely availability of the product
Cooperation with overseas regulators

Product & activity controls
Definition of a therapeutic product - use in, on or in relation to humans for a therapeutic purpose; natural health products are excluded

Clinical trials
Product approvals requirements - can’t be imported or supplied unless approve; different approval pathways possible
A license would be awarded for a clinical trial

clinical trial requires an authorisation - a license would be the usual way
- license holder must be a fit anad proper person, or a body corporate or the Crown
- respons ble person must meet qualifications, training & competency

Transition

Therapeutic purpose definition
Testing the susceptibility of humans to a disease or ailment - this seems far to excessive as a therapeutic purpose. For example, is determining someone’s height and weight (a potential risk factor for a range of diseases) a therapeutic purpose?

Questions:

1. What are the implications for manufactures of cell therapies in NZ conducting investigator-led-cell therapy trials?

2. Implications for co-operative group trials

March 2019 Consultation on New Zealand's first prioritisation vehicle for health research says
- specifically recommends, "Well-designed clinical trials will be an important tool… particularly multi-centre trials and those that are undertaken as part of international collaborations. Funders will work to improve clinical trial networks through work associated with Action 6 of the NZHRS: Strengthen the clinical research environment and health services research."

- we already find NZ shut out of some multicentre Australasian Leukemia & Lymphoma Group clinical trials for blood cancers, because of logistical difficulties and cost of getting the IP into New Zealand.

- any additional measures might exacerbate this situation, and run contrary to the stated goals of the March 2019 draft prioritisation vehicle for health research, which states that "clinical trials will be an important tool… particularly multicentre-trials… as part of international collaborations". This legislation must avoid complicating NZ's participation in international clinical trial networks.

- 158 Responsible person must comply with regulations
. (1) A respons ble person for a licence must comply with any requirements set out in the regulations in relation to any of the following:
. (a) quality control and assurance in relation to the carrying on of activities authorised by the licence:
. (b) record keeping, auditing, and giving information to the Regulator:
. (c) tracing and recall of therapeutic products:
. (d) qualifications, training, and competency of—
. (i) responsible persons:
. (ii) workers in the licensee's business:
. (e) oversight of the day-to-day operation of the activities of the licensee.
———————

Response to consultation:

Therapeutic purpose definition
Testing the susceptibility of humans to a disease or ailment - this seems far to excessive as a therapeutic purpose. For example, is determining someone's height and weight (a potential risk factor for a range of diseases) a therapeutic purpose?

What is a medicine definition:
(A) by pharmacologic, immunological, or metabolic means (how about 'or genetic')
Misses out genetic means?

Clinical trial definition, part c(iii) may bring observational studies into clinical trials. For example, an observational study involving assessing cardiac function in recipients of clinically routine chemotherapy for leukaemia would now become a 'clinical trial', whereas the treatment itself and its risks remain routine. There needs to be an exemption for this for studies that use an approved product within its approved indication, for example to establish optimal uses - such studies are often investigator-initiated trials, and are likely to be much lower risk - they are already subject to ethical approval and trial registration on international clinical trial databases.

Licensee requirements - deeply concerned at the chilling effect this will have on investigator-led clinical trials in New Zealand, particularly co-operative group research trials. License duration of 3 years is much too short - many trials last a decade or longer including follow-up periods. Minimum of 5 years, and ideally 10 years for license.

Co-operative group trials - need a fee waiver for investigator-initiated trials, and reduced requirements for international co-operative group trials, which have already been reviewed by similar regulators. Any way we can nominate a series of 'approved regulators' e.g. EMA, TGA, FDA, to lower the hurdle to NZ participation in studies that have already been through these processes?

Clause 151: Transfer of the license to the executor of the will in the event of their death - this is inappropriate, as the executor is unlikely to have the skill or knowledge to know what to do about this.

Transition arrangements: distinguish between trials where the therapeutic product is still under use (transitional license needed), versus those in follow-up, where a new license should not be required

Uploaded responses

B3 Part 1 of the Bill: Preliminary provisions
4(b)(i) regulation of therapeutic products should be "proportionate to the risks posed by the products"
- I agree with this, and would add that the risks posed by a therapeutic product must be interpreted in the context of the condition it is used to treat. For example, a higher risk level is generally considered acceptable for a product intended to treat a life-threatening disorder (such as an immunotherapy or cytotoxic chemotherapy for cancer), compared to that intended to treat a benign or cosmetic condition.

Question B3 Part 3
I am concerned about the impact that #51 and #52 may have on:
- Provisions for unapproved medicine use (current section 29 of the Medicines Act) - there are some conditions (typically rarer conditions) for which no medicines are approved in New Zealand, and the capacity to access these in specific circumstances is very important
- Some patients with life-threatening malignancies have been importing life-saving medicines that are not yet PHARMAC funded directly from overseas. It appears this bill intends to prevent this. This is likely to have a major adverse impact on the life expectancy of these individuals.
- Pharmaceutical company-run compassionate access schemes have provided an important way for patients to access life-saving medicines in New Zealand. In my own area, an example would be an access scheme run by Janssen for the drug ibrutinib for patients with relapsed/refractory chronic lymphocytic leukaemia. I

hope these provisions will not prevent such access schemes.

Question B7:
#75(a): Off-label use of approved medicines should not be recorded via a special clinical needs supply authority. Off-label prescription is routine in many areas of clinical medicine, including much of paediatrics and obstetric medicine. Indeed, in some instance, PHARMAC specifically funds medicines outside their label (following clinician-led applications)- examples in own area of expertise (haematology) are rituximab for hairy cell leukaemia and for autoimmune cytopenias, and erythropoietin alfa for myelodysplasia-related anaemia. Typically, this is already recorded in PHARMAC Special Authority records. Attempting to record all off-label use will be excessively burdensome for all involved, and must be avoided.

Question B10
#81 and 82: These paragraphs appear to be specifically designed to prevent personal imports of prescription medicines. There are many New Zealanders currently importing life-saving drugs for cancers, because they are not yet PHARMAC-funded in New Zealand. This will have a major impact on these individuals' life expectancy.

Question B11
#91: Another special situation to be accounted for in Section 79 is the importation or purchase of medicines for laboratory research or laboratory quality assurance activities. I work at a Medical Research Institute, and we routinely purchase small quantities of prescription medicines for use in laboratory research. In addition, clinical diagnostic labs may require small quantities of prescription medicines for quality assurance (for example, to validate and provide quality assurance assays for therapeutic drug level measurement).

Question B12
#105: A goal of health research investment strategies in NZ has been to preserve intellectual property within New Zealand. Therefore there may be a number of health researchers nationally who conduct clinical trials of devices or pharmaceuticals for which they hold a proprietary interest in the intellectual property or the manufacturing company. It is a conflict of interest, that is reported to human ethics committees and assessed in considering approval of the clinical trial. One should be cautious that this section does not make conducting the type of translational research encouraged in NZ an offence.

Question B14
#113: I am concerned about the impact of fees or regulatory burden on the approval status for infrequently used medicines. There are many older medicines (e.g. pentostatin in my own area of expertise) that are infrequently used in clinical practice because they are reserved for relatively rare conditions. If the fees or regulatory burden to maintain a license are set too high, I can imagine some sponsors withdrawing from New Zealand, requiring that any future prescription is on an unapproved medicines basis.

Question B16
#118(a) and (f): It is not clear to me how, outside of clinical trials, sponsors can be expected to provide thorough ongoing monitoring of clinical efficacy or of adverse effects. This reporting will rely on feedback to the manufacturer by prescribers, and will be patchy at best.

Question B18
#133 (and #140): It is important that specification of license locations is not burdensome. In clinical trials, it is common for trial sites to be added and removed on numerous occasions during a study. This should not require an update to the license (it already requires notification to the Ethics Committee). An alternative option might be to use the Permit subpart for clinical trials, which constitute a special purpose.

Question B19
#135: I am concerned that the licensing requirement as written could have a chilling effect on NZ participation in international co-operative group trials, including for cancer. The draft prioritisation vehicle for health research in NZ (MoH, March 2019) specifically highlights the value of, "multi-centre trials and those that are undertaken as part of international collaborations" and notes that "funders will work to improve clinical trial networks". Modern investigator-initiated co-operative trials in cancer often include multiple new medicines, to which participants are allocated to on the basis of disease characteristics. Often the trial sponsor is an overseas co-operative trials group and the manufacturer of some or all of the drugs involved may have no NZ presence, so the country Principal Investigator of the trial becomes the sponsor representative in NZ. Thus, this portion of the legislation may require already-burdened clinicians taking on additional roles as licensee for a number of new medicines from multiple manufacturers. I strongly recommend that any licensee requirements must be kept simple, or the Permit subpart used, and costs low (or waived), for HDEC-approved clinical trials. After all, such trials are essential to collect the key safety and efficacy data that may contribute to a future application for a medicines approval.

Question B20
Might this Permit subpart offer a more appropriate regulatory framework for clinical trials involving medicines that are not yet (and indeed may never be) approved in New Zealand, and which will only be used for a special purpose (i.e. within a specific ethics committee-approved clinical trial)?

Question B21
#141: The 3 year term of licenses (and 2 year term of permits) appears too short for clinical trial purposes. The clinical trials I take part in are rarely completed within this time period, once both recruitment and follow-up periods are included. A longer license term of 5 or 10 years may be more appropriate, or at least an option for renewal.

Question B24
#154: In relation to section 160, it should be recognised that GCP-compliant clinical trials already include systems (including Data Safety Monitoring Committees, trial monitors and ethics committees) that monitor the safety of a trial intervention. It is important that this work is not unnecessarily duplicated by the new Regulator.

Question B32
#209: It is very important that any fee structure draw distinction between investigator-initiated clinical trials (including international co-operative group trials) and commercial trials or applications for medicine approvals. For example, Medsafe, SCOTT and GTAC are able to provide fee waivers in such scenarios, and a

similar approach should exist with the new Regulator. Charging new fees for conduct of investigator-initiated clinical trials would discourage New Zealand health research and run contrary to the aims outlined in the consultation document for the prioritisation vehicle for health research (MoH, March 2019).

Question C1
#240: Compassionate access schemes where a medicine is licensed in other jurisdictions would be another example where this should be considered.

#241: Speed of obtaining SCNSAs - unapproved medicines can be clinically urgent, and may be required within hours or days. It will be critical that there is a mechanism for rapid approval of clinically-urgent SCNSAs. Also, the SCNSA system appears excessive for off-label use of approved medicines, as this is routine in many areas of clinical practice, not least paediatrics and obstetric medicine, and PHARMAC specifically funds many medicines for unapproved indications, for example in cancer. This could lead to unnecessary duplication of administrative work, prescribers potentially requiring both a PHARMAC Special Authority AND a SCNSA for just one prescription.

#244: Please consider whether the Permit system is more appropriate than the License system for investigator-initiated clinical trials, where the company that produces a medicine may have no New Zealand presence. This may be a particular issue platform trials (increasingly common in oncology studies) or early-phase trials in low-incidence conditions. In this scenario, the therapeutic product would be supplied for a very specific purpose (administration in the context of an ethics and SCOTT-approved clinical trial).

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.:
#270: There needs to be clarity in the transitional processes about clinical trials that are in long-term follow-up, but within which the therapeutic product is no longer administered. This is often the case for oncology trials, for example, where a product is given for a short period of time (e.g. weeks or months), then the recipients are followed-up for years. Since no more product is being administered or supplied, such trials should not be required to transition to a new process.

Question C4 - Please provide any comments on the approach to post-market controls.:
#277: I welcome the suggestion of using NZ's existing pharmacovigilance system (CARM) - duplication of work must be avoided.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
#280: The process of fee waivers, as currently offered by Medsafe, must be continued for academic and non-profit organisations manufacturing devices and medicines. If not, this will disrupt attempts to develop new medicines and devices in New Zealand, and hamper biomedical research.

#283: Australia's TGA provides an exemption to full GMP requirements for the local manufacture of therapeutic products for first-in-human clinical trials. Please consider providing a similar exemption in this New Zealand law, as this clause has undoubtedly fostered Australian biomedical innovation, and indirectly led to several successful new medicines, vaccines and serological products for international markets, to the benefit of Australia.

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?:
Yes, our understanding is that Medsafe already follows the European approach in licensing cell therapy manufacturers in New Zealand. We are keen to ensure that the law and fee structure continues to distinguish between manufacture for investigator-led clinical trial purposes, and for commercial products.

It is important that this new law does not adversely affect current timelines for approvals.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
#333: It is important that this new law does not adversely affect current timelines for approvals.

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.:
#351: Again, note that Australia's TGA provides an exemption to full GMP requirements for the local manufacture of therapeutic products for first-in-human clinical trials. Please consider providing a similar exemption in this New Zealand law, as this clause has undoubtedly fostered Australian biomedical innovation, and helped get several successful new medicines, vaccines and serological products for international markets, to the benefit of the Australian economy.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:
It should be made clear that the transitional arrangements should only apply to products that are currently being administered to humans - not to clinical trials that are closed to new patient accrual and already in long-term follow-up (of which there may be many more than current trials).

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
The clinical trial definition as it stands (particularly part C(iii)) is too broad, and will draw in many essentially observational clinical studies of standard-of-care therapies. For example, an observational study that uses additional tests (e.g. a blood test or an ECG) to compare outcomes among people receiving approved standard-of-care products would be drawn into the new Regulator's net. Such studies are already reviewed by ethics committees, and do not involve exposing participants to additional risk (since the therapeutic products are approved standards of care). Added regulatory burden may inhibit these important studies, which may help detect new benefits or risks of approved medicines that might inform the Regulator's other activities.

It will be very important to ensure these processes are streamlined, and run alongside other ethics committee processes, ideally using a shared online portal and shared forms, so the information provided is not duplicated.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:
It is important that transitional arrangements apply only to trials within which participants are still receiving the therapeutic product, and not to trials that are in long-term follow-up (where no more therapeutic product is being or will be administered) are excluded.

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?:
#569: The SCSNA system for off-label use of approved medicines is highly problematic, as a very large fraction of routine medicines use is off-label. This includes most paediatric and obstetric medicine practice and a large fraction of oncology chemotherapies. Indeed, it is often the case that clinicians won't even know whether a prescribed medicine is being used within its label or not. Older medicines are very frequently used for off-label indications. For example, warfarin is not licensed for stroke prevention in patients with prosthetic heart valves, but this and has been routine for decades. Also, PHARMAC specifically funds a number of medicines for off-label indications, so this process could result in clinicians having to complete both a PHARMAC Special Authority and a SCSNA for the same medicine for the same purpose.

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?:
#570: This clause will block the ongoing supply of life-saving medicines to a number of patients who are arranging personal imports of drugs not yet PHARMAC-funded in New Zealand, for example for oncology indications.

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?:

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 C22Which 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-G4KY-5

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-25 14:45:35**

Submitter profile

What is your name?

Name:
Rebecca Brookland

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
University of Otago

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:
Otago

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

Other (please comment)

If you selected 'Other' please comment;:
Public Health Academic

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 C22Which 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?:
Direct-to-consumer advertising is inappropriate. Information about prescription medicines, and their suitability or otherwise, should come from an independent source, not the manufacturers.

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-G4KT-Z

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-26 00:22:43**

Submitter profile

What is your name?

Name:
Joseph Scott-Jones

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Pinnacle Midlands Health Network

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;:

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).:
This all seems 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).:
Placing the scope of practice of a health professional body in the sole control of the minister of health opens the Minister up to pressures from professional bodies and lobbyists whose interests may be the professions, not the patients. This is a risk for the minister to manage. I think the wording should refer to the "Ministry of Health" not "Minister" this will allow broader input into decisions and less politically vulnerable decisions.

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 seems very sensible

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).:
This seems very sensible

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
"While generally a prescription issued by an authorised prescr ber would be required, it would be poss ble to use a licence, permit or regulations to authorise supply without a prescription. Situations where we expect this would be used include supply of vaccines for use in approved immunisation programmes and emergency supply by a pharmacist for a patient who has gone on holiday without their prescribed medicine(s). We also envisage it being used in future to authorise the supply, by pharmacists, of prescription medicines such as trimethoprim and the emergency contraceptive pill in specified circumstances"

The more providers of medicine you have the more medicines will be provided - the risk of removing the requirement for a prescription will lead to an uncontrolled pharmaceutical cost to the system, and make issues like managing antimicrobial resistance more difficult. I'd suggest keeping the requirement for a prescription.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
"While generally a prescription issued by an authorised prescr ber would be required, it would be poss ble to use a licence, permit or regulations to authorise supply without a prescription. Situations where we expect this would be used include supply of vaccines for use in approved immunisation programmes and emergency supply by a pharmacist for a patient who has gone on holiday without their prescribed medicine(s). We also envisage it being used in future to authorise the supply, by pharmacists, of prescription medicines such as trimethoprim and the emergency contraceptive pill in specified circumstances"

The more providers of medicine you have the more medicines will be provided - the risk of removing the requirement for a prescription will lead to an uncontrolled pharmaceutical cost to the system, and make issues like managing antimicrobial resistance more difficult. I'd suggest keeping the requirement for a prescription.

Question B7 - Please provide any comments on the authorisations for health practitioners :
SCNA sound like a large administrative burden for prescr bers especially given the wide range of "off label" provision of medicine that currently applies.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
This seems very sensible - school clinic nurses for example can supply paracetamol without a standing order - makes sense.

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).:
I am a little concerned about category 2 medications being freely imported as according to other changes this will include contraceptive pills and antibiotics. We need these to not be counterfeit.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
86. 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.

This is very vague - standing orders remain a vital part of the system in a range of services including rural clinics, school clinics and outreach services. They represent a "stepping stone" for nurses and others who are part of a team and supported to apply a standing order into more confident independent prescribing. They need to be protected.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
We should stop direct to consumer advertising, and by opening pharmacists to prescribe you have already broken the barrier between prescribers and the business of providing medication.

If you continue to allow this for pharmacists, you have to allow it for all prescribing providers - this will increase the supply of medications for patients and have a greater impact on the cost to the system.

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).:
seems sensible

Question B14

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

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).:
seems sensible

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

Question B16

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

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).:
seems sensible

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).:
seems sensible

Question B19

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

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).:
pk

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).:
ok

Question B22

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

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).:
By opening licences beyond pharmacies you will open the supply of medications through a much wider set of venues.

It makes no sense in this situation to prevent prescribers from having an interest in the business of providing medicines.

This will increase supply but also increase a risk of financial pressure on providers to prescr be.

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).:
seem sens ble if you are allowing advertising of medicines to ensure they are truthful and penalise severely things that are not truthful. The question arises how will you define truth as DTCA is currently cleverly manipulative in its use of language.

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

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):
Seems sens ble

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):
ok

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).:
ok

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).:
seems sensible

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).:
seems sensible

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).:
seems sensible

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 unreasonable to increase the compliance costs whilst at the same time restricting the ability to recoup costs form the market place - the government needs to be very cautious about allowing regulations to expand with increasing costs incurred without considering how to modify and address compliance costs

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).:
The minister would be under great political pressure applying this to the provision of prescribing. I would predict that every professional body will seek permission to prescr be and it will be hard politically to say no.

If legislation has allowed licenced premises to be providing class 2-3 medications for profit along side pharmacists who are providing class 1 medications for profit in the same premises you will create a demand to have similar business models across all health professions.

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).:
seems sensible

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).:
ok

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

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?:
ok

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).:
ok

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

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

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

Activity-based controls

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

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

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).:
ok

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

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

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

Activity-based controls

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

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

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 needs to e health and safety regulation covering non therapeutic and cosmetic devices such as contact lenses and dermal fillers. This bill is applicable to drugs and therapeutic products.

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?:
Would you include Ai driven algorithms on a smart speaker as a "device" - what about an exercise heart rate monitor ?

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

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

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

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

Activity-based controls

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

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

C4 Clinical trial sector

Question C16

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

Question C17

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

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 a good idea although it runs counter to the direction of the rest of the bill which will increase supply of medications in the community and therefore the cost to the system and pressure on patients disposable income. If you are opening the market internally why place restrictions on imports - you are creating an internal free market but not allowing overseas competition to impact on the market costs.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:
Seems sens ble - hawkers do have an impact on prescr bing and my preference would be to prevent this from happening altogether - however have a licence to sell medication and to promote it will give an opportunity to apply further rules to the process in future.

Transition

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

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 open access to medications at bulk supply levels 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?:
Yes, pharmacists are trapped in a retail business model which prevents them becoming part of GP teams

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
This will be resisted by the pharmacy lobby as it is very threatening to them. There is no such thing as a free lunch and whilst community pharmacists may well provide clinical advice to patients, they also sell them a lot of unnecessary stuff. The role of the clinical pharmacist in a GP team is very valuable and extremely worthwhile - help them escape the shops and step into the care team.

Question C22Which option do you support?

Not Answered

Question C23 - Why do you support that option?:
Neither.
Why do you think you need pharmacists in control of pharmacist services at all ? Why not other health professionals ? You have broken the barrier between prescription adn supply already because pharmacists prescribe - why not allow other health professionals to supply and dispense medications ? What value does a pharmacist qualification bring to this aspect of a pharmacy ?

In addition to this - if there has to be a pharmacist involved - ownership rules are not going to ensure this in either scenario. The world is globalising and the pressure on this regulation is why you need to change it now. I dont have an answer for this other than just forget the whoel thing and open up the market to everyone, that will improve access.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Neither.

Why do you think you need pharmacists in control of pharmacist services at all ? Why not other health professionals ? You have broken the barrier between prescription adn supply already because pharmacists prescribe - why not allow other health professionals to supply and dispense medications ? What value does a pharmacist qualification bring to this aspect of a pharmacy ?

In addition to this - if there has to be a pharmacist involved - ownership rules are not going to ensure this in either scenario. The world is globalising and the pressure on this regulation is why you need to change it now. I dont have an answer for this other than just forget the whoel thing and open up the market to everyone, that will improve access.

Question C25 - Are there ways in which Option 1 could be improved?:
it is too fatally flawed

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

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 - I dont think pharmacists need to control pharmacy.

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 - neither option makes sense.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
It shouldn't be applied

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
I can see what happened to Blockbuster video stores and see whats happening to community pharmacy - this idea is reductive and lacks insight into the market forces driving change in this country.

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

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 concept is archaic

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Neither.
Why do you think you need pharmacists in control of pharmacist services at all ? Why not other health professionals ? You have broken the barrier between prescription adn supply already because pharmacists prescribe - why not allow other health professionals to supply and dispense medications ? What value does a pharmacist qualification bring to this aspect of a pharmacy ?

In addition to this - if there has to be a pharmacist involved - ownership rules are not going to ensure this in either scenario. The world is globalising and the pressure on this regulation is why you need to change it now. I dont have an answer for this other than just forget the whoel thing and open up the market to everyone, that will improve access.

Question C34 - Are there ways in which Option 2 could be improved?:
No it is too fatally flawed

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
why do you want to do this at all ?

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 don't see a role for pharmacists in this function

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?:
You have already broken this seperation of function by allowing pharmacists to become prescribers - it makes no sense at all not to allow other prescribers to have financial interests in pharmacy services any more.

Is this a good thing ? That is a different question - you have already done it so presumably you have some thoughts on that.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
yes - give one to everyone in the sector fo everyday pharacy supply - this is a way to open up the market further whilsy still having the opportunity to regulate.

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

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?:
Ok

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 - why not ?

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
Yes - why not ?

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
not really

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 am concerned about the potential for political pressure to come to bear on the minister to prescr be under these circumstances.

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?:
This does seem sensible

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 is an important part of the health sector - standing orders provide a stepping stone for many nurses into wider prescr bing and provide safe access to medications for school clinics, rural clinics and outreach services. The current legislation works well in most cases and perhaps could be widened in its application.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
You need to avoid administrative burdens where poss ble. There are "off label" uses for paracetamol for example (it helps some people sleep) . Make this as easy as possible.

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 sensible

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 sensible

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:
Why would you impose a restriction on this in any circumstance ? I do not see any reason to prevent this from happening

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?:
Yes , again why would you want to restrict this ?

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?:
This will increase supply (and cost to the government) of medication to the people at large, this is good if you think you have access problems, less good if the

medicines are ineffective, costly or carry complications such as increasing antimicrobial resistance.

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?:
See above This will increase supply (and cost to the government) of medication to the people at large, this is good if you think you have access problems, less good if the medicines are ineffective, costly or carry complications such as increasing antimicrobial resistance.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
THis should be significantly regulated if allowed to continue -

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?:
It should not continue because :

It is effective in driving up prescription of DTCA medications :
evidenced by growing investment by drug companies in DTCA
"More advertising leads to more requests for advertised products and more prescriptions"
"If DTCA opens a conversation between patients and physicians, that conversation is highly l kely toend with a prescription, often despite physician ambivalence about treatment choice"

How does the harm of DTCA get countered when we are trained to be patient centred and include patients in their own management responsive to their perceived needs "What matters to you?" medicine leaves us at risk of addressing what people want rather than what they need.

DTCA is not educational it is :

Vague
Misleading
Unbalanced
Emotionally driven
Misinterpreted by the public
Medicalises normal human experience
Pushes "a pill for every ill"
Lack robust evidence and emphasizes poor evidence

Drugs are not l ke breakfast cereals - they are not a matter of choice and branding, they are important to well being and also potentially dangerous - why use the same model to educate people about them as you use to persuade them to buy a brand of breakfast cereal ? It is an illogical and dis-ingenuine to say that DTCA is informative - it is not it is a sales technique.

C9 Veterinarians

Question C54

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

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
If you continual to allow advertising Ok. But how do you define "misleading" ?

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 answered this very fully before.

DTCA is not educational it is

Vague
Misleading
Unbalanced
Emotionally driven
Misinterpreted by the public

Medicalises normal human experience
Pushes “a pill for every ill”
Lack robust evidence and emphasise poor evidence

DTCA is effective evidenced by the Growing investment by drug companies
“More advertising leads to more requests for advertised products and more prescriptions”

“If DTCA opens a conversation between patients and physicians, that conversation os highly likely toend with a prescription, often despite physician ambivalence about treatment choice”

DTCA interferes directly with the patient centred movement when we are trained to be responsive to people's perceived needs in “What matters to you?” medicine - we are led into providing what they have been sold and think they want - not what they need.

Stop this now. Please

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?:
Its ok - heavy handed to reduce availabilty - OK

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 sensible - reduces supply again

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?:
sounds sensible clinically but economically will increase consumer costs

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
yes. where there is a high cost of medicine here and a low cost overseas

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
Id like to see all health professionals supplying medicines withi their services and bu k supply processes in place .

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Open the market and reduce the costs improve access - there will be more medication supplied to people at greater cost, but it will improve access.

Question C22Which option do you support?

Not Answered

Question C23 - Why do you support that option?:
Neither - see above

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

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

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?:
Yes - this will improve access to the services for everyone,

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

Advertising

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

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 should be stopped

Growing investment by drug companies
“More advertising leads to more requests for advertised products and more prescriptions”
“If DTCA opens a conversation between patients and physicians, that conversation os highly likely toend with a prescription, often despite physician ambivalence about treatment choice”

How does DTCA fit when we are trained to be patient centred and responsive to their perceived needs “What matters to you?” medicine ?

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?:
see above

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 patients would liek to see an open market for medication access

Response ID ANON-DPZ8-G4KX-4

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-26 12:25:04**

Submitter profile

What is your name?

Name:
Julia McDonald

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
independent clinical pharmacist

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please 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).:

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

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).:
imported medicines, especially American must be repackaged to New Zealand standards.

The high dose aspirin product Alka Selter is marketed to stomach upset, when it causes stomach lining erosion.
This should be a pharmacist medicine due to misleading labelling

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.:

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 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 of pharmacist services will not be affected.

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?:
in current pharmacies with the pharmacist owner law, the owners operate as business owners, because their primary concern is being a successful business person.
Any advice or recommendations made by a pharmacist owner to a client have inherent bias. For example the owner will recommend the product with the highest profit margin.

There is risk that supervisory pharmacists will not be able to make claims against their employers in cases where clinical practice is unethical. This already happens, and as there is no legislated or protected way to submit a claim against a pharmacy owner, the only option for pharmacists is to find other employment options or tow the line.

Ensuring a legally protected pathway for supervisory pharmacists to be able to make complaints will improve the overall quality of clinical services.

Spot audit results from ministry of health show that under current regulations the quality of clinical services is low in pharmacies.

For the public costs of products would decrease, and more options would be available if bigger companies owned pharmacies.

PHARMAC limits most of the price difference negotiating power in dispensaries, unlike in Australia where pharmacists regularly do commercial deals on preferred/cheaper brands of medicines.

This opens a career progression pathway for pharmacists to work up to in community pharmacy. This is an often sighted reason for younger pharmacists to leave the profession.

The only negative to this situation may be pay for pharmacists.

Question C34 - Are there ways in which Option 2 could be improved?:
Protect the anonymity of claims made against pharmacy businesses.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
Yes, if anonymity can be guaranteed, and any review comes back to the owner as general audit or compliance form the Ministry of Health. The information must not be able to be linked to the source.

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. This would suit medicines review 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?:
Yes.

removing this restriction enables prescr bers to recommend products outside of PHARMAC limitations to customers that suit the business and give largest profit margins.
This currently happens where prescr bers write prescriptions to clients for no funded natural products or over the counter products as recommended by the pharmacy.
Clients are pressured to pay extortionate prices for unproven therapies to keep the relationship with their prescriber positive.

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

Rural communities. For example issue a mobile permit for a pharmacist to visit a small town once a week and provide clinical services, and medicines.

similar to the mobile surgery buses that visit rural communities.

Rural GP surgeries are over booked. A normal waiting time is 2-3 weeks for an appointment. Mobile pharmacies would provide valuable triage services and treatment for minor ailments

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
Remove the bricks and mortar requirement, allow the licence to be attached to the registered pharmacist, not the building.

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 important. Medicines safety controls should apply to anything that has potential to harm.

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 situations l ke rest homes, hospices, or other institutions where bu k supply is more cost effective. Delays in supply chains from rest homes to prescribers to pharmacies and back to rest homes on delivery cause client harm.

NO in retail or mobile pharmacy situations.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
In any institution. Bulk supply in institutions where administration has oversight is more cost effective to the institution, residents, and PHARMAC.

Including retail pharmacy in the supply chain is an unneccesary step that causes unneccesary prescription fees, dispensing fees, delays in urgent medicines to clients, and increases pharmaceutical waste.

For example; a rest home client will be assessed by the nursing staff as actively dying. Cue: call to prescriber, who assesses, then adds end of life medicines to electronic charting systems that take a long time to process. Pharmacy checks this 4 hours later. orders "urgent medicines", dispenses them and delivers them 12 hours later. The next day the medicines are returned because the person died because of the delay in the mediicnes supply chain. now the pharmacist has to wait for another pharmacists to be ther 9impossible insole charge pharmacies) to destroy the controlled drugs, also they have to send paperwork tot the Gp to be signed to claim for paymetn from PHARMAC for unused, wasted medicines. All this is happening once the client is already dead.

C7 Retail sector

Question C42

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

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?:
Yes.

Medicine review for safety concerns often stem from prescr bers using outdated medicines or in an unsafe way because they were taught to choose 20 medicines as their preferred list and prescribe those.

Consumers are empowered to ask for more current therapies.

Example; outdated guidelines in New Zealand for Type 2 diabetes still recommend a twice daily insulin, that is cloudy protaphane. this is not best practice. Direct to consumer advertising allowed clients to ask about the best practice medicine, a once daily preparation that is not cloudy: Lantus

Response ID ANON-DPZ8-G4K6-2

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-26 13:04:07**

Submitter profile

What is your name?

Name:
Fiona Gray

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:

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;:
individual

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).:

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.:

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?:

NZ is one of the few countries that allow this

Advertisements targeting the general public/patients are designed to sell the 'product' There is a need for people to have access to information about medicines, but this should come from an independent source, not the manufacturers.

Response ID ANON-DPZ8-G45S-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-26 21:26:23**

Submitter profile

What is your name?

Name:
Paul Greaves

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
UNWUW Limited, trading as Estate Aromatics

Submitter Profile (tick all that apply)

Disabled person

Retailer (non-pharmacy)

Active ingredients

If you select DHB, please state service area:

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

Other (please comment)

If you selected 'Other' please comment;:
Distiller making compounds fro native and exotic plants

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).:
part 5. not sure on the term respons ble person, This could be used to mean anyone and could be open to abuse?

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. but note fit and proper person refers to my last comment. I feel its a bit untidy.

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.:

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).:

C7 Retail sector

Question C42

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

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?:
source is ok but who from should be listed but not to defined by the regulations. the system is to regulate a product not who you buy from by defining it.

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 are times that supply may be limiting or priced wrong and sourcing from a other certified supply would be better suited and cost effective. If the supply chain becomes to laid out its open to price inflation for personal gain. The regulation are not there to control supply its there to control the product only not source.

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 C22Which 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 know this is to try and control given substances . but it should not control or align a preferred supplier.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
the pharmacy become a static distr bution point, yes easy to control but is ineffective in controlling product price. That would be the main issue with consumers.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
in stability if a pharmacy can't preform in a open environment. which could degrade the ability to supply the community what they need.

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?:
Yes. the problem at the moment is that there are to many steps to get to a given product. The risks associated with a doctor prescr bing are less. They are at the point of contact. But in saying that there should be a peer review process of reasoning of supplying a product of cat 3,

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

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?:
yes. If there is abroad range of a given product to treat a given case. the consumer should have the ability to validate for them selves that they are happy with the that product'

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-G4EX-X

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-28 10:09:04**

Submitter profile

What is your name?

Name:
Robert Haua

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
University of Auckland

Submitter Profile (tick all that apply)

M■ori

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;:
PhD Candidate in the School of Pharmacy, University of Auckland

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).:
Agree with purpose and principles of the Bill.

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).:
Agree with the definitions and meanings set out in the Bill. Minor comments:

Section 26 (2)(a) outlines what preparing for administration means. Should this include any of the terms: "suspend" "reconstitute" "emulsify", or do these come under the word "mix" which is in the draft Bill?

When defining and talking about compounding, should there be a clause in the Bill about the person manufacturing it to be satisfied that there is sufficient stability

data supporting the compounded product [potentially is this covered by 55 (2)(c) and (d)]? Or does this come under clinical competence i.e. HPCA Act?

Section 32 (3) talks about what preparing for administration means for a medicine. It states that it is not a part of the manufacturing process if done in accordance with the responsible manufacturer's product information, or in accordance with an authorised prescr ber's directions. Would there be any anticipated situations (for example, in hospital), where there are local directions used by nursing staff to prepare a medicine for administration, but which differ from the manufacturer's advice (there may not be, but just checking)? For example, diluting an IV powder for infusion in less fluid than stated in the data sheet due to concerns about fluid overload? There may be data supporting things like this in other appropriate sources, but not specifically by the manufacturer. If this did occur, it would typically be after consultation with the ward pharmacist, not the authorised prescriber i.e. 32 (3)(b) wouldn't apply.

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).:
Agree with the product approval controls.

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).:
Nil comments.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
Regarding section 57 (3) i.e. what is meant by licencing requirements, "(a) is working in a licensed pharmacy business" may poss bly be restrictive moving forward if, for example, a pharmacist other than a community pharmacist were wanting to perform a controlled activity e.g. a pharmacist who is usually working in a general practice who is working at a community event in the weekend who may want to supply category 2 or 3 medicines, but they don't work in a community pharmacy so they don't have a licence and would be unable to supply these? Or under Section 61 (2) would the pharmacist be able to supply a category 3 medicine (but not a category 2 one)?

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

Question B7 - Please provide any comments on the authorisations for health practitioners :
How would a health practitioner e.g. podiatrist order and store category 3 medicines for supply as per section 61 (2)? Would there be any regulations regarding how these medicines need to be stored?

Regarding SCNSA's: What about “unapproved formulations”. For example, propranolol modified-release capsules are currently approved, but immediate-release tablets are Section 29. NZF lists for migraine prophylaxis (a condition that I would say non-medical practitioners would/could prescribe for) to use immediate-release, but these are S29 – would that prescriber need a doctor to apply for it initially?

My understanding is that technically, the immediate-release product is a separate product from the modified-release one, meaning that it would be necessary for a doctor to issue a SCNSA in the first instance. However, I do think cases like this add an unnecessary extra step.

Question B8 - Please provide any comments on the authorisations for health practitioners’ staff (s 65).:
I generally do not think that health practitioners’ staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice, with the exception of if they had already discussed it with the health professional, been given advice, and were only needing to physically complete the purchasing transaction from the other staff member.

I do not think that a blanket rule that all health practitioners’ staff being able to supply category 3 medicines would be safe. Granted, there may be cases where some are, but I think you have to legislate for the most conservative of situations.

For instance, I do not think is it appropriate for a receptionist in a GP practice to be selling pharmacy only medicines. I do not think they would have the knowledge required to ensure the patient receives services of an appropriate standard, is fully informed, and can make an informed choice. I understand that the legislation says the staff member must be working under the general supervision of the health practitioner (similar to a pharmacy worker being under the general supervision of the pharmacist), but I think that a pharmacy worker is more likely to have received training from a pharmacist, and the pharmacist is literally right there and able to assist if needed. I would imagine it unlikely that a GP or a nurse in a general practice will have time to be referred by a receptionist to ta k about a pharmacy-only medicine. Pharmacists in a pharmacy are much more accessible in this respect.

As a final note, there are lots of pharmacy medicines that have been reclassified to prescription, and in some cases, controlled drugs. For example, pseudoephedrine, dextromethorphan (to pharmacist-only), and Gees Linctus. These were obviously perceived to be safe when introduced as pharmacy only, but have since been associated with dangerous use. This shows that pharmacy-only medicines also carry inherent risks, and I’m not sure we could expect the same level of rigor in selling these by receptionists and other health practitioner workers.

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

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:
Regarding section 76 (4)(b): what if the patient and person A are not travelling together for some reason? For example, the patient could have arrived on an earlier flight and forgot their medicines so asked person A to bring them to NZ for them? Would this be legal?

Regarding section 76 (4)(c): would it be possible for overseas jurisdictions to have a different definition of what a 'health professional' and/or 'authorised prescriber' is? And would this open up any ambiguity here?

Regarding section 76 (7): how does this cover for off-licence doses of medicines, which may be much higher than what the medicine's respons ble manufacturer recommends, meaning a higher than usual quantity would be imported.

I may be interpreting this wrong, but do these sections mean that a patient could go to a pharmacy for a pharmacist-only (category 2) medicine, have it deemed that this medicine is not appropriate for them for whatever reason, only to then be able to personally import it themselves? If so, it seems to undermine the efforts of having the medicine as category 2 in the first place.

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

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
Comments regarding DTCA and prescribers holding an interest in pharmacy business detailed in Chapter C responses. Nil other 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).:
Nil comments.

Question B14

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

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
Nil comments other than to say I strongly agree that sponsors have an obligation with regards to post-market safety monitoring and reporting.

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).:
Nil 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).:
I agree with the approach of when to use the Bill, regulations, licences, or permits. I strongly agree with the licence being able to specify where different activites can be carried out (e.g. compounding, dispensing, supply). I like this approach to allow for services to be provided potentially closer-to-home, and I l ke that it promotes pharmacists to get out of the four walls of a community pharmacy; I think this is an important step forward for pharmacy.

Will pharmacy licences allow for other services such as trimethoprim, oral contraceptive, and emergency contraceptive supply to patients outside of the pharmacy i.e. at community events etc.? What about warfarin testing (CPAMS), the administration of vaccinations by qualifed pharmacists? Or are these services covered by other legislation?

I have provided more feedback on this in Chapter C.

Question B19

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

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).:
Nil comments.

Question B22

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

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

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).:
Nil 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).:
Nil 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).:
Nil 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).:
Nil comments.

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).:
I agree with the proposed amendments to the HPCA Act to allow for the authorisation to prescribe to be in each profession's scope of practice. The proposed system will be much more flexible and it will be much easier to implement changes to prescribing scopes than with the current approach.

One question would be, the consultation document states that if a particular prescribing group had a list of medicines which they could prescribe, the Minister could delegate to the regulator the power to change that list. Would this include the ability to remove the list altogether, or would this have to go through the Minister? Some more comments are in my answer to C43.

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).:
Nil 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).:
Nil comments.

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

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
I agree with the proposed new approach to categorise medicines.

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

Question C4 - Please provide any comments on the approach to post-market controls.:
I agree with the approach to post-market controls and think it is an extremely important obligation by both the sponsors and regulator.

Activity-based controls

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

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
Nil 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?:
I strongly agree with the suggestions in the consultation document; marae-based pharmacy services, and services at community events would be extremely valuable for communities, and simultaneously would raise the profile of pharmacy, and allow pharmacists who supply medicines here to also provide clinical advice to service users.

I do think there is value in pharmacists working in these areas having access to pharmacy-only medicines to deal with minor ailments. I think pharmacists who are working within general practices or other integrated healthcare settings should have access to category 3 medicines to deal with minor ailments. I assume this couldn't occur under a pharmacy licence, as a pharmacist in this situation wouldn't be "working in a licenced pharmacy business [section 57 (3)]" (which seems to be a compulsory part of getting a licence). However, my understanding is that section 61 (2) could allow for pharmacists to sell category 3 medicines by non-wholesale supply.

I could see this example being expanded to include the dispensing of certain medicines – for example, ant biotics for infections, especially for things like rheumatic fever – the pharmacist in general practice could dispense the antibiotic to the patient there and then, take some swabs (or a nurse could do it), and the patient now has a "one-stop shop" which could improve access. I don't see this occurring for every medicine, particularly for chronic conditions, but for some acute situations I think it would be really useful. The pharmacist will be working collaboratively with GPs so I would see this model as being acceptable to GPs. I'm not sure if the legislation is set up to allow things l ke this, or whether something similar could be achieved by just using practitioner supply orders and standing orders (could the pharmacist then give this to the patient?). I'm also not entirely sure if this contravenes the rule of prescr bers not having a financial interest in pharmacy business, but I don't think it should if the pharmacist remains the respons ble person for the pharmacy-related services.

Moving forward, I think that realistically, the most efficient model for the distribution and supply of medicines involves automation, and probably more centralisation in terms of having big 'warehouses' etc. that supply the medicines to patients, placing more emphasis on pharmacists providing important clinical advice to patients on how to use their medicines safely and effectively. This will need to involve substantial changes to the way pharmacist-led services are funded in the community.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
Yes. I think the current licensing process is based too heavily on the model of a 'bricks and mortar pharmacy', which does not allow pharmacists to do as much for their communities as they could. While this legislation does not cover clinical services by pharmacists, the fact that pharmacists in the community are tied down to the actual four walls of a community pharmacy, I think, limits their capacity to work at the top of their scope clinically, and provide any sort of expanded clinical services.

Some people and organisations may say that patient safety would be compromised if the supply of medicines by pharmacists moved outside of the community pharmacy – but some of the latest audit results showed that nearly half of all audits returned showed some level of non-compliance, so my question is: would a new model where services by pharmacists are provided outside of the four walls of a community pharmacy actually be less safe than the current standard?

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
My feedback here is primarily around funding, but relates back to the Bill insofar as funding is linked to a contract which requires a pharmacy license, which requires a pharmacy business.

The consultation document notes that pharmacists do not require a pharmacy licence to provide clinical advice. However, my understanding is that many of the clinical services that are run through community pharmacists are connected with, and funded through, the community pharmacy contract (now Integrated Community Pharmacy Services Agreement – ICPSA). And, in order to get a contract with a DHB, the person/business needs to have a licence to carry out a pharmacy business. I wonder if this would act as a barrier for the expansion of pharmacist-led services in primary care, because it could make it difficult to access funding if these aren't being directed through a community pharmacy? There may be other funding avenues I am not aware of, but I think it is important to also consider the role of other pharmacists in primary care, e.g. general practice, independent contractors, mobile pharmacists, and how they can access funding when they won't have a pharmacy licence.

Such pharmacists' practice may also benefit from being able to supply medicines (categories 1 to 3). Is it the intention of Ministry, TAS, etc. that the ICPSA will continue to be focused on community pharmacy as the base for pharmacist services? If there is talk of moving things outside of the physical community pharmacy (as per the Integrated Pharmacist Services in the Community document by TAS and what I understand was a part of the original intent in changing the community pharmacy contract), then would it be an issue if the Act specifically says you need to hold a pharmacy licence to perform pharmacy business/activities? Would it be plaus ble or appropriate in the future for an individual pharmacist in other primary care settings to be able to supply/dispense medicines to patients?

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?:
This is a somewhat difficult decision, because it is hard to predict exactly what would happen were either option implemented. The current legislation and licensing around pharmacy ownership are not working, as outlined in the consultation document. In particular, I have major issues with corporates being able to monopolise over pharmacy ownership, and also with the point that two or more pharmacists can own an unlimited number of pharmacies.

My main issue with Option 2 is the "risk that commercial interests might override professional judgement in community pharmacies". I think there is already enough of this risk present with having pharmacists as the majority shareholders; it could only get exasperated if non-pharmacists were able to have effective 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?:
The main benefit I see is that we avert the risk of commercial interests overriding professional judgement in community pharmacies. I think deregulation comes with a huge set of potential risks and I don't see many clear benefits (explained in detailed questions related to Option 2).

I actually see the need for the regulator to ensure current pharmacies are still elig ble for a licence as a positive. Companies and/or individuals who are bypassing the original intent of the law (which is clear in my opinion) should not be able to continue to do so. I think it is driven by greed and they do not have effective control over their pharmacies. I think giving the regulator more power to ensure licensees are complying with the legislation is a positive, as is the ability to hand out penalties. One question I would have is at what level are the penalties going to be? There should be consequences (potentially more so for corporates) for attempting to bypass the intent of the law.

I see one risk as being inadvertently maintaining the status quo. As mentioned in the consultation document, when initially set up, the law did not mean for pharmacy ownership to head in the direction it is now in, but it did. It is hard to predict the future, and so I worry that down the track other loopholes are not found that keep us in the situation we are in now, although I would anticipate that lawmakers would try their best to prevent this from happening.

I see a risk as being reduced capacity for innovation. When you operate on the smaller scale (owning 1 or 2 pharmacies vs. a corporate that owns 10s to 100s), it is difficult to innovate, because the risk is much higher if the innovation does not pay off. You have less capital, and less ability to absorb the costs associated with implementing and running the innovation.

The compliance costs related to the regulator having to ensure licence applications comply with the requirements may be a risk for pharmacy owners.

Question C25 - Are there ways in which Option 1 could be improved?:
I can't think of any specific improvements (other than those specified in other feedback areas), only to say that if this option were implemented, then we need to do our best to make sure that it works as intended, unlike the previous iteration.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
I think the requirement should be for the activities listed in section 36 i.e. dispensing, compounding, supplying category 1 or 2 medicines by non-wholesale supply, supplying category 3 medicines by non-wholesale supply, supplying other medicines/medical devices by wholesale supply as permitted by regulations.

A question I would have, is how is the administration of vaccines by qualified pharmacist vaccinators currently regulated? Administering a category 1 medicine is a controlled activity, so I'm unsure if this needs to be covered in the regulations to include vaccines? Apologies if this is covered by other rules/legislation. Additionally, for CPAMS or any other testing/screening (lipid levels, AF screening, etc.), I'm not sure how this is currently regulated, or if this needs to be covered by legislation or not.

I would emphasise here that I strongly agree with the idea that pharmacy licences could dictate where and how pharmacists or pharmacy workers could do different services (making reference to the examples of supplying medicines at marae or field days, etc.). I would not want the legislation to further link the requirement of performing these activities strictly to a pharmacy shop, as this is something that I hope we move away from in time (and that funding mechanisms allow).

I do not think this is a part of the legislation, but I especially would not want the clinical activities of a pharmacist linked to the pharmacy shop – I think this would be a huge barrier to expanding pharmacist-led services in primary care.

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, I think that there could be different pharmacists performing each role. I think having to have one pharmacist for both requirements is overly restrictive, and having two pharmacists would actually probably be more effective, depending on the size and number of the pharmacies.

As the draft bill sets out, I think it would be important to have protections in place if any concerns need to be raised to the regulator by either party.

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 agree with the consultation documents stance that pharmacies differ in scale and can be geographically dispersed. I do not think that a pharmacist who owns five huge pharmacies in different parts of town, or even the country, can maintain appropriate oversight of them.

I agree with the suggestion to make the number limit a licencing requirement instead (by having appropriate oversight). I l ke the proposition put forward that the regulator could determine that the pharmacist has appropriate oversight of the pharmacy based on the number, scale, and location of the other pharmacies that they are responsible for. However, how would the regulator define “appropriate oversight”? I think there needs to be well-defined guidelines in place that are not ambiguous, so that it is clear how the regulator will make its decisions. Could this be defined in the legislation, whether that be regulations, rules, etc.? My only hesitation here is that a lack of clarity around what appropriate oversight is, could lead to a situation where, in fact, a pharmacist who owns many pharmacies may not actually have that oversight of the new pharmacy they are looking to get a licence for. As long as this doesn’t occur, then I think this option is more appropriate than having a set number.

Although, perhaps there could be an overall limit/maximum number of pharmacies one could own on top of the requirement of having “appropriate oversight”. I would anticipate that the more pharmacies one owns, the less able they will be to maintain appropriate oversight of those pharmacies, so having a maximum could add another layer of regulation here? I am unsure what that limit would/could be, and would confer with those in the sector to see if there is an arbitrary number that could be used.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
I’m not sure, but there would need to be efforts in place to prevent two or more pharmacists jointly owning an unlimited number of pharmacies.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
I do not know the community pharmacy landscape comprehensively to be able to offer information on this, but I agree with the consultation document that there will l kely be compliance costs, and a need for many ownership models to change in order to comply with the new licencing requirements – I think this is a good thing in the long-term.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
Again, I do not feel l ke I have the expertise to be able to offer a number here, but perhaps 12 - 24 months? I'm not sure.

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 the cleanest way forward would be to ensure that all pharmacies (except hospital owned ones) have a pharmacist with the majority shareholding and effective control, including for those pharmacies currently owned by friendly societies. However, I would not be completely opposed to them being exempt, assuming the regulator monitors their running.

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 think that the main risk is (as mentioned above) that commercial interests might override professional judgement in community pharmacies. I understand and acknowledge that there are sections within the Act aimed at minimising this, but I worry that it will still be very difficult for the responsible person to come forward to the regulator and ta k about any issues regarding the licensee, given that they are employed by them. In any work situation there are going to be hierarchies, and I think that this is a huge barrier to quality control and assurance, because a lot of the time the ‘subordinate’ person is too shy/scared etc. to raise these points.

The consultation document ta ks about deregulation increasing access (presumably because increased competition may result in increased pharmacies with increased opening hours), but I think in reality I agree with the Organisation for Economic Co-operation and Development study’s finding that most of these would be in urban settings, with no corresponding increase (and I believe, potentially even a decrease) in pharmacy numbers in rural areas. New pharmacies would typically be set up in areas that have higher retail sale volumes and profits, not because of locations based on meeting health needs for local populations. I think that this will mean a worsening in urban-rural inequities in the provision of pharmacist-led services, and an associated reduction in access for people living in this area. Those who face additional social, economic, or demographic barriers could be at a higher risk of reduced access, including older people and M■ori living outside of urban settings.

In NZ, I think we are lucky to have a higher percentage of independent pharmacies than in other parts of the world e.g. England, where in 2016, the top twelve players own almost 50 % of the market, and independents make up only 38.4 % of the market. I think if we deregulated pharmacy, we would only see greater

acquisition of pharmacy businesses by retail giants – meaning that one or two players dominate the market, which I see as reducing competition. Smaller pharmacy chains and independents cannot compete with these giants and their buying power and could be forced to leave the market. This week (March 2019) in fact, I read an article in PharmacyToday where a pharmacy in A bany, Auckland had to close down because it could no longer compete with the Chemist Warehouse that opened up on the same street. Not only do pharmacies have to compete with their lower retail prices on OTC medicines, but Chemist Warehouse and Countdown Pharmacies have no patient co-payment fee.

Clearly, they are able to absorb this cost, but an independent surely will not be able to do so. And yet, independent pharmacies, in the past, have been penalised and called out for charging patients more than $5 to make up for the fact that they were losing money on certain dispensings because of the way the community pharmacy contract was set up. This doesn't seem fair to me, and I think there needs to be a level playing field, especially when it comes to prescription fees, if deregulation were to occur. I agree as well with the comments that vertical integration between wholesalers and pharmacies could occur, which may reduce access to certain medicines – there is already disincentives to buy high-cost medicines for patients in the current climate, and certainly I have heard of stories where patients get referred to other community pharmacies, even if this isn't what they are supposed to do.

I do see benefits in the affordability of medicines, because of the buying power of bigger companies (in relation to OTC medicines), and their ability to offset losses in not charging patients a dispensing fee (in relation to prescription medicines). My concern here is that patients in this setting may not receive as much advice about their medicines as in independents. And of course, we have PHARMAC which means the actual cost of purchasing medicines that are funded isn't really an issue in NZ.

Pharmacists are health professionals. There is already a clear distortion in the public and other healthcare professional's perception of pharmacists and what they can do. I believe that the profession needs a licensing framework that enables them to work top of scope, use their skills and knowledge, get away from the dispensary, and provide more clinical care to their patient population. I do not think that deregulation will help this, and in some cases, I think it will be a barrier. The future of community pharmacy, as it currently stands, is already somewhat bleak, and a meaningful conversation about its future is overdue.

Question C34 - Are there ways in which Option 2 could be improved?:
I've always wondered why in urban areas, especially Auckland, a new pharmacy is able to open literally a two minute walk away from an already established pharmacy. Could there be (or are there and I can't see them) provisions in the legislation for a maximum number of pharmacies in a given area? I am by no means an expert in what is happening internationally, but in England, for instance, I believe that local Health and Wel being Boards typically have to establish that there is a current or future need for a pharmacy, and NHS England will accept or decline an application based on this. I think that a similar system that grants licenses based on actual need (or improvement on current) for pharmacy services is important in ensuring the sustainability of those pharmacies that already service a given area. This is clearly important in urban settings such as Auckland where closures may happen if major retail giants open up a pharmacy just down the road of an independent. The sheer number of pharmacies in Auckland is also lowering wages for pharmacists, and from talking to my pharmacist colleagues, is also affecting job satisfaction as well.

Essentially, what I am saying is that if deregulation were to occur, then similar "needs assessments" should be introduced, although I actually think they are beneficial for option one too. This may be in place already, but I am not aware of it, and if it is, I do not think it is working, especially in places like Auckland.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
As mentioned, I think that while the legislation does its best to protect the role of the supervisory pharmacist, I think it will be difficult to ensure that they are free from coercion at all times, and feel comfortable and confident enough to potentially ta k to the regulator about any of the licensee's misconducts.

I think we must also keep in mind that, despite talk about competencies and potential qualifications/experience needed for the supervisory pharmacist, at the end of the day, it is the licensee who appoints a pharmacist to this role. I am not saying that every licensee who isn't a pharmacist is naturally dishonest, but why would a licensee nominate a pharmacist they think would 'stand up' to them if they were to engage in something unethical. They would preferentially nominate a pharmacist that they think they could control. Again, I do not think this would happen regularly, but it is a concern that I have about this.

Having rules around experience and qualifications needed for the role may be useful, but I think it is actually the attributes of the supervisory pharmacist that is important – they need to be strong, confident, etc. and I'm not sure if these are things that can necessarily be taught, although having experience in similar roles would probably be useful here.

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 would be hesitant to broaden this to allow a pharmacist to provide clinical advice and oversight remotely. I think in order for clinical oversight to occur, the pharmacist does need to be there. However, this is based off my own experiences, and I have never worked with new technologies such as Skype for consultations etc., so perhaps this could work in practice.

I think that there would be such a variety of competencies between pharmacy workers that would make a broadening potentially appropriate in some circumstances, but not in other circumstances. One example could be where there is a small pharmacy with one pharmacist and one pharmacy worker who has just gotten their first job in the pharmacy. The pharmacist could have to go offsite, and the pharmacy worker may not be competent enough to decide if something warrants the review of a pharmacist or not. Furthermore, the pharmacist might not be able to answer/Skype in if contacted.

To put this into another context, would it be acceptable to have a situation where physician assistants/associates (granted, not commonplace in NZ, but are used internationally) would be able to diagnose, treat, and prescribe medicines for patients at a general practice when there are no general practitioners there? Would it be acceptable for a newly qualified nurse to work in general practice and diagnose, offer advice, etc., to patients if there was not a general practitioner there?

If it were broadened, I would say that the non-wholesale supply of category 2 and 3 medicines (that are not prescribed) should not be allowed. I would be more open to pharmacy technicians being able to dispense and compound medicines if the pharmacist were off-site. They could potentially supply this to the patient, but only if the pharmacist had clinically screened the prescription and was somehow able to give counselling (I don't know how they could do this if they weren't there at the time). I would be happy for a pharmacy technician who has done the PACT course to do the final check in the absence of a 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?:
I do think that restricting prescribers from taking a financial interest in community pharmacies is still required. I do think that there needs to be a disconnect between prescr bing and dispensing, because there is always the chance for financial interests to take over ethical patient care.

I think what would be the most common situation is where a medical practitioner wants to have a financial interest in a pharmacy. I have read time and time again about the concerns of medical practitioners, and the organisations that represent them e.g. NZMA, RNZCGP about the huge issues they have with regards to the perceived conflict of interest community pharmacists have as health professionals working in a retail setting. They raise concerns about the competing interests of pharmacy business success and providing certain health interventions, and see an ethical issue with being both a prescriber and a dispenser. While one person wouldn't necessarily fulfil both of these roles in a shared ownership model between medical practitioners and pharmacists, it certainly starts to blur the lines, in my opinion.

My point is that if medical practitioners have big concerns about these conflicts of interest for community pharmacists, then they should equally care about similar conflicts if medical practitioners have shares in a pharmacy i.e. pharmacy business success vs. ethical healthcare delivery.

A lot of this is "worst case scenario" and in the majority of cases I'm sure this wouldn't be an issue, but we have to anticipate those "worst case scenarios" in-case they occur.

If it were allowed that prescr bers could take a financial interest in community pharmacies, then the regulator should check/audit at given time points that there are no issues related to this.

I do agree that a benefit of this would potentially be better integrated health services, but I think this can also be achieved without a shared ownership model with prescribers. I agree with the intent to clarify that the law is intended to cover interests that affect the ownership, management or control of the pharmacy business. I support any efforts to improve shared systems between pharmacies and other primary care providers.

I disagree with the consultation document when it says that this restriction in place would impact the uptake of pharmacists becoming qualified as pharmacist prescribers. Pharmacist prescribers in their scope of practice must work in a collaborative setting alongside other healthcare professionals, so I don't see community pharmacists as being able to be prescribers anyway as they don't typically work in this close collaborative setting. I would imagine a change in scope of practice would probably be needed if community pharmacists were to have prescr bing rights. Perhaps an Integrated Family Health Centre/Health Care Home would be an appropriate model, but I'm not overly familiar with how these work in practice and whether a community pharmacy is a part of this model.

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

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
Nil comments, although I would encourage a strict approach to which category 3 medicines retail-only license holders can sell, given that there will be no access to a pharmacist, and staff will l kely have very limited knowledge about the products.

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 strongly support this, in order to ensure the safety and efficacy of the imported unapproved medicines for 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?:
Off the top of my head, I can't think of a situation in a community pharmacy whereby a pharmacist would anticipate a request to compound something, but in which a script could not be faxed through to make the compounding otherwise legal (in response to a request for a patient). Also, many compounded items have such short expiry dates, and some batch sheets may not be fully validated/have stability data. Furthermore, the methods of compounding have been shown to differ significantly between community pharmacies. So if compounded items are made in advance, can the pharmacist be sure they are safe and effective if they stay on the shelf/in the fridge for a longer period of time, in anticipation of having to supply it for a patient?

In in-patient hospital pharmacies I think there is more value in bu k-preparing compounded items for patients in hospital, but this could be facilitated through an authority to manufacture these items on its license.

However, I would not be opposed to this change being implemented if others feel l ke it would benefit the supply chain and make it more efficient.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
No. I agree with the proposed sections in the Bill.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
No.

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)?:
None other than to say I strongly agree with the proposed changes. I think the current arrangements are too rigid to allow timely and efficient changes with regards to health professional prescribers. The proposed arrangement seems much more flexible and straightforward if changes to a health professions scope of practice regarding prescribing were being proposed.

Slightly off topic, but just because it was highlighted in the consultation document, I too have issues with lists of medicines for certain practitioner groups regarding what they can prescribe. I think that what can be prescr bed comes back to each health professional's scope of practice; if I was a pharmacist prescriber working in a general practice and my specialty/scope was cardiovascular disease and diabetes, there is no way I would be looking to newly prescribe something l ke clozapine as it is not within my scope anyway. However, say I was looking after a patient with these conditions and they were also on clozapine under a psychiatrist (not an uncommon scenario), then it becomes a barrier when I cannot prescr be this medicine when they come into the general practice to say, get a repeat prescription (because it is not on my medicines list). Additionally, a quick look at the medicines list for pharmacist prescr bers showed me that a pharmacist prescriber could prescribe something l ke "daunorubicin" for acute leukaemias, but not clozapine, even though the majority of pharmacists would be much more familiar with clozapine. Again, this goes back to the pharmacist acknowledging the treatment of acute leukaemias is not within their scope so shouldn't prescribe this; but if this is the case for daunorubicin, why can it not be the case for other medicines that are left off the medicine list?

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?:
I would tend towards thinking that a consistent approach to the form and content of prescr bing provisions within scopes of practice would be a good idea, and therefore regulations should be developed to facilitate this.

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.):
None other than asking if it would be foreseen that standing orders that currently allow for warfarin monitoring and dose changing in community pharmacy (CPAMS) or travel vaccines, etc., would instead be preferentially changed to permits or similar?

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
I agree in principle with the approach suggested, however I wonder how it works in some situations practically. For example, in a hospital setting, a number of approved medicines are used for unapproved indications or routes, and these are considered normal practice. For example, iron polymaltose is approved for IM administration, but is almost always given IV, which is unapproved. Given the acute nature of secondary and tertiary care, is it going to be expected that prior to the administration of such medicines (which occur as a part of daily practice) a SCNSA be issued? And how long would this take?

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 do think that there are situations where it is standard practice to use an unapproved medicine in certain situations e.g. adding on metolazone in those patients with refractory oedema, and a prescriber other than a medical practitioner who is a specialist in these areas would be competent and able to prescribe this and make a decision around safety and efficacy. So in that respect, I think the approach could be broadened. However, I acknowledge the concerns raised in the consultation document regarding wanting to reduce the number of unapproved products used in NZ, so I understand the reasoning to restrict this part to only medical practitioners.

I would ask if the new approach will address situations where patients may not be fully informed and not give informed consent (Right 6 and 7 of Code of Health and Disability Services Consumers' Rights) about the risks vs. benefits of these medicines. In my practice at a hospital I often see unapproved medicines being used without informing patients of their unapproved nature and gaining verbal informed consent. I'm not saying this is necessarily bad practice, per se, but I do sometimes struggle reconciling this with the rights of patients as per the Medsafe website page on unapproved medicines. However, on the other hand, in some acute situations, patients may not be able to be informed and give consent (e.g. perhaps using unlicensed antiarrhythmics in life-threatening arrhythmias etc.), so I just wonder how the SCNSA process will deal with these potential issues.

Another question would be – is it anticipated that adding the SCNSA process could create delays in patients accessing these medicines? For example, similar to how if a medical practitioner does not apply for a special authority, then this creates delays for the patient while the pharmacist gets the prescr ber to apply for the SA.

I agree with other health practitioner prescribers being able to prescribe them once a medical practitioner has issued a SCNSA, on the proviso that they continue to ensure the appropriate monitoring of that 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?:
I strongly support this, in order to ensure the safety and efficacy of the imported unapproved medicines for 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?:
In out-of-stock situations, or in emergency situations (either a life-threatening situation, or for the interests of public health e.g. supplying vaccinations to areas in need of more due to outbreaks).

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?:

Unsure. Nil 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?:
Generally I do agree with this as it opens up access, and as mentioned, if health practitioners can administer them, then why can't they supply them; I assume in this instance that they know about the medicine and how to use it/what to monitor. The risk here is that an inappropriate medicine is supplied, or an inappropriate quantity is supplied, or inappropriate advice is given, but I don't see these as being major problems with category 3 medicines.

I am not familiar with any storage or audit requirements regarding pharmacy-only medicines in community pharmacies, but my question would be whether those other health professions who stock pharmacy-only medicines for supply would have the same requirements as pharmacies (if they exist).

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?:
Same answer as for Question B8. I generally do not think that health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice, with the exception of if they had already discussed it with the health professional, been given advice, and were only needing to physically complete the purchasing transaction from the other staff member.

I do not think that a blanket rule that all health practitioners' staff being able to supply category 3 medicines would be safe. Granted, there may be cases where some are, but I think you have to legislate for the most conservative of situations.

For instance, I do not think is it appropriate for a receptionist in a GP practice to be selling pharmacy only medicines. I do not think they would have the knowledge required to ensure the patient receives services of an appropriate standard, is fully informed, and can make an informed choice. I understand that the legislation says the staff member must be working under the general supervision of the health practitioner (similar to a pharmacy worker being under the general supervision of the pharmacist), but I think that a pharmacy worker is more likely to have received training from a pharmacist, and the pharmacist is literally right there and able to assist if needed. I would imagine it unlikely that a GP or a nurse in a general practice will have time to be referred by a receptionist to ta k about a pharmacy-only medicine. Pharmacists in a pharmacy are much more accessible in this respect.

As a final note, there are lots of pharmacy medicines that have been reclassified to prescription, and in some cases, controlled drugs. For example, pseudoephedrine, dextromethorphan (to pharmacist-only), and Gees Linctus. These were obviously perceived to be safe when introduced as pharmacy only, but have since been associated with dangerous use. This shows that pharmacy-only medicines also carry inherent risks, and I'm not sure we could expect the same level of rigor in selling these by receptionists and other health practitioner workers.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
Nil 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?:
I do not think that direct-to-consumer advertising should be permitted. I have not delved into the evidence supporting or refuting DTCA, but I think that pharmaceutical companies at the end of the day are out to make money, and the way they make money is by having more people on their medicine. Statistics can be easily manipulated to give the guise of being better than they actually are (e.g. relative risks and percentages vs absolute risks and numbers), and this can be misleading and potentially unsafe.

The fact that only NZ and the USA have DTCA I think says a lot about this.

It is hard (I think) for health professionals to refuse a prescription medicine that a patient keeps on pushing for, so I think it creates an imbalance in the health professional/patient relationship. I agree that DTCA could also lead to polypharmacy, and a less optimal treatment regime.

I'm not sure about the regulations around the advertising of non-prescription medicines, but this can be dangerous as well, especially when they are sponsored advertisements. For example, I have seen a situation where Voltaren Rapid was advertised by the company and the All Blacks were sponsoring it. A lot of men obviously watch and look up to the All Blacks, and this could easily lead to the inappropriate use of diclofenac in patients who have cautions and contraindications. This is especially relevant in M■ori and Pacific men, who we know are disproportionately affected by conditions such as gout, and yet receive less urate-lowering therapies and more NSAIDs for treatment than non-M■ori and non-Pacific.

Even health professionals who are trained in the quality use of medicines can be somewhat misled when drug companies come to promote and advertise their products to them, trying to get them to prescr be and sell it. So if trained and qualified health professionals can be influenced by pharmaceutical representatives, then I could definitely see the general public being easily persuaded by a TV advertisement or similar. I do acknowledge there would be some benefit in raising awareness of certain medicines/devices, for example, new inhaler devices which a patient might actually prefer to use, but their doctor doesn't talk to them about if they want to switch, however, I generally think the benefits would not outweigh the risks here.

C9 Veterinarians

Question C54

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

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Nil 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?:
I do not think that direct-to-consumer advertising should be permitted. I have not delved into the evidence supporting or refuting DTCA, but I think that pharmaceutical companies at the end of the day are out to make money, and the way they make money is by having more people on their medicine. Statistics can be easily manipulated to give the guise of being better than they actually are (e.g. relative risks and percentages vs absolute risks and numbers), and this can be misleading and potentially unsafe.

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Even health professionals who are trained in the quality use of medicines can be somewhat misled when drug companies come to promote and advertise their products to them, trying to get them to prescr be and sell it. So if trained and qualified health professionals can be influenced by pharmaceutical representatives, then I could definitely see the general public being easily persuaded by a TV advertisement or similar. I do acknowledge there would be some benefit in raising awareness of certain medicines/devices, for example, new inhaler devices which a patient might actually prefer to use, but their doctor doesn't talk to them about if they want to switch, however, I generally think the benefits would not outweigh the risks here.

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 don't see there being a sitation where it is not preferable and safer for the medicine to be imported by the standard means.

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 C22Which 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-G45U-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-29 14:45:49**

Submitter profile

What is your name?

Name:
Sharon Gardiner (on behalf of the CDHB Antimicrobial Stewardship Committee)

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Antimicrobial Stewardship Committee, CDHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Antimicrobial Stewardship (multiple services represented)

Pharmacist

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

If you selected 'Other' please comment;:

Next steps after the consultation

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 concerned about the proposed change to have authority to prescr be established and bound by scopes of practice under the Health Practitioners Competency Assurance Act. As scopes of practice are defined by the individual professional bodies, these groups may seek prescribing rights with potential for inconsistencies between professions and lack of appropriate oversight. Under the existing model, there are already inconsistencies in the educational requirements and competency assessments for non-medical prescr bers [Raghunandan et al., Ther Adv Drug Saf 2017; 8(11): 349] that could benefit from an improved consistent national regulated approach.

As an antimicrobial stewardship committee, our feedback is primarily focussed on antimicrobials (although the concerns outlined above reflect our wider viewpoint also). The proposal to establish authority to prescr be under the HPCAA could add to New Zealand's already high burden of antimicrobial usage (much of which will be in appropriate), which will be difficult to address in terms of effective antimicrobial stewardship, and hard to monitor.

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 – see above.

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?:

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 CDHB Antimicrobial Stewardship Committee do not support direct to consumer advertising (DTCA) of antimicrobial medicines. Human antimicrobial use in New Zealand is among the highest in the world. Much of this will be inappropriate. Strategies to achieve judicious antimicrobial use and to minimise the development of antimicrobial resistance must consider all aspects of antimicrobial use (agriculture, and animal and human health) and must be multilevel and multipronged.
The NZ Antimicrobial Resistance Action Plan (a joint initiative of the Ministry of Health and Ministry for Primary Industries) specifically highlights the need to review the appropriateness of regulations around pharmaceutical advertising of human health antimicrobial agents. Our view is that direct-to-consumer-advertising of antimicrobial medicines is not appropriate, as it may contribute to increased pressure to prescr be antimicrobial agents inappropriately.
We do not understand why NZ has DTCA that is at odds with all other 'similar' countries except the USA. This bill is an opportunity to align with similar nations (e.g. Australia) and to add governmental/legislative weight to antimicrobial stewardship.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G45Y-F

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-03-31 22:55:15**

Submitter profile

What is your name?

Name:
Feras Dawood

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Unichem Waiuku Medical Pharmacy

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Counties Manukau

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 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).:
Dispense a medicine (s 29) – the definition of dispensing has changed significantly. I am concerned about this change.
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. 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.

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).:
Fully Support

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.

This would greatly benefit patients by giving them fast access to their prescr bed 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).:

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.

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 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. I also support the mechanism requiring a SCNSA when obtaining a medicine from overseas, and that the importation of the medicines is managed by the medical practitioner, a pharmacist or a wholesaler.
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.:
Vending machines should only be authorised 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 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.:

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 dispensing and supply at an aged care facility. I 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 required for audit.

How would dispensing at an aged care facility 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).:

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).:
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.

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).:

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

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 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.

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?:
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 distr bution 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?:
I do not believe that current licensing requirements create a barrier to innovation. Licensing requirements establish the requirements for safe and effective provision of pharmacist services involving medicines.

Service innovation requires attention to factors, such as IT systems and processes as enablers for innovation (eg electronic health record), improved workforce collaboration (eg better integrated service models for meeting patient needs) and achieving alignment of policy and funding settings for primary care.

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.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
I am supportive of service innovations such as providing marae-based services or providing pharmacist services at events such as Fieldays as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this would not include dispensing outside of a pharmacy dispensary.

I am also supportive of mobile pharmacy vehicles as an alternative solution to service rural areas currently serviced by pharmacy depots but believe that this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place.

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?:
I strongly believe that there is strong public benefit 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 l kely 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?:
Ensuring that a pharmacist owns and controls a pharmacy is a social objective that reflects community expectations and the desire to maintain the integrity of the professional relationship between pharmacist and patient, 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.

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. This includes resolving minor health issues quickly in the pharmacy and helping patients find the right health services to meet their needs. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. I believe that corporate owners would l kely 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, however this risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.

There is a risk that there could be a lower level of external investment from the dividend requirements under Option 1. This could be mitigated by legally requiring the owner pharmacist to have a 'veto share' so that the owner pharmacist is always in control of all voting rights on governance and operating decisions that have an influence on public safety.

Question C25 - Are there ways in which Option 1 could be improved?:
There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. I believe that Option 1 could be improved with grandparenting provisions for pharmacy business that are operating legitimately under current rules.

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 flex bility 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 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 poss ble to another pharmacist, and 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 (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 respons bilities 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.

Effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both are legally respons ble 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)?:
I would be able to provide a more considered response if the Bill was clear around the criteria that would apply in deciding whether the number, scale and location of other pharmacies would allow appropriate oversight to the owner pharmacist.

The five-pharmacy limit means that pharmacy ownership is spread across a large number of individual pharmacists, it also means that no single pharmacist owner has enough market power to set market prices or contract terms. This means that current pharmacy ownership rules provide an important public benefit

I think appropriate oversight of a pharmacy is effective control – the owners need to demonstrate governance of the business (they control the board). The day to day clinical oversight of the pharmacy can be delegated to a pharmacy manager (who is a pharmacist).

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. The five pharmacy limit could be applied by only allowing a pharmacist owner to have five '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?:
From a pharmacist owner's perspective I think the impacts would mostly be financial. There is a risk that private investors may sell down their shareholding in pharmacy, leading to a 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 or if it was legally mandated that the owner pharmacist had a 'veto share' so that this pharmacist is always in control of all voting rights 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.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
That would depend on the scale of any impacts on the pharmacy sector. As a minimum, I would consider five years to be a reasonable time to transition, once the Act becomes
law.

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 support pharmacist ownership (Option 1) and think this should apply to all pharmacies.
However, in the case of Friendly Societies that are already established under current
rules and are unable to reasonably restructure their effective control arrangements,
grandparenting 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?:
I am concerned that removal of majority pharmacist ownership of a community
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.

Trained pharmacists in an investor owned/corporate pharmacy are l kely 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.

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.

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.

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?:
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 A berta, 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?:
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.

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?:
I think it is appropriate 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?:
I am 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.

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 prescr bers 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?:
I 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?:

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 believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.

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, I would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same qualifying 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?:
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.:

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?:

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 C22Which 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-G4KF-J

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-01 09:43:53**

Submitter profile

What is your name?

Name:
David Reith

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Medicines Adverse Reactions Committee

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

Pharmacist, Nurse, Medical practitioner (excluding Surgeons)

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

Government agency, Other (please comment)

If you selected 'Other' please comment;:
Ministerial advisory commmittee supported by Medsafe

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).:
All healthcare practitioners are required by their respective councils to have an understanding of all relevant legislation, which includes the bill that replaces the Medicines Act 1981. The Bill is difficult to read and interpret for healthcare practitioners as we are not versed in law or policy. Producing an easy-to-read format of the Bill and eventual Act would ensure we can have a good understanding of the law and uphold our professional obligations.

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 increasing numbers of biosimilars entering the international market, it is vital that the Bill ensures there are mechanisms in place for biosimilar products to be approved without the innovator already being approved in New Zealand. We understand the Bill intends to allow the regulator to approve biosimilars based on information about the innovator from overseas regulators (ss 207 and 209). This process should be free of significant barriers, to ensure patients have timely access to biosimilar medicines that may be required for their therapy.

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).:
The current wording of ss 118 is not sufficient to ensure sponsors have adequate vigilance and risk management systems. “Ongoing monitoring” (ss 118(1)(a)) is a very passive expression and does not specify what monitoring systems the sponsor is required to have and is open to interpretation. The Bill should specifically state that the sponsor must have a functioning vigilance and risk management system, consistent with international standards, which New Zealand should strive to meet.

A proper vigilance and risk management system has many more functions, including but not limited to signal detection and evaluation. A statement along the lines of “The sponsor must run a functioning vigilance and risk management system” would ensure this happens. Further definition in the Act or Regulations will be required, but this statement in ss 118 should be the bare minimum to enable the correct requirements to be enacted in the regulations.

We also note that ss 97(f) states in brackets that post-market vigilance will be required for sponsors; however, this is not specifically stated in ss 118. There appears to be a gap between the intention of the Bill and what is currently stated in regards to having vigilance and risk management systems in place.

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).:

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).:
As noted above (Question B16), the Committee considers the current form of the bill, specifically ss 160, does not require the regulator to have a functioning vigilance and risk management system. The wording “Regulator to monitor safety” is passive and only requires the regulator to collect adverse reaction reports. It does not imply that the regulator must take action when needed. The wording of the Bill should enable the regulator to take action as needed when medicine quality, safety or efficacy issues are identified and place an obligation on the sponsor to comply with any requests from the regulator.

A proper vigilance and risk management system has many more functions, including but not limited to signal detection and evaluation. A statement along the lines of “The regulator must run a functioning vigilance and risk management system” would ensure this happens. Further definition in the Act or Regulations will be required, but this statement in ss 160 should be the bare minimum.

We strongly support the powers given to the regulator in terms of Public Safety Announcements.

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).:

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.:
The Bill should mandate the requirement for both the sponsor and the regulator to have vigilance and risk management systems in place. The current wording in ss 118 and ss 160 is vague and is open to interpretation. We have discussed this in our answers to B16 and B24.

We understand the regulations will specify the requirements for post-marketing controls. We believe the following requirements to be the bare minimum:
• Requirement for each sponsor to have a Qualified Person for Pharmacovigilance (QPPV)
• Ability for the regulator to request Post Authorisation Safety Studies (PASS)
o PASS protocols should be submitted to the regulator for approval
o The regulator should have the power to audit these studies at any time
• Requirement to submit Periodic Benefit Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs) to the regulator
• Requirement to report adverse reactions and safety signals to the regulator

We are of the opinion that the ability to request a PASS should be stated in the Act. Conducting a PASS means generating new information rather than gathering information that already exists, and is therefore not covered by ss 185. PASS are not clinical trials and are excluded by their definition. These studies should be independently mandated by the Bill, defining them in the regulations and giving the regulator power to request them.

Additionally, the current form of ss 160 is too specific about which therapeutic products are to be monitored. The Bill should not discourage reporting of non-therapeutic products (including but not limited to excipients and natural health products).

The regulator should accept reports for (and therefore monitor) any product, regardless of its therapeutic purpose. The Centre for Adverse Reactions Monitoring (CARM)/Medsafe currently monitors suspected adverse reactions to both therapeutic and other products; however, the new Bill provides an opportunity to mandate this monitoring. For example, currently CARM receive reports of severe allergic reactions to excipients, natural health products and dietary supplements/foods. It will be important to continue to collect these as CARM puts a medical warning in the patient notes so that these substances can be avoided in the future. The Bill must not bar this activity.

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?:
We do not agree with the approach for the off-label use of medicines proposed.

The approach proposed in the Bill would be resource intensive and generate a significant amount of paperwork, which would be cumbersome and may affect practice. For some clinicians (eg. Paediatricians) who commonly prescr be medicines off-label, the proposed requirements may be unworkable.

We are unclear as to how and by whom this scheme would be enforced.

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 stated above, we believe the current form is inappropriate and would not work in practice due to the significant barriers it creates. We suggest an alternative scheme similar to that of the Australian Special Access Scheme. This comprehensive scheme has multiple pathways for patients to access unapproved

medicines. The scheme includes two notification pathways:
• Prescr bing for life threatening conditions
• Prescr bing unapproved medicines that are deemed to have an established history of use. These products are specified in a list along with their indication and the type of health practitioner authorised to supply these products for the respective indications.

Additionally, the scheme also allows an application pathway for prescr bing that does not fall under a notification pathway.

We believe such a scheme would provide the necessary safe-guards while ensuring patients are able to access medicines that are not currently approved in New Zealand.

Additionally, we have concerns that untrained clinicians will be expected to do the job of a regulator. The role of the regulator is to ensure medicines are safe and efficacious, from both a clinical and manufacturing perspective. It would not be appropriate to expect prescr bers to carry out a rigorous benefit-risk evaluation of an unapproved medicine to ensure it has acceptable quality, safety and efficacy prior to prescr bing.

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?:
No, direct-to-consumer advertising of prescription medicines should not be permitted in any form. A key concern is that the information presented in advertisements provides an unbalanced view of prescription medications in favour of benefits over harms, leading to unnecessary prescriptions, iatrogenic harm and increased costs. Consumers have the right to receive information on medicines prescribed to them, however this should come from an unbiased source (ie, not the manufacturer of the medicine). The evidence around DTCA generally refutes the view that its promotional bias can be effectively regulated.

Care should also be taken to ensure that disease awareness campaigns, including advertisements, cannot be used to promote products. The Bill should ban all forms of DTCA by drug companies to ensure consumers are not receiving biased information on medicines.

We instead recommend that a consumer medicines information strategy is developed to ensure consumers have access to information about medicines. A starting point for this would be mandating the requirement for Consumer Medicines Information in the Bill itself. The format and readability should be appropriate for the consumer-level. The information should be unbiased and contain relevant information that will enable consumers to make an informed choice about the medicine and to understand how to use it.

Response ID ANON-DPZ8-G45T-A

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-01 11:29:53**

Submitter profile

What is your name?

Name:
Brooke Mckay

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
queen street pharmacy ltd

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;:

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 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).:
Dispensing is much more than supply!! patient counselling, checking dose and thata product is appropriate among MUCH MUCH MORE

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).:
agree this would be helpfull

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).:
concerned - keep to regulated channels

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

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).:
longer license i agree with

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).:

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?:

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?:

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 must maintain controll it is unethical to change this !! professional obligations need to be maintained. it is not just a retail store

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?:

Response ID ANON-DPZ8-G453-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-02 20:23:27**

Submitter profile

What is your name?

Name:
Charlotte

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Ranolf Pharmacy

Submitter Profile (tick all that apply)

Industry body

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

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

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

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. I am concerned about this change.
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. 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.

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.
This would greatly benefit patients by giving them fast access to their prescr bed 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).:

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 access ble 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.

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 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. I also support the mechanism requiring a SCNSA when obtaining a medicine from overseas, and that the importation of the medicines is managed by the medical practitioner, a pharmacist or a wholesaler.
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.:
Vending machines should only be authorised 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 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).:
Section 124 would allow for dispensing and supply at an aged care facility. I 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 required for audit.
How would dispensing at an aged care facility 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).:

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).:
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.

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):

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).:

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?:
I do not believe that current licensing requirements create a barrier to innovation. Licensing requirements establish the requirements for safe and effective

provision of pharmacist services involving medicines.
Service innovation requires attention to factors, such as IT systems and processes as enablers for innovation (eg electronic health record), improved workforce collaboration (eg better integrated service models for meeting patient needs) and achieving alignment of policy and funding settings for primary care.
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.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
I am supportive of service innovations such as providing marae-based services or providing pharmacist services at events such as Fieldays as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this would not include dispensing outside of a pharmacy dispensary.
I am also supportive of mobile pharmacy vehicles as an alternative solution to service rural areas currently serviced by pharmacy depots but believe that this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place.

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?:
I strongly believe that there is strong public benefit 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?:
Ensuring that a pharmacist owns and controls a pharmacy is a social objective that reflects community expectations and the desire to maintain the integrity of the professional relationship between pharmacist and patient, 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.
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. This includes resolving minor health issues quickly in the pharmacy and helping patients find the right health services to meet their needs. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. I believe that corporate owners would l kely 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, however this risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.
There is a risk that there could be a lower level of external investment from the dividend requirements under Option 1. This could be mitigated by legally requiring the owner pharmacist to have a 'veto share' so that the owner pharmacist is always in control of all voting rights on governance and operating decisions that have an influence on public safety.

Question C25 - Are there ways in which Option 1 could be improved?:
There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. I believe that Option 1 could be improved with grandparenting provisions for pharmacy business that are operating legitimately under current rules.
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 flex bility 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 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 poss ble to another pharmacist, and 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 (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 respons bilities 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.
Effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both are legally respons ble 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)?:
I would be able to provide a more considered response if the Bill was clear around the criteria that would apply in deciding whether the number, scale and location of other pharmacies would allow appropriate oversight to the owner pharmacist.
The five-pharmacy limit means that pharmacy ownership is spread across a large number of individual pharmacists, it also means that no single pharmacist owner has enough market power to set market prices or contract terms. This means that current pharmacy ownership rules provide an important public benefit
I think appropriate oversight of a pharmacy is effective control – the owners need to demonstrate governance of the business (they control the board). The day to day clinical oversight of the pharmacy can be delegated to a pharmacy manager (who is a pharmacist).

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 38% 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 '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?:
From a pharmacist owner's perspective I think the impacts would mostly be financial. There is a risk that private investors may sell down their shareholding in pharmacy, leading to a 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 or if it was legally mandated that the owner pharmacist had a 'veto share' so that this pharmacist is always in control of all voting rights 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.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
That would depend on the scale of any impacts on the pharmacy sector. As a minimum,
I would consider five years to be a reasonable time to transition, once the Act becomes law.

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 support pharmacist ownership (Option 1) and think this should apply to all 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 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.
Trained pharmacists in an investor owned/corporate pharmacy are l kely 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.
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.
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.

Question C34 - Are there ways in which Option 2 could be improved?:
Yes - it should be removed as an option.

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

Can you really see s498 working in practice? I very much doubt it. The words "restructure" come to mind.

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 A berta, 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 prescr bers, 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 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?:

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 bu k 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?:
I think it is appropriate 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?:
I am 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.

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 prescr bers 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?:
I 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?:

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 believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.
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, I would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same qualifying 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?:
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 l ke 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.:

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?:
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 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?:
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 C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
I am supportive of service innovations such as providing marae-based services or providing pharmacist services at events such as Fieldays as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this would not include dispensing outside of a pharmacy dispensary.
I am also supportive of mobile pharmacy vehicles as an alternative solution to service rural areas currently serviced by pharmacy depots but believe that this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place. There are obvious problems with this model and makes a "mobile pharmacy" an easy target.

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?:
I strongly believe that there is strong public benefit 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.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Ensuring that a pharmacist owns and controls a pharmacy is a social objective that reflects community expectations and the desire to maintain the integrity of the professional relationship between pharmacist and patient, 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.
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. This includes resolving minor health issues quickly in the pharmacy and helping patients find the right health services to meet their needs. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. I believe that corporate owners would l kely 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, however this risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.
There is a risk that there could be a lower level of external investment from the dividend requirements under Option 1. This could be mitigated by legally requiring the owner pharmacist to have a 'veto share' so that the owner pharmacist is always in control of all voting rights on governance and operating decisions that have an influence on public safety.

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 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.
Trained pharmacists in an investor owned/corporate pharmacy are l kely 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.
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.
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.

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, I do not believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.

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, I would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same qualifying 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?:

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 l ke 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.

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-G4C7-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-04 10:07:10**

Submitter profile

What is your name?

Name:
Robyn Toomath

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Auckland District Health Board

Submitter Profile (tick all that apply)

Consumer

Health service provider (eg, Ambulance, M■ori or Pacific health provider etc), District Health Board (DHB)

If you select DHB, please state service area:
Auckland

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?:
When I last looked, the second most expensive item on the drug budget was omeprazole. It was nowhere on the list of most prescribed medicines on a talk that was given by a visiting Scot last week. This is entirely due to direct to consumer advertising.

I struggle to think of any justification for DTC and this view is presumably shared by legislators in every country in the world apart from us and the U.S.A. To encourage the purchase of unnecessary, expensive drugs by vulnerable, uninformed consumers is reprehensible.

Of course the advertising and sale of unproven alternative medicines is even more dangerous and the current practice of most pharmacies to stock shelves and shelves of these ineffective agents is a cause for distress.

Response ID ANON-DPZ8-G4C3-Q

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-04 10:13:09**

Submitter profile

What is your name?

Name:
David Spriggs

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Auckland district Health Board

Submitter Profile (tick all that apply)

If you select DHB, please state service area:
ZZ

Medical practitioner (excluding Surgeons)

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

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 is unusual in developed democracies (The USA is the only other jurisdiction allowing it). While the industry view is that this allows for health promotion and information sharing, the intent of direct to consumer advertising is to increase sales of the products advertised.
This results in disease anxiety within the population, over-diagnosis, increased use of medications that are of dubious superiority to non-advertised equivalents and increased costs.
These consequences are counter to the aims of the Ministry of Health and the government.

Response ID ANON-DPZ8-G4CD-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-04 18:54:55**

Submitter profile

What is your name?

Name:
Jacob Mete

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Public

Submitter Profile (tick all that apply)

Consumer, M■ori

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?

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 need a section to include sunscreens as therapeutic goods rather than the cosmetic goods umbrella they currently fall under. Some sunscreens do not fall into the “active ingredients” section of the proposed scheme.

Having such poor regulations and standards for sunscreens is a necessity for a country with the highest cases of diagnosed skin cancers in the world.

Adding sunscreens to the list of therapeutic goods and into this scheme will ensure the quality of the forefront of sun protection in our country.

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).:
emphasis on the incorporation of sunscreens as therapeutic products

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).:
Parallel imports should be allowed for products deemed therapeutic but not necessarily harmful. Supplements can be purchased online without restrictions and so should some therapeutic goods.

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).:
I believe supplements should be required to show efficacy in their reported benefits.

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).:
Clarification of what an active ingredient actually is is required. The guidelines for what is an active ingredient are not specific enough.

A lot of cosmetic products list "active ingredients" l ke salicylic acid s acrive ingredients while others do not.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4C2-P

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-06 12:27:53**

Submitter profile

What is your name?

Name:
Jim Grierson

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Vitality Wellness (NZ) Limited

Submitter Profile (tick all that apply)

Retailer (non-pharmacy)

If you select DHB, please state service area:
Canterbury

Other health practitioner (please comment)

If you select 'Other', please comment below;:
Dietary Supplement provider

Trial ethics

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).:
Agree with the principal of removing Natural plant based products from the current ana new therapeutics bill.

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).:
Do not apply to natural 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).:
N/A

Subpart 3: Authorisations (ss 56–80)

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

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

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

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

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).:
N/A

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

Subpart 4: Other offences (ss 81-94)

Question B12

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

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).:
Natural require the same

Question B14

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

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).:
N/A

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

Question B16

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

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).:
N/A

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).:
N/A

Question B19

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

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).:
N/A

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).:
N/A

Question B22

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

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).:
N/A

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).:
Agree with process

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

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):
N/A

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):
N/A

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).:
N/a

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).:
Agree

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).:
Agree

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).:
Agree

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).:
Until we know the cost involved it is difficult to make any comment. Keep the costs as low as possible for the user.

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).:
N/A

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).:
Should remain

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).:
N/a

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

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?:
N/A

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).:
N/A

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

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

Question C4 - Please provide any comments on the approach to post-market controls.:
Natural supplements are not medicines therefore there should be a separate work able Act that allows for the correct description and use of such products.

Activity-based controls

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

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
No hawkers allowed

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?:
N/a

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

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

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

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

Activity-based controls

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

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

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 not at all providing they are a validated product

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?:
Do not no

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
Keep medicines and natural products apart and under different acts

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

Question C4 - Please provide any comments on the approach to post-market controls.:
Manufacturing protocols should cover this

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

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:
None known

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

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
Natural products should have pre-clinical and clinical research carried out on them. Field testing should be a given as they are a natural product.

Question C17

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

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 licence should be required for natural products grown within New Zealand

Hawker’s licence

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

Transition

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

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?:
Pharmacies are qualified enough to retail natural products

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

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
All natural products should only go through the Pharmacy outlets not Super Markets where there is no back up. Price only not good for the Dietary Supplements

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 have qualified staff

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Not sure

Question C25 - Are there ways in which Option 1 could be improved?:
Not sure

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
Protection of the supplier and pharmacists

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?:
Could be seperated

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)?:
Be replaced

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

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?:
3 months

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?:
N/A

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

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

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?:
Clinical advice and oversight remotely

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?:
Should not have any financial connection

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Do not over kill

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

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

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

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

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
Yes and it should

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)?:
Happy for this to happen

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 but keep it simple

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.):
N/A

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
Should not happen

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?:
Only in certain situations

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 curtail

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 problem with that

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?:
Ok with that

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?:
Not sure

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?:
Not sure

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
There must be proven substance to any claim made when advertising

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?:
Should not be aloud

C9 Veterinarians

Question C54

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

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Allow for proven statement on advertising for natural products

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 as will fall into the wrong hands

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?:
N/A

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?:
N/a

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?:
N/A

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

Pharmacy licensing

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

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Pharmacies are trusted by the public

Question C22Which 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?:
Agree

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

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

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

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

Advertising

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?:
Yes Providing they are factual

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 but softer more practical regulations

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.:
N/A

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4CM-H

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-07 17:29:26**

Submitter profile

What is your name?

Name:
Shane Heswall

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Maunu Pharmacy Ltd

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;:

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).:
I understand the purpose and principles and have no concerns about these.

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 have concerns about s29, and the definition of Dispense a Medicine. Under the current Medicines Act the definition is simple and accurate, whereas under the draft TPB this is about manufacturing of the medicines, but does not accurately represent many of the core roles of dispensing eg Clinical Checks. This seems a very strange and the explanation that enables a Pharmacist being able to dispense without a licence to manufacture, is equally puzzling, as it totally misses what actual dispensing of medicines entails.

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 have no concerns about this

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).:
This is not part of my practice

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
Reference 68 states there is consideration to allow a Pharmacist to supply a medicine to a nearby Pharmacy, that is out of stock of a medicine requested by a patient, I think this is an excellent idea, and would benefit the patient, as they would not be put out by having to travel to another pharmacy, of which the are unused to, and which doesn't have their medical history.
This would also help Pharmacists manage left over high cost medications, by enabling them to sell these to another Pharmacy that needed the stock. I'd suggest that this doesn't specifically need to be a nearby Pharmacy, as couriers can have required medicines delivered throughout NZ overnight.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
I am happy with this.

Question B7 - Please provide any comments on the authorisations for health practitioners :
I think this is very sens ble in case of emergencies, and should be able to be part of a local Emergency Plan, to enable the best outcome for patients, in a state of emergency.
I would not like to see this as "business as normal".

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
I have no problems with the appropriate staff, under the direct control of the Health Practitioners doing this.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:
This has very little to do with my business practice and appears sensible.

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 this approach and rational, I also agree with the SCNSA mechanism.
I think section 76(5)(a) should be amended, to only allow the personal importation of Category 4 Prescription Medicines, otherwise this may leave a loop hole in regards to equivalent medications available in NZ.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
I am concerned with the risks surrounding vending machines, and the need for such, if a Community Pharmacy is in the location and open. If the vending machine is owned and operated by a Community Pharmacy in the location, as a means of dealing with after hours requirements, if unavailable, then that would make sense. For it to be supplied by a corporate entity, with no ability to supply oversight seems dangerous.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
I am happy with this

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 problems with this

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).:
No comments

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
No comments

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).:
I am concerned that section 124 allows for dispensing and supply at an aged care facility. We currently supply medications for patients in Aged Care, this is a highly regulated process and I cannot understant how Aged Care staff could manage this safely. It would work if there was a Pharmacy set up in the Facility, under the supervision of a Pharmacist.

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).:
I think this is excellent, we had an example in Northland, where a Community Pharmacy burnt down, there was no way for the Pharmacist to continue to supply their patients locally, it caused a huge amount of inconvenience for both patients and the Pharmacist.
This would solve that.

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).:
Currently Medsafe struggle to issue our licence on time, increasing the length of the licence, if there are no ownership change makes sense, and would decrease the compliance costs of all involved.

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).:
These are sensible

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 concerns here

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:
No concerns here

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 concerns

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 concerns

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 concerns

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 concerns

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 concerns

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 long as Community Pharmacy is funded to allow for this extra compliance cost. Compliance costs for Community Pharmacy are huge and we have not seen any of this offset by extra payments for dispensing and supplying a high quality service.

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 concerns

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 concerns

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 concerns

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
No concerns

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

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

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.:
It would be good to have these aligned across different suppliers, to make it a streamlined process, as this is a compliance cost to Community Pharmacy.

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?:
Yes, as patients often have limited knowledge of such devices, which could cause harm or misunderstanding eg Vaping devices and products

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.:
Seems sens ble

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?:
This is an excellent idea and would end the loop holes, to improve patient safety, without knowledge of the manufacturing process of overseas medications it is impossible to access their safety. There would also be no oversight by health professionals so there is a risk regarding appropriate use of medications.

Hawker’s licence

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

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 systems that promote patient health outcomes while not compromising patient safety, or the current Community Pharmacy model. The imagined inventions of non modelled and trialled systems are of concern in regard to this.
Patients continue to promote the value to face to face, easy access Community Pharmacist models through surveys. We need to ask the general public what they want also.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
No I do not believe they do. Over the last 10 years our practice has developed hugely, with the use of Robotic Aids to dispensing, to provision of services usch as Vaccinations.
Our main barriers to even better integration and service provision is often IT based, and due to poor primary care integration.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
I am very supportive of enabling different distribution such as Marae-based services or Field Days, to address health promotion or equity issues. Often we miss cohorts with health issues eg Farmers, so any opportunity to improve contact would be excellent. I also like the idea of mobile pharmacy vehicles, particulary for Emergency Planning response, this would best work as a collection point, as rules regarding Pharmacy licence would make this very difficult.

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?:
Pharmacist ownership and effective control ensures we are accountable and respons ble for patient care first and foremost, as per our Code of Ethics.
In other industries owned by corporates it appears the drivers are profit first and foremost for shareholders, this does not fit with a patient centred health model.

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 from Option 1 are the continued operation of models focussed on patient safety and care, with accountability and respons bility strictly in the hands of Community Pharmacist owners.
Currently most Community Pharmacies have arrangements for patients who have financial difficulty, allowing patient to take medicines urgently needed, without full payment, or with part payment, or payment arrangements. I have never seen this in a corporate model eg Supermarkets. This is the level of care a Community Pharmacist Owner feels respons ble for and shows the dedication to the patient outcome.
There is a risk that models currently operating legitimately now could not be legitimate under the new option 1, this would need to have a process to deal with this transition, to ensure these businesses can become adherent to the new rules eg Grandparenting

Question C25 - Are there ways in which Option 1 could be improved?:
Adding the Grandparenting/transitioning process, to ensure easy and effective change management where required would be helpful.
Ensuring owners are always in control of governance and operational decisions is very important, Owners should have a "casting" vote, to ensure effective control is in their hands, to avoid the need for regulating divident requirements in proportion to shareholding.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
All activies we currently perform, that require a pharmacy licence

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 I do, it's about effective control. This ensures the respons bility for put the patient first, as per our Code of Ethics, overides any other factor. If you separated the respons bilities to a non-pharmacist, who did not have a Code of Ethics responsibility I would be concerned for the care of the patients.

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 have not been involved in these arrangements so do not have a lot of information to offer. Oversight of my own business is difficult, so I cannot imagine being

responsible for any others, not under my direct control.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
Ensuring effective control seems the most important, whatever mechanism is employed.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
I would assume it would cause non pharmacist owners to leave the market, due to the difficulty in directing the business/loss of control level.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
Any reorganisation takes time to be done correctly, I would think a three to five year period would be adequate.

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 they should continue to be exempt, unless they are able to be reorganised to fit under Option 1. Those arrangements tended to be in areas where normal Community Pharmacies did not fit.

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 cannot see any obvious benefits from Option 2 but I do see considerable risk to patient safety, health outcomes, professional obligations and primary health teams.
Pharmacists are held respons ble by HDC and can lose their registrations and businesses if they do not comply with high standards of care for their patients. Currently Pharmacists provide many services free of charge, that is not a corporate theme. Most community pharmacies put in place arrangements for patients that cannot afford their medications, to ensure they still get their required medications, this is a financial risk to the pharmacist, and is not something I have seen in any other business model eg supermarkets. Owner operators tend to invest in their business in areas which are a long term plan/big picture goal, and work with DHB's/primary health care teams eg vaccinations, these are high cost projects and the business case models are not based on short term gain.

Question C34 - Are there ways in which Option 2 could be improved?:
No, it's all or nothing in that plan, legislating structures and tiers would be difficult to audit.

Question C35 - Are the requirements adequate to ensure the ‘supervisory pharmacist’ would be able to effectively perform this function?:
I think the whole concept of a supervisory pharmacist is a joke, it's not based in reality where accountability and respons bility is linked directly to effective control. I think this needs to be taken back to the drawing board or scraped, as the unintended consequences may be problematic.

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 I don't. I know there are Dr's doing consultations via IT platforms but I believe there would be safety concerns with patients receiving medicines separately from counselling on the use of such medications. Feedback from patients generally emphasises the importance of a one to one, face to face consult.

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, this prevents unwanted behaviours, such as directing prescriptions to specific pharmacies, for profit. Separation of prescribing and dispensing keeps control of that area.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Absolutely, in regards to provisions of medicines in the event of an emergency eg Fire destroying a pharmacy. This would allow customers to maintain access to medicine without a major disruption

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
I think the current rules should continue for depots, so they are under direct control of a full service pharmacy, having access to the pharmacists that dispensed their medications.

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 answered this question 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, this makes total sense, as many of our compounded medicines are complicated and time consuming to compound and are dispensed regularly.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
I think this is sens ble, allowing pharmacies to avoid wastage of high cost medicines and to improve access for patients. It also allows co-owned pharmacies to share stock for similar reasons or for bulk purchasing.

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.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
I think the SCNSA requirements make sense and should help patients when non subsidised medications are prescr bed, of which the prescriber is unaware. These would now be highlighted.

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 makes sense to me.

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've already answered this question

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 emergency situations

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?:
I am unsure of this.

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 don't. The rules around supplying pharmacy medicines are strict and audited strenuously , it would be hard to see a GP practice meeting the strict audit requirements in regards to required equipment, storage temperature, medicine storage etc.

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 above, this would only dilute the quality of the provision of the medicine, while still having all the concerns of the enviroment of supplying the medicines from. Pharmacists are always readily available to their retail and dispensary staff, this does not appear to be the case for other health practitioners, as these are often consult based practices, behind closed doors, and unaccessible due to patient privacy.

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?:
I do not like the present system, as patients tend to push prescribers for what is advertised/popular, rather than allowing a practitioners clinical judgement to decide the product selected.

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.:
Seems sens ble

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 do not like this practice, as I feel it puts pressure on prescribers to give patients what is popular/advertised, rather than what is the most clinically appropriate medication

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?:
I have already answered 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?:
I have already answered 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?:
I have already answered 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)?:
No I do not support this. I believe medicines need to be supplied under the oversight of a pharmacist, medical practitioner or wholesalers, to ensure safety and quality of medicines and to ensure 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?:
I've answered this question already

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
I've answered this question already

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?:
I've answered this question already

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
I've answered this question already

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
I've answered this question already

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?:
I've answered this question already

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've answered this question already

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
I've answered this question already

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've answered this question already

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?:
I've answered this question already

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 the approach is sens ble

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4C9-W

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-08 08:53:42**

Submitter profile

What is your name?

Name:
Jerome Ng

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Waitemata DHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Medication Safety Group

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).:
SS3 - Purpose - appears clear and succinct
SS4- Principles - please see "suggested considerations" to question A1 re: balancing innovation vs. regulation. It is encouraging to see SS4(b)(i) - proportionate to risks - so to keep in mind that appropriate levels of regulation in place to not stifle innovative practice, research and development; especially when initiated by DHB to solve local care challenges

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).:
Pg 14 – 49 (j) - Type 4 product – welcome this introduced category for future proofing
Pg 14 – 49 (m) – administer a medicine - Welcome the new concept for nurses to reconstitute and mix medicines for administration without being considered compounding.

Questions were raised about MABs/chemo preparations. Do these need to have similar/higher restrictions due to potential risks? And does Regulator have a position about whether these can be undertaken in the ward or part of “manufacture”
Pg 15 – 49 (r)- manufacture and remanufacture - Act covers and allows for calibration, refurbishment, and assembly in accordance with manufacturer instructions but does in-house clinically engineered, modified or developed products (e.g. either physical or digital) where significantly different from original require approval from regulator
Pg 15 – 49 (s) – pharmacy business and activity – Please further clarify as it appears pharmacy =category 1&2. But pharmacy activity = 1-4 but example is more about store being able to supply (i.e. cat 3 – which appear narrower in scope) for access reasons so there appears to be a discrepancy between example and

intent

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).:
Pg 17 – 51-52 Recognise the need for regulated and controlled import of high quality and safe products but for balance - would the inability to parallel import potentially decrease competition which may result in an increase in costs of therapeutic products and reduce resiliency on their supply/availability (i.e. monopolising market). Consideration for software and how regulated for import/export.

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).:
Pharmacy and medicines generally covered and in place but may need to consider implications for fleet management, procurement, clinical engineering, clinical trials etc for medical devices and digital products.

NB: Waitemata has a medicines-related digital technologies governance policy which may help inform digital related products.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
No concerns or issues

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
No concerns or issues

Question B7 - Please provide any comments on the authorisations for health practitioners :
Does this mean that a nurse may potentially be able to supply a pharmacy only medicines to their patients without necessarily a prescription? Please clarify supply in this context

Under the new TPB, unapproved medicines (e.g. s29) OR approved medicines used “off-label” will now require a special clinical needs supply authority (SCNSA)- so what does this look like, to whom and what is the process? Does Medsafe/MoH have any figures on the size/extent of such use currently and what the implications of this may be on administrative/ staffing time?

Potential implications that there will be significant effects on administrative tasks on healthcare practitioners. E.g. Paediatric medicines

Question B8 - Please provide any comments on the authorisations for health practitioners’ staff (s 65).:
Does this mean that a nurse may potentially be able to supply a pharmacy only medicines to their patients without necessarily a prescription? Please clarify supply in this context

Under the new TPB, unapproved medicines (e.g. s29) OR approved medicines used “off-label” will now require a special clinical needs supply authority (SCNSA)- so what does this look like, to whom and what is the process? Does Medsafe/MoH have any figures on the size/extent of such use currently and what the implications of this may be on administrative/ staffing time?

Potential implications that there will be significant effects on administrative tasks on healthcare practitioners. E.g. Paediatric medicines

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).:
Given SCNSA, most medicines will NOT be approved for veterinary purposes so will all products require an SCNSA?

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).:
No concerns or issues

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
No concerns or issues

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
No concerns or issues

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 concerns or issues

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
No concerns or 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).:
No concerns or issues

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
No concerns or issues

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 concerns or issues

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 concerns or issues

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
No concerns or issues although additional clarity on the implications to clinical trials, services (e.g. Sterile services department) within DHB will be great

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 concerns or issues

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 concerns or issues

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:
No concerns or issues

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 concerns or issues

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 concerns or issues

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:
No concerns or issues

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 concerns or issues

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):
Potential unintended consequence where sponsor/pharmaceutical company drag out decisions with high legal costs associated with appeals to district courts with downstream effects of high expenditure for NZ

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 concerns or issues

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 concerns or issues

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 concerns or issues

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).:
Potential for costs to be passed downstream which increases healthcare expenditure

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 concerns or issues

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).:
Qs: In hospitals, medications are “orders to give” rather than prescriptions so if pharmacists are to prescribe a patient’s’ regular medicines, can an authorisation be sought? And if so, what is this process?

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 concerns or issues

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 concerns or issues

Question B36 - Please provide any comments on the use of regulations, rules or regulator’s notices for particular matters (Schedule 3).:
No concerns or issues

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 concerns or issues

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 concerns or issues

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
No concerns or issues

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
No concerns or issues

Question C4 - Please provide any comments on the approach to post-market controls.:
Welcome better oversight and vigilance of therapeutic products

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
No concerns or issues

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
Welcome the ability to have better oversight of "hawking" activity of therapeutic products

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 concerns or issues

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
No concerns or issues

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
No concerns or issues

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
Welcome better oversight and vigilance of therapeutic products

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
No concerns or issues

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
No concerns or issues

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:
No concerns or issues

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 - if it poses a significant risk to public health and patient safety

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

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
No concerns or issues

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:
No concerns or issues

Question C4 - Please provide any comments on the approach to post-market controls.:
Welcome better oversight and vigilance of therapeutic products

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:
No concerns or issues

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:
No concerns or issues

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:
No concerns or issues

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
No concerns or issues

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:
No concerns or issues

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 concerns or issues but to consider whether there may be unintended effects of monopolising the market and reduced competition

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:
Welcome the ability to have better oversight of "hawking" activity of therapeutic products

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:
No concerns or issues

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?:
Potentially mobile and centralised delivery systems to improve access to medicines (but coupled with appropriate medicines use advice and contact)

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.:
Will the regulations be similarly applied to non-pharmacies which supply medicines?

Question C22Which option do you support?

Not Answered

Question C23 - Why do you support that option?:
Either model with the proviso that the regulations ensure safe and effective use of medicines. As noted within the document, there appears to be no strong evidence which suggests that one model or the other has significant benefits to better medicines use and/or medicines related health outcomes and mixed results on accessibility (i.e. to rural areas where improved access is potentially and significantly more important than urban areas). To help inform the response to this question, it may be worthwhile examining recent Medsafe audit results on community pharmacies and analyse their results based on their ownership models to see if a particular model is associated with higher quality medication management systems.

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?:
Not necessarily

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)?:
Pharmacist, with the necessary expertise and experience, must have appropriate oversight of the pharmacy and its activities regardless of the model

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?:
As noted within the document, there appears to be no strong evidence which suggests that one model or the other has significant benefits to better medicines use and/or medicines related health outcomes and mixed results on accessibility (i.e. to rural areas where improved access is potentially and significantly more important than urban areas). To help inform the response to this question, it may be worthwhile examining recent Medsafe audit results on community pharmacies and analyse their results based on their ownership models to see if a particular model is associated with higher quality medication management systems.

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?:
This appears to put the supervisory pharmacist in a compromising situation which is neither ideal nor satisfactory. There is the potential that if quality management systems were inadequate, the supervisory pharmacist is held accountable despite system failures.

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 – given improving mobile digital and communications technologies, this would be appropriate. One example would include telehealth consultations in conjunction with adequately trained and accredited support staff (e.g. ECP, trimethoprim, sildenafil, vaccinations, 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?:
No concerns with prescr bers taking a financial interest in pharmacy providing that the regulator was confident the associated risks could be managed

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Yes, civil emergencies or where access is an issue

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 concerns or issues but to consider whether there may be unintended effects of monopolising the market and reduced competition

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 - e.g. paediatric formulations, special circumstance for chronic conditions where product is safe and clinically appropriate. Pragmatic reasons for improved access bility and convenience for the patient/caregiver

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?:
Under the new TPB, unapproved medicines (e.g. s29) OR approved medicines used “off-label” will now require a special clinical needs supply authority (SCNSA)- so what does this look like, to whom and what is the process? Does Medsafe/MoH have any figures on the size/extent of such use currently and what the implications of this may be on administrative/ staffing time?

Potential implications that there will be significant effects on administrative tasks on healthcare practitioners. E.g. Paediatric medicines

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?:
Would existing unapproved medicines that are used in practice exempt? E.g. duloxetine, oxandrolone?

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 concerns or issues but to consider whether there may be unintended effects of monopolising the market and reduced competition

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:
What is the rationale behind the provisions to allow the supply of either medicines or medical devices from one health practitioner prescriber to another? Appropriate for emergency/critical situations where one prescriber may have access/supply to medicines or medical devices.

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?:
What is the rationale behind the provisions to allow the supply of either medicines or medical devices from one health practitioner prescriber to another? Appropriate for emergency/critical situations where one prescriber may have access/supply to medicines or medical devices.

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?:
The more medicines there are in circulation the greater the potential for misuse/accidental poisoning. For example, consider opioids. Based on NZ and local mortality and opioid harm rates, most of the harm were due to prescribed/OTC opioids and NOT illicit opioids. Research suggests that up to 60% of patients have left over opioids at 3 months and 34% of patients have left over opioids at 6 months. Anecdotal evidence from DUMP (safe medicines disposal programs) suggests this pattern of leftover medicines is also observed for other medicines. A significant proportion of harm seen in hospitals are from accidental poisonings/overdoses (e.g. child poisoning from leftover/inappropriately stored medicines or patient inappropriately using previously prescribed/OTC medicines). There is also evidence to suggest leftover medicines are shared, sometimes inappropriately, with other family members/friends. Allowing health practitioners to supply category 3 medicines may provide convenience for patients but there is a risk of harm from increased medicines in circulation. The administration of medicines, as part of care, is still valid however, to extend to supply may potentially increase the risk of harm. Furthermore, how will the medicines be recorded/documented - for example if patients are receiving medicines from multiple sources, the ability to reconcile and ensure optimal medication regimen may be compromised. Given the strategic and digital direction of healthrecords being "one patient, one source", there may be important implications by increasing the number of prescribers/suppliers of medicines leading to potential interactions and harm.

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?:
Please refer to the response to Question C50. The ability to allow health practitioners’ staff to supply to patients of the practice may further increase the risk associated with increased medicines in circulation.

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?:
No 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?:
Under the new TPB, unapproved medicines (e.g. s29) OR approved medicines used “off-label” will now require a special clinical needs supply authority (SCNSA)- so what does this look like, to whom and what is the process? Does Medsafe/MoH have any figures on the size/extent of such use currently and what the implications of this may be on administrative/ staffing time?

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Would existing unapproved medicines that are used in practice exempt? E.g. duloxetine, oxandrolone?

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 concerns or issues but to consider whether there may be unintended effects of monopolising the market and reduced competition

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?:
Potentially mobile and centralised delivery systems to improve access to medicines (but coupled with appropriate medicines use advice and contact)

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Will the regulations be similarly applied to non-pharmacies which supply medicines?

Question C22Which option do you support?

Not Answered

Question C23 - Why do you support that option?:
Either model with the proviso that the regulations ensure safe and effective use of medicines. As noted within the document, there appears to be no strong evidence which suggests that one model or the other has significant benefits to better medicines use and/or medicines related health outcomes and mixed results on accessibility (i.e. to rural areas where improved access is potentially and significantly more important than urban areas). To help inform the response to this question, it may be worthwhile examining recent Medsafe audit results on community pharmacies and analyse their results based on their ownership models to see if a particular model is associated with higher quality medication management systems.

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?:
As noted within the document, there appears to be no strong evidence which suggests that one model or the other has significant benefits to better medicines use and/or medicines related health outcomes and mixed results on accessibility (i.e. to rural areas where improved access is potentially and significantly more important than urban areas). To help inform the response to this question, it may be worthwhile examining recent Medsafe audit results on community pharmacies and analyse their results based on their ownership models to see if a particular model is associated with higher quality medication management systems.

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?:
The more medicines there are in circulation the greater the potential for misuse/accidental poisoning. For example, consider opioids. Based on NZ and local mortality and opioid harm rates, most of the harm were due to prescribed/OTC opioids and NOT illicit opioids. Research suggests that up to 60% of patients have left over opioids at 3 months and 34% of patients have left over opioids at 6 months. Anecdotal evidence from DUMP (safe medicines disposal programs) suggests this pattern of leftover medicines is also observed for other medicines. A significant proportion of harm seen in hospitals are from accidental poisonings/overdoses (e.g. child poisoning from leftover/inappropriately stored medicines or patient inappropriately using previously prescribed/OTC medicines). There is also evidence to suggest leftover medicines are shared, sometimes inappropriately, with other family members/friends. Allowing health practitioners to supply category 3 medicines may provide convenience for patients but there is a risk of harm from increased medicines in circulation. The administration of medicines, as part of care, is still valid however, to extend to supply may potentially increase the risk of harm. Furthermore, how will the medicines be recorded/documented - for example if patients are receiving medicines from multiple sources, the ability to reconcile and ensure optimal medication regimen may be compromised. Given the strategic and digital direction of healthrecords being "one patient, one source", there may be important implications by increasing the number of prescribers/suppliers of medicines leading to potential interactions and harm.

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?:
Please refer to the response to Question C50. The ability to allow health practitioners' staff to supply to patients of the practice may further increase the risk associated with increased medicines in circulation.

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?:
No 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 - if it poses a significant risk to public health and patient safety

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.:
This is a welcome approach. However, within the regulations, it should specify that individual systems must be aligned/linked with national systems to ensure aggregated data collection, analysis and oversight

ADDITIONAL - as there is no "Any other suggestions/comments" box:
Thank you for the invitation to comment on the TPB. Overall, we agree with the TPB and its intended impacts. There are several clarifications sought which may become more evident with the regulations. Several comments, suggestions and questions have been included for consideration by the policy team to help modify either the TPB and/or include within the regulations and rules.

Response ID ANON-DPZ8-G4CY-W

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-08 16:03:30**

Submitter profile

What is your name?

Name:
Jennifer Goldsack

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Individual

Submitter Profile (tick all that apply)

Consumer

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?

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).:
Objectives are not attainable or acceptable:
a) Risk Management is too broad to meet expectations - poss bly try to monitor some aspects of risk management - these to be clearly itemised sothat the objective is more attainable
b) Principle of stifling competition will NOT create Efficient, Cost-effective regulation
c) The flexibilty and measuring of effectiveness needs to be up front and immediate as this will be a test to adjust guidelines and Ease of Use.
d) Accountable decision-making comes with continuity - which does not happen currently in Government Departments. Who will be accountable for any business failures, incorrect devices, cost of devices, denial of devices. How will they be accountable - sell their home to reimburse injured party? Once the name of the Government Department has been set up this needs to be set in stone so that a name change does not avoid accountability.
e) reliability, sustain capability - have you ever tried to ring the IRD or Customs?
f) This initiative does NOT support New Zealand's trade and economic objectives - ask the Chinese and other Trading Partners if they agree exclusion unless a particular company gains New Zealand Registration and Individual Approval Product by Product in an Acceptable Time Frame
g) Pharmac has generally struggled to retain trust and respect due to various constraints - all of which and more will apply to a new Therapeutic Denial Department

h. What has been suggested so far does not support consumer access and individual respons bility for care - the complete reverse. An individual will have to get the Doctor's approval for an imported medicine or device - which the doctor has no knowledge about - and the individual (presumably sick) will need to fill in the required forms to get approval - for something the Therapeutic Department will not have the knowledge to approve ...

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).:
Re:
a) Health Practitioner Prescr ber - this needs to be listed health area by health area and clarified. Nurses have been given 'prescribing powers' - what Level of nurse? What are they prescribing - is it a medicine or a health food. Medical Clinics have nurses performing many duties now. This could load a lot of costs to a Doctor's visit. What is prescr bing - via a written script?
d) Therapeutic Product needs to be defined substantially. Pharmac recently put out a Tender that did not touch the sides as follows:
(i) Mobility devices:
•■Wheelchairs
•■Walking frames
•■Walking sticks
•■Crutches
•■Gait trainers
•■Care chairs
(ii) Physical therapy equipment:
•■Hand therapy devices
•■Balance boards
•■Parallel bars
•■Rehabilitation staircases
•■Height adjustable steps
•■Standing frames
•■Tilt tables/inversion tables
•■Rehabilitation tables and chairs
•■Massage tables
•■Taping tables
•■Mat tables
•■Ramps
•■Incline mat
•■Therapy balls
•■Foam rollers
•■Therapeutic ultrasound devices
(iii) Gym equipment:
•■Weights and accessories
•■Pulleys
•■Resistance products
•■Exercise equipment
(iv) Hot and cold therapy products:
•■Hot/cold packs, patches, pads and wraps
•■Hot/cold device covers
•■Cold compression systems and accessories
•■Warmers including dry and moist heat
•■Other hot and cold therapy devices not within the scope of Patient
Warming and Cooling Products
(v) Hydrotherapy:
•■Whirlpool therapy baths
•■Hydrotherapy chairs
(vi) Assessment devices:
•■Strength measurement devices eg. hand dynamometer
•■Range of motion measuring devices eg. goniometer, inclinometer
•■Gait assessment devices
•■Other measurement devices
(vii) Injury prevention, restraints and patient positioning products:
•■Pressure care mattress overlays
•■Pressure care products for specific parts of the anatomy
•■Anti-slip socks (excluding those already listed for use with VTE
Prevention stockings)
•■Anti-slip mats
•■Falls prevention monitors eg. sensor mats, bed and chair exit alarms
•■Limb protectors
•■Patient restraints

•■Padding, pillows and cushions eg. support cushions and pillows, positioning pads, leg spacers, wedge pillows
•■Patient lifting and transfer devices eg. hoists, slings, transfer belts, slide sheets
•■Bed accessories eg. trapeze bars, bed cradles, bed sides, bed ladders, bed footboards
(viii) Bathroom aids:
•■Commodes
•■Over toilet frames
•■Raised toilet seats
•■Bath boards/seats
•■Bath transfer benches
•■Shower stools/chairs
•■Bath steps
•■Portable patient baths
(ix) Podiatry orthotics and specialised footwear:
•■Insoles
•■Heel lifts
•■Custom made orthotics
•■Heat moulded orthotics
•■Foot impression boxes
•■Post-operative shoes
•■Therapeutic footwear eg. paediatric spina bifida shoes, anti-varus shoes
•■Podiatry materials eg. felt, foam
(x) Immobilisers, bracing and support devices:
•■Slings
•■Splints
•■Straps
•■Supports
•■Stabilisers
•■Immobilisers
•■Braces
•■Walker boots (moon boots)
Halo units (excluding those already listed in the Orthopaedic category)
•■Traction devices (excluding those already listed in the Orthopaedic category)
•■Fasteners eg. clips, clamps (excluding those already listed in the Orthopaedic category)
•■Collars
•■Bands
•■Tapes and strapping not previously submitted as part of Woundcare
(xi) Other products used in rehabilitation:
•■Assistive devices for activities of daily living eg. adaptive eating utensils, dressing and grooming aids, easy reach sticks
•■Acupuncture needles
•■Transcutaneous electric nerve stimulator (TENS) machines
•■Joint mobility systems (passive and active) eg. continuous passive motion (CPM) machines, jaw motion rehabilitation systems
•■Pneumatic pressure devices (for the treatment of lymphoedema and chronic venous insufficiency)
•■Posture mirrors

Why has this not been classified at least a little yet - is a Sling a Medical Device? There are hundreds of different slings alone.

Please start work on LOW RISK "DEVICES" to remove them from this exercise.

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).:
53. http://www.imdrf.org/consultations/cons-clinical-evaluation.asp
Overseas controls are lining up

https://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm089686.htm

Behind closed doors

The product approval process should apply to medicines and medical devices that are used for post operative or internal application. The majority of products do not have to come under this regime. There is a call for a DHB purchasing review - which is in progress and will always be on-going - but it should not be controlled by companies that can afford this agenda as their product is not necessarily 'the best' or 'most suitable' or 'less costly'.

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).:
Clarify the Therapeutic Devices.
Are they medicines or products?
Are individual New Zealanders going to have to have approved medicine cabinets and hold a permit or licence?

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 :
https://healthcareweekly.com/prior-authorization-process/

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).:
Definitely quantity restrictions
Definitely not individual restrictions unless there is an exceptionally good reason.
Pharmac is not funding so definitely there is a need for personal importation.
To stop this would be criminal.
No-one person, Ministerial Office, other, has all knowledge of all "medical devices".
The ceasing or controlling of "medical devices" would take New Zealand back to excessive pricing by the few lucky licence holders - and I mean lucky.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
An Importer's staff are supplying against customer's orders. We will end up with everyone in New Zealand with an Authorisation, a Licence or a Permit to wear a Moonboot or a Sling. Then suddenly we said unauthorised person can obtain "medical devices" from a vending machine. Every cruise ship would need a New Zealand Registration and Authorisation and Licence for all "medical devices". All Air Operators would require the same. I wouldn't worry about 'visitors' coming with "medical devices" - they come here to get free ones.

Where are all these regulations going to be notified? The 'general public' and the "medical fraternity" are too busy doing their jobs to know or have time to refer to :
"trimethoprim is a prescription medicine except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16–65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists' training in the treatment of urinary tract infections. types of convoluted confusing information.
How many "medical devices" are going to require this level of regulation explanation?

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
97) Advertising - This is a minefield. A lot of advertising is from off-shore.

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).:
107. In broad terms, the applicant would need to satisfy the regulator that:
the quality, safety and efficacy or performance of the product are satisfactorily established (s 95(a))
the l kely benefits of the product outweigh its likely risks (s 95(b))
the applicant meets the criteria for being a sponsor (s 97)
the product will meet the product standards (s 96).

IS the Applicant the End User, the Hospital or Clinic or the Middle Man - the Importer/Supplier - who would not be doing this if there was no End User. If the

product has been in use for 40 years with no problems is that 'established'?
The Expert knows the use and efficacy. The Importer may never un-box the product as it may then be not fit for purpose. IS the product approval process aimed at the correct area relating to each product? Can a Sponsor be identified?

WHO is paying for this - Oh 118. This should eliminate the range available very effectively. Most Importers work on small margins and high turn-over. To have to fork out excessive fees to get 'approvals' will increase the cost of "medical devices" substantially.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
105.
https://www.greencrosshealth.co.nz/

Welcome to Green Cross Health, a provider of primary health care services to communities the length and breadth of New Zealand.
We are passionately committed to providing support, care and advice to our communities through our pharmacies, medical centres and community health services.
= Unichem, Life Pharmacy, The Doctors, Access Health
Our Green Cross Health group now has 359 pharmacies, 43 medical centres and services more than 21,000 clients in their own homes through Access Community Health. With a bold vision of Because of what we do, everyone is healthier, we are passionately committed to the health and wellness of New Zealand, and to providing the best support, care and advice to our communities.

I wonder what this business thinks of 105.?

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).:
All Low risk "medical devices" should be approval exempt
If not supermarkets and pharmacies will have a lot less on their shelves and individual smuggling will increase.

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
123. How can the "Sponsor" be responsible for "while the product is in the supply chain." That is extremely unfair. A nurse is quite capable of fitting a Philadelphia Collar upside down. DHBs have now tasked nurses with a wide range of duties they may or may not be for for - due to budget constraints as much as anything. If the product is not used according to the instructions or intended use the Sponsor is NOT responsible.

124. The "Sponsor" would not have access to Patient's Files or information to whom the "medical device" was issued to "Post Market" Report!!!!!

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).:
There needs to be Categories of Licences
Categories of Licensed Persons
This is all to convoluted with too many exclusions and inclusions that would be simplified with Categories

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
There needs to be Categories of Licences
Categories of Licensed Persons
This is all to convoluted with too many exclusions and inclusions that would be simplified with Categories

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).:
If the Licences and Permits are to hold any validity full inspections of premises need to be conducted regularly - like food premises - but better.
Renewals should meet the same criteria as New - or there will be slipping under the radar.

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).:
Who is going to inspect?
What is this going to cost?

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):

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).:
209 Cost recovery - is a Big NO. Why should all 'innocent' parties pay for the cause of this regulatory body? If the people want this - please ask - then the Govenment pays for it in its entirety. There is no excuse for charging the providers of "medical devices" for ALL these unnecessary over-regulations that relate to the minority of "medical devices". This is a complete over-use of powers. Clarify what you are trying to protect the New Zealand public from and regulate for that - NOT ALL 'MEDICAL DEVICES" as classified- or in fact totally NOT classified. If we need protection from toothpaste manufacturers regulate for that - not all grocery products.

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?:

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?:
Generally No.
Too much regulation for No Risk and Low Risk medical devices is unnecessary.

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?:
Generally too much regulation for No Risk and Low Risk medical devices is unnecessary.
Clarify this and the whole exercise will make more sense.
I have not seen clarification - just everyone copying everyone else's unclear models

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.:

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?:
Doctor's approval for an imported medicine or device - which the doctor has no knowledge about - and the individual (presumably sick) will need to fill in the required forms to get approval - for something the Therapeutic Department will not have the knowledge to approve. Over-ruling individual rights. Not conducive to good outcomes. How many New Zealanders have died from taking imported medical devices? How many have dies from medical misadventure? A frightening number. this is Administrative Misadventure.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
Do I believe many New Zealanders are going off shore for treatment they cannot access in New Zealand? Yes. Do I believe that our Health System cannot supply all available medications and medical devices? Yes. Do I believe that if a person wants to take snake oil they can? Yes. They always have and they always will. Do not interfere with individual preference for health treatment as they may be right and New Zealand Administrators may not know everything.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
Not associated with Medical Clinics

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

Question C22Which 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?:
Clarify the product criteria and the products would be included if necessary.

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 don't need all this protection
I think most New Zealanders do not need all this protection.
How many citizens have completed this Consultation?
How many know about it?
It has not been advertised publicly which is NOT GOOD

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4ET-T

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-08 16:25:20**

Submitter profile

What is your name?

Name:
Gary Smith

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Feilding Health Pharmacy

Submitter Profile (tick all that apply)

Consumer

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?

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).:
ok

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).:
ok

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
How does the Ministry ensure a "respons ble person" is actually the person responsible for day to day maintenance of standards, safety 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).:
I support the use of permits to cover any situation deemed by Medsafe (or the Ministry) to be necessary, as a SHORT TERM solution to a problem. (up to 12 months at a time)

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).:
Please, Please, Please keep the bureaucracy around permits simple, both for compliance and administration.

Question B22

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

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).:
ok

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).:
Cost recovery seems a good idea, until one realises it grants the regulator an open cheque to on-charge others for whatever whim is deemed necessary.
I believe there is a significant public good in many situations where the regulator charges industry high enough fees to ensure a product can not get to market, due to marginal economics.
Perhaps fees should not be allowed to increase faster than CPI without ministerial consent.

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).:
ok

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.:

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

Hawker's licence

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

Transition

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

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?:
With the widespread adoption of courier services, replacing post, and allowing timely door-to-door delivery of medicines the need for medicine supplies outside pharmacies is reduced, l kewise the need for "depot" arrangements.
Many pharmacies operate via the internet, and again this provides access to medicines at a distance from a pharmacy, without the need for a depot etc.

These arrangements can be safely discontinued, with medicines supply through licenced pharmacies only, and therefore always under pharmacist supervision. Currently some medicines with abuse potential are sold through non-pharmacy outlets, e.g. meclozine through airport shops, and this should cease. There is no

reason why a person who suffers from travel sickness can not visit a pharmacy before their trip to source appropriate medication and advice.
The ability for a pharmacist to provide "mobile" services, by visiting patients should be allowed, but mobile dispensing would be hard to establish in a safe manner. Perhaps an add-on to a specific pharmacy licence could permit mobile pharmacy services, via a vpn link into the pharmacy database?

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
Current arrangements allow non-pharmacists with no professional or personal commitment to patient care, or the community, to operate cut-down, low-cost pharmacy services that do not meet the needs of their community. For example Countdown pharmacy locally discounts Government prescription co-payments in order to attract customers for their retail offering, but the prescription service is low-cost, slow and generates complaints from patients whose service expectations have not been met. A professional service provided in a timely manner is not compatible with a cost-cutting model of delivery, and in the end patients' lives depend on quality, not price. L kewise, cherry-picking the profitable dispensing, but giving slow or no service to complex and time consuming items, such as extemporaneous items will result in these services being lost to the community once the competing full-service pharmacies have disappeared.

Pharmacists in New Zealand have proved to be early adopters of innovative services and methods of delivery, and providing appropriate funding is available are keen to adopt new services, such as domiciliary visits and marae/workplace services. Unfortunately funders ignore pharmacy-based proposals and channel all funding for cognitive pharmacist services through Doctor-led Primary Health Organisations, meaning community pharmacies are shut-out from developing and implementing new services.

These barriers are not due to licencing requirements, but to funding mechanisms.
Community pharmacists are already capable of offering out-reach services to the public, but funding is denied - the only funding mechanism is through dispensing-related fees.

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?:
Unless there is pharmacist ownership it is impossible to ensure effective control, indeed even with pharmacist ownership it is difficult to mandate high quality procedures and policies. I am CEO of a company owning and running 3 pharmacies, in close geographic proximity, and it never ceases to amaze me how different pharmacists have differing standards and attitudes towards rules! I am talking about ethical professional people, who still interpret requirements in variable ways!
It is a constant battle to get consistent following of procedures.
I personally believe the old system of a single pharmacy per owner is safest for patients, and has the highest genuine accountability, with genuine dedication to patient service.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
A colleague once spent a stint in the Uk as a pharmacist locum. He was appalled at the low standards of practice in some pharmacies, especially "ethnic owned". Not a racist - just his observation. He quit one job when the non-pharmacist owner demanded he substitute a (cheapest) penicillin for a different antibiotic - erythromycin. As a non-pharmacist he was unable to understand the patient benefit of receiving the ant biotic prescribed, rather than the cheapest the pharmacy could purchase!!!
Benefit of option 1 is safety and accountability. There is no value to the patient above if the pharmacy loses its licence months after the patient harm occurs. Professionalism is needed at the first patient contact, not after it all goes wrong.

Question C25 - Are there ways in which Option 1 could be improved?:
Option 1 could be improved by reducing the 5 pharmacy limit to a truly manageable 2 or so. I am finding 3 more than a handful.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
All pharmacy activities, including advice - if accountability is required.

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?:
For full accountability ownership and control should vest in one entity.
The more you separate the two the more you dilute accountability.

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 5 is too many to effectively control. 2 or 3 at most

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
Exactly - that is the question. This is the case in our practice, and in the end a single person is the default person in charge - where the buck stops. That is myself. The other two shareholder pharmacists each manage a pharmacy, however I still get the curly questions, and end up dealing with the problems.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
I suspect barrier to entry for a young pharmacist would decrease, through not having to compete with large corporates to buy or start a pharmacy practice. This may result in decrease in value of pharmacy businesses (such as our own).
Long term, I believe it would enhance patient care and improve accountability.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
2 years. 5 years if number of pharmacies owned were to decrease to 2 or 3

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?:
Friendly societies should continue, provided there is an identified manager, perhaps with a shareholding interest.
Other currently extant corporates could be "grandfathered" for say 10 years to allow orderly transition, with the same proviso as above.

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 - our pharmacy business would likely be worth more, as a larger number of potential buyers would compete to buy it when we decide to sell.
Risks - when a pharmacy business can be owned literally by anybody, with a nominated pharmacist "responsible" for standards and ethics, the risk of pressure being brought to bear on the pharmacist to "upsell", or act in other ways contrary to best practice, in order to increase sales, is high.
I am aware of such situations, even in largely ethical practices, where subtle but strong pressure is put on managers to increase sales.

Question C34 - Are there ways in which Option 2 could be improved?:
No. I consider option 2 to be counter to accountability and good pharmacy practice.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:
No. Money always talks.

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?:
This already occurs with some patient consultations, when a person is unable to come to the pharmacy, and no doubt could be extended for a mobile pharmacist - this also already happens. Regarding provision of advice to the dispensing staff, and oversight of dispensing from afar - this would work for the easy cases, but not work in many situations. For example, there has been recent publicity about forged prescriptions being presented, and dispensed at multiple pharmacies. Without seeing a prescription personally it would be impossible to tell if it was "real". It is hard anyway at times.
Modern pharmacy practice allows pharmacist access to patient medical records at the health centre, via secure link, but this may not be secure if pharmacists are not even at the pharmacy. How would confidentiality/privacy be protected?

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 a prescriber can have a direct effect on the income of a pharmacy, through prescr bing more expensive treatments, greater numbers of prescriptions, or using more profitable brands, I believe prescribers should not have a financial interest in a pharmacy, especially in the locality the prescriber practices in.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Permits should be available fo allow pharmacy practice to continue, for example after a fire or earthquake, where premises may not be completely up to standard, but good enough to allow continuation of service in an emergency.
It is not acceptable that pharmacy services should be made unavailable to a community in such circumstances, just because of bureaucratic requirements.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
I do not believe depots or retail-only licences are needed in this era of modern communications, and courier delivery. It is possible to order products on-line and have them delivered around the world in a couple of days, so should be possible for door-to-door delivery of medicines to be managed without depots.

Retail-only licences allow distribution of poss bly harmful medicines by untrained staff, and this is also no longer needed. There is no reason a person can not purchase travel-sickness medication, or a cold remedy from a pharmacy prior to travel, just as one does with regular medications.

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 sounds reasonable, provided cost is not added for the patient due to bureaucratic requirements.

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?:
Surely such a decision should be the professional respons bility of the pharmacist involved. I see no logical reason why a pharmacist shouldn't compound whatever quantity they deem necessary, either extemporaneously, or in anticipation of a request. Pharmacists train for 5 years to safely provide medicines for people, and should be left to get on with it.
Clearly, if audit finds inappropriate compounding the pharmacist should face whatever consequences are appropriate.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
I support allowing a pharmacist/pharmacy to supply another pharmacist/pharmacy any product and quantity of product the two pharmacists deem necessary, provided quality considerations are met. (storage/cold-chain etc)
L kewise, a pharmacy shoudl be free to supply other health profesisonals by wholesale, within the ethics and quality considerations of each profession.

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)?:
As a pharmacist, the first ever midwife prescription I was presented with (and declined to dispense) was for a woman in her 70s, for a variety of medications to treat a skin condition. This appeared to me to not be an appropriate midwife prescription. It turned out the prescription was for the midwife's mother. This is before the modern jargon of "scope of practice".
Any arrangements need to explicitly define what is regarded as within scope, and what is unacceptable.

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.):
Standing orders are a useful way to ensure timely treatment of various conditions, under responsibility of an appropriate prescr ber, and such a modality needs to be continued where deemed appropriate. Obviously the person supplying/administering the medication/treatment has to be appropriately qualified and experienced, and operating within their scope/knowledge base.

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

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

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?:

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?:
What oversight would exist in this situation?

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 - only the practitioner taking responsibility for the personal treatment of their patient

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
Medicines advertising continues the age-old tradition of mis-information and telling only part of the story. I believe, even with the current TAPS scheme much of the advertising is misleading. We regularly have to ta k people out of taking a medicine they have seen on Tv or read about in a web advert. I'm not convinced that any advertising benefits the public, except general advertising around consulting doctor/pharmacist/midwife etc.

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 advertising of prescription medicines, such as Vioxx, Xenical has in my view caused harm to patients, either their health or their wallet. Conversely products such as Viagra have helped many people who would otherwise not benefit from knowing their condition can be treated. The balance can be achieved by allowing advertising of treatment for a condition, rather than naming the treatment.
DTCA of named pharmaceuticals should be stopped.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:
Seems fine, however why not enable professionals (Veterinarians) to supply other Vets, and regulate if it is found to not be working.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Direct to consumer advertising of medicines is not working, because the advertisers often use promotional techniques that are convincing, without telling the adverse effects in a meaningful way. People regularly come to the pharmacy and request products that are not suitable, and don't readily accept advice against using products.
There needs to be much stronger oversight of DTCA, or otherwise it should be stopped.

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 believe DTCA is causing harm to consumers, and placing health practitioners in an invidious position when consumers demand products which may be not as suited for that person as other products.
On balance I believe it should be stopped, unless Medsafe is prepared to take a pro-active monitoring and policing role.

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?:
I concur

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 concur

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 Agree

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
When there are good quality suitable alternatives available overseas at a cheaper price.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
Pharmacists already can, and do visit rest homes, and deliver medications from the pharmacies the rest home deals with. There is no way to ensure safe and correct, temperature controlled storage of medicines in a van, on a marae, or in a tent at Feild Days. The wide distr bution of pharmacies ensures accessibility to medicines in almost all populated parts of NZ.

Any approach allowing van-sales of medicines would have to be audited, policed by Medsdafe, quality assured, and safety to the public ensured.

(I wonder if the peddler's van would be allowed to finance the medicine deals in a similar manner to the trucks currently trading in general goods in poorer areas of NZ? Could be very profitable.)

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
The current arrangements allows NZ patients ready access to pharmacy goods and services throughout our sparsely populated country. Allowing various hawkers and itinerants to "cherry pick" profitable products and services would threaten the current suppliers and the widespread availability of pharmacy service. As pharmacy had become more competitive in this region over the last 30 years we have completely lost pharmacy services in the towns of Raetihi, Waiouru, Hunterville, Ashhurst, Shannon, Woodville; and other pharmacies have closed in Taihape, Marton, Feilding, Dannevirke, Pahiatua, Foxton, Waipukurau, Waipawa. These had previously been viable business serving their local communities well. Many of the towns that lost their pharmacies lost their resident medical practitioner soon after, leaving the residents no option but to travel many kilometres to access medical services. Is this really a trend our society wishes to increase? No problem to city dwellers of course - there will always be a handy discounter to go to.

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?:
I disagree with the 5 pharmacy limit as it is manifestly ignored by many pharmacy accumulators, and as an owner of 3 pharmacies I believe that is more than enough to manage, to ensure good standards are adhered to in practice. I would favour a return to tighter restrictions on numbers of pharmacies owned. (Maybe 2)
Having worked in the industry many years I know only too well how difficult it is to ensure consistent quality of service over several stores.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Stronger accountability is exactly what it says - the current system allows individual pharmacists to hide behind shared responsibility when something goes wrong.
I have had personal experience of having to share the blame for a simple (serious) dispensing error which simply should not have happened.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Option 2 allows an unscrupulous owner (or ownership entity) to get away with shoddy quality practices, while the pharmacist nominally in control is left with the blame when things go wrong.
In the old sole owner regime the buck really did stop with the person doing the job.

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?:
I support REGISTERED health practitioners being authorised to suipply medicines within scope of practice, provided other standards - storage etc are maintained equal to a pharmacy.
Benefits in access for patients.
Risk in the practitioner prescribing the profitable treatment, but most ethical practitioners are capable of self-managing, as are pharmacists.

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?:
Only under direct personal supervision of the practitioner.
benefits/risks as above

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-G4CQ-N

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-09 10:04:11**

Submitter profile

What is your name?

Name:
Alison McMillan

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Surgico Medical & Surgical Ltd

Submitter Profile (tick all that apply)

Industry body

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?

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).:

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).:
Some Medical Devices do not have a single Distributor in NZ.
The requirement for the registered Sponsor to have to give permission for another company to also Sponsor a particular product put the registered sponsor in a position of power where they can eliminate a competitor.
We presume the registered Sponsor is the FIRST to register a product, however being the first to register does not necessarily mean that company is the best Distr butor for the End User.
The Manufacturer or Suppliers freedom to choose or allow multiple Distributors in NZ for a Device has been removed and given to a NZ Distr butor.
A NZ Distributor may be cut out of the NZ market for a device not because of sub standard performance in the eyes of the Manufacturer or Supplier, nor for breaches of NZ Regulator requirements, but purely by the original Sponsor not allowing their registration for that device - that is as a means of eliminating competition.

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).:

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).:

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).:

Response ID ANON-DPZ8-G4CT-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-09 15:15:14**

Submitter profile

What is your name?

Name:
Roger Smart

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Douglas Pharmaceuticals Ltd

Submitter Profile (tick all that apply)

Medical devices, Medicines, Active ingredients

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?

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).:
Section 3 (b): The regulation needs to be pragmatic in its application so as to serve New Zealand's needs and ability to provide in order that it does not become costly in terms of economics, resource or time.
Section 4 (a): I'd suggest the word "should" be removed since the likely benefits need to outweigh the l kely risks so as unsafe products do not become available for use.
Section 4 (d): Compliance with international obligations should also be pragmatically applied in accordance with the type of health care that use of therapeutic products comes under e.g. in the case of medicines, it is wasteful of resources to apply the EU form of pharmacovigilance to NZ since the EU form is more for innovator type medicines where little is known about the full range of AEs that a product may exhibit, whereas NZ under Pharmac's policies has become a generic market where the AEs that a particular medicine may cause are well known.

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. Please consider API for Active Pharmaceutical Ingredient rather than AMI for active medicinal ingredient as API is commonly used internationally.
2. Is the inclusion of "or an animal" in Section 26 (1) (b) intentional since the bill is for therapeutic products for humans.?
3. Out of interest, the current act includes the following statement in the interpretation of the word "administer" :"whether by direct contact with the body or not". This statement is not in the draft bill definition of "administer". Is there a reason for this?
4. Section 32 (2) states that: "...dispensing a medicine is part of manufacturing a medicine", however, Section 32 (3) states that: "Preparing a medicine for administration is not part of manufacturing the medicine if the preparation is done (a) in accordance with the responsible manufacturer's product information; or (b) by, or in accordance with the directions of, an authorised prescriber for the medicine. This appears wrong since in general dispensing involves a pharmacist taking a medicine in its final form and passing on to the patient with instructions as to use, i.e. the medicine as purchased by the pharmacist is unchanged during the dispensing process. Whereas if the pharmacist needs to do something to the manufacturer's supplied medicine such as reconstitute with water then the patient does not receive the medicine as supplied by the original manufacturer. Dispensing, compounding or preparation of a medicine for administration should not have any reference to manufacture as they are procedures employed for supply to an individual whereas manufacture should be kept strictly for supply to a a population.

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).:
Douglas Pharmaceuticals Ltd conducts a large research program in New Zealand for the purpose of developing generic medicines and seeking new dosage forms/indications for already known medicines. An essential requirement of this is the ability to import small quantities of reference listed drugs (RLD) from overseas for the purpose of comparative in-vitro and clinical trial investigations without RLD sponsor approval. It is essential that this import for non-sale purposes not be impeded or prohibited.

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).:
What is the relevance of reference to Pharmacist A (general supervision) and Pharmacist B (direct supervision)? Could be interpreted as requiring at least 2 pharmacists per pharmacy before additional pharmacy technician staff could be employed which may not be poss ble in the regions.

Question B7 - Please provide any comments on the authorisations for health practitioners :
Section 61 (4) should include the statement: “the patient is in New Zealand or is ordinarily resident in New Zealand” otherwise NZ health practitioners serving overseas with the military might not be able to administer therapeutic products to NZ military serving overseas. Or is this omission del berate in order to allow a health practitioner (HP) such as an HP serving in the military to administer a medicine to anyone irrespective of where they are in the world? How would this work with compliance with other country laws?

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).:
Should there be a definition of the word “patient” in the Interpretation section to define non-human animals as the patients of veterinarians and human animals as the patients of medical practitioners as defined in the Health Practitioners competence assurance act. If not, it appears that veterinarians could supply medicines to humans. Alternatively insert the word “animal(s) into each subsection of ss 66-70 to specify that patients in these sections are nonhuman animals.

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.:
Douglas Pharmaceuticals Ltd supports maintenance of the current right to advertise medicines directly to consumers under a self regulation system backed up by a regulatory compliance requirement where outcomes of the self regulatory scheme are ignored. Company advertisements complying with regulatory requirements as enforced by the self-regulatory scheme provide fair and balanced information and seldom if ever, provoke complaints to the Advertising Standards Authority

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).:
1> Product standards referred to in section 96 need to be pragmatic such that meeting them does not impose excessive costs on companies. The standards and their /interpretation application need to be clearly stated in order to prevent as far as possible "Regulatory Creep" occurring over time such as has been seen with application of the PH.Eur microbiological contamination requirements.
2. If a product is approved in New Zealand, will it require a second approval for export or does approval in New Zealand also allow export?
3. Further consultation on Section 100 is required as it has the potential to introduce major confusion in the supply of Therapeutic Products especially if it becomes a requirement to include product licence numbers in the labelling.
4. Section 102(2) should state: “The Regulator will, on application…” instead of: “The Regulator may, on application…” since the use of the word “may” indicates that even if satisfied, the Regulator can still refuse to transfer without having just cause to do so and this would be unfair. Section 102 (3) allows the Regulator to refuse transfer for just cause.

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).:
1. Section 121(2) should contain a third option being: “(c) the date of rejection of the application if not approved.” If an application is not approved, there is no reason to not allow another company to submit an application based on their own work.
2. Section 121(3). If the Regulator declines the application for an innovative medicine, why should there be a second protection period? This prevents another applicant applying even though they may independently have the API information that would allow their application to proceed.

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).:
1. Douglas Pharmaceuticals Ltd would ask that licences continue to specify classes rather than names of Therapeutic Products
2. In Section 127 (2) why is the word “may” used when the regulator is satisfied rather than “must”. Use of the word "may" gives the regulator the opportunity to decline issue of a licence without due cause. Section 127 (3) allows the regulator to decline with just cause.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
1. What is meant by Section 128(1) (b): “the number of responsible persons for the licence is not less than the number specified in the rules” Why would the number of responsible persons need to be specified with a lower or potentially upper limit?
2. Does Section 128 (2) (g) mean that a licence will be required for each and every clinical trial that a person may wish to conduct? Would there be any

opportunity for a CRO that conducts trials according to a defined protocol such as bioequivalence trials where only the Therapeutic product being trialled changes to be granted a single licence for all such trials to be conducted within a defined time period such as 3 years?

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).:
1. Same comment applies to Section 134 (2) as descr bed for Section 127 (2) above

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).:
Douglas Pharmaceuticals Ltd agrees with the proposal to grant licences for 3 years and permits for two years.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:
Should there be an additional statement in Section 151 that allows the transferred licence or permit to remain in effect until such time as the Regulator makes a decision of continuance or cancellation?

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):
If the outcome of an application for review is setting aside the original decision and referral back to the Regulator for a new decision, is there any provision for refund of the review fee since it would not have had to be paid if the correct decision was made in the first place. The further review under the decision would still be covered by the original fee paid.

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).:
Does the term: “Certificate of Status for overseas supply of therapeutic product” in section 221 include the certificate that is currently issued as a “Certificate of Pharmaceutical Product”? If it does is the intention behind use of the new term to allow the Regulator to issue certificates relevant to more than just pharmaceuticals?

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).:
Section 229 (3) seems to be in opposition to Section 230 in that 229(3) states the section does not prevent proceedings being brought where an enforceable undertaking relates, however, Section 30 states no proceedings may be brought where an undertaking is in force.

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).:
In Section 235(3) the Regulator is given opportunity to make submissions to the court concerning suspension or cancellation of the licence or permit. However, there appears to be no allowance for the defendant to submit counter submissions. The same observation occurs in relation to Section 236(3)

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).:
1. Douglas Pharmaceuticals Ltd does not agree with Section 267 (3) as it appears to give an opening to the regulator to ignore issuance of consultation on regulations, rules, notices and exemptions. This has been an issue in the past where Medsafe gave an undertaking to the Industry to consult on changes to the Therapeutic guidelines and then proceeded to make changes in some instances without consultation.
2. It appears that the current exemption of therapeutic products regulated under the medicines Act being exempt from requiring approval under the HASNO Act will not apply under the new bill. APIs will still come under HASNO and the appropriate pharmaceutical ingredient standard, however, finished product exemption from HASNO should be retained since they will have been assessed by a Regulator having a competence equivalent to the EMA.

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).:
Since there appears to be nowhere to comment on Schedule 1, I'm going to do so here

1. Schedule 1, Subpart 1 (7): Transitional evaluation fee for pending applications: Please confirm that applicants/sponsors only pay one fee for evaluation, either the fee due under the current Medicines Act or the transitional evaluation fee but not both.
2. Schedule 1 Subpart 12 (3) equivalent to a Medicines Act 1981 24(5) referral to the Minister appears to indicate that the CMN is rejected and a new application with new fee is required unlike now where the notification becomes in effect an application but no additional fee is applied.
3. Schedule 1 Subpart 14 (2) (b) gives a 6 month dating to a temporary approval issued under the new bill covering change from medicine to medical device, however, Subpart 14(3) appears to allow up to 1 year to submit an application for approval of the device., suggesting there could be a 6 month period where the device cannot be sold. Is this correct?
4. Schedule 1 Subpart 17(3) appears to be irrelevant since the sponsor is already stated to be and will be held under the bill to be respons ble for ensuring compliance of their therapeutic product(s) with regulatory requirements including manufacture so why should there be the need for a statutory declaration?
5. What does Schedule 1 Subpart 36 (1) refer to when stating "…clinical trial that is lawfully being carried out…have not been approved by the …." It is the understanding of Douglas Pharmaceuticals Ltd that currently no clinical trial can be carried out unless it is approved under Section 30 of the Medicines Act 1981.
6. Schedule 1 Subpart 39: Please confirm that applicants will not be paying fees twice for the same activity if started under current act and completed under new bill.

Schedule B question
Douglas Pharmaceuticals Ltd considers that in addition to the sponsor, the applicant also should have the right to apply for review of S 107 and S 109 decisions.

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).:
Douglas Pharmaceuticals Ltd supports the approach of setting performance targets and reporting against them. Performance targets provide industry with some indication as to when approval of new applications/variations might be expected which is helpful for planning product launches.

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.:
See response in Section B concerning fees payable

Question C4 - Please provide any comments on the approach to post-market controls.:
Please ensure that post-market controls applied are pragmatic and applicable to the generic market that NZ substantially is.

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.:
Douglas Pharmaceuticals Ltd endorses the move to have Hawkers activity authorised under the companies wholesaling 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?:
The only issue we can see here is how are such products going to be prevented from being used for a therapeutic purpose if they have similar features? If they have similar risks, should they not be regulated as devices?

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

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.:
We agree

Question C4 - Please provide any comments on the approach to post-market controls.:
Please ensure such controls are pragmatic and relevant to the market that New Zealand is

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.:
Why is there an indication that registration of specified trial information appears to be required to only occur in a publicly accessible registry that could be entered via the search portal on the World Health Organization's International Clinical Trials Registry Platform? The common registry used b New Zealand trialists is the ANZ clinical trial registry which is accessible on-line but not through the WHO. The ANZ registry is still easily access ble.

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:
Douglas Pharmaceuticals Ltd agrees with this approach

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:
No comment

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Douglas Pharmaceuticals Ltd endorses continuation of DTC advertising under a self-regulatory system with a secondary system of regulator enforcement if an advertiser ignores the outcomes of the self-regulation process. A regulator based control and enforcement should not be the first step as this can be a lengthy process with potential to firstly hold up release of advertising beyond the time it would be most effective and secondly not result in early action related to 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?:
Douglas Pharmaceuticals Ltd endorses continuation of DTC advertising. Advertisements compliant with regulatory guidelines and legislative requirements provide fair and balanced commentary compared to advertisements for non-regulated therapeutic products. It is important to note that under the self-regulatory scheme that operates in New Zealand, the Advertising standards authority has received little to no complaints about the quality of regulated therapeutic products

Response ID ANON-DPZ8-G4C6-T

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-09 16:10:12**

Submitter profile

What is your name?

Name:
ali alwash

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
PSNZ

Submitter Profile (tick all that apply)

Consumer

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:
Palmerston North manawatu

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?

Neutral

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).:

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?:
Mobile pharmacy services sound interesting and could be a great way to provide services in events and in disasters where one could set up shop quickly.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
yes. Pharmacists services should not be confined to the four walls of the pharmacy. Pharmacists can go to rest homes or patients homes to do medicine use reviews, advice and assessments. Regardless of being associated with a pharmacy the service is the same and should be enabled so patients can get the benefit of their services.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
pharmacists must get paid for their services not based on prescriptions dispensed. The advice and time we put into our patients need to be valued and paid for to encourage more quality services that lead to long term positive health outcomes for the patients. Major health improvements cannot happen overnight and regular advice and coaching is what pharmacists are great at so this should be incentivised.

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?:
Options 1 because I believe pharmacist are health professionals first then business people and every day we make decisions that are not in the best interest of the business and more for the best interest of the patient. I strongly believe if corporates are given the ownership and the power despite keeping a pharmacist in charge, financial incentives will have a much stronger sway on our decision making, as the bottom line is better profits for the shareholders. The pharmacist in charge would feel pressured to meet targets and maybe pharmacists who are more willing to work to that end will be more popular. Hence incentivising the profit first behaviour would change the pharmacy culture and expectation as we all want a job and to pay our mortgage and maybe go to Hawaii if we meet X target.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
That we continue to discuss how much we should get paid per dispensing instead of focusing on what services we can provide that we will get paid for.

Question C25 - Are there ways in which Option 1 could be improved?:
we need a body that represents all the pharmacists in the country to make our voice heard. Not the guild (pharmacy owners), or green cross, or PSNZ as they have many roles.

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?:
Yes ownership and control should be the same

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?:
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?:

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
because I believe pharmacist are health professionals first then business people and every day we make decisions that are not in the best interest of the business and more for the best interest of the patient. I strongly believe if corporates are given the ownership and the power despite keeping a pharmacist in charge, financial incentives will have a much stronger sway on our decision making, as the bottom line is better profits for the shareholders. The pharmacist in charge would feel pressured to meet targets and maybe pharmacists who are more willing to work to that end will be more popular. Hence incentivising the profit first behaviour would change the pharmacy culture and expectation as we all want a job and to pay our mortgage and maybe go to Hawaii if we meet X target.

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, I don't know if it is wise to be able to generate prescriptions and dispense them. This may lead to advising patients to use your pharmacy which is unethical

as it can limit the patients' choices or make them feel obliged to go there.

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-G435-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-09 22:51:43**

Submitter profile

What is your name?

Name:
Frances Hill

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Unichem Onerahi Pharmacy

Submitter Profile (tick all that apply)

Consumer

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).:
I have never considered dispensing to be a manufacturing activity, the compounding aspect of a few items we dispense in a pharmacy might be considered manufacturing eg suspensions for babies , mixing of creams where no proprietary products are available, but dispensing generally is matching an already manufactured product to a person, a therapeutic need, a prescription request from another health practitioner, a check for interactions, dosages, patient suitability, and fit for purpose for the condition the patient is presented with, attached to counselling, adherence and patient need. Not manufacturing, but a patient centred service, Dispensing doesnt align with manufacturing, as a patient centred function , it is more of a fit with a clinical focus

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 this section as it maintains quality and safety for the New Zealand consumer

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).:
I support this section and if you are looking further at the fine print, it would be good for a pharmacist to be able to supply 5 days worth of medicine for an emergency supply. Some of our holiday weekends are more than 3 days long. I think the pharmacist has the professional ability to supply 5 days safely in sepcific situations

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59).:
I support this, enabling pharmacies to supply another pharmacy in certain situations like stock shortages and the ability to use up part packs of expensive medicines would be helpful in reducing wastage costs. It would also enable the utilisation of scarce resources to the most needy patients in short supply situations

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

Question B7 - Please provide any comments on the authorisations for health practitioners :
Community pharmacies have a good coverage across New Zealand. If some areas are lacking access, supporting pharmacies into those areas would be a good option to enable access for patients. Maintaining a distribution service separate to prescr bing is important to both maintaining quality of the supply chain - storage, security , - cost effectiveness of the supply chain/logistics and patient safety. 1 practitioner prescribing and a 2nd practitioner checking, through the dispensing of the product helps maintain patient safety. Currently community pharmacy is the main gateholder of the prescription record, monitoring for interactions, duplication of therapy and appropriateness for patients as patients are seeing more different prescr bers for more diverse needs eg mental health team, GP, eye specialist... these prescr bers are not always connected with each other, pharmacy maintains the connection for the patient and can oversee those combination prescr bers to keep the patient safe. If more health practitioners were enabled to prescribe, then more patients could access funded medications, which could help reduce equity barriers.
Pharmacy and Pharmacists must meet very strict quality and code of ethics obligations when medicines are supplied. Equivalent rules would need to be imposed on other health practitioners if they are allowed to dispense pharmacy and pharmacist level medications, recalls, adverse event reporting, misuse monitoring

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
Quality controls would need to be tight around the training requirements of health practitioner's staff and how control/ what supervision of those staff would entail. Pharmacy has rigid training obligations for continuing education, qualifications and supervision of staff. Processes around dispensing are tight to maintain patient safety. Near miss, incident learning, dispensing accuracy, systems analysis, maintaining dispensing records - all of this would need to be considered in the training of any staff and set up of any location, that would be involved in dispensing to ensure a safe process for patients/consumers. It is not the sale of any good, it is a therapeutic product - safety and quality is paramount to improving health outcomes, reducin ghte burdon on our hospitals

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

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

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
Enabling suitably qualified pharmacists to prescr be certain medications in specific situations seems reasonable in terms of reducing barriers to access in a safe way, and potentially reducing some general practise workload, particularly in the area of minor ailments
Supplying therapeutic products via a vending machine should be a last resort approach, so only in areas where a community pharmacy service is not viable, quantity and type of product would need stringent regualtion. Oversight of any vending machine should come under the clinical oversight of a full service pharmacy

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
not sure about this/ seems reasonable

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).:
Sorry, I havent read the detail on this

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
Sorry, I haven't read the detail on this

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).:
Sorry, I havent read the detail on this

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

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:
Sorry, I haven't read the detail on this

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).:
Seems reasonable

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 concept of one type of licence with varyng scope and content seems reasonable

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
Dipsensing within a licence would need to still be in a location that provides safety to all concerned eg access to equipment, storage requirements and I guess these minimum standards would need to be a part of the licence - not sure how that is anticipated to work

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 seems like a good option

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).:
This looks good

Question B22

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

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).:
Seems reasonable

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).:
Sorry havent read this though to enough detail to comment

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:
Sorry havent read through thoroughly enough to 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):
Sorry havent read through with enough thorouhness to 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

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).:
seems reasonable

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

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

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

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
Whilst compounding in a pharmacy could be considered manufacturing, I dont see hbow dispensing can be. Dispensing is a patient centred activity

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?:
It makes sense that people need to use the regulated supply chanel to source medicines from overseas. This will aid safety and appropriateness of treatments

Hawker’s licence

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

Transition

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

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?:
Safe, High quality, Patient centric, Timely , accessable
Dispensing in licenced premises alongside onsite clinical advice relevant to the prescription
Other clinical pharmacy services could be offered at locations convenient to the situation eg in the patients home,at a gp surgery, in a hospital, in a community pharmacy

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
Specific clinical services can be provided now in a patients home, in a GP surgery, at field days, on a marae, in a hospital, in a mobile van, in a pharmacy. As far as I am aware current pharmacy licencing requirements enable this. Dispensing however needs to be at a "licensed premise" , some aspects of clinical service are best done at the site of dispensing , timeliness and accessability being major considerations

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
Dispensing needs to be at a "licenced premise" to maintain quality, efficiency of supply chain, access bility close to home, timeliness, security . As dispensing is highly patient centric, it needs to be at a place where pharmacists can have immediate clinical input. Dispensing to known customers improves adherence, l kely reduces errors and improves safety and clinical care

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?:
Commercialisation of pharmacy business by big, remote operators can put undue pressure on the responsible pharmacist to improve profitability. There is likely to be a power imbalance between the owner and the responsible pharmacist who wants the job/ needs the job,making it difficult to maintain ethical and professional standards, customer experience, taking on hte more difficult services/ inputs that are needed to reduce inequities

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 - improved ability to form long term relationships between the pharmacist, the patient and other local health practitioners. Ownership ties a pharmacist to one pharmacy for a longer period of time, often a lifetime, this stability can be helpful to providing patient specific care .
Reputation/customer experience/ service quality - is way more important in a smaller business - if a person has invested their own livelihood into a business - the motivation to succeed becomes even more important. This connection is often lost for wage/salary earners
Pharmacists often have a duty of care that goes beyond profitability. Historically we have provided advice/services at no charge. We have enabled a model of everyone can see a pharmacist within 15 minutes, always, mostly at no charge - no other health provider does this. This is often done without consideration of profit, large players are unlikely to do that to the same extent, as their is no financial incentive to provide these extra services.
Effective control is easily identified back to the owner/controlling pharmacist via option 1. This can be enforced easily by the pharmacy council

Question C25 - Are there ways in which Option 1 could be improved?:
Ensuring the owner pharmacist has full control of all operating decisions is a simpler cleaner situation than option 2 . The code of ethics, pharmacy council has full control of continuing education, quality and behaviour expectations and can act swiftly if required for poor performance

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
All oversight of dispensing, clinical services, advice, sales of pharmacy/pharmacist medicines - governance and operating decisions, training and development of employees

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?:
For ownership requirement to be effective both majority ownership and effective control needs to be combined

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)?:
maximum of 5 pharmacies per pharmacist should continue. It would be very difficult to maintain effective oversight with more than 5 pharmacies

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
Equal and joint respons bility. If one partner holds greater than 50 % of the shareholding then they should be deemed to be the major shareholder and have the responsibility of effective control

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?:
Ideally current ownership models would be grandparented. All new ownership would need to fit with the new law, existing models phased out as ownership changed

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 dont know enough about friendly societies to 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?:
Risks - the respons ble pharmacist being unable to maintain professional integrity under the imbalance of power from an owner intent on commercial success.

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, I don't see how the risks could be mitigated

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?:
. Pharmacy technicians are not skilled enough to understand clinical decision making to a level required to keep the patient safe. They need NCEA level 2 and attain a level 4/5 certificate - no where near the depth required for clinical decision making.

Remote oversight would be incred bly difficult to attain in real life. Emergencies happen now and need to be dealt with quickly and effectively - eg customers dropping off forged prescriptions, medical emergencies eg potential anaphylaxsis, seizures - customers do this in pharmacies reasonably often. Prescription issues that need urgent attention eg urgent medicines with clinical interactions, the patient doesn't have time to wait The pharmacist needs to be at the patient interface not the technician. eg last week the technician rushed through a script for Rivaroxiban and Digoxin thinking this is a very simple script and wondering why it was taking so long to get out- no attention was given to the dabigatran supplied last week, the renal function, time of day requirement for digoxin blood levels, the fact that the man is on the verge of needing rest home care and not managing well at home, living alone , the need to consider LTC registration and care - just a patient on 2 tablets a day

Remote clinical advice would be appropriate in certain situations, medicine reviews, medicine therpay assessments, specialist clinics eg diabetes could be done anywhere. Dispensing and its associated clinical component needs to be in a fixed space, easily identifiable and available to the public, large enough to hold range of medicines and provide these in a timely manner, close to home, quality safe systems. Hubs of a size that patients can form relationships with the team, the pharmacist can help advocate for the patient to navigate the health system, become more involved in population health initiatives, risk management - keep people out of hospitals by providing a stable trusted point of contact - continuity of the medication record.

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?:
It is hard to see how this conflict of interest could be mitigated

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

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
Depots and retail only licences should only be available in areas wher pharmacies are not viable - inability to attract staff. population numbers too low to support a viable 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?:
Personal importation should be banned, controlled access to medicine is important to maintain safety of the individual and the population. There are adequate supply chanels to access medicines from overseas via the standard controlled channells

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?:
If quality standards are met and quantities can be expected to be used within a reasonable timeframe, then this should be a permitted activity

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
Supply to another pharmacist in low stock situations would be helpful. As would pharmacies being able to pass on broken packs of expensive medications to be used at another pharmacy - this would be helpful to reduce waste - both monetary and envoronmental

C7 Retail sector

Question C42

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

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 seems reasonable

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.):
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?:
this looks good, it seems to be supported better informed consent

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?:
Only medical practitioners should be able to prescr be non registered therapeutic products

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?:
positive, Medicines can be safely accessed via standard approved pharmacies/wholesalers. This is safer for the individual and the country as a whole

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:
I can't think of any

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?:
I don't know

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, dispensing by a second health practitioner is a very important safety net for the patient.
They have not been trained to dispense. They are unlikely to have the systems or premises at the standard required for dispensing.
Increase the scope of practise for prescribing so the patient can access funded 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?:
No - they do not have the training, systems or premises in place to safely do this. They have not been trained to "dispense". Dispensing involves a lot more than just taking a product off the shelf and putting a label on it

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?:
Seems reasonable

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, the adds never give a comprehensive view point. People can be very convinced by ads and it gets difficult to reason with them

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?:
Seems reasonable

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 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?:
I support this

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
not aware of any situations where this might apply

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:
Dispensing at licenced premises supported by clinical pharmacists on site

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Some clinical activities can be performed anywhere that best suits the patient or situation eg diabetes clinics, in homes , in gp surgeries, in hospitals, in community pharmacies - medicine use reviews, comprehensive medicine management, disease information type clinics - but keep the clinical aspects of dispensing integral to the dispensing -

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?:
Commercialisation of pharmacy business by big, remote operators can put undue pressure on the responsible pharmacist to improve profitability. There is likely to be a power imbalance between the owner and the responsible pharmacist who wants the job/ needs the job,making it difficult to maintain ethical and professional standards, customer experience, taking on hte more difficult services/ inputs that are needed to reduce inequities

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Benefits - improved ability to form long term relationships between the pharmacist, the patient and other local health practitioners. Ownership ties a pharmacist to one pharmacy for a longer period of time, often a lifetime, this stability can be helpful to providing patient specific care .
Reputation/customer experience/ service quality - is way more important in a smaller business - if a person has invested their own livelihood into a business - the motivation to succeed becomes even more important. This connection is often lost for wage/salary earners
Pharmacists often have a duty of care that goes beyond profitability. Historically we have provided advice/services at no charge. We have enabled a model of everyone can see a pharmacist within 15 minutes, always, mostly at no charge - no other health provider does this. This is often done without consideration of profit, large players are unlikely to do that to the same extent, as their is no financial incentive to provide these extra services.
Effective control is easily identified back to the owner/controlling pharmacist via option 1. This can be enforced easily by the pharmacy council

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Risks - the respons ble pharmacist being unable to maintain professional integrity under the imbalance of power from an owner intent on commercial success.

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

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

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 -

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-G4C5-S

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-10 14:30:56**

Submitter profile

What is your name?

Name:
Tyson Hammond

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Tui Balms

Submitter Profile (tick all that apply)

Industry body

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?

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 hope when you class Category 4 medicines that may be more of a therapeutic Natural Health Product than a medicine, that you don't make it too difficult and

expensive for small NZ businesses to make a therapeutic product with simple natural ingredients that can be sold in retail shops. I would l ke that Natural therapeutic products be able to claim a therapeutic use if there is sufficient evidence to back it up. Plus for the evidence used to be able to be from both traditional use and clinical use, not just clinical evidence. Traditional use evidence is important I believe in this country.

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).:
For me this all depends on what you class as a medicine. We work in the Natural Health Products Industry but we also create products that are in their essence therapeutic. If you class our therapeutic products as medicines and we have to get them approved before exporting them then this could become problematic and an extremely slow process based on my experience with governing bodies of these kind of 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).:
For us it's important that there isn't just broad spectrum controls for the manufacturing of therapeutic products. For example there doesn't need to be the same restrictions/rules for the manufacturing of an anti-inflammatory topical cream as there for a pharmaceutical drug for Heart congestion. Surely the two can be differentiated between one having more controlled manufacturing and one having a less controlled manufacturing standard.

I think great care needs to be taken if natural products like essential oils or infused oils for topical use gets tighter controls over manufacturing, storage and transport etc... The supplier would need to invest in the infrastructure to do this which would raise the cost of the oil, therefore the cost of the product, therefore some consumers from the lower socio-economic class wouldn't be able to afford it unless it's subsidised but I don't see that happening. So therefore the tighter controls push this kind of product out of reach for some people that may really benefit from its use.

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).:
Again we'd l ke to see different tiers of all the therapeutic products with Tier 1 being high risk products that could cause a lot of harm to someone if the dose or the ingredients were slightly different. Whereas the lowest tier would be a topical cream the may be good for inflammation for example and the worst that could happen if there was a mistake in the manufacturing would be it didn't reduce the inflammation of the muscle. With those tiers ideally would come more relaxed manufacturing protocols, conditions and regulations for the lower tiers compared to the high risk products in the Tier 1 category.

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).:

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).:

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

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.:
We think it's important to differentiate between high risk and low risk therapeutic products when it comes to good manufacturing practices (GMP). If we choose to make a massage balm that has some therapeutic action but we have to manufacture it based on the Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice we will probably think it's not worth the time, effort and investment to make it a therapeutic product. This is where a lot of niche small scale therapeutic products could be lost in NZ if there not a tier system of rating which are high risk and which are low risk products relating to how they are manufactured. Sure they have to have safe ingredients and be made in a sterile production room but not to the level of making a pharmaceutical tablet that is ingested for angina or high blood pressure. Commonsense should be a high priority if we are to support this kind of grass roots NZ product.

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.:

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 C22Which 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?:

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?:

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.:
Minor breaches of advertising laws should warrant a warning to change was is being claimed or advertised before a fine or prosecution. Using fear of prosecution or heavy fines can often force an adverse and more cunning way to be found around the law. Creating fear in people to control behaviour doesn't always create positive reactions.

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 think DTCA of prescription medicines should continue to be permitted. My reasons are that it only supports the larger pharmaceutical companies who can afford the most vis ble advertisements to sell more products which may not be the most suitable or most effective for the patient. The biggest argument for the DTCA to continue seems to be that it prompts people to go to the doctor to discuss their symptoms which may or may not be real symptoms, or symptoms important enough to go to the doctor for. GP's are already over-loaded in this country and there are many nutritionists, Chinese medicine practitioners, Naturopaths, Medical Herbalists that these patients could go to first before their GP if only the government would support these alternative practitioners by integrating them more into the mainstream healthcare system therefore creating a more holistic healthcare system.
This DTCA largely creates fear in people that they have a certain condition which drives them to their GP. Is creating fear a good motivator?? Stress creates disease!!

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Minor breaches of advertising laws should warrant a warning to change was is being claimed or advertised before a fine or prosecution. Using fear of prosecution or heavy fines can often force an adverse and more cunning way to be found around the law. Creating fear in people to control behaviour doesn't always create positive reactions.

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 think DTCA of prescription medicines should continue to be permitted. My reasons are that it only supports the larger pharmaceutical companies who can afford the most vis ble advertisements to sell more products which may not be the most suitable or most effective for the patient. The biggest argument for the DTCA to continue seems to be that it prompts people to go to the doctor to discuss their symptoms which may or may not be real symptoms, or symptoms important enough to go to the doctor for. GP's are already over-loaded in this country and there are many nutritionists, Chinese medicine practitioners, Naturopaths, Medical Herbalists that these patients could go to first before their GP if only the government would support these alternative practitioners by integrating them more into the mainstream healthcare system therefore creating a more holistic healthcare system.
This DTCA largely creates fear in people that they have a certain condition which drives them to their GP. Is creating fear a good motivator?? Stress creates disease!!

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?:
Sounds good to me.

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 C22Which 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-G43K-Y

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-10 16:47:03**

Submitter profile

What is your name?

Name:
Marie Bennett

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
All Seasons Pharmacy Ltd

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).:
Dispense a medicine (s 29) – the definition of dispensing has changed significantly. I am concerned about this change.

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. 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.

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.

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.

This would greatly benefit patients by giving them fast access to their prescr bed 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).:

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.

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 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 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. I also support the mechanism requiring a SCNSA when obtaining a medicine from overseas, and that the importation of the medicines is managed by the medical practitioner, a pharmacist or a wholesaler.

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.:
We support the replacement of 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 and will reduce wider workforce demands on General Practitioners.

Vending machines should only be in locations without a pharmacy or pharmacy depot, and to ensure correct clinical oversight, should be controlled by a full-service pharmacy.

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).:
Section 124 would allow for dispensing and supply at an aged care facility. I 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 required for audit.

How would dispensing at an aged care facility 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).:
The benefit of a single licence is that it will maintain clinical oversight and transparency over every aspect of pharmacy activity.

It is difficult to see how medicines can be safely dispensed outside of a pharmacy given they would not have access to equipment, record systems and clinical resources.

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).:
It is important that the system is flex ble enough to respond quickly in emergency situations to minimise disruption to patients' access to medicines.

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).:
Issuing licences for three years should be the norm unless quality concerns that have arisen during the licence term have not been promptly rectified. This will reduce compliance costs.

It is appropriate for licences to be automatically transferred in specified circumstances to prevent disruption to patients that would arise from the sudden closure of a pharmacy business.

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.

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 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.
The safety profile of medicines imported from outside the approved supply chain is unknown. Restricting personal importation ensures 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.

Patients that import medicines for personal use miss the opportunity to receive the appropriate care and advice 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:

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?:
Alternative distribution systems, and new models of health care must not undermine the intent, security, and integrity of the services of which patients are entitled to rely on.

The Consultation Paper gives practical examples of pharmacist services at a marae and major public events. These are opportunities to engage with the public, improve health literacy, and provide other services, e.g. blood pressure checks, etc. that would not normally be provided outside a pharmacy.

We do not, however, see how medicines can be dispensed outside a properly-equipped and staffed pharmacy dispensary.
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?:
I do not believe that current licensing requirements create a barrier to innovation. Licensing requirements establish the requirements for safe and effective provision of pharmacist services involving medicines.

Service innovation requires attention to factors, such as IT systems and processes as enablers for innovation (eg electronic health record), improved workforce collaboration (eg better integrated service models for meeting patient needs) and achieving alignment of policy and funding settings for primary care. 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.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
I am supportive of service innovations such as providing marae-based services or providing pharmacist services at public events as a way of addressing health equity issues, as well as increasing health literacy and encouraging regular contact with a health professional, assuming this would not include dispensing outside of a pharmacy dispensary.

I am also supportive of mobile pharmacy vehicles as an alternative solution to service rural areas currently serviced by pharmacy depots but believe that this should be as a collection point, as opposed to a vehicle within which medicine dispensing was able to take place

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?:
The public benefits when the network of community pharmacies is owned by pharmacists accountable for their patients' care.

I strongly believe that there is strong public benefit 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?:
Ensuring that a pharmacist owns and controls a pharmacy is a social objective that reflects community expectations and the desire to maintain the integrity of the professional relationship between pharmacist and patient, 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. This is overseen by the owner pharmacist.

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. This includes resolving minor health issues quickly in the pharmacy and helping patients find the right health services to meet their needs. This is particularly valuable where patients have cost or appointment barriers to accessing other front-line primary health services, such as general practice. I believe that corporate owners would l kely 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, however this risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws.

There is a risk that there could be a lower level of external investment from the dividend requirements under Option 1. This could be mitigated by legally requiring the owner pharmacist to have a 'veto share' so that the owner pharmacist is always in control of all voting rights on governance and operating decisions that have an influence on public safety

Question C25 - Are there ways in which Option 1 could be improved?:
There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. I believe that Option 1 could be improved with grandparenting provisions for pharmacy business that are operating legitimately under current rules.

The Bill should consider improving Option 1 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. 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 flex bility 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 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 poss ble to another pharmacist, and 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 (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 respons bilities 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 decisions that affect patient safety. 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 respons ble 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)?:
I would be able to provide a more considered response if the Bill was clear around the criteria that would apply in deciding whether the number, scale and location of other pharmacies would allow appropriate oversight to the owner pharmacist.

The five-pharmacy limit means that pharmacy ownership is spread across a large number of individual pharmacists, it also means that no single pharmacist owner has
enough market power to set market prices or contract terms. This means that current pharmacy ownership rules provide an important public benefit

I think appropriate oversight of a pharmacy is effective control – the owners need to demonstrate governance of the business (they control the board). The day to day clinical oversight of the pharmacy can be delegated to a pharmacy manager (who is a pharmacist).

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. The five pharmacy limit could be applied by only allowing a pharmacist owner to have five ‘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?:
From a pharmacist owner’s perspective I think the impacts would mostly be financial. There is a risk that private investors may sell down their shareholding in pharmacy, leading to a 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 ‘veto share’ so that this pharmacist is always in control of all voting rights that affect patient safety, and therefore has effective control. This would enable the Bill to consider flex bility 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.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:
The Act should include provisions for grandparenting the pharmacy businesses that are operating legitimately under current rules.

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 support pharmacist ownership (Option 1) and think this should apply to all pharmacies. However, in the case of Friendly Societies that are already established under current rules and are unable to reasonably restructure their effective control arrangements, grandparenting 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?:
I am concerned that removal of majority pharmacist ownership of a community 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.

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.

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.

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.

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?:
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 prescr bing 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 A berta, 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 prescr bers, 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?:

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 bu k 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?:
I think it is appropriate 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.

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 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.

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 prescr bers 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?:

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

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 believe that health practitioners should be authorised to supply category 3 (pharmacy) medicines to their patients.

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, I would expect that if health professionals were to be able to supply category 3 medicines, that they would have to meet the same qualifying 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?:
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 l ke 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.:

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 C22Which 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-G43Z-E

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-10 21:16:59**

Submitter profile

What is your name?

Name:
Shirley Vollweiler

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
NA

Submitter Profile (tick all that apply)

Consumer

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?

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).:

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.:

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?:
DTCA should be banned. It is inappropriate; people are not given enough or balanced information in such advertising.

Response ID ANON-DPZ8-G43A-N

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 11:49:39**

Submitter profile

What is your name?

Name:
John Cassidy

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

Consumer

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?

Not Answered

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).:

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.:

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?:

Advertising should not be permitted. The general population do not have the expertise to understand or assess advertisers claims and are hence vulnerable to being misled. Surely that is obvious. I understand that academic studies and GP experiences confirm this. The fact that only NZ and US allow direct advertising is alarming (and has echoes of the poor gun laws NZ has suffered from).

Response ID ANON-DPZ8-G43R-6

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 12:52:42**

Submitter profile

What is your name?

Name:
Eamon Duffy

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Auckland DHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Antimicrobial Stewardship

Pharmacist, Other health practitioner (please comment)

If you select 'Other', please comment below;:
Feedback is on behalf of Auckland DHB Antimicrobial Stewardship Committee

If you selected 'Other' please comment;:

Next steps after the consultation

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?:
The committee reviewed the proposed regulatory scheme and did not agree with the continued permission for direct-to-consumer advertising, and thought that New Zealand should be in line with the rest of the world (excluding the United States) in proh biting this activity.

The committee noted that continued DTCA was in contradiction to the Ministry of Health's Antimicrobial Resistance Action Plan (Priority Action Area 15) which would look to limit the availability. Continued DTCA of antimicrobials could directly counteract any activities that the Ministry, DHBs or PHOs undertake to promote limited and rational use of anti-microbials to prevent or slow ongoing antimicrobial resistance. Industry would be free to advertise and promote the use of broad spectrum ant biotics to the general public, that would no doubt be considered effective treatments and therefore meet current standards, but would not be in line with standard practice and be contradictory to messaging from governmental agencies.
The committee could see no positive benefit in Industry being allowed to continue to advertise antimicrobial agents to the general public.

Response ID ANON-DPZ8-G43X-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 13:08:40**

Submitter profile

What is your name?

Name:
Michael Hammond

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
WDHB

Submitter Profile (tick all that apply)

Health service provider (eg, Ambulance, M■ori or Pacific health provider etc), District Health Board (DHB)

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please 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).:

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?:

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?

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.:

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 should no longer be allowed. Only two countries in the world currently allow this; New Zealand & the United States.

Direct to consumer advertising can be misleading and increase the incidence of "Dr Google" behaviour. By removing DTC advertising patients will gain unbiased medical/medication advice from suitable medical professionals.

DTC advertising allows for larger pharma companies to push their products onto consumers; while they may not be the most suitable option. e.g. the heavy advertising of Breo has an significant increase in request from mild asthma sufferers for whom the product is not suitable as Breo is 2 x as strong as other agents.

It may perhaps be better to allow advertising of conditions advising to see their HCP if they are experiencing these signs/symptoms rather than the drug itself.

Therapeutic Products Consultation: Submitter Profile

If you elect not to use the online tool to complete your submission, please ensure you complete the following submitter profile form and send in via email with your submission.

☐ Individual ☒ Organisation

Name (of individual or organisation): Reynard Health Supplies

Email address: robin@reynardhealth.com

Profile (tick all that apply)

Perspective

☒ Consumer ☐ Disabled person ☐ Māori ☐ Pacific peoples

☒ Other Manufacturer

Industry

☐ Industry body
☐ Advertising
☐ Retailer (non-pharmacy)

Importer	Manufacturer	Wholesaler
☒ Medical devices	☒ Medical devices	☒ Medical devices
☐ Medicines	☐ Medicines	☐ Medicines
☐ Cells and tissues	☐ Cells and tissues	
☐ Active ingredients	☐ Active ingredients	
☐ Veterinary medicines	☐ Veterinary medicines	

Health sector

☐ Professional body (eg, Colleges, Pharmaceutical Society etc)
☐ Health service provider (eg, Ambulance, Māori or Pacific health provider etc)
☐ Private hospital
☐ Pharmacy organisation
☐ District Health Board (DHB) - please state which service area: Click here to enter text.

Health practitioner

☐ Pharmacist	☐ Surgeon
☐ Nurse	☐ Optometrist
☐ Midwife	☐ Dietician
☐ Dentist	☐ Medical practitioner (excluding Surgeons)

☐ Other health practitioner (please comment) Click here to enter text.

Clinical trials

☐ Medicines (other than cell and tissue)
☐ Medical devices
☐ Cells and tissues
☐ Trial ethics

Other

☐ Government agency
☐ Crown entity
☐ NGOs
☐ Veterinarian
☐ Other (please comment) Click here to enter text.

Official Information Act statement

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

Reynard
Health Supplies

17 Napier Road
Havelock North 4130
New Zealand
[redacted]

18 March 2019

SUBMISSION – THERAPEUTIC PRODUCTS BILL

Dear Sirs

I am writing to voice my concern over Medsafe's decision to now regulate "Antibacterial Hand Sanitiser" as a medicine. This is setting a dangerous precedent and in theory, every other Antibacterial product should be classed the same way.

Medsafe are saying that Antibacterial Hand Sanitiser has a Therapeutic purpose – I disagree 100%. Sanitiser cannot prevent or cure a disease. It is a tool, along with thousands of other tools (hand soap, cleaning wipes, floor cleaners) which all work together to keep a health facility clean and bacteria free.

I appreciate the bill is an extremely complex document – but if the "meaning of therapeutic purpose" is not clear, then it really makes a mockery of the whole bill.

The bill clearly states that the product, in this instance, "antibacterial hand gel" –

- "Preventing, diagnosing, monitoring, alleviating, treating, curing or compensating for a disease, ailment, defect or injury"

I disagree that antibacterial hand gel does any of them.

Yours faithfully

Robin Ferguson

Robin Ferguson
Managing Director
021 515 302
E: robin@reynardhealth.com

Response ID ANON-DPZ8-G45Z-G

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 15:12:52**

Submitter profile

What is your name?

Name:
Anna Kyle Clinical Advisory Pharmacist on behalf of T■Ora Clinical Group

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
T■Ora (Compass Health)

Submitter Profile (tick all that apply)

Health service provider (eg, Ambulance, M■ori or Pacific health provider etc)

If you select DHB, please state service area:

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

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

Other (please comment)

If you selected 'Other' please comment;:
Primary Health Organisation

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).:
Support the intent of the Bill for flexibility with detail and controls in other instruments attached to the Bill.
Flex bility to adapt and evolve supply and provision of medicine/ devices etc over time is necessary whilst ensuring no one rorts the legislation by not following the intent of the Bill.

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).:
Support this section of 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).:

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).:
Support the intent of this section

Subpart 3: Authorisations (ss 56–80)

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

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:
Support intent of this section

Question B7 - Please provide any comments on the authorisations for health practitioners :
Support this section provided practitioners are registered under their authorities appropriately and acting under their scopes of practice.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
Support if under direct supervision of the health practitioner for their patients.

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 intent of this section- quality and reliability of products is paramount

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

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
Strongly advocate for removal of DTCA provision in line with other countries (except USA) as per University of Otago petition and RNZCGP and other health agencies in NZ.
Recommend no 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).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:
Agree with intent of 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).:
Agree with intent of 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).:
Agree with intent of 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).:
Agree with intent of 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).:
Agree with intent of this section and flexibility.
Enables changes to future models of care.
Important for deprived communities to access medicine/ devices and via technology/ telemedicine/ depots. mobile services.
This may help improve equity for patients.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:
Agree with intent of this section as above

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).:
Agree with intent of this section

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).:
Agree with intent of this section

Question B22

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

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).:
Agree with intent of this section

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).:
Agree with intent of this section

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).:
Agree with intent of this section

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).:
Agree with intent of this section provided patient safety is paramount

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).:
Agree with intent of this section

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).:
Agree with intent of this section

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).:
Agree with intent of this section

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).:
Agree with intent of this section and need for consultation to ensure these are appropriate and robust

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).:
Agree with intent of this section.
Patient access to timely medicine/ devices is paramount and if this can be done more effectively/ simply then it should be.

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.:
Agree with intent of this section
Need for suppliers to be more helpful with information particularly on adverse effects/ use in particular patient populations eg elderly, pregnant and children

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?:
Agree with intent of this section

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.:
Agree with intent of this section. Legislation must align

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
Agree with intent of this section strongly in supporting ongoing pharmacovigilance which is world leading.

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.:
Agree with intent of this section
Also consider that if a medicine/ device has been beneficial for a patient that they be allowed to continue to access this without financial constraints at the end of the trial

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?:
Agree with intent of this section

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?:
Agree with intent of this section

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.:
Agree with intent of this section

Question C4 - Please provide any comments on the approach to post-market controls.:
Agree with intent of this section strongly

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.:
Agree with intent of this section.
Also encourage consideration of allowing patients to continue on a treatment that has been beneficial past the end of a trial rather than to have it stopped or a huge financial barrier imposed

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?:
Agree with intent of this section,
Safety and integrity of products needs to be improved and this may help in this regard from products not sourced through the usual supply chain

Hawker’s licence

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

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?:
Flex bility in services offered and supply of medicines to patients especially in remote/ isolated/ high deprivation communities eg mobile services, depot/ telemedicine, virtual contact eg skype as they may not have a pharmacy premise

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:
Need flexibility for services/ activities that do not involve dispensing

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:
Provided it is secure/ safe and overseen by a Pharmacist then allow activities/ supply however the community requires it.

Question C22Which 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?:
Some communities may not be able to sustain a pharmacy business in the current model.
Support open ownership, removal of 5 pharmacy limit but with appropriate detail in instruments to limit the potential risks eg fewer medicines offered/ supplied (cherry picking) and ensure pharmacists supported legally so owners cannot force undue pressure to not comply with legal requirements with heavy penalties if not done.

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?:
Provided the instruments/ detail of the Bill is robust o activities and who can do them, then it may not matter

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)?:
This number may no longer apply in the age of virtual contact/ technology and so we support removal of this or a change to a more appropriate figure as determined via consultation and evidence

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?:
If open ownership is allowed- then this may not be an issue provided all legal requirments where followed as in the instruments of the Bill

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Allow different communities/ areas to access the pharmacy activities they need/ want with appropriate DHB approval and control on what will be supplied as conditions of a license

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?:
Need to ensure the instruments also support the supervisory pharmacist with strong penalties for non-compliance/ undue pressure on the pharmacist

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?:
Broaden this to allow virtual oversight/ advice eg Skype/ telemedicine especially in remote/ isolated or areas of deprivation that may not have a pharmacy service

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 this is not required but with provisos
Risks- conflict of interest and increased volumes of prescriptions
If the appropriate instruments/ controls are detailed and prescribers are monitored by their authorising bodies then this could be mitigated and the 99% of prescribers who do this ethically and professionally would not be hampered by a litigious system.

Monitoring of ePrescr bing will be easier and allow backroom audits/ monitoring to be done and further investigation if required.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
Agree with intent of this section
Areas of deprivation/ isolation/ rural and after emergencies/ disasters

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:
Agree with intent of this section

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 with intent of this section

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?:
Agree with intent of this section
eg emergencies/ disasters
If an area suddenly has no pharmacy service due to death/ illness and known that there will be a strrong demand eg epidemics

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:
If the medicine/ device was needed in another area and wholesale supplier unable to supply in time or at all eg short stock/ lack of imported supply/ supply chain break but individual Pharmacies have some in stock.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:
Agree with intent of this section

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)?:
Agree with intent of this section provided it does not cause undue financial or compliance burden

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.
Agree with intent of this section - every prescriber must do this with the utmost quality and professionalism and safety for patients.

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.):
Agree with intent of this section

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:
Agree with intent of this section
Always important for risks to be weighed against benefits if off-label/ unapproved use to protect patients

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 with intent of this section
But must ensure ongoing benefit to patient or review after specified time or ongoing monitoring as part of good prescribing/supply

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 with intent of this section
Too many products of unknown quality / guarantee being imported.
Some prescribers under pressure to prescribe when they are not familiar with or lack safety/ efficacy data.
This is done to reduce financial burden of some products- is there a way this could be addressed if the product was beneficial for the patients treatment?

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:
as in C7
eg in times of supply chain interuption/ epidemic/ emergency or post emergency if they have supply and a patient requires it

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?:
as above
make it as simple as possible to supply the patient if they need it whilst ensuring supply chain integrity eg cold chain

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?:
Agree with intent of this section.
Does the category "pharmacy medicine" need to be changed to reflect where/ who can supply it? eg "authorised practitioner" medicine or something l ke that"

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 under direct supervision/ instruction of the health practitioner acting within their scope of practice

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
Make DTCA illegal in line with all other countries (except USA) and in light of petitions from Otago University April 25 2006, RNZCGP and other health agencies

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?:
It should not continue it puts undue pressure on prescribers to use the "latest thing on TV" even if patients are not suitable or it is possibly not appropriate for them as Ads do not involve the complete clinical scenario for patients.
It sets up unrealistic expectations of the public and patients and potentially undervalues/ dismisses safer more widely used treatments that would be more appropriate for the patient

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:
Agree with intent of this section and maintaining supply chain integrity and reducing risks of diversion/ unsafe use

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
Make DTCA illegal (as per previous sections)
Agree with intent of this section

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?:
It should stop (as per response in previous section)

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?:
Agree with intent of this section

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 with intent of this section

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?:
Agree with intent of this section providing there is not an undue financial burden to patients if the treatment is appropriate/ beneficial

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:
Possibly
eg for a rare condition and/ or a medicine not likely to be available under the NZ supply chain or which is too expensive to obtain via other channels if it has been shown to be effective and safe for that individual patient

Pharmacy licensing

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

Mobile services
Virtual services/ access to clinical advice remotely and subsequent supply
Anything that makes it easier to get the medicine/ device to the patient and reduce opportunities for the patient to not get the item e.g cost, travel, transport, time

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:
Agree with intent of this section and building flexibility into the Bill by keeping it broad to facilitate new arrangements over time that we dont even foresee yet

Question C22Which 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?:
Flex bility of supply / activities is paramount for different communities/ areas where a pharmacist ownership is not financially viable or available
Employing pharmacists to do activities may be a more cost effective option for some areas

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:
Some areas wont have a pharmacy if they are financially not viable/ sustainable

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:
Cherry picking (not carrying full range of medicines required by customers)
Financial pressure on staff/ pharmacists to operate in an unsafe environment eg huge volumes of prescriptions, time constraints where appropriate advice is unable to be given

ensure the Bills instruments eg conditions of license contain correct detail to mitigate and prevent this from occurring

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?:
Yes, provided they are "suitable/ authorised persons" for a patient under their care
Possible risk of supply to non-patients but this should not occur if practitioner acting under their professional/ legal and ethical responsibilities

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 if under direct supervision/ Okay of their health practitioner for a specified patient

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:
Agree with intent of this section as per previous section response
Make DTCA illegal

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?:
It should not continue
all other countries (except USA) do not allow DTCA
undue pressure by public on prescribers even if the "new product" is not suitable/ appropriate for them/ their condition
Fully support and endorse positions put forward by University of Otago and Royal New Zealand College of General Practitioners.

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, to ensure quality/ safety for consumers provided no undue financial/ compliance burden for a useful/ beneficial product

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.:
Agree with intent of this section

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Dear MOH

I wish to make a brief submission/statement on the impending Therapeutic Products Bill which is below.

"My name is John Goodwyn Lewis and I am a scientist working at Canterbury Health Laboratories in Christchurch Hospital. I have worked in a diagnostic setting for 40 years and have a Ph.D from the University of Otago and degrees in Chemistry and Biochemistry. I have published over 140 research papers in peer reviewed medical and scientific journals mostly about the invention, development, validation and clinical application and utility of novel diagnostic tests.

In this endeavour I am not unique as many of my colleagues similarly invent and innovate flexible diagnostic tests across a wide range of pathology disciplines with the ultimate aim of improving patient care. This is one reason why Canterbury Health Laboratories is regarded as a leading provider of specialist diagnostic testing in the southern hemisphere and an integral part of our wider teaching hospital campus.

Indeed as much as 70% of our overall test menu involves the use of "in house" invented tests which have all been soundly validated and are accredited by IANZ, the national accreditation agency. Therefore we view the impending Therapeutics Products Bill with some caution as some unintended consequences could arise as outlined in some bullet points below.

- It could compromise the flexibility of diagnostic testing which often depends on the needs of the patient
- It could stifle the ability to innovate new tests as medical and scientific knowledge advances
- Regulatory costs could prohibit the application of low volume or "in house" tests for patient care
- Proposed regulatory processes may duplicate existing mechanisms such as IANZ and practicing certificates

Whilst I am not against the need for regulation of some therapeutic products consideration should be given to waiving or exempting the proposed regulations and associated costs for specialist diagnostic testing, in approved facilities where, in most cases, the risk for patient harm is negligible."

Many thanks for this opportunity.

Yours sincerely

John G. Lewis

John G. Lewis Ph.D Steroid Biochemist
Steroid & Immunobiochemistry Laboratory
Canterbury Health Laboratories
P.O. Box 151
Christchurch
New Zealand

Dear Staff,

I support the concept of non- pharmacist owned pharmacy premises with the proviso that they have full professional oversight by a pharmacist. This will allow pharmacy access to those who live remotely or have no transport(via online based ordering systems).

I support the abolition of all DTC medication advertising (this creates bias in the market, and can lead to patient pressure on doctors to prescribe products for which there may be no benefit, high costs, and cause inappropriate prescribing in general). We must note that very few Western countries allow DTC drug advertising now.

We need to simplify the application process for special authority drugs, to reduce the huge admin burden on primary care ! There are also quite often delays due to IT issues/ incompatibility. I suggest you allow Fellows of the College of GPs more ability to prescribe more freely(we have very high quality specialist training) and those without speciality training (there are many " GPs" who have done NO GP TRAINiNG) will need to have more complex application systems to be safe.

We need to simplify the off label use of some drugs- there should be simple tick boxes on the script electronic field so it is clear that the use of these drugs is carefully discussed (eg quetiapine , which is far too widely used to help sleep disorders when it is actually an anti psychotic). The Section 29 bureaucracy needs to be overhauled- it is far too complex and time- consuming now to manage in primary care, esp for medications that are low risk such as melatonin etc.

yours sincerely

Dr SETalbot

GP

[redacted]

Response ID ANON-DPZ8-G4CP-M

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 17:38:24**

Submitter profile

What is your name?

Name:
Judith

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;:

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).:

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 and medicine definitions: Sun screen and herbal medicines/dietary supplements should also be included in this legislation, either from the start or in the near future. If the scope is broadened to include medical devices and an “unknown” future category, then surely it could be expanded to include both of these. Herbal medicines can be dangerous from their adverse effects, potential contamination, interactions and use in place of other medicines. Regulation would send a signal to consumers that just because they are “natural” they may not always be “safe”. Sunscreen is one of the main preventions of melanoma. By excluding them from regulation, sunscreens may have an SPF well below labelled level, which may increase the melanoma risk for those who believe they are protected.

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).:
60- supply of prescription meds by authorised pharmacists without a prescription shouldn't just be in the future, but needs to be immediate when the bill starts because this is already the case for trimethoprim, sildenafil, selected oral contraceptives and certain vaccines (currently the ECP, which was your other example is a restricted/pharmacist medicine).

Another idea that could be considered for future-proofing is to expand the definition of a "prescription".

In the last few years rest homes have move to electronic charting. These charts are approved by a medical practitioner with a personal log-in before being supplied. Would it be possible to move entirely to electronic charts? If a doctor has approved a medicine electronically, why should they also need to spend their time signing the paper that the pharmacy generated?

And for non-rest-home patients, they could also be on a charting system - the doctor prescr bes by charting, and must add a review date. Then pharmacists are able to supply medicine up until the review date, with a limit to the amount supplied at once, and the chart would have information about how much supply the patient has been given, visible to other pharmacies, to avoid over-supply. This chart would be accessible to pharmacies and prescribers, and synced immediately so everyone has an updated medicine list, therefore eliminating the need for medicines reconciliation. The consumer interface (app/website) could allow them to track what medication they are on, links to medicine information, and the ability to check when they need to go to a pharmacy or review with the GP or specialist. The chart could be integrated into dispensing and prescr bing software, and include medicine allergies and relevant details like renal impairment. This system would eliminate the need for repeat prescriptions, which are at worst filled with errors, and without the latest changes, or at best are a hassle for patients, pharmacists, reception staff and GPs to request, chase up, check and sign. When we have a GP shortage, this is a way of freeing up their valuable time and reducing their admin tasks, while not compromising clinical appropriateness.

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).:
I agree with the need to have different qualifications for pharmacy workers, allowing them different levels of activity - for instance then a locum pharmacist will know whether they can trust a pharmacy worker to suggest a suitable OTC product for a simple query, and know when to refer. But I am worried that if there is a minimum required level it might impact the number of staff available, putting too much pressure on the pharmacist, and might also devalue the experience of some pharmacy workers. If compulsory qualifications are introduced there should be a way to credit experience.

Question B7 - Please provide any comments on the authorisations for health practitioners :
71- As long as there is relevant training that goes alongside - they might know what is needed, but should also know relevant precautions/interactions/contra-indications for the product. There would also need to be care taken that medicines are only sold under the correct scope - e.g. a podiatrist couldn't sell an antifungal cream for ringworm that the patient happens to have on their arm, even though it is the same product.

75 - off-label prescribing by non-medical practitioners should only be if both the medicine and the condition treated are within their scope. Some off-label uses are much more accepted and much more evidence-based than others, e.g. doxycycline for malaria prevention is standard practice and in guidelines, whereas quetiapine for sleep is more controversial. The same goes for unlicensed products - some are used less often so would require a medical practitioner to decide it is suitable, but others, such as melatonin are much more accepted. Personally I would prefer a nurse practitioner or pharmacist prescriber to be allowed treat insomnia with melatonin rather than quetiapine. There should also be a separate category for non-approved generics of an approved medicine, especially where the non-approved product is subsidised by Pharmac (usually in response to a stock shortage). This situation happens very frequently (recently with montelukast, oxybutynin, propranolol), and usually the prescriber is completely unaware that the brand being used is not licensed, and has no choice in the matter. If Pharmac has decided that a product is suitable to subsidise, then it should be considered safer, and should have similar requirements as off-label use.

To have a tick-box for a non-approved generic there would also need to be compulsory regular updates to medical practice software that requires the correct brand to be selected, and would also require hospital and specialist prescriptions to be computer generated. A tick-box should also briefly explain why it's needed, like "I understand this medicine is not licensed in NZ, so medsafe cannot guarantee its quality, safety or efficacy".

I agree that repeat prescriptions should be able to be written by other prescribers, with only the initial decision to prescribe being made by the medical practitioner. But there will need to be clarification around when a product either loses its license, or when a stock shortage means an unlicensed product is used, or even if something becomes off-license (as recently has happened for valproate for women of child-bearing age for bipolar) - can a nurse prescr ber repeat a prescription for this? Who will be responsible for knowing about the updated licensing?

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65).:
77- Their staff should only be allowed to supply pharmacy medicines on the recommendation of the health practitioner, or at least with similar training to pharmacy staff.

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 risks of non-approved non-prescription medicines are just as high as for prescription medicines - just as much chance of bad manufacturing conditions or counterfeits.
Allowing consumers to directly import bypasses the pharmacy and pharmacist, creating a loophole for people to have access to medicines without any health

professional oversight, essentially making class 2, 3 and 4 all just class 4, general sale. This means people are at higher risk of adverse effects from their medicines, interactions with other medicines, leaving more severe conditions untreated by masking them with continual use of OTC medicines. It also means that those abusing medicines have greater access to them, like codeine-containing products, dextromethorphan and promethazine. If you have any reason to decide that a medicine needs to be class 2 or 3, then there needs to be the same regulation across any means of purchasing those medicines.
Currently overseas importing probably only makes up a small portion of the market, but in the future postage will be cheaper, marketing greater, and the generations who are comfortable with online shopping will be at an age more l kely to purchase medicines online, and at greater risk of interactions and adverse effects. It should be assumed that this will be a major method of purchasing medicines in the very near future, which is why it is very important to ensure suitable regulation.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.:
92/93 - I agree that this would simplify classifications, but there should be brief mention of it still in the schedule.
95 - yes for general sale medicines, and possibly for pharmacy medicines but with questions/info that is presented first.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:
97/100 - advertising of medicines seems ok at the moment, but the problem is with dietary supplements / herbal products, which although their wording complies with current standards, consumers are l kely to misinterpret. If a regular consumer hears "supports healthy blood pressure and cholesterol" for a "natural" product, they are led to believe that the product will reduce their blood pressure and cholesterol as effectively as their prescr bed medicine, and since it's "natural", must be better, and therefore they take it instead of their prescribed medicines. The bill should include regulation of advertising of these products even if it doesn't regulate the product itself.
105 - Should also add in that a dispensing pharmacist cannot hold interest in a prescribing business, and proh bit the same individual or group from holding interest in both a pharmacy and prescribing business. But since the idea is to avoid conflict of interest, all these situations should be allowed if the two are not within a certain distance of each other, and there is a maximum percentage of crossover of prescriptions. This would allow a pharmacist who owns a pharmacy and then becomes a prescriber to still own the pharmacy, provided they only prescribe at a practice in another area of town where there is sufficiently minimal prescription crossover, and therefore would be no conflict of interest.

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).:
118 - "Non-payment of fees would be a ground for cancellation" - but if Pharmac continues to subsidise the product, prescribers will continue to prescr be it, the company will see no change in revenue, but the impact will be on the wholesalers, pharmacist and consumer, who end up with the additional admin to supply a non-licensed product. The penalty needs to be something that will actually make a difference to the company.

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).:
152 - I think the ability to split a pharmacy into category 4 + retail/cosmetics and the pharmacy activity is good, because it means that a shop with a relatively small dispensary could keep part of the shop open later hours without the pharmacist. But it could also cause confusion for consumers.

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).:
156F - Will this mean that there will finally be a centralised database for certain pharmacist-only medicines?
Ideally all codeine sales will need patient name and date of birth, to link the sale to their NHI. Then an alert could automatically pop up if they have purchased too many within a certain timeframe. The regulator could also put additional alerts on this system for patients who have been abusing prescription opioids.
False prescriptions will soon be near impossible with NZePS, but a similar system could build in the alert to dispensary software for relevant NHIs.
There is too much reliance on pharmacists to judge a customer on their appearance and ability to answer certain questions, when even psychologists can't always tell if someone is purchasing opioids for legitimate pain relief or for misuse.

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).:

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.:

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?:
A license to be a non-compounding pharmacy will be great for mobile pharmacies, but if traditional bricks-and-mortar pharmacies are also able to do this because it is a more time-consuming aspect of dispensing, it will reduce access to medicines. There will need to be a requirement either in regulations or DHB contracts to reduce this risk.
In principle, I think expanding the definition is great, and will enable NZ pharmacies and pharmacists to provide good care to our customers, rather than them switching to overseas online stores. But care will be needed when licensing, to make sure that they can a: ensure that a category 2 or 3 medicine is suitable, and b: ensure appropriate counselling can go alongside medicine supply.

In the future, I think that medicine supply via centralised systems for regular medicines should be more common. The consultation aspect with medicines explanation, discussion and advice being given at the local pharmacy where the medicine is collected, and any one-off or new/urgent medicines are dispensed.

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 were thought to be more ethically minded, but there are many pharmacists in New Zealand who studied pharmacy purely for the business opportunity and don't have much interest in patient well-being; there are also many non-pharmacist business owners who do care a lot about people. But as pointed out, pharmacists are also bound by other legislation, so the consequences of not acting in the patients' best interest are greater than for other business owners.
But there definitely needs to be more regulation in place because as I mentioned above, there are a lot of pharmacists who do the bare minimum clinically with their main goal of making money.

Another option, although I know it is not realistically possible, is a third option. Option 2 but only for the non-medicines side of pharmacy, then dispensaries and category 2-3 (or 2-4) medicine sales DHB or govt owned. The DHB could employ a few pharmacist managers to oversee them, but employed based only on clinical and management rather than business incentives (with a minimum business level or training). It would mean no risk of conflict of interest, and prices would be more reasonable. It would mean better communication with hospital, easier distribution of staff, standardisation of services and ability to lower service costs in deprivation areas, even if it means the dispensary is run at a loss. Centralising some services like compliance packing, allows for more investment and utilisation of technology. Stock sharing would be easier, especially for less common expensive medicines. And if there is money made, it would be much needed income for DHBs.

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 main benefit is that there are other legislations that pharmacists need to act under, including the code of ethics and HPCAA.
The risk is that in reality nothing changes, and charge pharmacists are under pressure to meet their employer's demands for productivity, and that they foster a culture of a money-making approach.

Question C25 - Are there ways in which Option 1 could be improved?:
Auditing by anonymously talking to staff and patients of the pharmacies, to ensure that the person in charge is able to keep the pharmacy run clinically well without conflict of interest.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:
At least the dispensary, and sale of medicines (including category 4) and vitamins/minerals/herbals, and medical devices/products (e.g. first aid, bandages, blood pressure monitors etc). A pharmacist or non-pharmacist could have majority shares for the cosmetics and fragrances etc.

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?:
Could be separated, as long as the owner is also responsible for the pharmacy being run ethically.

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)?:
Could replace it with a maximum average prescription count if more than 1 pharmacy is owned. But otherwise I think it should be kept.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:
Each pharmacist should have up to 5 that they are allocated to, and even if ownership is joint, they should have responsibility for running just those pharmacies. You could also include a rule that an owner pharmacist must spend a minimum number of hours working from those pharmacies.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:
Hopefully it would improve the ethics of the corporate-owned stores

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?:
Continue exemption. I have worked at one of these and a number of pharmacies owned by a couple of other corporates. Of all the corporate-owned stores I have worked in, they are the most professionally run, even if they don’t have a pharmacist on their board. Their business model is not that great, and sales don't seem to be overly pushed. Overall they already seem to care less about business than on providing good healthcare.

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 are that pharmacist owners will be driven out, and the big corporate-owned stores will take over. If the large companies no longer need pharmacist oversight, they are more likely to force lower pay, lower prices devaluing pharmacy work, and making the environment too busy to provide effective healthcare. The pharmacist will be stuck behind the counter all day, and levels of healthcare will drop.
Even if the bill includes legislation that the supervisory pharmacist is obligated to report unethical standards, they won't speak up. Even if technically they can't fire the pharmacist, they can prevent a promotion or make work difficult for them, forcing resignation. And with pharmacy being a small world, they can make it difficult to get another job.

Question C34 - Are there ways in which Option 2 could be improved?:
Robust legislation that encourages supervisory pharmacists and other staff to speak up if they feel that business is being promoted above patient well-being. Auditing by anonymously talking to staff and patients of the pharmacies, to ensure that the pharmacy is run clinically well without conflict of interest.

Question C35 - Are the requirements adequate to ensure the ‘supervisory pharmacist’ would be able to effectively perform this function?:
Definitely needs a minimum number of years experience in community pharmacy.
Best people to check this with is dispensary mangers (or pharmacist store managers) for larger Green Cross owned stores, or Chemist Warehouse or Countdown Pharmacies. Ask them what would make them feel confident in their job security if they were to report their employer.

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?:
This would need to be the exception rather than normal. A pharmacy should require that to be a condition in their license, which should specify when it can/would happen, and how it would happen. It should generally only be done if there is the pharmacy workers have a highest level of qualification so they know what to refer, and if prescriptions are being dispensed there would need to be an accuracy checking technician available.

I can imagine it would happen in small or rural pharmacies for up to 2 days in a row when no locum cover is available, to cover for illness or emergencies, or over lunch breaks for sole-charge pharmacies. Sometimes an additional remote pharmacist could be useful as an extra, even if there are pharmacists in store.

Concerns I have are:
- It could become normalised, and push pharmacists out of jobs, only requiring dispensing technicians and pharmacy workers
- As a pharmacist there are so many times when I will overhear and intervene without actually being approached - times when the pharmacy worker doesn't realise it needs to be referred.
- Sometimes it is also important to ta k to the patient directly – I am more likely to pick up on unsaid details talking direct rather than ta king via a pharmacy worker, and possible to view rashes, eye conditions etc. A video consultation would usually be required, even if it's just to see that the patient is elderly or frail or when knowing the ethnicity might change the most l kely diagnosis.

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?:
Maybe not necessarily, but is there any benefit in them being able to take a financial interest?
Could also add in that a dispensing pharmacist cannot hold interest in a prescribing business, and proh bit the same individual or group from holding interest in both a pharmacy and prescr bing business. But since the idea is to avoid conflict of interest, all these situations should be allowed if the two are not within a

certain distance of each other, and there is a maximum percentage of crossover of prescriptions. This would allow a pharmacist who owns a pharmacy and then becomes a prescriber to still own the pharmacy, provided they only prescribe at a practice in another area of town where there is sufficiently minimal prescription crossover, and therefore would be no conflict of interest. I don't think it would prevent the progression of the pharmacy profession because those who are motivated by purely clinical aspects are less likely to own a pharmacy.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:
For temporary pharmacies for events, such as music festivals and orientation-week at universities. These could be just for certain product ranges, not necessarily needing a full pharmacy, even just the medicines likely to be requested (and suitable).

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?:
Wholesalers are often the best at knowing where and how to source different medication.
If pharmacies are going to import it themselves, the pharmacists would need some degree of training to know how to assess the quality of a product/company. And there should be no obligation to source it if we have doubts about the quality of the product. For instance for a CBD product, pharmacists should be allowed to decline to import a particular requested brand/product if we have doubts about the quality, and can recommend a product of safer quality.

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, definitely. It can take a lot longer to compound, and therefore usually means the patient can't get the medicine until a few hours later or the following day. Some things that are commonly used, e.g. hydrocortisone ointment, should be able to be made in advance, but requirements around the amount made, and shelf-life. A manufacturing license should not be needed for something that has always been expected of a pharmacist for centuries - it's simply part of the profession.

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-G4DE-A

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-11 21:34:09**

Submitter profile

What is your name?

Name:
Adam Fenemore

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:

Submitter Profile (tick all that apply)

Consumer

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?

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).:

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.:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:
a. regulatory requirements that are consistent with international approaches and effectively administered

Currently New Zealand and the United States of America are the only developed countries that allow DTCA of named (ie, branded) prescription medicines in a form that allows a product to be identified.

Choose one, you cannot have both

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?:
Please read my full submission. In short:
- The motivations for DTCA are clear, to make a profit at the potential risk to the health of a consumer
- The opinions are clear, that those making the profit are happy and the general public and medical professionals are not at all happy
- The evidence is clear that there are some benefits and more disadvantages
- There are better ways to achieve those same benefits without the disadvantages, and it is absurd that we are not exploring these methods and instead looking to simply modify the punishments and hope for the best

You simply cannot allow DTCA in New Zealand and at the same time say that you are listening to the people, listening to the medical sector, listening to the evidence, finding solutions to this problem, being consistent, or doing what is right. You cannot allow it.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4D4-S

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-12 10:07:01**

Submitter profile

What is your name?

Name:
Lindsay Boy

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
AbbVie Limited

Submitter Profile (tick all that apply)

Medicines

If you select DHB, please state service area:
North Island

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?

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).:
AbbVie Limited agrees with the purpose and principles as outlined in ss3 and ss4.

Specifically, 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 this Act should be 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. Further comment is made below on these principles:

ss4(b)(i) Risk-proportionate regulation
The principle that regulation is proportionate to the risk of the products (ss4(b)(i)) is strongly supported. We also strongly support the intent that regulatory requirements for different kinds of products and activities are to be tailored to accommodate their different characteristics and risk profiles.

The intent to have a wide and flexible range of product approval pathways, dependent on risk is strongly supported. 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.

Ss4(b)(ii) Timely availability of therapeutic products
The principle that the regulatory scheme will support the timely availability of therapeutic products (ss4(b)(ii)) is strongly supported. We believe this is an essential principle as a successful regulatory scheme should ensure that people that need access to these products, get access in the timeliest manner poss ble while ensuring the appropriate checks have been performed. A successful regulatory scheme should not create undue delay and uncertainty to the availability of therapeutic products. As above, we strongly support the intent to have a wide and flex ble range of product approval pathways, dependent on risk. Furthermore, we support the proposal to replace the current provisional consent with the ability to have approvals with conditions (ss105-107). The principles of the TPB are supported with the all above proposals.

However, in order to meet this principle, the scheme will need to establish transparent and meaningful timeframe target setting and reporting of the regulator's performance. There is not much detail given in the TPB or in the consultation document to ensure that this will be provided. Therefore, assurance is sought that this principle in the TPB will keep the regulator accountable to making decisions in a timely manner. Assurance is also sought 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.

Ss4(c) Open and transparent regulator
The principle that the regulatory scheme is administered openly and transparently (ss4(c)) is strongly supported.

However, we seek further information on how this principle will be achieved. With the current 3 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?

Furthermore, although we are supportive overall with regard to the purpose and principles of the Bill, one addition should be made to principle ss4(c). It is stated in the paragraph 45 of the consultation document that the purpose and principles "act as a guide to actions and decision under [the scheme]". Therefore, it is essential that it is stated in the principles that as well as the administration being open and transparent, the administration of this act should be carried on in a fair manner. This is necessary as the TPB is highly enabling to the regulator. The TPB gives the regulator a high degree of power and choice for making decisions with regard to tools 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, it is important that it be included in the principles of the TPB, that decisions are to be made fairly, and decisions must be proportionate to the given situation.

Therefore, it is suggested that the word 'fair' is incorporated into principle ss4c so that it reads "the administration of this Act should be carried on in a fair, open and transparent manner".

Ss4(d) Regulator's reliance on overseas regulators work
The principle of having a regulator who 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, is strongly supported.
We trust that this will increase the 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.)

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 meaning of therapeutic purpose and ss16 meaning of therapeutic product
The definition of therapeutic product needs to be further expanded to include devices.
It is noted that the regulations offer the ability to clarify in some instances whether a product is or is not considered a therapeutic product. We agree that it is necessary to have this ability to provide clarification in certain instances.

Ss27 meaning of clinical trial
To align with international terminology, it is suggested that the meaning of clinical trial in this section follows international definitions, including the WHO definitions.

Request for Additional Definition to be included for "person"
A definition that a "person" is either a body corporate or an individual person, should be added to the formal definitions, as outlined in the "tips to help with understanding the draft Bill. This is particularly relevant to (ss30; ss42; 44; 52 and 83(2)(a)(i) where it is not always an individual person who imports, supplies or advertises a product.

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 could this rationale be further explained as compounding or dispensing by the 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.

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, that this may unreasonably pass liability to a broad range of persons such as freight operators and we question the rationale for this broad definition.

Ss31 meaning of manufacture, manufacturer, and responsible manufacturer

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

We question why the relevant considerations for determination of a ‘respons ble 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 device or type-4 product it is noted in ss31(5)(a) that a person may be a ‘responsible manufacturer’ “whether or not they personally undertake the manufacture of the product”, whereas for a medicine or AMI such a clause is not included. We suggest that the same approach of “a person may be a ‘respons ble manufacturer’ whether or not they personally undertake the manufacture of the product”, should apply to a medicine or AMI as well.

For instance for multi-national companies, the parent company (international headquarters) is best placed, and best suited to be the ‘respons ble manufacturer’ for a medicine or AMI. The parent company may not personally undertake the manufacture of a product, but they will have oversight of the full process, and its name or trademark would be attached to the medicine. Furthermore, we note that ss31(6) explains that the matters listed in ss31(4) and ss31(5) are not determinative considerations and do not limit the matters that may be taken into account in determining the responsible manufacturer. We infer that there may be differences due to the different characteristics of the products and their manufacturing. However, we do not believe this is necessary and we recommend that the considerations for the different products type are better aligned to each other. The consideration that “a person may be a ‘responsible manufacturer’ “whether or not they personally undertake the manufacture of the product” should feature for all product types.

Our understanding from the reading of the definition of a ‘responsible manufacturer’ (ss31(3)) in particular the considerations of 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.
We seek confirmation from the Ministry of Health that this is the correct interpretation.
In this situation, nominating the parent company (international headquarters) of the local New Zealand sponsor could be the appropriate decision. In many cases, the parent company will hold agreements with the many parties involved in manufacture of a medicine. Additionally, pharmacovigilance and other reporting is reported back to them. Therefore, the parent company (international headquarters) is often in the best position to assist with supply of required information back to the local New Zealand sponsor as and when required.

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. If a pharmacy is permitted to supply by wholesale we strongly recommend that the pharmacy must meet the requirements of a wholesaler as per Part 4 of the New Zealand Code of GMP, Wholesaleing of Medicines and Medical Devices (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.

Ss39 Meaning of special clinical needs supply authority
SCNSA – It is queried what controls will be in place to prevent HCPs from bulk buying unapproved medicines which they may be able to purchase more cheaply overseas. In addition what controls will be in place with regard to Buyers clubs?

With the tightening of unapproved supply, plus a high likelihood of increased fees, it would be pertinent for the regulator to look at having an orphan designation/application pathway with associated reduction in fees for rare diseases. With NZ’s very small population there may be a handful of patients treated each year for rare diseases and for many products in this space, it will not be commercially viable to register these in NZ. If there is a partial fee waiver in place, this would also assist in giving the regulator more control over what is being supplied in NZ in these circumstances.

Ss47 fit and proper person and Ss48 meaning of senior manager

Ss 47 defines the decision of whether a person is a “fit and proper” person
It is noted that the TPB asks for additional considerations compared to other NZ legislation ie whether a person has been bankrupt/insolvent and whether they are of good character as well as checking for contravention of other laws.

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”.
There is no differentiation for this 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 it has been drafted, if Person A is an individual then the regulator would need to consider, any company of who 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 or a partner or director. It may also consider any individuals that are currently, or were 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 any individual that is currently or has ever been a director, CE, CFO or similar of Company A,

and any company that is able to exert significant influence over the management or administration of Company A. This provision can be quite wide reaching depending on whether they refer to a “person” as being an individual or a body corporate. For ss47(2) and ss48 it would be clearer if the definitions were based on whether “person A” is an individual or a body corporate.
We also suggest there be a time limit or timeframe given in the senior manager definition (to avoid including past senior managers). As it is currently written, it appears to be unreasonably wide-reaching for the ‘fit and proper’ person test.

In addition, the reference to equivalent Australian Commonwealth and state law, under 47(3)(n) makes this a very far reaching statement and would seem to be challenging to administer.

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
We 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
The provision to proh bit parallel importation is supported.

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, the rationale for including compounding and dispensing in the definition of manufacturing a medicine is queried. 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 further clarified “(which, for medicines includes compounding and dispensing)” in order to state that compounding and dispensing is also a controlled activity. For clarity, it is suggested that these activities are separated from the definition of manufacture and listed separately as a controlled activity in ss53.

Ss55 Persons in supply chain must comply with regulations
The description of activities persons in the supply chain must comply with, is broad 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).

In view of the vast range of supply chain activities defined in s44(1), the regulations would need to be specific regarding application of requirements across the range of persons in the supply chain.

Subpart 3: Authorisations (ss 56–80)

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

A point to note is 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.
It is noted that, S119 descr bes that if someone imports a product without the sponsor’s permission sections S116-S118 [Obligations of Sponsors] do not apply. However, from a pharmacovigilance perspective this may be complicated when needing to identify product belonging to a Sponsor.

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
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 date of last product expiry in the market before de-registering the product.
We suggest that a ‘use of current stock’ notice could be used for cases 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, 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 section 79 which will 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
A definition of promotion should be added to the Bill in order to clarify the differentiation between education and promotion

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).:
ss94 Approval of medicines, medical devices and type-4 products
ss95 Criteria for products approval
ss96 Product standard

There is general agreement with the information contained in the above three sections.

Ss97 Criteria for sponsor of approved product
ss97(c)
A contractual relationship is required with the responsible manufacturer. The rationale for this requirement is reasonable – to ensure the Regulator can use the sponsor as a contact person when information is required, or urgent safety issues arise. However, some local sponsors who are part of large multinational pharmaceutical companies would not ordinarily hold individual agreements with each of the many manufacturing sites. These agreements are held by the parent company and an agreement between the local affiliate and parent company is standard practice. For companies that are “outsourced” sponsors because there is no NZ affiliate of the parent company, the NZ sponsor is usually procured by the parent company via an Australian or regional affiliate and there are no contracts direct with manufacturers. The requirements of this contractual relationship should be more clearly defined for local affiliates and outsourced companies who are sponsors of medicines.
The understanding from the reading of the definition of a ‘respons ble manufacturer’ (ss31(3)) 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. We seek confirmation from the Ministry of Health that this is a correct interpretation.
In this situation, nominating the parent company (international headquarters) of the local New Zealand sponsor could be the appropriate decision as in many cases, the parent company will hold agreements with the many parties involved in manufacture of a medicine. Additionally, pharmacovigilance and other reporting is reported back to them. Therefore, the parent company (international headquarters) is often in the best position to assist with supply any required information back to the local New Zealand sponsor as and when required.

As a further point, it is questioned why the determinations of a ‘responsible manufacturer’ for a medicine differs substantially to that for a medical device or type-4 product (ss31(4) vs ss31(5). For medical device or type-4 product 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 as for a medicine or AMI such as clause is not included. It is suggested that the same approach of “a person may be a ‘respons ble manufacturer’ “whether or not they personally undertake the manufacturer of the product”, should apply to a medicine or AMI as well.
As explained above, the parent company is best placed, and best suited to be the ‘responsible manufacturer’ for a medicine or AMI. The parent company may not personally undertake the manufacture of a product, but they will have oversight of the full process, and its name or trademark would be attached to the medicine.

ss97– Criteria for sponsor of approved product
The draft TPB proposes that the respons ble 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 “respons ble 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. 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. 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 the approval will be required to list an extensive array of sites directly and indirectly involved in product manufacture or, given the broad definition of manufacturer in s31.

Ss99 Scope of approval
Please refer to comments on ss100 below

ss100 – Major changes results in new product
It is understood 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 understood, during 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 for 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. The practicality of the major changes processes would therefore need to be further 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 - TGA Grouping.

For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a permit/licence/exemption. 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)." This would be an opportune scenario to issue a "use of current stock' notice.
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.

ss101 – Sponsor must notify regulator of certain minor changes
The management of changes to an approved product based on a framework of risk-based assessment of minor variations is supported. The 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 of those that require evaluation is supported.

Ss102 Change of sponsor
We support the requirements set out in ss102 for changing a sponsor (transferring an approval).

ss103 – Duration of approval
The proposal for product licence approvals generally not to have expiry dates is supported. Thus licences are perpetual until such time that the Sponsor or regulator considers cancelling the licence. This is aligned with current Australian practice (ie TGA). Under the current New Zealand regulatory system where product approvals 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 product approval. There does not seem to be any compelling reasons to assign an expiry date on the licence.
We anticipate that the conditions applicable to a "maximum duration for the approval", where applicable, will be specified in the regulations (ss103 (2) (b))

Ss104 Approval lapses on death, bankruptcy, or insolvency of sponsor
Please refer to the 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 – 107 – Conditions on approval
It is agreed that the regulator should have the right to impose conditions on approval and also agreed that the sponsor also has opportunity to comment.

ss108 – 112 – Cancellation of approval
There is agreement that the regulator should have the right to cancel an approval based on the grounds cited in s108. In addition, there is agreement that the sponsor also has opportunity to comment

ss113 – Therapeutic products register
There is agreement in principle, with the proposal to develop a Therapeutic Products Register (s113) which contains a copy of the latest prescribing information and consumer medicine information for approved products. It is unclear whether the practice of assigning a registration number to the product (ie TT-50 number) will continue under the new regulatory scheme. Please also see response to s98 on manufacturers identified in the approval.

It is agreed 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 improved transparency over recent years. However, we do not agree that all declined 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 (l ke 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. On the reverse side, 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).:
ss114 – 115 – Subpart 2 – Approval-exempt products

The understanding is that Medsafe would like a sponsor (even though approval is not required) in order to contact someone in the event of any issue with the product.
However, would it be a possibility for the regulator to develop a list of approval-exempt products (like the TGA does) so you would not have to obtain an approval/licence for these exempt products? If so, then consideration would need to be given whether 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).:
ss116-119 – Subpart 3 – Obligations of sponsors

The draft TPB proposes that the respons ble 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 respons bility 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 respons ble 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. This section of the TPB seems to duplicate the intent of s55, 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 to perform.

In general, the introduction of a new tiered offence structure for offences is supported.

However, further information on some aspects is sought. It is noted that Band A offences relate to offences that have a real potential to cause harm (ss 198). It is queried if this objective is achieved if a sponsor or individual may commit these offences without knowledge of the circumstances and the potential harm. It is also queried whether the defences are reasonably open to provide protection for inappropriate prosecution as descr bed in the consultation document (ss 201). For example, should there be a defence that there was no real potential to cause harm by the conduct. Furthermore, the penalty (up to $300,000) appears high for a strict liability offence.

ss119 – There is full agreement that the sponsor is not responsible for approved products imported without consent.

These sections discuss the requirements for compliance with obligation and the penalties that apply to breaches. Details are lacking on what sponsor obligations in relation to Pharmacovigilance are tied to the penalties outlined in subsection (1) and subsection (2).

Whilst we agree that sponsors should be accountable for complying with applicable obligations, 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 PV requirements are legislative requirements:
• Reporting of ICSRs
• Reporting of SSIs
• Notification of the PV contact person
• Archiving of records

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.

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 3 – Obligations of sponsors

The data protection provisions set in the draft TPB 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.

We do 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 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 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, there is 10 years of market exclusivity with a potential 2 year extension if extended to juveniles, a territory New Zealand is negotiating a future trade agreement with. 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 the EU (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.

With use of the term active moiety 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). However, the draft TPB 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. It is requested that the TPB be revised to include suitable data protection 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
AbbVie Limited agrees in principle with ss123.

Ss124 Content of Licence
ss124(1) (e) – The TPB indicates that the licence will list the therapeutic products covered by the licence. Does this imply that all products will be named individually for all sponsors? 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 trial or the investigators that seek the license.

SS126 Effect of pharmacy licence: additional provisions
N/A

Ss127 Grant of Licence
AbbVie Limited 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/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) explains that a clinical trial licence requires either ethics approval, or certification from a relevant ethics approval entity that ethics approval is not required for 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 and what impact this may have on timelines.
There is concern that licence applicants will need to submit a significant amount of information to the ethics approval entity so that the entity can make a decision that the trial does not need an ethics approval. We seek further information on the process for deciding that ethics approval is not required. 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). 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

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 affiliate 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. 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) – Is it correct to assume that the criteria for importing an approved product without the sponsor's consent will be outlined and specified in the 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 list 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 in order to meet criteria, at the request of the Regulator.

SS135 Criteria for granting permit
We support in principle the criteria list in ss135. 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 l kely benefits of therapeutics products should outweigh the l kely 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 support in principle ss136 which gives the regulator power to split up a licence or permit into multiple licences/permits if it is more appropriately regulated this way. However, ss136(2) gives the Regulator discretion to assess the application together, or as discrete applications. One concern, we have regarding this is 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 likely to be split, so applicants may be able to prepare ahead of time an appropriate application so that it is processed as efficiently as possible.

ss137 Duration
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, has consideration been given to the timeframe and cost involved with making multiple updates during this time period?
We submit that 3 years is too short for some CT activities. Clinical trials were not previously regulated via licences, unlike the other activities that require a licence. Although it is agreed that a licencing system for clinical trials fits well within the TPB's regulatory, further considerations are 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, this length of time still does not work well for clinical trials.
For practical reasons, licences for clinical trials should be for the expected duration of the particular clinical trial as identified in the trial's protocol. As an example, trials measuring overall survival after an earlier intervention may require more than 5 years of follow-up with participants. We also seek further clarity around requirements of licencing for instances where participants have completed treatment but remain in follow-up.

SS138 Conditions
We agree with ss138.

Ss139 Regulator may impose conditions and ss140 Variation
Further information is sought 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 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. The practicality of this process is queried. 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 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 Regulator of the death within 5 working days could result in a business continuity issues or for the licence to lapse. As an example, there would be ethical and operational issues if a clinical trial had to be suspended.

Furthermore, this clause would not necessarily be applicable for licensees or permit holders who are body corporates. If the intent is that it is applicable to certain classes of controlled activity that are typically conducted by individuals, the draft TPB could be more explicit about this.

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 respons ble 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 respons ble 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).:
s160 allows the regulator to 'perform monitoring', with respect to safety monitoring. This would introduce the ability for Medsafe 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 access cannot be prevented, 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

ss168 – 171: Clarification is sought whether "person" in theses clauses relating to Directions orders and Product Prohibition orders extends to the sponsor or an individual only?

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 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 2012ss183, 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 if 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 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).
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
AbbVie Limited 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 by Sponsors. 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 TPB (ss203) does not specify the timeframes given for convening the review panel or the review timeframe for the review panel to provide a decision. It is requested that an equivalent timeframe of 30 or 60 working days is included in the TPB 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 TPB 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:
(i) changes be made to the Bill that provide for timings for the convening of the review panel and the provision of decisions; and
(ii) 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).:
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 not much detail given in the TPB or in the consultation document regarding how this will be ensured. Therefore, assurance is sought 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. We strongly suggest that maximum evaluation timeframes are stipulated in the regulations.

ss207
In addition, in relation to product approval, the draft TPB (ss207) states that the regulator may rely on reports or assessments made by recognised authorities to enable efficiencies. AbbVie Limited is in agreement 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 and ACSS Consortium). 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 major changes. 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 current draft TPB only refers to targeted timeframes at this stage which provides no change from the current situation.

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 of 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;

(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).:
The proposed sections (ss 223-232) covering enforceable undertakings and a court’s ability to grant injunctions are supported. The ability to offer ‘enforceable undertakings’ provides useful, constructive flexibility in addressing 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. 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 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).:
Subpart 3 – Offences

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. 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.

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” should 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. Further clarification on this is sought.

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 proposed sections (ss 249-255) covering infringement offences and the related penalties and processes are supported. 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 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 AbbVie Limited is not opposed to a cost recovery model, this would also require 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 TPB and is requested to be included. Clear and transparent timelines are paramount in being able to monitor progress, which is lacking under the current regulatory system. The current draft TPB 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 not much 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. Assurance is also sought 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 strongly suggest that maximum evaluation timeframes are stipulated in the regulations.

With the tightening of unapproved supply, plus a high likelihood of increased fees, it would be pertinent for the regulator to look at having an orphan designation/application pathway with associated reduction in fees for rare diseases. With NZ's very small population there may be a handful of patients treated each year for rare diseases and for many products in this space, it will not be commercially viable to register these in NZ. If there is a partial fee waiver in place, this would also assist in giving the regulator more control over what is being supplied in NZ in these circumstances.

Ss267 Consultation

We support the approach of making the TPB 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. There are 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.

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
AbbVie Limited 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).:
We understand that the contents of the Bill are at a high-level.
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. 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 of 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).:
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 for 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. The practicality of the major changes processes needs further consideration 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 - TGA Grouping.
For cases where an amount of the original/unchanged product is still present in the market, this could be regulated by a permit/licence/exemption. 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.
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) would 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 medicine labels so there would not be an issue arising from harmonizing labels for Australia and New Zealand. However, it may create a point of confusion for those working across both territories, or those transferring to the New Zealand market from Australia.

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 seeking assurances that the Regulator will be adequately resourced during this transition period and once normal operations 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?
• 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.

However, 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 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.:
As a general comment, we agree in principle, but 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.

AbbVie Limited 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 can we clarify if the draft TPB requires the sponsor contact for dealing with pharmacovigilance matters and reporting to Medsafe to be a NZ resident. Currently this person can be based overseas as long as they are contactable during NZ business hours.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
Please refer to the response to B2

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

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?:

In principle, this is agreed.

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?:
If there are safety risks to the general public, then it is appropriate that these products be regulated.

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 New Zealand regulator, having limited resources in this area is encouraged to adopt and accept approvals granted in other recognised jurisdictions.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
Please refer to the response to B13

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:
It is considered appropriate to impose restrictions on use or supply in certain situations, dependant on the device and its intended use within the population.

Question C4 - Please provide any comments on the approach to post-market controls.:
As a general comment, we agree in principle, but 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 any risk management.
AbbVie Limited would continue to welcome a pragmatic approach, particularly with regard to accepting overseas approaches 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 can we clarify if the draft TPB requires the sponsor contact for dealing with post-marketing safety matters and reporting to Medsafe to be a NZ resident or are they able to be based overseas as long as they are contactable during NZ business hours?

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:
The transition provides a 6 month period for applications for approvals and licences. Due to the widened scope of the scheme to include medical devices and other 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 seeking assurances that the Regulator will be adequately resourced during this transition period and once normal operations 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?
• 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)

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.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:
Please refer to the response to B2

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:
The transition provides a 6 month period for applications for approvals and licences. Due to the widened scope of the scheme to include medical devices and other 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 seeking assurances that the Regulator will be adequately resourced during this transition period and once normal operations 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?
• 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)

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.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:
License to run CTs:
The ability to have one licence to cover a range of activities involved in the running of a clinical trial is supported. 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. Therefore, it is requested that a clinical trial license to be granted for a longer period, to cover the protocol requirements, rather than relying on extensions.
Clarity around requirements of when a licence can cease is also requested ie. is the licence required after patients have completed treatment and remain in the follow-up phase.
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 also unclear if applications not referred to the Health Research council will have the same quick timelines as those currently reviewed by HRC. What details will be provided for performance targets and what avenues exist for escalation of issues/ or targets not being met?
It is also requested to align the Clinical Trial terminology with international terminology and definitions, in order to avoid confusion.

Importation of Investigational Medicinal Products (IMP)
Reference to the importing of IMP could not be found and it is assumed that this comes as part of the regulators' approval of the trial. Please can this be clarified

Exporting biological samples (blood/serum) and tissues
Reference to provisions for the export of samples or tissues derived from Clinical Trial participants is not able to be found. It would be good to ensure that reasonable provisions are in place, such as a permit to do so, as part of approval of Clinical Trials.

The Regulator also has the power to monitor trials and audit CT sites… p90 of the consultation document
A major concern is how outcomes of such activity is reported, in order to ensure that data quality reputation (which is currently high) remains intact. Please could further information and detail regarding the intentions here be provided.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:
Schedule 1 – Transitional Arrangements
It is not practical for the principal investigator to apply for a temporary licence to carry on the activity. It is recommended that this be changed to reflect the sponsor of the study.

Please note that there is a request to align all Clinical Trial terminology and definitions with that under ICH GCP to avoid any confusion both locally and internationally

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
The provision in the Bill for supply of an unapproved product via a Special Clinical Needs Supply Authority (SCNSA) is supported. It is important that requirements for supply via this mechanism are clear in the regulations, including:
- Respons bilities 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 bu k 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:
AbbVie Limited 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.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:
The transition provides a 6 month period for applications for approvals and licences. Due to the widened scope of the scheme for example to include medical devices and activities (e.g clinical trials), 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 seeking assurances that the Regulator will be adequately resourced during this transition period and once normal operations 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?
• 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).

Our concern is that receiving these approvals will take a long time considering the number of device approvals that will be submitted, and the number of licence applications that will be received during the transition period. This would potentially have an impact on clinicians and patients.

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?

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?:
AbbVie Limited is supportive of this approach.

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?:
-

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.:

AbbVie Limited 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) as AbbVie Limited believes the benefits for consumers of DTCA 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, independent, review process (via TAPS) 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, the prescription medicines industry via the Medicines New Zealand Code of Practice and the Advertising Standards Authority's (ASA) Therapeutic and Health Advertising Code adds a further level of self-regulation.

In addition, under the new Bill, the regulator can issue Advertising Remediation Orders, which provides a further level of control if necessary. However it is expected that the need for the Regulator to utilize the Advertising Remediation Orders will rarely be needed for prescription medicines DTCA. This is based on existing and historic data and experiences of all parties within the existing government regulation, co-regulation and self-regulation environment. All this has provided stringent control on the content and quality of prescription medicines advertising, as well as remediation.

Currently the Medicines Act 1981 and the proposed legislation establish the basic legal guidelines for DTC advertising of therapeutic substances, devices and methods of treatment. In addition, the Medicines Regulations 1984, lays down detailed requirements regarding the inclusion of statements about authorised uses, appropriate precautions and contraindications in medicines advertising. It is certain that the future regulations generated under the proposed legislation, will also provide clear requirements.

The Commerce Act 1986 also establishes the legal framework for fair competition, and the environment within which prescription medicine advertisers are required to do business. The Fair Trading Act 1986 legislates against unfair and misleading advertising. These Acts therefore also have bearing on how pharmaceutical companies market and sell prescription medicines.

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 also 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 who can impose sanctions ranging from the suspension of the advertisement or marketing practice to a fine of $80,000.

The evidence that all forms of current regulation highlighted above are effective around DTCA is seen in the extremely low number of complaints made to ASA on 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 on prescription medicines and only 2 complaints were upheld as bona fide issues requiring remediation, which was actioned by the advertiser. Please refer to the Medicinces New Zealand response for additional details and relevant references.

In conclusion, AbbVie Limited is are supportive of continued government regulation and enforcement around DTCA on prescription medicines, which should not be in lieu of the currently established independent mechanisms. Both systems together will continue to maintain the quality and content of all prescription medicine DTCA promotion and 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?:
AbbVie Limited's strongly held view is that regulated direct-to consumer advertising (DTCA) of prescription medicines should continue to be permitted. The continuation of well-regulated DTCA of prescription medicines should remain in force given all the benefits it provides.

New Zealand-based evidence overwhelmingly concludes that the regulated DTCA of prescription medicines promotes health awareness and encourages patients to take a proactive role in the management of their own health and does not create any personal or community health issues. Please refer to the Medicines New Zealand submission for full information.

All the prescription medicines advertised via DTCA are registered medicines with Medsafe, who reviews the scientific dossiers and confirms the safety and efficacy. The DTC-advertised and Regulator-registered prescription medicines adhere to the requirement that "likely benefits of the therapeutic products should outweigh the l kely risks associated with them" – a core Principle of the proposed legislation. Therefore prescription medicines not only meet the Principle but also meet the Purpose of proposed legislation around assuring public safety via Regulator oversight.

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. There is a rapidly-increasing amount of health care information directed at consumers via the Internet, that promotes potentially unsubstantiated therapeutic claims for all sorts of health conditions. The focus of any regulation should not be banning of the already well-regulated prescription medicines DTCA, but concern over un-regulated Internet sites or activities which represent a clear risk to both personal and community health.

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.
For example, in 2017 it was shown that only 33 prescription medicines were advertised in New Zealand, but only 6 medicines were advertised on television. The total of 33 medicines included 2 clinical trials advertisements for potential prescription medicines, compared to over 200 health supplements and over-the-counter medicines. Advertising expenditure estimates indicate that DTCA for prescription medicines represented only 0.2 to 0.3% of total spending in New Zealand per year between the three most recent year period of 2016 to 2018.
In all cases the prescription medicines advertised in New Zealand were approved by the Regulator from a safety and efficacy perspective and 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. Please refer to the Medicines New Zealand submission for full information and relevant references.

Pharmaceutical 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. All claims must be able to be substantiated and have references available on request. As noted elsewhere, all online and mainstream DTCA are independently assessed for compliance with New Zealand laws, regulations and industry codes by the Therapeutic Advertising Pre-vetting Service (TAPS). Most importantly, without this independent review by TAPS, the media in New Zealand will not run the DTCA campaign.

Given the requirements of the independent TAPS pre-vetting and approvals process, as well as the internal processes required by companies, including full legal and scientific review, misinformation and overselling of benefits versus risks are negated.
Furthermore, TAPS will engage with Medsafe to clarify perspectives on DTCA for specific products. This helps to ensure that no misinformation or 'oversell' of benefits over risk occurs.
Therefore, 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. Please refer to the Medicines New Zealand submission for full information and relevant references.

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 express concern if the practice of DTCA were to be banned. No major issues have been highlighted in a range of studies and surveys. Please refer to the Medicines New Zealand response for full information and relevant references.

Furthermore, the public's and community's ultimate safety is also ultimately protected by the fact that prescription medicines cannot be directly obtained by the consumer in New Zealand without first obtaining a prescription from a registered medical practitioner or other approved prescriber. Therefore, a further mechanism is in place to provide public safety around DTC-advertised prescription medicines.

New Zealanders enjoy one of the best doctor-patient relationships in the Commonwealth. From surveys conducted by The Commonwealth Fund over the past decades, NZ ranks in the top 3 out of 11 comparative countries. 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. 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 also showed that the majority of Doctors responded to the requests with alternative treatments or lifestyle advice instead. Please refer to the Medicines New Zealand submission for full information and relevant references.

There are multiple benefits of DTCA in New Zealand from prescription medicines including increased health awareness where patients encouraged to act on undiagnosed (eg Hepatitis C) or poorly managed conditions. In addition, patients feel better about medicines when they have initiated discussion and been involved in decision-making and also display better treatment compliance which in turn leads to better health outcomes.

DTCA helps make patients aware of new medicines and gives them enough information to decide whether or not to discuss a medicine with their doctor which then creates an opportunity for Health Care Professionals to talk to patients about various treatment options. In addition, it encourages patients to visit their doctor about a medical condition they had not discussed before or to discuss a previously diagnosed condition. This helps them start conversations about their health conditions, which otherwise may go untreated or under-treated and also presents doctors a valuable opportunity to screen for related health conditions.

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. The conclusion is that DTCA does not affect the doctor's independence or increase pressure to prescribe, however it encourages patients to visit their doctor as discussed above.
Please refer to the Medicines New Zealand submission for full information and relevant references.

In summary, AbbVie Limited believes the benefits for consumers of DTCA 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, independent, 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.

Continuing DTCA therefore reinforces patients' rights to find out about treatment options. DTCA of prescription medicines has been allowed in New Zealand since 1981.

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.:

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the majority of patients neither asked for, nor received a prescription as a result of DTCA, and also showed that the majority of Doctors responded to the requests with alternative treatments or lifestyle advice instead. Please refer to the Medicines New Zealand submission for full information and relevant references.

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DTCA helps make patients aware of new medicines and gives them enough information to decide whether or not to discuss a medicine with their doctor which then creates an opportunity for Health Care Professionals to talk to patients about various treatment options. In addition, it encourages patients to visit their doctor about a medical condition they had not discussed before or to discuss a previously diagnosed condition. This helps them start conversations about their health conditions, which otherwise may go untreated or under-treated and also presents doctors a valuable opportunity to screen for related health conditions.

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. The conclusion is that DTCA does not affect the doctor's independence or increase pressure to prescribe, however it encourages patients to visit their doctor as discussed above.
Please refer to the Medicines New Zealand submission for full information and relevant references.

In summary, AbbVie Limited believes the benefits for consumers of DTCA 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, independent, 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.

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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.

Continuing DTCA therefore reinforces patients' rights to find out about treatment options. DTCA of prescription medicines has been allowed in New Zealand since 1981.

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 C22Which 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.:

04 April 2019

Therapeutic Products Regulatory Scheme
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Consultation Submission

Submitter Profile: Ross Seal (non-aligned individual)
Director & Publisher http://rejigit.co.nz/
[redacted]

It beggars belief that the New Zealand Ministry of Health currently has no direct regulatory oversight in terms of establishing that orthopaedic devices implanted into New Zealand patients are fit for purpose.
There is growing international concern regarding some medical implant devices being unfit for purpose.
Media reports describing an Australian man's horrendous experience focused attention on what is an international problem.
The man in his fourties, underwent a surgical implant of a partial replacement shoulder with what he understood to be state-of-the-art technology manufactured in the USA. About two months later his drama ramped up somewhat when upon lifting his arm, he heard a very audible squeak emanating from within and when he attempted to move his arm, his shoulder seized and the accompanying pain was excruciating. The man consulted another surgeon who recommended that the malfunctioning shoulder device be urgently removed and replaced. The defective partial shoulder implant was a PyroTITAN device, manufactured by a U.S. company and made of a relatively new pyrolytic carbon material which comprises sheets of graphene. The surgeon who carried out the second partial shoulder replacement described finding slivers of black material floating about in the patient's shoulder area.

Notwithstanding that the Australian man's PyroTITAN device was made in the USA, the U.S. Food and Drug Administration had not certified the implant for use in the U.S. The do however permit overseas sales of the device under section 801(e)(1) of the Food, Drug and Cosmetics Act which relates to "export only" devices and which also specifically precludes such "export only" devices from being used within the U.S.
Effectively, U.S. law appears to have regard for the well-being of U.S. citizens but allows the export of potentially harmful medical implant devices to the rest of the world.
Approximately 4600 such devices are registered with the FDA as "export only" devices and the FDA says its oversight is limited in as much as "The FDA does not have the authority to take action on export-only devices marketed in other countries simply because they do not meet the agency's requirements for marketing in the United States."
The PyroTITAN device has had numerous historic and documented problems and the manufacturer has previously alerted various medical authorities that their product could fail. At least nineteen patients have been required to have PyroTITAN shoulder implant devices removed and replaced.
Research by 252 journalists from fifty nine media organisations in thirty six countries who comprise the International Consortium of Investigative Journalists has uncovered a litany of problems in the global medical device industry including that 1.7 million people have suffered adverse side-effects as a consequence of the implanting of medical devices. Their investigations also revealed how international regulator's dependence on jurisdictions like Europe can mean potentially problematic devices are able to be re-exported. European "CE" assessments are carried out by for-profit private certifiers who are described as "notified bodies."
The PyroTITAN device was approved for general use in Australia and the Australian TGA indicated they had approved it because the device carried EU "CE" certification.
The U.S. manufacturer reportedly obtained its initial European PyroTITAN approval by arguing that its product was substantially equivalent to other steel devices it produces and that prosthetics made from different materials would be comparable.

A paper dated February 2016 and prepared by the Medical Technology Association of New Zealand for submission to the Ministry of Foreign Affairs and Trade with regard to a proposed European Union / New Zealand Free Trade Agreement includes the observation; “New Zealand has a Mutual Recognition Agreement (MRA) with the EU which may also support the reliance by Medsafe (the current NZ Ministry of Health therapeutic regulatory authority) on the conformity assessment procedures undertaken by European Notified Bodies. Under a FTA with Europe there could be an additional benefit for Medsafe to have access to the audit reviews of the Notified Bodies.”

The only requirement of New Zealand importers of medical devices is to register themselves (to be described as Sponsors) together with the devices they intend to import on the NZ WAND database administered by Medsafe.

In response to an email message from this submitter asking if the PyroTITAN Shoulder Joint device was registered on the NZ WAND database, Medsafe responded;
..The purpose of the WAND database is to provide information to assist with the investigation of post-market medical device issues and concerns, by identifying the organisations supplying particular medical devices in New Zealand, or exporting medical devices from New Zealand.
..The WAND database is not an approval system. Notification of a medical device to the WAND database does not constitute an approval or endorsement of the device by the New Zealand Ministry of Health.
..As such there is no public access to the information entered into the WAND database. I am unable to assist you with your query.

A New Zealand Accident Compensation Commission report by Natalie Hardaker dated January 2013 on the safety and clinical effectiveness of pyrocarbon joint resurfacing of the shoulder, stated “The Ascension PyroTITAN shoulder joint replacement device does NOT yet have FDA approval. All cases performed in New Zealand should follow a simple and standardised follow up protocol (Oxford scores pre-operatively and yearly follow up, X-rays post op and at yearly intervals). This information could be independently assessed over a period of a few years until more international information is available. The Ascension PyroTITAN shoulder joint replacement device is currently the only one available in New Zealand.”

It is ironic that in the absence of any effective regulatory control over the use of medical devices in New Zealand there is however a "New Zealand Medicines and Medical Devices Recall Code" which includes;
“Those responsible for the importation, manufacture or distribution of medicines and medical devices (Sponsors) must be able to take prompt corrective action when it becomes apparent that product in the distribution chain does not meet acceptable standards of safety, quality, efficacy or performance”.

This submitter is of the view it is outrageous that any New Zealander facing the daunting prospect of a medical device implant is prevented from accessing whatever limited information may appear on the NZ WAND database and that there is no other means of confirming anything about their intended new body part.

Publicly funded replacement procedures in New Zealand in 2018 (source: New Zealand Ministry of Health - Analytical Services);

- Shoulder replacement: 715 of which 74 were “revision” procedures.
- Hip replacement: 6,358 of which 887 were “revision” procedures.
- Knee replacement: 5,493 of which 399 were “revision” procedures.

During a six year period in Australia 12,249 medical implants were the subject of safety complaints, 8,696 were involved in serious patient injury and 170 were implicated in patient deaths.

It is to be hoped the proposed Therapeutic Products Bill will bring provide for the New Zealand Ministry of Health to have full and effective control over the certification of all Medical Devices intended for use within New Zealand.

Response ID ANON-DPZ8-G43B-P

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-12 11:00:18**

Submitter profile

What is your name?

Name:
Mary-Anne Woodnorth

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Auckland District Health Board

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:
Research Governance

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

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

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).:
Compassionate access. Its important that the bill leaves room for compassionate access schemes that enable trial participants to access unapproved study medicines after their participation in the trial has ended. Access is normally recommended by a participant's study doctor on the basis that it is in the patient's best interest, and approved at the sponsor's (drug company's) discretion. Access schemes are considered a hallmark of ethical trial conduct. They may be the only means for patient's to continue to obtain benefit from cutting edge new investigational products when available alternatives are inferior. Logistically many years may intervene between an individual patient's participation in a medicines trial, the conclusion of that trial, and the trial medicine being approved in New Zealand. The credentialing for a sponsor to operate a compassionate access schemes could be built into the approval for a clinical trial.

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).:
55. For the sake of clarity, re controlled activity l: conducting a clinical trial of a therapeutic product, is this context restricted to trials of unapproved therapeutic products? Or is it intended to include comparative effectiveness trials of existing therapeutic products? I hope the regulator would not wish to wade into this territory, which already has adequate protections in place via ethical, peer review (scientific) and locality (hospital or health care setting) frameworks. Including comparative effectiveness trials within the Bill will mean a significant set-back to national health research strategy objectives to improve the environment for such trials.

56. Is it the intention that the clinical trial is licensed or the person responsible for the clinical trial? In our current context approval for a clinical trial is trial-specific, not person-specific and probably more analogous with a permit than a license. What greater protections is it expected a licensing scenario will add? Is it intended that the regulator will have a role in reviewing trial progress, investigator/sponsor performance or adverse events? There is a shortage of these activities in NZ at regulator level. Health and Disability Ethics Committees have reporting requirements but are otherwise hands off in terms of post-approval oversight. Instead trial performance and safety monitoring occurs in a somewhat ad hoc environment, currently, with independent data safety monitoring boards (DSMB), sponsor's internal DSMBs and no DSMBs all being the norm. How is it intended that the regulator as licenser will operate to actually improve the trials environment in a way that serves the public interest? Its important that licensing adds a value that mitigates the potential bureaucratic burden for investigators of complying with licensing rules (whatever these might be). If the value cannot be conceived at the time of writing the Bill then the scope for the regulator should be limited to "approver" or "permit writer" analogous to the way MedSafe currently operate in this space.

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).:

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).:

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).:

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.:

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.:
Its progress that the Bill proposes regulatory oversight for cell and tissue medicines research and medical devices research. There are seriously novel and exciting but unproven products coming into NZ hospitals for early phase trials. Our hospital research committee does its best to monitor these high risk studies via a register but this is at best a minimal safeguard and we will welcome the regulator's involvement. However, there should be a room for a very expedited process for trials of devices that are mere iterations from the parent device. The regulator should have a process that ensures more scrutiny is applied at the high risk end and little at the low risk, or it could easily get bogged down.

Earlier sections of the consultation document are ambiguous about whether the intention of the bill to capture trials of unapproved medicines only, or also of approved medicines. This section is 100% clear that all medicines trials are in scope. My question then would be around what expertise the regulator will provide to improve the trials environment in the public interest when the trial is just looking at already approved medicine. We see these reasonably often in our hospital - there are several therapeutic products in usage (clinician's choice) for a certain indication in a certain group of patients, and genuine equipoise about which treatment is better. In this scenario the ethical imperative is to perform a trial to answer a question about whether one medicine is superior (or equivalent with fewer side effects, or equivalent and less expensive). Without a robust portfolio of such trials in NZ we will inevitably expose our patients to treatments with no evidence base and incur unnecessary costs to the health system. If such trials will now need to be "licensed" there needs to be a strong rationale provided about why this is an important thing to do, and a true value offering from the regulator.
The potential for parallel processing of approvals with HDEC is highlighted, which is great, but a parallel process is not synonymous with no extra effort. Those preparing the Bill need to be aware that any extra forms and acts of compliance impose bureaucratic burden on investigators. The individuals who undertake trial of this nature in NZ do not work for pharmaceutical companies. They are clinicians and academic clinicians who are doing research in their spare time and frequently also having to raise funds to do so. In my role I see real life examples weekly of our locality approval been delayed (sometimes by months) because a researcher can't wade through the technical requirements of interacting with HDEC, even after 7 years experience with the electronic submissions system. So unless there is going to be tang ble value in involving the regulator in licensing investigator-initiated comparative effectiveness research I would suggest that the next version of the draft Bill drops this aspect of the scheme.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:
I can only comment that the formal application after the 6-month temporary license for device trials has the potential to halt research in this area for a period of time. Those preparing the Bill must consider that when we undertake clinical trials on a sponsor's behalf we are paid by the sponsor for the costs we incur. There won't be a budget line for preparing therapeutic product license applications for any of the many device trials we have in the hospital so if the law changed tomorrow the hospital would incur a very large cost for which we would not be reimbursed in six months time. Those drafting the Bill should be mindful of the operational basis of our research units and burden of complying with the new Act.

Therapeutic Products Consultation: Submitter Profile

If you elect not to use the online tool to complete your submission, please ensure you complete the following submitter profile form and send in via email with your submission.

☐ Individual ☒ Organisation

Name (of individual or organisation): GS1, Avenue Louise 326, 1050 Brussels, Belgium

Email address: [redacted]

Profile (tick all that apply)

Perspective

☐ Consumer ☐ Disabled person ☐ Māori ☐ Pacific peoples

☒ Other (GS1 - Global standards organisation)

Industry

☒ Industry body
☐ Advertising
☐ Retailer (non-pharmacy)

Importer	Manufacturer	Wholesaler
☐ Medical devices	☐ Medical devices	☐ Medical devices
☐ Medicines	☐ Medicines	☐ Medicines
☐ Cells and tissues	☐ Cells and tissues	
☐ Active ingredients	☐ Active ingredients	
☐ Veterinary medicines	☐ Veterinary medicines	

Health sector

☐ Professional body (eg, Colleges, Pharmaceutical Society etc)
☐ Health service provider (eg, Ambulance, Māori or Pacific health provider etc)
☐ Private hospital
☐ Pharmacy organisation
☐ District Health Board (DHB) - please state which service area: Click here to enter text.

Health practitioner

☐ Pharmacist	☐ Surgeon
☐ Nurse	☐ Optometrist
☐ Midwife	☐ Dietician
☐ Dentist	☐ Medical practitioner (excluding Surgeons)

☐ Other health practitioner (please comment) Click here to enter text.

Clinical trials

☐ Medicines (other than cell and tissue)
☐ Medical devices
☐ Cells and tissues
☐ Trial ethics

Other

☐ Government agency
☐ Crown entity
☐ NGOs
☐ Veterinarian
☒ Other (please comment) Global standards organisation

Official Information Act statement

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

Brussels, 6 April 2019

Therapeutic Products Regulatory Scheme
Ministry of Health
P O Box 5013
Wellington
New Zealand 6140

GS1 Healthcare[1] welcomes the New Zealand Government's initiative on the new Therapeutic Products Bill and its endeavours to facilitate access to healthcare and move to better and more efficient healthcare services.

Global Learnings for Safe & Cost-Effective Healthcare

Regulators, suppliers and healthcare facilities globally have recognised in the last decade that *standardized unique identification*, *automatic data capture* of such identification (and related data such as batch code, serial number, expiry date) and interoperability standards to *share* information facilitate an efficient healthcare supply chain and increase patient safety outcomes.

How and *why* savings and quality can be made not to be in conflict was articulated in an influential study by McKinsey in 2012[2]. In essence, alignment on global standards is required.

Implementation of Global Standards

In many jurisdictions today such as Europe, U.S.A[3], Argentina, South Korea, Turkey, China[4] and others, the regulatory requirements for pharmaceutical and medical device identification and traceability are requiring implementation of GS1 standards. England's National Health Service (NHS) is a prime example of a leading healthcare jurisdiction that has mandated the use and implementation of GS1 standards. The NHS is realising significant positive financial and healthcare related outcomes.[5,6]

[1] www.gs1.org/healthcare
[2] McKinsey (2012). Strength in Unity. *The promise of global standards in healthcare*. McKinsey & Company. 2012. Available at: www.mckinsey.com
[3] https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/
[4] http://www.cpia.org.cn/news/dt2240943101100.html
[5] Lord Carter, (2016). Operational productivity and performance in English NHS acute hospitals: Unwarranted variations. An independent report for the Department of Health. Lord Carter of Coles. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf
[6] England Department of Health (2007). Coding for Success. *Simple technology for safe patient care.* Health Quality Directorate. National Health Service. London, 2007.

Key Standards

1. **Identification**

For New Zealand to align with global regulators, GS1 Healthcare strongly recommends the use of the **Global Trade Item Number** (GTIN) as the globally unique product identification code - supplemented by associated product attributes (e.g., batch/lot, serial number etc.,).

2. Automatic Data Capture

To streamline supply chains ('scan-in and scan-out' stock management & fulfilment) and minimise administration errors (bedside verification), the Global Trade Item Number should be machine readable by being encoded into either a linear barcode or a GS1 DataMatrix barcode (or ideally both). Both these 'data carriers' are almost ubiquitous globally now on healthcare items; requiring them to be available predictably will allow New Zealand healthcare to deliver enhanced interoperability both nationally and internationally along with opportunities for streamlined supply chains and ultimately, improved patient healthcare outcomes.

3. Data Sharing / Traceability

GS1 standards for master data and traceability are widely deployed globally to manufacturers, distributors and healthcare providers to share accurate, standardised and synchronised product traceability data electronically, such as is required under the European Falsified Medicines Directive[7]. The GS1 system of standards therefore, builds a global and secure framework for identification and traceability systems worldwide that New Zealand will be able to align and interoperate with.

Alignment with HISO

New Zealand's HISO Standards have already endorsed GS1 standards[8,9]. This endorsement was done specifically to enhance safety and efficiency.

Extant Implementations of GS1 Standards in NZ

The Global Trade Item Number (GTIN) is the primary identifier used in GS1 New Zealand's National Product Catalogue (NPC) which is a product master data synchronisation platform built using a globally standardised infrastructure known as the Global Data Synchronisation Network (GDSN[10]) and open global data standards. The National Product Catalogue is a shared infrastructure between GS1 New Zealand and GS1 Australia and is used by each country's respective supplier/ jurisdictional user communities.

In New Zealand healthcare, the National Product Catalogue is used by over 130 organisations representing over 100,000 products across all packaging hierarchies (i.e., both consumer and logistics units) to identify and synchronise medical devices, pharmaceuticals and medical consumables between suppliers and end users – including hospitals, healthcare related agencies and retail outlets.

[7] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/falsified-medicines-overview
[8] HISO 10024.2:2017 - Medical Device Terminology and Identification Standards
[9] HISO 10063 – GS1 Standards
[10] https://www.gs1.org/services/gdsn

Originally deployed in New Zealand by Health Benefits Limited (HBL), the NPC is currently used in New Zealand healthcare by Southern Cross Hospitals for enhanced purchasing, procurement and clinical decision making, in conjunction with their community of suppliers and trading partners.

The New Zealand Universal List of Medicines (NZULM[11,12]) interoperates directly with the NPC for supplementary pharmaceutical information including GTIN and the Global Location Number (GLN).

Alignment with the NZ's Whole-of-Government Initiatives

1. Global Location Number / NZ Business Number

GS1 Healthcare also strongly recommends the use and implementation of the Global Location Number (GLN) for both legal entity and physical location identification. The New Zealand Business Number (NZBN) is a globally unique identifier that utilises the GS1 Global Location Number (GLN) conforming to ISO/IEC data standards, enabling global uniqueness and interoperability for New Zealand businesses.

The NZBN is issued to businesses by the Ministry of Business, Innovation and Employment and is provided in law by the New Zealand Business Number Act 2016. The Minister of Finance and State Services also has in place a Direction to support the whole of government approach to the NZBN. The Direction sets out requirements for agencies to implement the NZBN. This process is ongoing and shows a clear commitment on behalf of the Government to drive adoption of the NZBN in New Zealand.

2. E-invoicing

The New Zealand and Australian governments are also working on a joint approach to e-Invoicing which will make it easier for businesses on both sides of the Tasman to work with each other and across the globe. The NZBN links all key information that others need in order to trade with a business. The New Zealand Government has already announced that the GLN will be the standard of use for e-invoicing. The e-invoicing initiative will strengthen the use case of the NZBN moving forward and has potential to drive efficiencies in the therapeutic domain.

3. Recall

The Therapeutic Consultation Document references the regulator's ability to issue recall orders. GS1 New Zealand operates a modern, web-based business-to-business recall solution (ProductRecallNZ[13]) which is used extensively in the food and grocery sector by over 2900 organisations including major sector retailers (incl: Foodstuffs, Countdown, Z Energy). Regulators MPI and MBIE are key supporters of the recall workflow.

ProductRecallNZ is an industry designed: industry driven product recall/withdrawal solution developed in direct response to what was considered a sub-optimal system

[11] www.nzulm.org.nz
[12] https://www.gs1.org/sites/default/files/docs/healthcare/gs1_hcreferencebook_17-18.pdf
[13] www.productrecallnz.org

operating in the food and grocery sector at the time (i.e., manual, inefficient and expensive to implement). GTIN and GLN are the primary identifiers used in ProductRecallNZ. GS1 strongly recommends the use of GTIN and GLN (and where necessary for more effective recalls, the use of GS1 product application identifiers such as batch/lot, serial number) in healthcare recall notifications. Implementing these identifiers and attributes will greatly assist in streamlining recall procedures throughout New Zealand healthcare.

In Summary

Finally, the adoption and implementation of GS1 global standards as outlined will have a significant and positive outcome for New Zealand's global competitiveness and economic growth. A reduction in supply chain complexity, cost and risk for all stakeholders is also a desirable outcome enabled by the use and implementation of the suite of GS1 Standards.

We invite you to directly contact our colleagues at GS1 New Zealand for more details on how the GS1 standards can help you in supporting patient safety.

GS1 New Zealand contact:

Gary Hartley
General Manager - Customer
[redacted]

Yours sincerely,

Ulrike Kreysa
Vice President – GS1 Healthcare