

Response ID ANON-DPZ8-G43T-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on 2019-04-17 13:20:28

Submitter profile

What is your name?

Name:

Anthony Aitken

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Organisation:

ProPharma - pharmaceutical wholesaler

Submitter Profile (tick all that apply)

Medicines

If you select DHB, please state service area:

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

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

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

Chapter A (A1 - A5)

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

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).:

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).:

The definition for dispensing a medicine needs to include clinical checks, preparing a medicine, supply to the 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):

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):

We are supportive of the ability for one pharmacy to supply a medicine to another pharmacy that is out of stock of a medicine required by a patient. This will result in better service for the patient particularly if the medicine is uncommon. It will also reduce pharmacy wastage and potential savings in the pharmaceutical budget spend.

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

No comment

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

We are supportive of health practitioners supplying each other with small amounts of medicines in an emergency when a pharmacy is either not accessible or cannot provide the medicine in a timely manner. There should not be the ability for stock to be traded between medical practitioners and the legislation will need to define what a small amount of medicine is.

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

No comment

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

No comment

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

Personal importation of medicines should only occur through the appropriate regulated channels to ensure patient safety is not compromised. We support the SCNSA mechanism but would like to highlight that often requests for unapproved medicines need to be actioned urgently . The current s.29 medicines are often imported as the approved medicine is unavailable or in scarce supply. This may necessitate stock holding of the unapproved medicine to enable speedy supply when required. We believe that the personal importation of medicines should be limited to category 4 prescription medicines.

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

The use of vending machines should be linked to a pharmacy license to ensure the appropriate patient advice and clinical oversight is provided. Vending machines should only be authorised for use when patients do not have access to a pharmacy or pharmacy depot.

Subpart 4: Other offences (ss 81-94)

Question B12

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

No comment

B6 Part 4 of the Bill: Product approval

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

Question B13

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

No comment

Question B14

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

No comment

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

Question B15

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

No comment

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

Question B16

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

No comment

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

Question B17

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

No comment

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

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

We do not agree that an Aged Care facility should be able to dispense medicines without an onsite pharmacy dispensary. An aged care facility would need have the required dispensary equipment, access to reference resources and standard operating procedures required for audit.

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):

We are supportive of the introduction of permits for shorter term and urgent situations. The permit system would need to be 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):

We are supportive of increasing the period that licences are valid for as this should reduce compliance costs for both the pharmacy sector and the licensing authority.

Question B22

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

No comment

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

Question B23

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

No comment

B8 Part 6 of the Bill: Regulator

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

Question B24

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

No comment

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

No comment

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

Question B26

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

No comment

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

Question B27

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

No comment

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

Question B28

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

No comment

B9 Part 7 of the Bill: Enforcement

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

Question B29

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

No comment

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

Question B30

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

No Comment

Subpart 6: Infringement offences (ss 249–255)

Question B31

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

No comment

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

Question B32

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

No comment

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

Subpart 1: Repeals and revocations (s 275)

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

Question B33

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

No comment

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

Question B34

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

No comment

B12 - B15, Schedules 1 - 4

Schedules

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

No comment

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

No comment

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

No comment

C1 Medicines (excluding cells and tissues) sector

Product-based controls

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

No comment

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

No comment

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

No comment

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

No comment

Activity-based controls

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

No comment

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

No comment

C5 Wholesale sector (including importers and exporters)

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

Licence to wholesale

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

We are supportive of SCNSA mechanism for the importation of a medicine when managed by a medical practitioner, pharmacist or wholesaler. We believe only category 4 medicines should be allowed to be imported by an individual.

As detailed in an earlier question, the issuance of a SCNSA may need to be actioned urgently therefore the process needs to be flexible, simple and quick.

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.:

We are in agreement with the proposed transition arrangements.

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

We believe the current supply chain model can be enhanced by making improvements to the efficiency, viability, sustainability and resilience of the current model. Current issues include:

1. Scarce product management due to Pharmacist's sole supply agreements increasing cost on the supply chain. There needs to be cost recovery from suppliers and compensation paid to the supply chain and pharmacy
2. Explosion of pharmacy numbers increasing numbers of orders, inventory holding costs, debt risk and reducing patient services. Limits are needed on the issuance of new licenses and contracts and higher pharmacy standards set
3. Changing Supply Chain requirements due to increased cold chain products in particular. High value and high cost distribution model requires a higher level of remuneration for services

3.

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

We don't believe the current licensing requirements create any barriers to innovation.

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

We are supportive of service innovations such as mobile dispensaries and event/marae based services as long as the dispensing was from a pharmacy dispensary for patient safety reasons.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

It is proven that there is a strong public benefit in an effective network of community pharmacies owned by pharmacists who are in control of, and accountable for the decisions made in the interests of patient care. Pharmacist ownership and effective control assures the public that patient care is the focus of the 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.

Requiring community pharmacies to be owned by pharmacists means that health professionals with 'skin in the game' focus first and foremost on delivering quality health outcomes to maximize 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?:

- Pharmacists are directly accountable and liable for the services they provide and there is a professional relationship between the pharmacist owner and the patient

- Under the current legislation the community pharmacy network delivers many benefits to patients at no cost to the patient or the government
Option 1 provides less risk than open ownership (option 2) with no negative impacts on access to services, no negative impact on quality and efficiency of pharmacy services and no negative impact on the delivery of other pharmacy services as presented in the Pharmacy Action Plan.

Overseas examples highlight the risk to rural and provincial population access to pharmacy services when there is open ownership.

It would be a lower risk option (Option 1) to strengthen existing ownership legislation at a time when the government and the profession are working to efficiently integrate front line primary healthcare services and thereby maximizing the benefits from the existing community pharmacy network.

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

Need to a grandfather clause for community pharmacy businesses that are operating legitimately under the current legislation but might not be legitimate under the new proposed Option 1.

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 license such as the provision of medicines outside of general sale 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?:

No comment

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

No comment

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

Effective control could be shared between 2 pharmacists with an equal stake of 26% for example. The five pharmacy limit could be applied by only allowing a pharmacist owner to 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?:

no comment

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

No comment

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

No comment

Detailed questions relating to Option 2

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

No comment

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

No comment

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

No comment

Other changes to pharmacy licensing requirements

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

no comment

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

Yes s.94 is still required as there is a conflict of interest if prescribing and dispensing were not separated

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 events such as civil emergencies to allow pharmacies to get back up and running quickly in temporary premises.

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

We believe that depots should be authorized via the license of a linked full service pharmacy to provide effective pharmacist oversight.

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

It is not safe to allow personal importation of medicines and therefore we believe it should be curtailed.

Pharmacist and pharmacy worker authorisations

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

No comment

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

It would be appropriate for pharmacies with a common ownership to provide medicines between each pharmacy. This activity reduces wastage particularly of high cost medicines.

C7 Retail sector

Question C42

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

No comment

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G467-E

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 14:19:06**

Submitter profile

What is your name?

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What is your organisation?

Organisation:

Occupational Therapy Board of New Zealand

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Regulatory Authority

If you select 'Other', please comment;:

Other (please comment)

If you selected 'Other' please comment;:

Regulatory Authority

Next steps after the consultation

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

Chapter A (A1 - A5)

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

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

The OTBNZ supports the purpose of the bill in protecting personal and community health, and adopting a risk-based approach to regulation.

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).:

Definitions and meanings are generally clear and understandable.

B5 Part 3 of the Bill: Dealing with therapeutic products

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

Question B3

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

The OTBNZ is supportive of regulations that lead to better client outcomes. The OTBNZ would be concerned about regulation that would lead to a limiting of client

care due to regulatory barriers.

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):

Agree that manufactures and wholesalers should be accountable for the products they are manufacturing/importing.

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):

The OTBNZ would support the informed personal importation of devices in some situations, such as a client in the “Enabling Good Lives” approach. The OTBNZ supports limitation around the personal importation of higher risk devices that have the potential to cause harm when used inappropriately.

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

Custom made devices may be manufactured for a wide variety of reasons and settings. Regulations and policy regarding the manufacture of a custom made device for a client should be set to ensure that practitioners are able to manufacture and supply the appropriate device, or ensure that the device is manufactured to the appropriate standard without reference to the regulator on each occasion. The OTBNZ would be concerned if an approved device became unavailable due only to sponsor non-compliance, instead of risk to the public.

Subpart 4: Other offences (ss 81-94)

Question B12

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

Agree with offences being appropriately enforced.

B6 Part 4 of the Bill: Product approval

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

Question B13

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

The OTBNZ supports the supply of safe and effective medical devices, of an acceptable quality. The OTBNZ would be concerned if the regulatory burden of approval limited the availability of existing products currently available from trusted suppliers.

The OTBNZ is concerned that the definition of medical devices is very broad and may inadvertently capture many commonly used low risk products. The appropriate setting of policy and subsequent regulation around this is paramount in ensuring this does not impact on the ability of practitioners to deliver appropriate client care.

The limiting of products to those approved by the regulator also needs to be carefully considered in the case of readily accessible products. Approved products may reinforce inequities through greater geographic or financial barriers than the same product that has not been approved which is covered under existing consumer law.

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):.

The OTBNZ considers that the regulator should have adequate powers to allow for robust investigation and enforcement. The regulator should be subject to the usual requirements for open and transparent justice, and review/appeal of decisions.

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):.

The OTBNZ acknowledges that health resources within the system are limited. The OTBNZ would be concerned if significant resources were used in fulfilling the regulatory requirements of the bill, without a corresponding improvement in health outcomes.

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):.

As the OTBNZ does not have authorisation to prescribe this change is currently not applicable.

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):.

The regulatory burden in making minor changes to products should be minimised, particularly where the change is an enhancement requested by

practitioners/users.

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 OTBNZ considers post-market controls are important in allowing collated evidence to determine products carrying unidentified risks. A central database with known reporting lines may be the best option for this. For example, the recent deaths linked to bedrail use have led to changes in design to prevent a recurrence

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?:

The OTBNZ considers the risk/s to the public should be considered when making these decisions.

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 OTBNZ supports the use of the global model in the regulation of medical devices

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

The regulatory burden in making minor changes to products should be minimised, particularly where the change is an enhancement requested by practitioners/users.

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

The OTBNZ supports this proposal where the risk to the public outweighs the benefits of unrestricted supply. Some devices have the potential to cause harm when used inappropriately for example: high-level pressure care devices.

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

The OTBNZ considers post-market controls are important in allowing collated evidence to determine products carrying unidentified risks. A central database with known reporting lines may be the best option for this. For example, the recent deaths linked to bedrail use have led to changes in design to prevent a recurrence.

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

The OTBNZ would wish to ensure that any transitional arrangements did not interrupt the supply of services/ therapeutic devices to clients.

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 OTBNZ generally supports requirements, but would want to ensure that research and clinical innovation were not unnecessarily impeded.

Question C17

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

C8 Health practitioners (including pharmacists)

Prescribers

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

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

More practitioner groups are developing the skills to allow prescription of relevant medicines. A standardised approach would reflect this transparently to other

stakeholders.

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.:

The OTBNZ endorses the provision of accurate information to the public when advertising therapeutic products, and ensuring the enforcement of regulations regarding this. The OTBNZ considers that this also applies to the advertising of therapeutic methods and this should also be adequately regulated. A similar approach to that used by AHPRA in Australia may be appropriate.

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

C10 Advertising sector

Question C52

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

The OTBNZ endorses the provision of accurate information to the public when advertising therapeutic products, and ensuring the enforcement of regulations regarding this. The OTBNZ considers that this also applies to the advertising of therapeutic methods and this should also be adequately regulated. A similar approach to that used by AHPRA in Australia may be appropriate.

Question C53

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

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G4KZ-6

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 14:30:57**

Submitter profile

What is your name?

Name:
Vasavi Nagalla

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Sysmex NZ

Submitter Profile (tick all that apply)

Medical devices

Medical devices

If you select DHB, please state service area:

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

Medical devices

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).:

There should be co-operation with overseas regulators --- can we have more info on the sort of co-operation expected and their terms?

compliance with international obligations - What compliance is expected? and to what standards? What evidence or information is expected to show compliance?

Alignment with international standards and practice - Need more elaboration on this. What standards are we considering here?

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).:

d. therapeutic product - the definition is not explicit enough to define what products fall under therapeutic. Also, it seems to be evident that the definition is taken from IMDRF, however, TGA defines it more explicitly

" any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper

application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
diagnosis, prevention, monitoring, treatment or alleviation of disease;
diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
investigation, replacement or modification of the anatomy or of a physiological process;
control of conception;
and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means;"

As an organisation that develops health software and also distributes medical devices, it would be clear if the definition includes devices and any associated software, in that way it helps us exclude our health software like laboratory information system and clinical data repository.

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):

With regards to product criteria defined in Part 4, Subpart 1, 95 (a to c) - What do we have to provide in terms of proving quality, safety (we can demonstrate certain stds like IEC for safety from electric shocks and so) but for quality or efficacy or performance, what do you expect?

Can you please provide a list that defines those?

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 disposal - would it be enough to source a company that does this, and obtain a certificate of disposal from them?

What other requirements do we have to comply with in terms of disposal?

Subpart 3: Authorisations (ss 56–80)

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

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable

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

Not applicable to us

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

None

Subpart 4: Other offences (ss 81-94)

Question B12

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

None

B6 Part 4 of the Bill: Product approval

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

Question B13

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

1. Part 4, sub part 1, 94, (2) - (b) - product, if approved, will comply with the specified product standards - what standards are we exactly referring to?

Also, as a company importing medical devices including reagents that support the functioning of the medical device is from the parent company, then what sort of authorisation is required?

Also, does medical device include reagents, spare parts and other accessories? how are they to be approved ? along with medical device? or separate application?

Question B14

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

None

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

Question B15

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

need more specifics around what fall under approval exempt products - spare parts? accessories? antivirus software that will be installed for a medical device along with the software? any trolley items to hold medical device or reagents? transport belts that carries tubes?

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

Question B16

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

118 (1) (a) mentions about sponsor's obligations to product quality, safety, efficacy or performance -- If the sponsor is just an importer and distributor, they would only have the ability to secure the necessary information. Would that suffice?

118 (1) (b) - product and consumer information for the product - is again sourced from the manufacturer.

Also, the packaging and labelling is done by manufacturer in accordance to global requirements? Are NZ requirements different to those?

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):

Not applicable

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):

With regards to clinical trial, can it be more clear:

1. As an importer we apply for permit, but that could be for an IVD product - which can be used for In Vitro purpose or for Clinical Trial, so do we have to apply for 2 permits under different purpose or can we have one and rather use it for either.
2. The organisation or person responsible for conducting the clinical trial is required to apply for a permit and not the importer or distributor? or does both need to be?

Question B19

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

Why does a company have to list the details of the person and their controlled activity area?

So, if the person leaves the organisation, what is the turnaround time to have the license updated to include the new staff detail and their controlled area?

If we do an organisation restructure and add or remove existing areas, then license has to be updated?

What are the associated costs with each of these? Rather can we not have a license issued under the name of the organisation and list the activities that fall under this license? to keep our administration simple and effective?

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):

Basically a permit is provided for a short term to import a medical device or associated reagents, to perform a controlled activity.

So, can we apply for a permit for clinical trial? for a single product item and once its use is established can we apply for a license?

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):

For any medical devices, that are classified as InVitro Diagnostic (IVD) devices, can these be grouped ? And apply for one license?

Question B22

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

Also, if we are taking over from an existing distributor of medical devices that could be IVD's or non-IVD, then can we use their reference to transfer the license?

As of now, if they do not have license, then is it a new application? or reference to that would suffice?

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):

More details to be provided to the licensee on these requirements.

Depending on the size and scale of operations, the organisation could decide if one staff member could perform multiple roles or not. But the way the regulatory body considers this could be different, and would be the license be issued based on this?

B8 Part 6 of the Bill: Regulator

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

Question B24

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

The intention of section 179 is to ensure that where someone has misrepresented something as a therapeutic product, the regulator would be able to make an order, even though the product does not meet the definition of a therapeutic product. -----

We would like more clarification on section 179. Our assumption is that the regulator would issue the permit only if the application meets the requirements rather than issuing the product to a misrepresented information and placing the order as described above.

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

None

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

Question B26

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

None

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

Question B27

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

None

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

Question B28

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

None

B9 Part 7 of the Bill: Enforcement

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

Question B29

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

Under point 194, does that mean a sponsor company would be audited? If there is any finding it should follow the auditing principles to allow the sponsor to respond to the Non Conformance and agree upon the actions.

As an importer and distributor we are the suppliers of the medical devices, but if the customer does any modifications to the configurations set by us, then it is not our responsibility should that lead to any untoward event. So, there must be enough time provided to identify the root cause, and if the cause is with the customer or user of the medical device not following the instructions or have modified any settings without our guidance, then it shouldn't be the suppliers responsibility.

Can this be more clear?

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).:

Same as B29

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).:

Same as B29

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).:

Can the product grouping be considered? to reduce cost burdens? and can comment further upon seeing the costs per activity.

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

Subpart 1: Repeals and revocations (s 275)

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

Question B33

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

None

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

Question B34

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

None

B12 - B15, Schedules 1 - 4

Schedules

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

None

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

None

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

N/A

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

C2 Cell and tissue sector

Product-based controls

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

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

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

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

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

Activity-based controls

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

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

C3 Medical device sector

Question C11

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

Product-based controls

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

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

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

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

Under the new scheme, product approvals may be cancelled but not suspended. The purpose of this provision is to avoid legal uncertainty for those in the supply chain. 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 use existing stock (s 78).

Could you give us an example of why an approval would be cancelled if its not safety related ? Also, if its safety related it should go through Adverse Event Reporting and implementing Corrective Action/Preventive Action/ issue of FSCA or FCA rather than cancelling an approved product by the regulator. This would impact our customers and business so need more info on this.

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

Activity-based controls

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

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

C4 Clinical trial sector

Question C16

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

Question C17

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

C5 Wholesale sector (including importers and exporters)

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

Licence to wholesale

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

Hawker's licence

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

Transition

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

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.:

As per the advertising requirements section 83)2) (a) - do we need to include the name of the person or just the company as an importer or distributor?

The person promoting the product would be the CEO of the company or the Sales Director with the approval of the CEO. Can we not just limit this to company name instead in case the person leaves the organisation or changes departments and we would have to spend time and effort on recreating the adverts? or limit to job title? but prefer company name.

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?:

Not Applicable

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

15 February 2019

Rt. Hon. Dr David Clark
Minister of Health

Dear Minister

My name is Andrew Hou - I am a born and raised constituent of Dunedin North, and very proud to have our local MP as Health Minister.

I am also a Pharmacist and own a Pharmacy in your constituency - Unichem Roslyn Pharmacy. Our Pharmacy is a busy community Pharmacy and we proud our selves in delivering exceptional Pharmacy and other health services to our community. We have recently undergone some investment in our business, undergoing an extensive refit which has enabled us to build two private consultation areas for current and future Pharmacist services, such as vaccinations, smoking cessation services and weight management services. We have also opened a healthy eating eatery next to our Pharmacy. We believe through educating our community in the principles of healthy nutrition - primarily eating a whole foods diet high in unprocessed grain and low in sugar we can achieve fantastic health outcomes for all in our community. As you can see our values and goals for our community is congruent with those our local DHB and and PHO hold.

Which bring me to the point of writing you this letter. I understand that the Pharmacy licensing criteria is now being considered as part of the new Therapeutic Products Bill. There is a discussion on deregulating the rules of Pharmacy Ownership. Deregulating Pharmacy ownership will cause a tectonic shift in the way Pharmacy services will be offered in New Zealand. Large corporations such as Countdown and Chemist Warehouse will seize on this opportunity to flood the market with multiple new sites, causing a situation where few independent Pharmacies will be able to continue to trade. Market forces and consumer choice is acceptable in a level-playing ground - but make no mistake, these corporations have deep pockets and will devalue the services that we are able to provide now. These corporations are not incentivised from doing good for our community - they are doing this solely for profit and to give their shareholders a boost. They will offer loss leading prescription services so that the public will purchase 2 L of Coke, a 6 pack of beer and a packet of cigarettes as they pick up their insulin prescription for their woefully controlled diabetes that will result in kidney disease and dialysis - at huge expense to the health budget.

Deregulating Pharmacy ownership will cause a change so large, so quickly, that the industry will not be able to recover from. Pharmacy Services will be negatively impacted on. Pharmacy staff will be pressured to meet growth KPI's and be under pressure, causing an increase in dispensing errors. As a Pharmacist, Pharmacy Owner and a member of your constituency I would love to have the opportunity to meet with you to discuss this topic more. I understand that you are a very busy person so please let me know when you are available to meet, I will make any-time that suits you work.

I really appreciate your time.

Yours Sincerely

Andrew Hou MPSNZ

Response ID ANON-DPZ8-G47V-E

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 14:38:57**

Submitter profile

What is your name?

Name:

Cath Knapton

What is your email address?

Email:

What is your organisation?

Organisation:

Midland Community Pharmacy Group

Submitter Profile (tick all that apply)

Pharmacy organisation

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).:

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

We are concerned that the Draft TPB may increase patient risk as it reads that there is a level of simplicity in the dispensing of a medication as merely a preparation process. This simplicity and lack of clarity around the provision of information and advice and the clinical checks that go with the dispensing of a medication such as clinical checks on "other" medications, interactions etc needs to be considered to ensure patients safety and optimisation of therapeutic benefit.

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):

We are supportive of the move to enable one pharmacy to supply medicine to another pharmacy that is out of stock of a medicine requested by a patient. Consideration needs to be given to the prevention of Cherry picking e.g. a pharmacy chooses not to stock and expensive medicine thereby avoiding expiry risk etc and utilise another pharmacy to fill a gap they have created.

The intent of this component is great and would hopefully help to minimise waste. This is also great when a medicine goes into short supply or is discontinued but a patient needs or wants this med.

It would be great for the TPB to consider the supply of medicines for innovations such as for the treatment of mild impetigo the pharmacist under an accreditation could dispense antibiotics to a patient without it falling outside the rules for a Standing Order.

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:

Standing Orders stifle innovation at present. Please ensure that Standing orders don't prevent us from developing and implementing services that will best meet the communities needs. An example of this is the treatment with antibiotics for mild to moderate skin conditions via Community Pharmacy. With robust accreditation processes and checks and balances in place we need the system to be more flexible to meet the needs of our most vulnerable populations who cant or wont attend GP's.

The supply of medicines from a vending machine would ideally be backed up with a link to professional care and advice. Not as a stand alone device that provides medication but somehow through use of technology or specifications such as contact with a health professional/pharmacist or signposting for further clarification or questions about their medicines. There is a risk here that the machines could be managed and run by a corporate firm who employ stockists to fill the machine but then an issue arises with the machine (i.e. wrong medication falls out of the machine) the patient would need to be provided with a contact person that is not the vending machine supplier or stockist... there would need to be the provision of clinical care and advice ie if the patient took some of this medicine and then realised what had happened.

Subpart 4: Other offences (ss 81-94)

Question B12

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

105. This is confusing as a GP can hold an interest in a pharmacy at present but not as a majority owner. Anyone can own a pharmacy at present but not as the 51% owner (on paper). We have seen in practicality that there is a multitude of ownership models out there ... just the paper version varies. With a professional code of ethics and the right regulatory levers a prescriber could own a pharmacy.

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 think this is the correct approach for patient safety.

Hawker's licence

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

Transition

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

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

Consideration needs to be made to patient safety at all times. Care and advice, monitoring, education and the ability to support a patients medicine therapy and regime must always be paramount. Access and supply is important but not as a stand alone service we already see so many patients not taking medication as prescribed so we need to ensure systems, checks and balances optimise this part of the patients therapy and put patient safety first.

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

IT does not aid innovation and causes fragmentation of service delivery. For a truly collaborative and integrated service we need to make sure IT issues are resolved. Patient safety is paramount and at the moment without One integrated record there are too many unknowns. Innovation such as Flu vaccination was hindered by IT issues. By introducing other means of supply and distribution without fixing the IT issues we could potentially be creating issues for patient safety. At present GP know what the patient has had dispensed and by introducing other models to the arena this could cause further fragmentation unless we can close the loop.

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

Supportive of this as long as there is holistic service delivery not just about supply. Ensuring patients have access to care and advice and information to improve health literacy and understanding their medicines.

We need to ensure there is still somewhere for patients to go (especially in our most deprived communities) to receive immediate care and advice and treatment in an ever decreasing and difficult to obtain immediate Primary Care environment.

Pharmacists are very skilled and very able to "prescribe" antibiotics for example for Mild to Moderate skin issues with the right education, skills and scopes of practice. We make it too difficult to develop innovations such as this when we know we have the most vulnerable, hard to reach communities needing opportunistic services.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Pharmacists abide by a code of ethics, rigorous training and accountability, monitoring and disciplinary actions where required. We have noted in recent years with non pharmacist "investors" there is increasing pressure on pharmacists to do things outside of their "comfort zone" and in some cases "questionable" with some bullying behaviours and fear amongst staff for not complying to their "owners" wishes. We need to be mindful of this type of behaviour and if we move to a different model we need robust clinical governance/governance structure much like the finance industry where it is very clear "owners" are accountable and can be disciplined by a regulator.

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?:

Governance structures that place liability on all owners no matter what percentage of shares they own. I am worried some pharmacies are "owned" by a pharmacist on paper only. We need to consider how this works in reality for the safety of that pharmacist who is named as the majority owner when in actual fact they need to comply with their investors.

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?:

I am concerned this option could impact patient safety as pharmacist are at present guided by a code of ethics and monitored by regulators. Pharmacists legitimately concern and care for their patients. This option could be all about profit driven behaviours which I think we are trying to move away from.

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?:

Clinical Oversight needs to be in place at some point via either review, or monitoring or guidelines. As this is only the provision of care and advice I think this can be done via an accreditation programme with regular monitoring as part of the oversight.

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?:

Unsure. Has evidence from anywhere around the world shown this to have a negative impact on prescribing volumes/behaviour?

I would not like to see this impact on innovation and the ability to enable new services where we see pharmacist prescribing for example antibiotics for mild to moderate skin infections.

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

Emergencies e.g. Christchurch Earthquake, Outbreaks of diseases.

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

Oversight and monitoring needs to be considered so attached or linked to a licenced premises seems a logical solution. We need to ensure patient safety so need to ensure care and advice is provided. This is not just about 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?:

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?:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4FD-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 15:02:04**

Submitter profile

What is your name?

Name:

Philippa Pringle

What is your email address?

Email:

What is your organisation?

Organisation:

NZPSHA

Submitter Profile (tick all that apply)

Private hospital

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;:

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 think that this is a sensible approach

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.):

The use of Standing orders is integral to the way that Private hospitals operate. We would like to be involved when these are being consulted upon in the future.

NZPSHA

Rose Geden – Executive Director | New Zealand Private Surgical Hospitals Association Inc.

PO Box 25448 | Wellington 6140

Website www.nzpscha.org.nz

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

Does this refer to Section 29 drugs as well? If so this has long been a contentious issue both in terms of management in that the drugs on this list change from month to month and ongoing consent requirements.

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?:

Not sure that health literacy rates in NZ would support appropriate consumer discernment.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G46Y-G

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 15:08:30**

Submitter profile

What is your name?

Name:

Judith Swan

What is your email address?

Email:

What is your organisation?

Organisation:

Southern DHB & University of Otago

Submitter Profile (tick all that apply)

Consumer

District Health Board (DHB)

If you select DHB, please state service area:

Haematology Oncology

Nurse

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

If you selected 'Other' please comment;:

Health Practitioner Education - Medical School

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

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 clear distinction between administration and preparation for administration as NOT a manufacturing process while compounding and dispensing are part of manufacture could be strengthened with an addition to s26. In the same way that s28(3) states compounding is part of manufacture, s26 could say that preparation for administration is not part of manufacture.

s26 will be useful to nursing as a clear statement of activities undertaken by nurses.

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 :

s61(2) has the potential to be very useful, particularly in the circumstances described in the consultation document. My slight concern is that the skill set to complete the instructions for patients (or carers) are NOT routinely taught to health practitioners other than pharmacists. In particular as supply/dispensing has previously been a prohibited activity for nurses, as a group we don't know how to complete this activity correctly. The appropriate authorities will need to include education around these skills to their registrants to ensure that both s61(1) and s61(2) are safely enacted in practice.

s61(2) does not enable health practitioners to supply general sale - category 4 - medicines. Sometimes these are the very medicines that are needed. For example a card of paracetamol at 11pm. Here, of course, I'm assuming that paracetamol is general-sale and not pharmacy.

s61(4) seems to say that the only people who can administer approved or approval-exempt category 1 medicine are health practitioner prescribers. This would mean that registered nurses (not prescribers) wouldn't be able to administer these category 1 medicines.

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):.

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):.

This overall structure seems to provide for a useful and flexible approach that should facilitate timely alterations to practice in changing conditions.

In this structure the Regulator is in a pivotal position as there is a huge diversity of responsibility that is vested in their position. It seems to me, given this diversity that 'the Regulator' may not, or should not, be a single person but rather a small team with differing backgrounds, interests, and skills.

The Regulator does need to be independent of industry, the various health practitioner groups, and central government funding but equally will have to develop and maintain close working relationships with all of these groups.

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?:

C8 Health practitioners (including pharmacists)

Prescribers

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

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

Yes.

Increasingly patients are receiving care from many health care practitioners (HCP) from many scopes of practice. A consistency in the form and content of prescribing across these practitioner groups will facilitate the patient and the HCP groups to understand who can prescribe, who can prescribe what and when, and why there are differences between the HCP groups.

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?:

I have not read all of this section in detail so may have missed this link, in which case ignore this comment.

The piece that is not clear in this area is how an unapproved medicine can also be a prescription medicine.

If a medicine has not been approved in NZ presumably it has not been assessed carefully enough to know whether it would be a prescription medicine if it was to be approved.

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?:

Following the completion of appropriate education and demonstration of competence in the specific skills associated with supply (rather than administration) this could be beneficial to patients.

Benefits could include increasing the availability of medicines to hard to reach communities and at difficult times (after hours, weekends etc).

Risks include that currently the knowledge base of some practitioners is insufficient for safe supply (calculating the number of pills, writing the instructions, including expiry dates, special instructions, charging, recording 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?:

Not until supply has been embedded and normalised as part of the health practitioners' practice.

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?:

This provision has the potential to create confusion as the same terminology (special clinical needs supply authority - SCNSA) is being used for a fairly relaxed approach to off-label medicine use as for quite tightly controlled unapproved medicine use.

While I can see why you'd like to only have one instrument in use (SCNSA) either a different name for each use (see below) or the same level of strictness of rules for each use would be preferable.

Special Off-Label Supply Authority (SOLSA)

Special UnApproved Supply Authority (SUASA)

These could be, in essence, the same forms and same process but with different names to highlight the different requestors, different follow up, and different rules.

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?:

At the moment I think retaining this request level with medical practitioners is reasonable. However, in time this should probably change as other health practitioner prescribers expand their prescribing knowledge and skill set. Potentially a demonstrated competence, regardless of type of health practitioner, could become the basis for authority to request a SCNSA for unapproved medicines.

As this reads I'd like another, probably, time-based checkpoint.

So the scenario becomes: Dr assesses patient and gets a special clinical needs supply authority. NP continues the usual prescribing including the SCNSA. Then annually the patient needs to see the Dr and be re-evaluated to see that the SCNSA is still relevant and appropriate to their health care needs.

The bill is trying to limit the use of unapproved medicines to situations that really need them. By not then re-evaluating the patient the risk is that these unapproved medicines continue to be used long after they are appropriate. This could be due to changing health status, new medicines becoming available, new approvals occurring, or some other change.

As prescribing authorities for health care practitioners change these will need to include the ability to continue SCNSA prescriptions from medical practitioners.

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

I have no particular products that I'm concerned about.

Some of these products probably don't need specific regulation. What could be needed is an explicit expectation that potential risks are explained to customers, specific contra-indications are explored and similar practices.

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-G4RK-X

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 15:09:06**

Submitter profile

What is your name?

Name:

Judy Turnbull

What is your email address?

Email:

What is your organisation?

Organisation:

Waiheke Pharmacy LTD

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please comment;:

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

Chapter A (A1 - A5)

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

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

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

Question B19

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

Subpart 2: Permits (ss 131–135)

Question B20

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

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

Question B21

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

Question B22

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

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

Question B23

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

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

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

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

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

It would be a backwards step to the health on New Zealanders to open up ownership to large single owners.

The models in UK and US of large corporations owning the majority of Pharmacies are not working as effectively as the current individual NZ models of Pharmacy.

The public's access to Pharmacists are restricted by the corporate models with drive on volume and costs cutting, and this will reduce consumers access to a valuable resource the community Pharmacist. NZ community Pharmacists have their own dedication to their communities by actively participating as NZ owners helping their communities.

I have included 2 letters given to me from customers living in UK who speak to me often how much better the Pharmacist service is in NZ.

As follows (these were customers in the Pharmacy that I had met once as their advising Pharmacist and when they mentioned how much better the NZ model was I asked them to put this in writing.)

Uk Customer Feedback 1.

' Dear Judy

Thank you so much, yet again, for your helpful advice today it was for my sore lip and night cramps.

The lip sore remedy is already proving effective.

As a visitor to Waiheke I have come to depend upon pharmacies for my first line of advice. Recently I had a leg sore that wouldn't heal and it looked ready to turn into an ulcer. The pharmacist at Ostend advised me on treatment and also on what signs I should look out for that would indicate I needed to see a doctor. I followed her advice and the sore started to heal within the time scales she advise giving me peace of mind and saving the GP time.

I wish we had such ready access to pharmacist in our chemist outlets in the UK. We can only get advice from the sales assistants who, whilst trying to be helpful, tend to suggest the most advertised/popular medication . Pharmacist tend to be busy behind screens making up prescriptions and access to them is policed by sales staff.

I believe that in an attempt to take the pressure of GPs the UK NHS may be looking at ways to make pharmacists, practice nurses, nutritionist etc more access ble to the public for first line advice. I hope they look to the systems in place in NZ especially the helpful and medically sound advice the public get from pharmacists I ke your self.

Many thanks

Rosemary Phillimore

██████████
██████████

UK Customer Feedback 2

Dear Judy

When we visited your pharmacy at Oneroa on Waiheke Island last week we were very impressed with the quality of the service we received.

We are visitors from the UK and were struck by the vast difference between the chemist shop in England and the NZ pharmacy. At home, our pharmacists are behind counters and hardly seen. Even when one asks for advice they seem reluctant to offer it and always suggest that one should go to see one's GP. Our independent pharmacies are nearly all swallowed up by large companies such as Boots and they mainly operate as shops which concentrate on selling merchandise, with minimal interest in medical matters. This means that the Doctors are overworked and people have to wait for appointments, sometimes up to a week or even two. A consultation with a pharmacist could have solved minor problems, thus saving the NHS time and money.

The Pharmacist in Oneroa offered a professional and informed consultation, gave advice, suggested medication and medical guidance regarding prevention and further care of the condition.

We would hope that independent pharmacists will be able to continue their practices in NZ and that they will not suffer the same fate as the British Pharmacy profession.

Yours sincerely
Glynis James,
Bath, England.

I see a lot of visitors in our Pharmacy and they often say that the NZ Pharmacy service and advice from Pharmacists in NZ is far better than UK and US where corporate models have taken over limiting access to community Pharmacies by offering big retail chains.

Detailed questions relating to Option 1

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

- option 1 protects Pharmacy in NZ from monopolies largely owned by over seas companies. These companies would dominate and destroy community Pharmacist owned Pharmacies.
- Pharmacies would continue to be owned largely by NZ Pharmacists who individually and as teams contribute to the health of their communities.
- NZ public would continue to have access to their Pharmacists for first line advice.
- this option saves the Government millions by having the Pharmacist be involved in first line primary health care to keep people out of hospital by allowing easier access for patients to Pharmacists. Overseas examples of deregulation corrode this access. It is widely observed and known in UK .

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

Agree that it needs to be tightened up in the loop holes so that Chemist warehouse and other large international models do not get around the rules.

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

All current.

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)?:

Continued .

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?:

- Risk corrosion of NZ Pharmacy model that works - having Pharmacists as forefront of First line community Advice works. Deregulation will risk this.

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 - keep it as it is it safe guards patients from prescriber financial interests.

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?:

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?:

Good idea.

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

Yes if it was not available in NZ and was approved for use by NZ Medicine Control.

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?:

Doctors should not be able to sell Pharmacy and Pharmacist only medicines.

There could be a problem if Doctors sourced these subsidised items on MPSO and then sold them for profit.

For example- Clomazole Vaginal thrush treatment sourced free on MPSO emergency supply-

Sold to patient for less than cost eg \$5 but Prescribers still made all profit as was supplied at no charge.

Doctors get around the quantities by getting multiple MPSO from different Doctors.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Too much pressure could be put on Pharmacists from large companies not necessarily in the best interest of patients.

Eg retail targets, restricted Pharmacist numbers so patients do not have good access to Pharmacist advice. Budget driven.

Option 1 keeps the Pharmacist owner as forefront of decisions best for their own communities.

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

- Benefit - keep a model of Pharmacy that currently works- NZ Pharmacists are at forefront of community care accessible to patients.

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

Risk - destruction of current Pharmacy models in NZ by allowing large chains to dominate.

Patients could have diminished choice of health options and ranges as large company decisions affect multiple sites.

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

Huge risk - They can source some of them fully funded on MPSO and then onsell to patients for profit.

This would completely undermine current model of medicine supply that works well.

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 required to sell the products for care safely.

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-G4D1-P

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 15:48:53**

Submitter profile

What is your name?

Name:

Charlotte Korte

What is your email address?

Email:

What is your organisation?

Organisation:

Mesh Down Under

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

Auckland

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 Access restrictions need to be established and applied to BOTH medical devices and medicines. The reasoning and wording in this paragraph is too loose and it is a clear loophole, "the scheme would enable supply restrictions and/or use restrictions on a device or class of devices". For the regulator to be able to determine a 'safety concern' they need to follow a lengthy complicated process which is extremely convoluted and can last for many years. To substantiate this proof of evidence, the NZ regulator would need to rely on overseas regulatory bodies for 'evidence'. Using the surgical mesh issue as an example, there is clear evidence documented (globally) showing how overseas regulatory bodies have used flawed clinical research to base their decisions on for approving devices. It is understandable that there is a strong pushback from industry to validate the safety of their products, which includes documented conflicts of interest from industry with close links to international regulatory bodies. The surgical mesh issue is the perfect example of how even when serious safety concerns about patient safety are evidenced it takes years for any action to be taken to address serious safety concerns.

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):

B4 (i) Interpretation- Access restrictions need to be established and applied to BOTH medical devices and medicines. The reasoning and wording in this paragraph is too loose and this is a clear loophole, "the scheme would enable supply restrictions and/or use restrictions on a device or class of devices". For the regulator to be able to determine a 'safety concern' they need to follow a lengthy complicated process which is extremely convoluted and which can last for many years. To substantiate this 'proof of evidence', the NZ regulator would need to rely solely on overseas regulatory bodies for this 'evidence'. Using the surgical mesh issue as an example, there is clear evidence documented (globally) which has shown that overseas regulatory bodies have used flawed clinical research to base their decisions for approving surgical mesh devices. Moreover, the 510k process weakens the ability of the FDA to make sound judgements about the safety of new devices as decisions are based purely on only substantial equivalence. This loophole allows manufacturers to bypass a much more extensive scrutiny,

which means they do not have to provide actual clinical research based evidence. Although the FDA have stated they are strengthening their guidelines, it is understandable that there will always be a strong pushback from industry to validate the safety of their products. It is also important to consider that several reports have documented close links of some industry to international regulatory bodies, such as the FDA. The surgical mesh issue is the perfect example of how even when serious safety concerns about patient safety are evidenced, it can take years for any action to be taken to address serious safety concerns. It is important to ensure that a categorisation system be introduced for devices as well as medicines, both need the same level of scrutiny and legislative mechanism.

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:

Advertising (ss 82-83)- I do not agree that direct consumer advertising of prescription medicines should continue and increased regulation in this area is absolutely required.

Misrepresenting a therapeutic product (ss 88)- Within the TPGB there have been no provisions made which relate directly to the advertising of procedures, unfortunately only therapeutics products have been included. Consideration regarding the inclusion of procedures is needed and I would like to request that the working group make changes accordingly. Specifically, the language used in any information which is provided to the public, must be a balanced representation which details all risks as well as the positive impacts and this needs to be extended to information provided in video format or electronic media. There also does not seem to be a clear enough distinction as to what is specifically classed as an advertisement or article. One example of this is the article/advertisement, which was placed in the Listener in 2015, called the Leaky Person Syndrome. It is very unclear as to whether this is an article or advert, but regardless the information should not be misleading. The focus for the advert/article was for women suffering with stress urinary incontinence, sadly only the positives of surgical mesh were highlighted with no mention of any risk at all about the procedure included, nor alternative surgical options provided. At the time of publication, there was plenty of clinical research and evidence which demonstrated serious concerns regarding these procedures and our petition to parliament for an inquiry into the issue had been accepted in parliament and was under review. These devices and procedures were already known as high risk but none of these risks were mentioned. A clear distinction needs to be made as to what constitutes an advertisement or article and we need to ensure that procedures are included in any legislative changes made. Please read this link: <https://www.noted.co.nz/health/health/leaky-person-syndrome/>

Health practitioner prescriber must not hold interest in a pharmacy business (S 93) This clause is only in relation to pharmacy and medicines. Why does this not extend to health practitioners who may have a commercial incentive for a medical device? They have the same potential financial benefits which could lead to basing clinical decisions resulting from a conflict of interest. Strengthening the legislation so it is extended to health practitioners using devices is important- at the very least they should tell the patient that this commercial incentive exists, but, although this is already an expectation this needs to be able to be mandated and included in the legislation.

B6 Part 4 of the Bill: Product approval

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

Question B13

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

ss371) (C12) Criteria for approval- "safety and performance of a device to be satisfactorily established"

This is difficult to ascertain if a product has come through the 510k process and is subject to criteria of approval only based on a predicate device. In many cases the predicate device that this new device has received approval through, has also gone through this same process. This 510k approval pathway is not robust enough to ensure the safety of these products and history has shown that the risks cannot be 'satisfactorily established.' As an example, the Protegen Sling made by Boston Scientific in 1996 had a very high complication rate and was recalled in 1999. The FDA stated that "Use of ProteGen in the treatment of female urinary incontinence is associated with higher than expected rate of vaginal erosion and dehiscence and does not appear to function as intended". Ironically the Protegen itself was approved through the same 510k process, yet the predicate devices it was based on were not made of the same material (polypropylene) and the surgical approach to implant this device was completely different. (see second link below) The TVT which is the most commonly used surgical mesh device in NZ currently, is based on the ProtGen predicate device. Of great concern, the FDA have no authority to remove a subsequent device which has been based on a predicate device and has been subject to a level one recall (because of safety concerns). Globally the most serious device related issues and majority of problems that have been associated with medical devices, have come about because of this process. Although the FDA are strengthening their guidelines this 510k process remains.

For more information: <https://www.scientificamerican.com/article/four-medical-implants-escaped-fda-scrutiny/>

Pages 14 onwards:

file:///C:/Users/cmkor/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/Full-evidence-text%20(1).pdf

How will this new legislation address the weaknesses of this loophole to ensure that products which come through this avenue have met safety standards. How will the TPBG and regulatory body determine and ensure that the 'benefit' of the device does outweigh the risk?

(ss372) "we intend to specify product approval criteria" Who is we and who will develop this product criteria? What product standards is this referring to? Can this information be made clear within the bill? Information regarding precisely what the Mutual Recognition Arrangement is between NZ and other countries needs to be documented.

(ss372) My understanding that a 'family' of devices are variants of the same thing (i.e. different length but otherwise the same). This is unclear within the document can this please be addressed?

(ss374) Conformity assessment certificates in the EU (and this process) is known to have several weaknesses, this needs to be acknowledged and addressed within the new legislation. This is especially important for devices or 'family' of devices which are registered under the highest risk category.

The issue of the notified bodies in the EU being under-resourced is well known, this has been shown to affect their ability to cope with compliance standards and the demands of industry. For example, there have been delays and an inability for notified bodies to conduct their audits in a timely manner (including unannounced audits). The number of notified bodies have reduced significantly and in order to cope with these demands, there have been reports of some of these 'authorities' having fast tracked conformity assessments and device approvals. Some of the notified bodies are now no longer accredited for certification because they did not pass the mandatory re-designation audits. The limitations and the shortcomings of these authorities under pressure to provide robust assessments, needs to be acknowledged. This weakness needs to be addressed within the legislation as the 'authority' which NZ will rely on for conformity assessments and device approvals. Conformity assessments should therefore only be allowed for devices in the lowest risk category to ensure patient safety. Should we be using conformity assessments at all?

(ss378) I commend this recommendation that a publicly accessible register of medical devices be established. This is important and needs to be fast tracked before completion of the new legislation.

(ss 382) I am concerned regarding this statement as it seems to imply that parallel importing is okay? What financial penalties will be implemented for people buying devices on eBay or importing without lodging purchases on the WAND database. How will this be enforced?

Question B14

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

(ss107) In broad terms, the applicant would need to satisfy the regulator that:

(a) "the quality, safety and efficacy or performance of the product are satisfactorily established" - How is this determined?

(ss107)
(b) "The likely benefits of the product outweigh its likely risks" (s 95(b))- Specifically how will this be determined? What changes will be made within the new legislation to address the potential weakness in this area? Using the surgical mesh issue for example, it was stated for many years that the benefit outweighed the risk for surgical mesh devices and procedures. It took too long for the regulator to acknowledge the safety concerns of which was available in the emerging literature, many more injuries were sustained, and still are. What benchmark measure will be established to ensure that the risk of harm ratio can be substantiated? Can a new risk harm ratio be established?

(ss109)

If a product has come through the 510k FDA process, it is difficult to determine the quality or safety of a product when the device approval has been based on only the characteristics or 'evidence' from a predicate device. Surgeons' knowledge (in general) of the 510k process and the pathway of how devices come onto the market is limited and this needs to be considered at length. A surgeon needs to be made aware of this information so they can make sound judgements about which products to use and determine what they base their clinical decisions on. If a device has come through the 510k approval loophole, then a unique code identifier should be established as an extra precautionary and each device should be labelled with this. Can this unique code identifier be established and implemented?

(ss114)" We are very aware of the critical importance of manufacturers keeping sponsors informed about planned changes to products and inventory and quality issues".

Is this able to be legislated and made mandatory and what pecuniary penalties will be applied. How can this be enforced?

(ss119) Products that have been approved or declined, and information regarding applications that are pending need to be available to the public. This information should be made publicly available and transparency in this area is important.

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):

(ss130) "For most medical devices, a licence would not be required for non-wholesale supply (ie, supply to the end user) or use on a patient".

Although the supplier to the end user will not need a license, will all purchases be registered and tracked to a locally centralised database? If not intended, this needs to be considered.

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):

(ss154) "In addition, section 160 requires the regulator to have a system to continuously monitor the safety of approved, approval-exempt and lawfully supplied unapproved products and to do so in accordance with requirements to be set in the regulations."

This section 160 states that it requires the regulator to have a system for post monitoring purposes, how will the regulator be kept accountable for ensuring this system is working effectively, who will determine if this mechanism is adequate and who will have the authority to address this within the legislation if it is found to not be working to a satisfactory level? Who is the regulatory body accountable too?ss109)

If a product has come through the 510k FDA process, it is difficult to determine the quality or safety of a product when the device approval has been based on only the characteristics or 'evidence' from a predicate device. Surgeons' knowledge (in general) of the 510k process and the pathway of how devices come onto the market is limited and this needs to be considered at length. A surgeon needs to be made aware of this information so they can make sound judgements about which products to use and determine what they base their clinical decisions on. If a device has come through the 510k approval loophole, then a unique code identifier should be established as an extra precautionary and each device should be labelled with this.

(ss154) "In addition, section 160 requires the regulator to have a system to continuously monitor the safety of approved, approval-exempt and lawfully supplied unapproved products and to do so in accordance with requirements to be set in the regulations."

Section 160 requires the regulator to have a system for post monitoring purposes, how will the regulator be kept accountable for ensuring this system is working effectively, who will determine if this mechanism is adequate and who will have the authority to address this within the legislation if it is found to not be working to a satisfactory level? Who is the regulatory body accountable too?

(ss 162-182) Recall orders- Will the regulator be able to alert the public or individual who has been implanted with a device when a recall order has been issued? At what stage or level of recall will this be actioned? The public have a right to know if a product inside of them is defective or if there are any safety concerns, as this way they can be more closely monitored by their clinician. How will the regulatory body alert the public when a recall order has been issued?

If a range of products have been recalled, or voluntarily withdrawn off the market by the manufacturer for "commercial" reasons, and this range of products, or similar products have known to have caused significant harm previously, and used in high risk surgical procedures (such as surgical mesh), regardless of whether these products have been used or not in NZ, this information is important for clinicians to be made aware of to stay informed of emerging trends and patterns relating to these products in general. One example of this is the range of BARD surgical mesh devices- withdrawn in 2019 for "commercial" reasons- the manufacturer chose to withdraw these devices, instead of providing the evidence of safety required for these products which was requested by the FDA. Although these particular devices were no longer being used in NZ, they had been previously prior to 2011. There needs to be a balance in not overloading clinicians with too much information regarding recall orders, but clinicians also need to be made aware of updated events globally for them to inform their practice and subsequently base their clinical decisions on. Relevant and important information aides' clinicians in determining what products they choose to use or procedures they undertake. What process will be developed within the TPGB legislation so the regulator can ensure they are keeping the health sector aware of important and relevant information? How will the regulator determine what is important information for clinicians to know?

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):

(ss 176) Merits review panel- strict guidelines about exactly what constitutes as a conflict of interest needs to be developed and written into legislation.

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):

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):

(ss218 a) I am unsure as to why this section relates only to pharmacy- and clinicians prescribing? The HPCA act also covers clinicians undertaking surgical procedures using medical devices. Why then is pharmacy only included within the provisions of this section of the TPGB? There is no one currently with the mandate or who has the legislative powers to monitor and enforce anything within the private sector. The private sector are not accountable to anyone other than having to abide by the HPCA act- this needs to change. We need to strengthen the powers of the regulator or other relevant body and give them the authority over the private sector, this is vital.

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):

(ss372) "we intend to specify product approval criteria" Who is 'we' and who will develop this product criteria? What product standards is this referring to? Can this information be made clear within the bill? Information regarding precisely what the Mutual Recognition Arrangement is between NZ and other countries needs to be documented.

(ss374) Conformity assessment certificates in the EU (and this process) is known to have several weaknesses, this needs to be acknowledged and addressed within the new legislation. This is especially important for devices or 'family' of devices which are registered under the highest risk category.

The issue of the notified bodies in the EU being under-resourced is well known, this has been shown to affect their ability to cope with compliance standards and the demands of industry. For example, there have been delays and an inability for notified bodies to conduct their audits in a timely manner (including unannounced audits). The number of notified bodies have reduced significantly and in order to cope with these demands, there have been reports of some of these 'authorities' having fast tracked conformity assessments and device approvals. Some of the notified bodies are now no longer accredited for certification because they did not pass the mandatory re-designation audits. The limitations and the shortcomings of these authorities under pressure to provide robust assessments, needs to be acknowledged. This weakness needs to be addressed within the legislation as the 'authority' which NZ will rely on for conformity assessments and device approvals. Conformity assessments should therefore only be allowed for devices in the lowest risk category. Should we be using conformity assessments at all?

(ss378) I commend this recommendation that a publicly accessible register of medical devices be established. This is important and needs to be fast tracked before completion of the new legislation. For surgeons purchasing devices for non-wholesale supply (to end user) can we mandate that all devices purchased are registered on a central database?

(ss 382) I am concerned regarding this statement as it seems to imply that parallel importing is okay? What financial penalties will be implemented for people buying devices on eBay or importing without lodging purchases on the WAND database. How will this be enforced?

(ss396) Product Vigilance- This section states that the regulator will have an "obligation to ensure that it has a system in place to monitor the safety of products." Who will the regulator be accountable to? What systems will be created to ensure that the regulator is being monitored and is monitoring the safety risks to an acceptable standard? Precisely what mechanism and or processes will be created to monitor the regulator?

Currently the regulator is not required to report recall or safety alert information to the public unless it is a level one recall, more of an emphasis on transparency is needed within the new TPGB reforms. Will the TPGB address this to ensure that more detailed and relevant information is made publicly available? Who will identify what information is important and relevant for the public and how will this be determined?

(ss397) Medsafe currently overseas post-marketing surveillance, due to its legislative limitations it has not been able to do this to an acceptable standard and patient safety has come into question. This is one of the most important reasons for creating new legislation. Precisely how will these current initiatives be "potentially enhanced" and will these new enhancements be documented within the new legislation?

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

(ss371) (C12) Criteria for approval- "safety and performance of a device to be satisfactorily established"

This is difficult to ascertain if a product has come through the 510k process and is subject to criteria of approval only based on a predicate device. In many cases the predicate device that this new device has received approval through, has also gone through this same process. This 510k approval pathway is not robust enough to ensure the safety of these products and history has shown that the risks cannot be 'satisfactorily established.' As an example, the Protogen Sling made by Boston Scientific in 1996 had a very high complication rate and was recalled in 1999. The FDA stated that "Use of ProteGen in the treatment of female urinary incontinence is associated with higher than expected rate of vaginal erosion and dehiscence and does not appear to function as intended". Ironically the Protegen itself was approved through the same 510k process, yet the predicate devices it was based on were not made of the same material (polypropylene) and the surgical approach to implant this device was completely different. (see second link below) The TVT which is the most commonly used surgical mesh device in NZ currently, is based on the ProtGen predicate device. Of great concern, the FDA have no authority to remove a subsequent device which has been based on a predicate device and has been subject to a level one recall (because of safety concerns). Globally the most serious device related issues and majority of problems that have been associated with medical devices, have come about because of this process. Although the FDA are strengthening their guidelines this 510k process remains.

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Pages 14 onwards: <https://www.parliament.nz/.../861343a36cc964e44c2af9f61401375a13b9a2d5>

How will this new legislation address the weaknesses of this loophole to ensure that products which come through this avenue have met safety standards. How will the TPBG and regulatory body determine and ensure that the 'benefit' of the device does outweigh the risk?

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):

(ss384) Changes to approved products. Changes to the risk classification of a product or device is important for the consumer to be made aware of, especially if the changes are major- for example reclassifying a device or instrument to the highest category. How will the regulator advise the consumer and public of this information? It should be a mandatory obligation for the regulatory to keep the consumer informed and the TPGB legislation needs to provide provision for this to be established.

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:

(ss418) Will the NZ government and Ministry of Health (MoH) sign the World Health Organisation (WHO) joint statement?

It is important to incorporate legislation within the TPGB reforms so NZ can align with global best practices in clinical trial transparency. Legislation needs to be incorporated into the new TPGB reforms to make it mandatory for all clinical trials to be registered on an approved WHO-approved [primary] register. The TPGB needs to state clearly that registration must be completed before the recruitment of the first patient and start of the trial.

Ensuring that registry data is updated regularly is important and is in the best interest of both patients and researchers. Outdated registry entries make it difficult

to identify whether a trial is ongoing or still recruiting. This makes it harder for patients to locate the trial they are registered on and makes it more difficult for the recruiting of patients. Prospective trial registration is only 'required' in NZ, there have been significant improvements in this area already, but we need an effective monitoring system in place and sanctions made available so that this can be enforced. Financial penalties need to be applied for non compliance.

The declaration of Helinski clearly states that all clinical trials being undertaken must publish their trial results and if this does not happen this is in breach of research ethics. It is concerning that in NZ trials do not have to be published regardless of whether there is a positive or negative outcome and ethics approval is only 'encouraged'.

Summary results of all clinical trials need to be posted on the registry (or registries) within 12 months of study completion and a 'mechanism' needs to be established to be able to enforce this. If trial outcomes and summary results are not published, there is a risk that valuable research findings are wasted because they are not available to the scientific and clinical community. This can also result in harmful drugs and devices being marketed which brings patient safety into question. Negative trial outcomes are extremely relevant for clinicians to make informed decisions about what procedures and devices they use, so it is even more important that these trials are accessible. Currently it is not in the best interest for manufacturers to publish poor trial outcomes, which is why incentives need to be created to ensure that this happens.

Ethics approval is only required and is not mandatory within NZ- this needs to change. Although there has been advances in this area, of note, on the ANZCTR clinical trial registry "only 50% of trials prospectively registered had ethics approval at the time of registration. (2006-2015)" refer to ANZCTR Clinical Trial Landscape Report.

(ss419)- The denominator of all trials conducted in NZ is unknown, a centralised national database is needed to get a better understanding of what is happening in the clinical trial sector and to ensure that NZ is meeting their ethical obligations. From a consumer perspective it is important for these new reforms to have a much bigger emphasis on increasing the transparency of clinical trial reporting. Currently it is very hard for consumers to access clinical trial information, changes need to be made so this information is readily available.

Question C17

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

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?:

(ss601) "evidence is unclear as to whether this results in a positive outcome (due to more people accessing therapeutic products and services that they need) or a negative outcome (due to people being given medicines they don't need)".

From a consumers perspective I do not think there is enough research based evidence in NZ to justify the continuation of direct to consumer advertising, especially when NZ is only one of three countries that continue to do this (along with Poland and the United States). A lack of 'available' evidence about the positives and negatives of direct to consumer advertising does not necessarily mean that there is no evidence. There needs to be a proper inquiry established to determine whether this should continue.

In regards to patient wellbeing, it is important to consider the negative consequences of the public buying products that they wouldn't normally buy, or products that are not research based with evidence to support their effectiveness. Off the counter medicines such as cough medicines, pain erazors, are just some examples of products that have been found to not be effective or are in fact harmful.

In simple terms, using the white coat scenario, if the member of the public sees a person advertising a product they are more likely to believe that this person is a doctor who is someone who can be trusted and therefore know what they are saying. This means that the advert is more likely to be successful. There needs to be a disclaimer to alert the public that the person selling the products is in fact an actor and not a doctor.

"The choice of medical treatment should be made on the basis of best evidence combined with patient history and values, not on the cleverest or most compelling marketing message". <https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1401/6278>

Response ID ANON-DPZ8-G4ZZ-N

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 16:21:53**

Submitter profile

What is your name?

Name:

David Anderson

What is your email address?

Email:

What is your organisation?

Organisation:

Insight NZ Ltd

Submitter Profile (tick all that apply)

Advertising

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

C10 Advertising sector

Question C52

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

Insight New Zealand is a specialist health and wellness advertising agency. Our clients include those in the Pharmaceutical sector, New Zealand based natural health product manufacturers and NGOs.

Insight New Zealand has worked with TAPS (Therapeutic Advertising Pre-vetting System) since its inception in the mid-2000s. We strongly believe that it is a world-class robust, independent mechanism for all therapeutic advertising (prescription, OTC medicines, natural health products, medical devices and services) to be pre-vetted for compliance with the relevant codes and regulations.

The fact that only 1 out of 603 ad complaints received by the Advertising Standards Authority (ASA) in 2017 was for a prescription medicine. The complaint was deemed to have no grounds to proceed. This shows the strength of the regulation and the compliance of the pharmaceutical industry.

Balance of information is enshrined in both the Advertising Standards Authority Therapeutic & Health Advertising Code and the Medicines New Zealand Code of Practice. These are rigorously enforced by TAPS and the pharmaceutical companies themselves.

Sources:

Advertising Standards Authority (2017). ASA Annual Report 2017. Retrieved from: http://www.asa.co.nz/wp-content/uploads/2018/05/ASA-Annual-Report-2017_web.pdf

Advertising Standards Authority (2018). ASA – Search/browse decisions by year 2017. Retrieved from: <http://www.asa.co.nz/decisions/search-browse-decisions/>

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?:

Insight New Zealand is a specialist health and wellness advertising agency. Our clients include those in the Pharmaceutical sector, New Zealand based natural health product manufacturers and NGOs.

DTCA advertising is an important communication channel to reach and inform people about maintaining and improving their health. We strongly advocate that it should continue to be permitted.

Why? There are a number of compelling reasons:

- DTCA increases health awareness and encourages patients to take an active role in their health and treatment options. This is especially relevant for conditions like asthma and diabetes, where patients need to be aware of changes to their treatment as their disease progresses, or as new treatment options are listed by Medsafe.
- DTCA provides a reliable source of approved product information – which can be hard to find in a world dominated by Google searches and 'Fake News' (For example, malicious anti-vaccine misinformation).
- DTCA helps to reach patient groups that do not regularly see their doctor, for example, encouraging those in their early 20s to see a doctor about HPV immunisation or to reassess their asthma prevention treatment.
- DTCA encourages patients to act on undiagnosed or poorly managed conditions by prompting a discussion with their GP – leading to improved patient outcomes. Ultimately patients feel better about medicine when they have initiated discussion and been involved in decision- making.
- DTCA is always supported by providing doctors with relevant clinical data, to ensure the correct diagnosis is made and that patients receive the correct treatment for them.
- DTCA campaigns augment work done by the Ministry of Health, Health Promotion Agency and other NGOs – and can help reduce the costs to New Zealand of undertaking those campaigns.

Response ID ANON-DPZ8-G41B-M

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 16:33:19**

Submitter profile

What is your name?

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Richard Stevens

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What is your organisation?

Organisation:

Brandworld

Submitter Profile (tick all that apply)

Advertising

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 don't support

C10 Advertising sector

Question C52

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

BrandWorld does not wish to see any changes to the current direct to consumer advertising processes for any kind of therapeutic 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?:

BrandWorld submits that direct to consumer advertising (DTCA) of prescription medicines should continue to be permitted on the same basis and under the same controls as at present.

The Public Interest

We believe that the public interest, in health as in other sectors of the economy, is best served when organisations have the right to distribute information that contains accurate information that the consumer can use, is presented in a socially responsible way, has had its content independently checked and verified, which conforms to any regulations particular to that content category, and where any person is confident that their complaint about the content or presentation of such information will be fairly adjudicated.

In the case of DTCA of prescription medicines, these conditions have been applied for more than twenty-five years for medicines that have been extensively, and expensively, researched and developed to be beneficial to the patients for whom they are intended.

The New Zealand Bill Of Rights has a high threshold for anyone seeking to limit any communication, including commercial communication. We do not believe that evidence of harm allegedly caused by DTCA of prescription medicines has been objectively presented, or has met the evidence-based standards required to justify a change in public policy. Such standards of evidence would, in our view, need to be compelling, scientifically settled and unambiguous to justify the removal of a communications right that exists.

The Communications Environment

It seems paradoxical to limit access to medical information when we enjoy the benefits of an informed and open society. Medical professionals share with their progressively more health-literate and engaged patients in a world of unlimited and unthrottled access to information.

The development in new digital and social media and 'immediate access' technologies over the last decade includes social media, on-line patient support groups, and peer-to-peer influence. Public and one-on-one discussion of health issues that were once taboo or not openly discussed are now normal.

The way people now interact has inevitably blurred the boundaries between the different components that make up 'information': advertising, public relations, public service messages, advocacy, endorsement, social media platforms, social influencers, health sector websites and individual discussion around the same subject, product, or service. We are all influencers of each other.

The DTCA of prescription medicines is therefore only one of many sources that impact on information and opinion affecting the patient - doctor interaction. This diversity of influences means that we should especially value information from sources that consistently deliver a 'premium' on accuracy, honesty, relevance, authenticity, and social-responsibility.

DTCA of prescription medicines carries such a premium. It is probably the most vetted source for accuracy, consumer safety and compliance with regulatory and industry requirements in New Zealand.

Information Access and the Medical Profession

Universal citizen access to multiple sources of information will continue to influence how the medical profession engages with patients, and how prescription decisions are made. Doctors, after all, have long used multiple sources of information to maintain their professional development.

Doctors share with their patients a growing preference for convenience, immediacy, and 'mobile-centricity.' Telemedicine, virtual home visits, remote or video consultations are with already here, and medical practices are mainstream users of social media to engage efficiently with their peers and patients. We are all 'digital natives' now.

For most relationships 'difficult conversations' are a part of everyday life. It will be no different - in some circumstances especially difficult - for GPs. It is suggested that GPs are irritated at consultancy time being 'lost' by having to deal with patient questions arising from DTCA of prescription medicines. If this is true, then some GPs must be even more annoyed by questions asked because their patient has read an in-depth health feature in The Listener, or have 'Googled' their symptoms.

Perhaps the more narrow concern of some medical professionals is about DTCA of prescription medicines on television, on the basis that television has a particular power to reach to a certain 'type' of indiscriminating patient. Since most people don't like taking medication by choice, it is somewhat patronising to suggest that advertising leads to patients 'demanding' what they have seen or read. It is the medical professional, after all, who decides the prescription.

Given the emphasis of Government health policy on self-care and health awareness it would be disappointing if such views were held, let alone expressed.

The Prescribing Environment

The GP is only one part of the primary healthcare journey.

Drugs progressively go 'off patent'--perhaps as much as 80% of prescription medicines dispensed are now generic substitutes. GPs increasingly leave it to the pharmacist's discretion to make the final choice of which 'brand' or generic to dispense. This can be confusing - even alarming - for a patient who, after taking the same 'brand' for a long time, finds themselves with an alternative that may have unwelcome side effects.

DTCA of prescription medicines can help mitigate this confusion by reminding the patient that their 'brand' is still available, even if at an additional cost. We suggest it is not right to close down an information source that allows a consumer to express a view, because a 'consumer' also happens to be 'patient.'

DTCA of prescription medicines and Marketing to the Healthcare Professional

It makes sense for pharmaceutical companies go to considerable lengths to ensure that their DTCA campaigns are 'matched' with their other communications directed at healthcare professionals. They want to ensure that such investment is well-supported by healthcare professionals and other health influencers.

The Medicines New Zealand industry code explicitly requires pharmaceutical companies to notify doctors and pharmacists at least seven days before the start of any DTCA campaign. It should therefore come as no surprise to GPs if some patients ask questions as a result of these campaigns.

Incidence of DTCA of Prescription Medicines

The incidence of DTCA of prescription medicines is not as prevalent as its opponents infer.

Over 2016 – 2018 on average 10 different 'brands' of prescription medicines were advertised in mainstream media like TV, radio or Press, each year.

These have been for treatments for chronic conditions such as asthma, diabetes, arthritis and psoriasis, and for vaccines to treat conditions such as shingles or cervical cancer.

These are significant conditions, and those who suffer from them or are concerned about them have, we believe, the right to access information about the full range of prevention or treatments, irrespective of its source.

Many of these campaigns are addressing significant public health issues, and are timed, whenever practicable, to support Government-led health initiatives.

Expenditure on DTCA of prescription medicines

The advertising expenditure on these campaigns is not even to the figures claimed by those who oppose DTCA of prescription medicines.

The average annual media expenditure on mainstream media at ratecard value for 2016 – 2018 averaged around \$5m - \$6m per annum. This is about 5% - 6% of the total expenditure for all therapeutic products, where the average ratecard spend is about \$100m per annum.

The total advertising spend in all categories is about \$2.5 billion per annum. Out of that the annual spend on DTCA for prescription medicines was about 0.2 of 1% - ie: two tenths of one per cent of all advertising expenditure in New Zealand.

(Note: Ratecard media spend is not necessarily the same as actual dollar spend. It does not account for discounts that clients receive from the owners of media outlets, so actual expenditure may be only 50-60% of the figures reported by Nielsen, the media ratings agency)

Regulation of DTCA for prescription medicines

DTCA of prescription medicines is well regulated and policed in New Zealand. The TAPS (Therapeutic Advertising Pre-vetting Service) peer-review process, introduced in 2000 has successfully ensured that advertiser's content conforms to statutory requirements, and other industry codes.

Complaints

Over the last five years, the Advertising Standards Authority has received 11 complaints about advertising for prescription medicines, compared with 3587 complaints about all types of advertising. On average only 2 complaints a year.

Of those 11 complaints over five years only one was partially upheld. That complaint was not brought by an individual, but by an industry representative group against a medical professional who featured a prescription product in their own advertising without adequate product information.

This suggests to us that public concern about DTCA of prescription medicines is effectively non-existent, that there is a high level of social responsibility in the creation of the content, and that the regulations applying to DTCA of prescription medicines have been consistently adhered to.

Comment

The core purpose of the Therapeutics Products Bill is to protect the safety and well being of the public. With respect to information and advertising there is, in our view, no risk to public safety that justifies a policy change to remove the long-standing communication right that allows for the DTCA of prescription medicines.

Banning or restricting DTCA of prescription medicines shuts down one narrowly-specified and appropriately and effectively-regulated information source while allowing, because they cannot be regulated, other sources and delivery systems of health advertising and information that cannot be moderated and vetted to the standards that have long been effective for DTCA of prescription medicines.

Response ID ANON-DPZ8-G4ZM-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 16:52:11**

Submitter profile

What is your name?

Name:

Grant McRae

What is your email address?

Email:

What is your organisation?

Organisation:

Palmerston North Hospital 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

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).:

Alternative medicines should within the categories of inclusion in the Bill.

The lack of regulation of alternative medicines places New Zealanders at considerable risk, there is no control on where these products come from, how they are made or what they contain. Periodically one is found to be adulterated with prescription medicines and it then withdrawn, it would be safer to adopt and Australian like system and licence each product subjecting them to assay and testing.

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):

There are times where continuity of supply is impaired, ss51 and 52 appear to prevent alternative supply chains to be accessed.

A consequence of Pharmac's sole supplier agreements has been a number of notable out of stock situations for basic and important products, including antibiotics (such as recently was the case for piperacillin-tazobactam). During these supplier out of stock situations alternative supplies are sought for some months in some cases.

Whilst it is agreed that there needs to be a tightening up of internet importation of therapeutic products, changes in the Bill need to be designed in a way that does not make ordinary business more difficult. Patient safety depends of continued availability of staple medicines.

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 :

Section 61 would provide health practitioner prescribers with the authority, in the stated circumstances, to supply, prescribe, administer and dispense an approved or approval-exempt medicine and to issue a standing order.

Although detail is limited in the Bill, it appears that Health Practitioner's other than Pharmacists are not subject to the same rules, standards and audit that Pharmacists are, in Sections 56 to 60 compared to section 61.

Section 62 would provide the same authorisations for unapproved medicines, but would include the additional requirement for a complying special clinical needs supply authority (SCNSA). Note, that a product approval only approves the product for the purposes specified in the approval (s 99(2)). This means that whenever a medicine is prescribed for off-label use it is an unapproved medicine and would require a SCNSA.

Here there is again a risk of making ordinary business more difficult. There are a number of items used in common practice in every Hospital every day that are unregistered medicines. At last count in our hospital we had 200 such item in stock and regularly use about 200 more. Some of these items are every day items that were Registered Prescription Medicines that a sponsor has elected to remove from the market, but still supply from another market, such as:

bupivacaine local anaesthetic ampoules,
cyclophosphamide tablets,
cyproheptadine tablets,
demeclocycline capsules
digoxin injection,
esmolol injection,
ethambutol tablets,
etomidate injection,
ganciclovir topical gel,
glyceryl trinitrate injections,
indigocarmine dye,
labetalol injection,
mefenamic acid capsules,
methylene blue dye,
nifedipine capsules,
nitroprusside injections,
pabrinex multivite injection,
praladoxime injection,
pyrazinamide tablets,
sodium bicarbonate 8.4% injection,
talc for pleurodesis,
tetracycline capsules,
thiamine injection,
thioridazine tablets,
trifluoperazine tablets,
vitamin E solution.

This is but a few of the everyday things that without we could not operate our Intensive Care Unit, Coronary Care Unit, Operating Theatres, undertake breast cancer, or bowel cancer surgery, provide standard TB therapy, safe maternity practice.

A requirement to go through a SCNSA process every time one of the above medications was required is not only impractical, but will inversely impact on patient safety

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

Section 65 would essentially broaden access to pharmacy medicines by also allowing their supply by staff of a registered health practitioner if they are under the

supervision of that practitioner.

In a way Section 61 appears to allow other Health Practitioners dispensing right without the check and balances required for Pharmacies to provide the service, section 65 appear to do that for sale of non-prescription medicines.

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

The wording in ss66(1), ss66(2) and ss66(4) "for a patient of the veterinarian" does not state the patient has to be an animal, just that the patient has to be in New Zealand, and ordinarily resident in New Zealand.

Whilst Veterinary practice is by definition for animals, this should be stated in ss66, as it does so state in other sections

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

This is one area where the Bill is confusing - A Health Practitioner has to go through a SCNSA process for each occasion a non-approved medication is sought for each patient in an effort to tighten up use of unapproved medications from unregulated sources, but then under ss76 individual patients are exempted all controls and can side step the legislation providing it is for them self or someone they are a carer for.

Because of ss76 and 77 the Bill will do nothing to curtail medicine from pouring in from overseas

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:

Alternative medicines should within the categories of inclusion in the Bill.

The lack of regulation of alternative medicines places New Zealanders at considerable risk, there is no control on where these products come from, how they are made or what they contain. Periodically one is found to be adulterated or tampered with, including the addition of prescription medicines to them, they then are covered by the Medicines act and can be withdrawn. It would be safer to adopt a system like the Australian system and licence each product, subjecting them to assay, testing and batch control, both before marketing/delivery and then randomly/periodically off the shelf. This should be done under the umbrella of the Therapeutic Products Regulatory Scheme rather than a separate and potentially parallel system, as it will reduce potential for duplication and loopholes.

I am against direct to consumer advertising of prescription medicines.

Most Countries in the world do not allow it, because it drives unnecessary prescribing. Only the worried well can usually afford the medicines advertised which tend to be those that are not subsidised through Pharmac or those that required Special Authority, thus tying up Medical Practitioner time either explaining why the patient can not have the medicine or does not qualify for funding, or has to pay fees for it which are not generally part of the advert.

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):.

I am generally in favour of the responsible person having to be present and available during business, but once again if other Health Practitioners are going to have dispensing rights and be able to sell non-prescription medicines then they also have to be 'on the premises' in the same way a Pharmacist is compelled to be.

Consideration will need to be given as to how a Pharmacy business out side of the traditional model will be able to comply with this requirement to be on the premises if there are no set premises.

B12 - B15, Schedules 1 - 4

Schedules

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

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

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

C1 Medicines (excluding cells and tissues) sector

Product-based controls

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

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

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

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

Activity-based controls

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

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

C10 Advertising sector

Question C52

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

Question C53

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

I am not in favour of direct to consumer advertising.

Only us and the USA allow it, the fact that most other Countries in world don't allow direct to consumer advertising suggests it is a flawed idea.

Adverting rarely tells the whole story, and even when compelled to include warnings etc they generally appear in such a way that they are easily over looked. Take the Celebryx and Vioxx adds, these concentrated on GI toxicity, ignoring non-GI adverse reactions one of which eventually resulted in the withdrawal of the Vioxx from the market. Ask anyone today what are the likely side effects of a NSAID and they will tell you GI side effects, which to them means dyspepsia etc not gastric ulceration with or without perforation, and patients are generally quite surprised to hear of nephrotoxicity or cardiovascular adverse reactions. Did you ever notice that with both Celebryx and Vioxx they nearly always showed senior citezens gardening or playing golf when patients over the age of 65 was a caution against use?
This is the power of advertising.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4DF-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 17:04:48**

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Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Northland

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).:

ok

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).:

Part O--s29 says Pharmacist can dispense without manufacturing and in the start it states dispensing as specific manufacturing activity.

This is confusing as Dispensing has got nothing to do with manufacturing, both are different operations.

Need to separate them and recognize dispensing as a core Pharmacy service which involves the preparation of the medicine, advice about its use, and clinical checks and is at the heart of a pharmacists' contribution to primary health care.

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).:

Support this part.positive for patient safety

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 as it allows emergency supply to be dispensed to patient.

Subpart 3: Authorisations (ss 56–80)

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

support

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

support

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

Oppose...need changes. Rather than allowing other Health Practitioners to supply category 3 meds (pharmacy only), its better to increase the scope by allowing them to prescribe more wide range of medicines.

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.

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

Oppose...The ability for a health practitioner to supervise their staff to supply these medications under direct supervision is limited due to consultations generally occurring behind closed doors.

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

ok

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

support

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

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:

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):

ok

Question B14

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

ok

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):

ok

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

Question B16

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

ok

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).:

ok

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).:

support One license proposal as it helps maintain transparency over every aspect of Pharmacy activity but 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.

Question B19

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

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).:

Support

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

Question B21

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

3 year license is good as it reduces clerical workload of Pharmacist/owner to re-apply every year.

Question B22

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

Its good to allow transfer to prevent any disruptions to patients.

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

Question B23

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

We need to understand the reasons which can lead to Employment tension which can be any one out of the follows:

Not enough staff support given to responsible Pharmacist

Not having proper Locum cover for Pharmacist allowing time off when needed whether sick or holiday.

Commercial incentives like trying to push sale of Natural health or other products as an add on sale to prescription.

No breaks for Pharmacist or too much pressure to handle busy pharmacy (dispensary) with minimal staff support.

A Licensee who is non-Pharmacist will never be able to understand the ethical side of Pharmacist.

It says it will be an offence not to provide resources to Responsible person. But who has the say on how much resources are needed for e.g. staffing---Who decided how many staff are needed in a busy dispensary including Pharmacist and Technicians?

Do you plan to set a guideline stating No of Rx done by Pharmacy and no of staff needed to make sure safe dispensing and counselling done to patients?

Average 150 Rx per day-- 1 Pharmacist, 1 Technician

Average 300 Rx /day-- 2 Pharmacist, 2 tech etc

No i don't think you can set any guidelines like that.

So you need to keep the control of Pharmacy with Pharmacist and having their say in all matters related to Pharmacy from staffing, stock control, ordering, counselling etc

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):.

ok

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

ok

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):.

ok

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):.

ok

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

Question B30

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

ok

Subpart 6: Infringement offences (ss 249–255)

Question B31

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

ok

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

Question B32

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

ok

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

Subpart 1: Repeals and revocations (s 275)

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

Question B33

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

ok

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).:

ok

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

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?:

ok

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?:

okok

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?:

ok

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?:

Support

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.

Hawker's licence

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

ok

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?:

Oppose

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.

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

Oppose

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.

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

Oppose

I do not, however, see how medicines can be dispensed outside a properly-equipped and staffed pharmacy dispensary.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Pharmacists have professional obligations that are in fact higher than those that the Regulator might impose. A non-pharmacist investor owner is more likely to want to meet minimum compliance standards at minimum cost.

The only reason to bring new option is when we find flaws in existing one.

With the existing system is there any shortage of Pharmacies across NZ?

You will find Pharmacy almost everywhere there is a medical centre in NZ, there is no Pharmacist shortage either in NZ, don't know why u need another option.

Need is to strength the existing Option 1 as it is getting misused by some big Investors like Countdown and Chemist Warehouse.

These big players are giving prescription meds for free as a way to attract patients to Pharmacy. As nobody likes to run business with a model where you running it at a loss by paying co-payments from your own pocket, their idea is to get patient in and sell other Natural supplements etc to make profit.

If this goes on any small pharmacies (in a rural area 40-50k from city) may start losing business as patient may be motivated to drive and get meds from one of these pharmacies to save money.

So what will happen eventually that Pharmacy may close because its not able to sustain in such a competitive environment and town will lose a Pharmacy as these big players will never go in small towns.

So at this stage patient will have to travel far to get meds for acute and chronic conditions.

This will affect patient compliance and create more health issues rather than solving it.

Detailed questions relating to Option 1

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

Support Option 1

Community pharmacies, under the current majority pharmacist ownership requirements, deliver many benefits at no cost to patients or the government. They resolve minor health issues quickly in the pharmacy, assist patients to find the right health service, and deal with cost or appointment problems with other primary health services, such as general practice.

Option 2 risks reducing such services because there is no funding to incentivise their owners to provide them

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

This option is getting misused by some big players as well like Chemist Warehouse and Countdown Pharmacies.

They split Pharmacy Shares into A and B shares.

A shares are only voting shares which don't hold much value whereas B shares are all the capital shares which hold all the value.

Some times some smart Shareholders woo newly registered Pharmacist into ownership by promising part ownership. But how its done is that they sell them 50% A shares which makes them Responsible person of Pharmacy and only 10% of B shares. So the new Pharmacist gets trapped into running and controlling all the Pharmacy aspect from daily running,staffing,ordering etc while only get a little bit return from it at the end of day.

To improve option 1,it should be made mandatory to have major shareholding of Capital shares to be with Responsible person in Pharmacy.

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

Stricter criteria for Pharmacy ownership with effective control and share to major Pharmacist (1 Pharmacist), even in case of 2 or more Pharmacist are Shareholders.

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 other business sector, including in health, has its licence depending on how its shareholding is arranged. Provided a pharmacist has the operational professional and ethical control of everything done in the pharmacy there is no need for the Regulator to micro-manage where the other shareholders come from, or how they make their investment.

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 Act needs to be clear about the definition of effective control. Effective control drives governance and operating decisions.

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

It should be applied by stating that 1 Pharmacist can't have interest in no more than 5 Pharmacies, doesn't matter whether he has less shares or more shares.

No more than 5 Pharmacies at all.

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

Effective control provisions are grounded in a pharmacist owners' obligation as registered health professionals under their Code of Ethics, and pharmacists are highly trained medicines experts who must put their patients' interests first, before profits or shareholder value.

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

The Bill is not clear about the criteria that would apply in deciding whether the number, scale and location of other pharmacies would allow appropriate oversight to the owner pharmacist.

A transition period to offset potential financial risks. An immediate change would result in a sell down by private investors which would lead to a loss of value, where investors would no longer see pharmacy as an attractive investment.

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 already established should continue to operate under their current ownership and business arrangements and constitutions, provided these do not change

Detailed questions relating to Option 2

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

Oppose

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.

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

Such pharmacies can be expected to focus on increasing product turnover and margin rather than on patient experience and health outcomes.

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

Option 2 would lead to increased compliance costs because of accountability conflicts, and limit workforce development, with pharmacists unable to progress their careers. Community Pharmacy has the benefit of a relatively young workforce, with many attracted to the profession by the opportunity to one day own their own business.

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?:

Oppose

Would allow for pharmacy activities to be conducted with a pharmacist monitoring 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?:

OPPOSE

It is essential to avoid conflict of interest by keeping prescribing and dispensing process separate.

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

Allows for permits to be used for some pharmacy activities instead of a licence

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

Support

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?:

Support

It is safer to produce a larger quantity of a compounded product when there is appropriate staffing and space in the pharmacy to do so in a safe manner.

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

Support

Would allow for pharmacists to provide medicines by wholesale in certain circumstances without a wholesaling licence.

The situations where this is appropriate could be governed by the Pharmacists' Code of Ethics where the supply of the medicine would support patient access.

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)?:

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

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

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

Support

Allows for the supply of unapproved medicines.

The introduction of a special clinical needs supply authority (SCNSA) is a positive change. It will support patients being given clear advice around what they are being supplied, enabling them to make an informed decision.

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 issue a SCNSA. Other health practitioner prescribers are generally only able to provide a narrow scope of medicines and it is appropriate that if an unapproved medicine is required that a medical practitioner was consulted

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 its good,should stay like that

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 long as its ethically right.

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 i have not noticed it much.

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?:

Oppose

Allows for other health practitioners and their staff to supply category 3 (pharmacy only) medicines 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?:

Five years of training, and obligations for continuing education, are considered necessary to ensure medicines 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.

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

Not seen any adverts breaking any rules,so dont know.

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 is ok as long as its not misleading and explains to patient use and see doctor and whether funded or not.

Must also state risk factor for patients who cant take it clearly rather than in fine prints or stating it too fast for patient to understand at the end of advert.

C9 Veterinarians

Question C54

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

Not my area

C10 Advertising sector

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?:

As long as its legally and ethically right and not misleading and explain risk factors to patients clearly.

C11 Patients, consumers and disabled people

Unapproved medicines

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

as long as prescriber is confident about what they are prescribing and explains to patient about off licence use and SE.

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?:

Its ok no issues

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?:

Oppose

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

no its not right,should not happen

Pharmacy licensing

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

Option1

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

ok

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

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

Discussed earlier

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

Discussed earlier.

Option 2 is a disaster, there is no problem with option 1, it is working well but just needs strengthening the rules for option 1

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 discussed earlier

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 discussed earlier

Advertising

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

Discussed earlier

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?:

Discussed earlier

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?:

Discussed earlier

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.:

From a patient and consume prespective there are lot of loopholes which need to be fixed as discussed above.



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10 April 2019

Therapeutic Products Bill Consultation
Ministry of Health

therapeuticproducts@moh.govt.nz

Dear Sir/Madam,

Subject: Therapeutic Products Bill Consultation

Pegasus Health (Charitable) Ltd is a large primary health care organisation in Canterbury with around 435,000 people enrolled in its general practice services, representing the majority of the Canterbury population. Pegasus is committed to promoting, maintaining and restoring the health of its enrolled population. Pegasus aims to achieve improved health through high quality and innovative community and primary healthcare.

Please accept feedback on the following aspects of the proposed Therapeutic Products Bill:

1. Direct to consumer advertising (DTCA) of prescription medicines
2. Software and medical devices
3. Off-label use of medicines
4. Pharmacy
5. Supply of pharmacy medicines from staff of other health practitioners
6. Continuity of supply
7. Exclusion of natural products
8. Penalties
9. Selection of Regulator

1. Direct to consumer advertising of prescription medicines (DTCA)

Pegasus Health is extremely concerned about the suggestion that the draft bill continues to permit direct to consumer advertising (DTCA) of prescription medications. Pegasus Health calls for an end to DTCA of prescription medicines to bring us in line with all other developed countries worldwide outside of the United States. We are not alone in this call with consumers and health

professionals in NZ also opposed to DTCA [Every-Palmer 2014]. The Therapeutic Products Bill provides the best opportunity to reverse this situation.

It should be noted that the failure to regulate DTCA was a likely omission from the Medicines Act 1981 as advertising of medicines did not occur at the time. The development of the Therapeutic Products Bill provides the opportunity to finally address this omission.

DTCA persuades rather than informs an individual

It is well documented that DTCA does not provide balanced information for patients to make an informed decision on their treatment. Treatment effects are often vague and when they are stated they are often presented in ways exaggerating benefits, for example citing relative rather than absolute risks.

The commercial imperatives of a pharmaceutical company promoting its product via DTCA will dictate that the focus of such promotional material must be on achieving higher sales and revenue, rather than the provision of information to maximise public health and safety.

Pegasus Health supports provision of high quality, independent, unbiased, evidence based information to patients to help inform them to make decisions on their health. We believe this is also what patients expect. It is highly unlikely that pharmaceutical company advertising will achieve these aims.

The provision of consumer health information that will maximise public health and safety and support quality use of medicines is better achieved by organisations that are not conflicted with the need to promote sales and increase profits.

DTCA worsens health inequity and those 'at risk' may be more vulnerable

Recent New Zealand research suggests that individuals, especially those who are 'at-risk' (i.e., with poorer self-reported health status, older, less educated, lower income and ethnic minorities), may be more susceptible to drug advertising and may make uninformed decisions accordingly [Khalil Zadeh 2017].

US research into people with serious mental illness (another 'at risk' group) found that exposure to DTCA led to increased non-adherence to medication. In this study, a minority of the patients discussed their decision with the prescriber of the medications, most respondents relied solely on the information they had received from the advertising material to which they had been exposed [Green 2017].

Many pharmaceutical companies have been found guilty of unethical marketing

Many major pharmaceutical companies have been found guilty of unlawful promotion of medicines and failure to report safety data resulting in billion dollar fines. The pharmaceutical industry continues to use techniques such as ghost writing, suppression of unfavourable results, flawed study designs and undeclared payments to health professionals [Schwartz 2019]. This undermines the evidence base for the best practice and quality use of medicine.

The advertising budget for DTCA in the US exceeds the FDA budget for evaluating medicines 10-fold. In New Zealand, expenditure on DTCA is likely to be in the tens of millions of dollars annually [Every-Palmer 2014].

DTCA has been linked with inappropriate prescribing and overtreatment. It drives overdiagnosis and ‘disease mongering’

DTCA promotes medicalisation by expanding the definitions of a disease (also known as ‘disease mongering’). For example, the diagnosis of overactive bladder has widened the definition of incontinence so that pharmacological treatment is now promoted to individuals with a milder form of incontinence, and a new indication (and hence a much larger market) has been established for Detrusitol™ – widely promoted on Family Health Diary on TV.

DTCA also promotes medicalisation through inflating the seriousness of a particular condition. For example, promotion of Losec™ for acid indigestion “*missing the food you love because of acid indigestion*” – TV advert.

Brandworld state that 94% of pharmacists believe Family Health Diary increases sales and 99% receive enquiries about advertised products [Brandworld 2019, Every-Palmer 2014].

Overseas research has shown that in comparison to Canada where DTCA is banned, patients in the United States are more likely to believe they need medication for a particular condition, request advertised products and receive prescriptions for these [Every-Palmer 2014]. There is no reason to believe the New Zealand experience is any different.

In 2004 in the United States the average television viewer watched 4 hours 22 minutes a day, which included as many as nine DTC adverts. This equates to around five and half minutes of DTCA per day or over 30 hrs a year [Brownfield 2004]. In comparison, the average American spends 15 minutes with their GP a year. This means that for every one minute with the GP they would have been exposed to 120 minutes of DTCA. On New Zealand television there is one-seventh to one quarter less DTCA than in the US [Mintzes 2012]. The exposure to DTCA in 2019 is likely to now be much higher, particularly with digital innovation and social media.

In the United States, overuse of medical interventions (which includes medications) is estimated to represent 6-30% of the cost of health services provided to patients [Glasziou 2017, Morgan 2015]. Overuse can also divert funds so less money is available to address unmet needs and the social determinants of health [Glasziou 2017]. The Institute of Medicine estimated the annual cost of wasted healthcare resources in the USA was US\$765 billion in 2010 (including \$210 billion in unnecessary services and \$55 billion in missed disease prevention) [Saini 2017a].

DTCA increases the risk of patient harm by encouraging preferential uptake of newer medicines

DTCA increases the risk of patient harm as it is new (on patent) medications that are advertised, as opposed to older medications with a longer track record of efficacy and safety. A fundamental safety principle underpinning the quality use of medicines is that less is known about the long term safety of newer medicines than older treatments. Newer treatments should generally not be prescribed unless there is strong evidence of additional benefit. Examples of DTCA driving use of newer treatment options over older ones include: Flixotide™, Seretide™, Symbicort™, Vioxx™.

Rofecoxib (Vioxx™) is an infamous example of DTCA. This was aggressively promoted for arthritic pain and frequently requested by patients, yet later found to have fatal side effects and withdrawn from the market. Insufficient measures to ensure drug safety before licensing Vioxx™ alongside the intensive marketing made it likely that far more people took this medication than would have been the case without promotion by DTCA [Alpert 2005, Dieppe 2004, Every-Palmer 2014].

DTCA undermines the culture supported by the Choosing Wisely global initiative

Choosing Wisely New Zealand is health professional led, patient focussed, and here to promote quality care, through better decisions. It encourages patients to take a considered approach and discuss both the potential benefits and potential harms of interventions with health professionals. Choosing Wisely is a global initiative that has been implemented in a number of countries, including USA, Canada, the UK, Australia and some of Europe [Choose Wisely 2019].

DTCA undermines the culture of Choosing Wisely. It effectively turns patients into salespeople for particular branded medications; discussion and choice become driven by unbalanced and misleading messages from the advertising of a single branded product rather than by objective assessment of advantages and disadvantages of all treatment options.

DTCA cannot be regulated effectively

Neither pre-vetting nor regulation of DTCA is likely to be achievable in a timely manner to ensure advertising promotes the information needed for patients to make an informed decision.

A recently published review of medical marketing in the US demonstrates how regulation of DTCA is inadequate in the US, a large, well-resourced country. From 1997 to 2016 promotional materials related to DTCA of prescription medicines submitted to FDA for review increased from 34,182 to 97,252. In 2016, the FDA were able to review only 41% of core materials (i.e. key messages, risk disclosures) for new drugs or indications prior to launch. Of note, most violations since 2015 have involved inadequate risk information [Schwartz 2019].

If a large, well-funded and resourced body such as the FDA is unable to keep up with the regulation of DTCA then it would seem unreasonable to expect New Zealand to be able to do this effectively. The Pegasus Health view is that any money directed into regulating or pre-vetting DTCA of prescription medicines would be better directed into the development of independent, evidence based consumer health information.

eDTCA (online interactive social media) is widely prevalent and poses further challenges for regulation

The use of internet and social media for DTC advertising (eDCTA), is rapidly increasing but is completely unregulated, further exposing patients to potentially illicit and misleading information [Mackey 2015]. A marketing whitepaper was released to show pharmaceutical companies how to use social media to target patients directly, cutting out the middleman (i.e. health professionals) [Cutting Edge Information 2015]. Like traditional DTCA, the intention is to persuade patients through these media, not provide all relevant and useful information to support patient to engage in an informed decision making processes.

There are few data on how this form of pharmaceutical marketing impacts consumer behaviour, public health and healthcare utilisation. Given the difficulty already experienced by regulators of DTCA, it is unclear how it will even be possible to keep up in this area [Mackey 2015].

2. Software and medical devices

Software will increasingly be used for therapeutic purposes and Pegasus Health believe that in some cases software should be considered as Medical devices. There is currently a continuum of software use cases and tools that could fall into the proposed definition. This includes:

- Systems used to capture and store information about a patient, such as a patient management systems or electronic medical record, referral management systems etc.
- Software integrations that enable data to be shared between systems.
- Reports and foundational analytics which provide feedback to clinicians about patients who meet specified (simple) criteria. These are often extended to include the use of more complex algorithms utilised to select patients based on a range of information contained in the medical record or inferred based on other available information. These algorithms equally have the potential through the use of big data and data science techniques to identify clinical risks through unrelated data, or predict the likelihood of future adverse events.
- Clinical decision support tools that, based on the information about a patient, guide (or direct) clinical decision making.
- Knowledge bases that may be queried, based on the information about a patient, to ensure relevant clinical information is available to the clinician and or patient to inform clinical decisions.
- Patient applications which support self-management.
- Artificial intelligence tools used to automate a clinical process, such as the management of repeat prescriptions.
- Artificial intelligence tools used to automate clinical decision making.

Current software tools sit at the lower complexity end of this continuum and are likely to present little risk. Research, however suggests that there is the potential for automation of up to 33% of the tasks currently completed by Health Care Practitioners through the use of Artificial Intelligence (AI) and automation techniques [Muro M 2019].

The future use of AI and automation presents general practice with significant opportunities for productivity gains, while providing opportunities for improved health outcomes. While it is appropriate to consider some software as medical devices within the bill, consideration should be given to ensuring that this is targeted towards use cases (for example reading diagnostic images) rather than a blanket approach that potentially includes all software. For software associated with these uses cases, the mechanisms for approval must strike a balance between enabling innovation and ensuring safety. We would suggest that in considering the use of software, the bill should focus on software utilising artificial intelligence process that operate as “black box” rather than tools that provide clinicians with transparency in their decision making process.

Pegasus Health supports an approach that balances regulation for patient safety without sacrificing availability or innovation.

3. Off-label use of medicines

Pegasus Health does not support the current recommendation requiring a special clinical needs supply authority for off-label use of medicines. Off-label use of medicines is very widespread and there is often very good clinical evidence to support the use of the product for the prescribed indication. Many products will always be used off-label as there is no financial incentive for a company to add to the licensed uses for the product once it is widely available in the market.

Adding further paperwork into the process of using a product off-label is impractical, requires some level of administration and does not support better patient care. Many prescribers are unaware of the actual licensing status of some commonly prescribed medications – examples include beta

blockers for palpitations and tricyclic antidepressants for pain. Collecting information on these off-label uses is unlikely to improve or alter patient care.

4. Pharmacy

Pegasus Health supports models of care that promote quality, patient safety, collaboration and address health inequity. We support a model of care that allows pharmacists to work at the top of their scope. To this end we support the recommendations for pharmacy businesses to be able to operate in a more flexible manner.

Restrictions on prescribers holding an interest in pharmacies may become out of date due to the expanding number of prescribing professions in primary care. An ownership model that clearly prioritises professionalism, pharmacist oversight and patient safety is most important.

5. Supply of pharmacy medicines from staff of other health practitioners

Pegasus Health supports collaboration between health providers to share information in relation to the use of therapeutic products. In Canterbury, community pharmacists have access to HealthOne™ records of medication dispensing alongside the pharmacy dispensing record. In addition there are trained pharmacists available to identify and check any safety issues related to the use of pharmacy medications. This allows for a safety check when supplying pharmacy products. It is important to ensure there is no added risk to patient safety if pharmacy medicines are being supplied by staff of other health practitioners.

For example: there is a potential risk of harm for a receptionist to sell NSAIDs when they don't have access to a full patient medication record and the patient may already have been prescribed an NSAID from another provider/GP, or the patient may have a condition/other interacting medications that precludes use of the product.

It is imperative that the health practitioner recommending the product has a full understanding of the patient's medication history and has sufficient knowledge and competency in this area to safely endorse supply of a product to a patient via their staff members. Ideally this supply should be captured in a shared medical record to avoid fragmentation of supply and care.

6. Continuity of supply

We seek assurance that the timeframes for implementation of these changes are reasonable. Specifically, has sufficient work been done to ascertain the scale of regulation that will need to be undertaken to ensure continuous supply of therapeutic products in the New Zealand market?

Additionally, is there a risk management strategy should some suppliers decide to remove their product from the market rather than have it regulated under the new bill?

We currently experience numerous shortages of medicines in primary care and PHARMAC will sometimes use unlicensed products to fill the gaps. Recent examples of commonly prescribed medications in short supply include paracetamol tablets and ethinyoestradiol with levonorgestrel tablets (combined oral contraceptive) [PHARMAC 2019] - could this get worse?

7. Exclusion of natural health products

Pegasus Health understands the decision to exclude natural health products from this bill, however it is our expectation that regulation does occur for this group of products. Patient harm occurs from unregulated natural health products that are perceived by members of the public as safe, due not only to the lack of regulation but also to no limitations on availability and supply. There are no robust mandatory processes for capturing adverse effects information, and information on adverse effects is scarcely reported until significant adverse effects occur. A recent example is *Artemesia annua* extract and hepatotoxicity [Medsafe NZ 2018].

8. Penalties

Pegasus Health supports the intention of raising penalties to a level that is in line with the offence. We would expect that the actual dollar amounts should be included in Regulations rather than the Act to allow for more rapid updating of amounts, or for the level of penalty be tied to inflation in some way so that they don't once again become out of date (as has been the case with the Medicines Act).

9. Selection of Regulator

We would like to comment that there should be some consideration given when choosing the regulator to ensure this is not unnecessarily costly to the health system, and doesn't result in delays in access to therapeutic products.

Thank you for taking the time to consider our submission on the Therapeutic Products Bill.

Kind regards,



Vince Barry
CEO
Pegasus Health (Charitable) Ltd

Email: [REDACTED]

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Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 18:29:29**

Submitter profile

What is your name?

Name:

Gary Stewart

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Hunts Pharmacy (Retail 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?

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).:

Dispensing a medicine is NOT a part of manufacturing a medicine. When a medicine is manufactured there is no check for interactions or dosage checks, and communication with the patient does not occur.

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):.

Allowing one pharmacy to supply another pharmacy in short supply situations would be very helpful. Borrowing a medicine from another pharmacy would be faster than waiting for a wholesaler delivery the next day. There would be less waiting time for the patient.

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

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

Allowing health practitioners to supply each other with small amounts of medicine in an emergency situation would be beneficial in remote or rural areas or even in urban areas in the event of a natural disaster.

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):.

It seems wrong that a person can import a prescription medicine at present, have it held by customs, then get a prescription to cover it. Surely if there is no prescription before the importation, then Customs should just destroy the imported prescription medicines.

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

Vending machines need to have pharmacist oversight in some way, otherwise the people using those machines will get sub-standard or no service.

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):.

Dispensing at an aged care facility. Who would be doing this ? Where would the stock come from? How would the controlled drugs be signed off and stock checked? This would only work if a pharmacy was built inside the rest home, which probably would not be economic.

Question B19

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

When I was an intern pharmacist we were told that only a pharmacist could hold the keys for a pharmacy. Somehow that law or rule has changed to allow responsible persons to hold the keys to a pharmacy. Who changed this rule ? Was it a legal change? The result is that retail shop assistants end up holding the pharmacy keys at some Unichem pharmacies. This does not seem desirable, and has produced bad outcomes already. Medsafe should be before the HPDT , for allowing the situation to occur.

Subpart 2: Permits (ss 131–135)

Question B20

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

Short term permits for urgent situations would be ideal.

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):.

Applying for a pharmacy licence every year is time consuming and expensive.

Having to find a JP or lawyer can be difficult and the \$1000 fee seems profiteering for what is mostly a reprint function. A longer licence fee would be helpful or a reduced fee.

Pharmacies are not the cash cows that they were in the 1970's, and a lot of pharmacies are struggling to pay their staff and suppliers.

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?:

Hawker's licence

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

Transition

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

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

Dispensing should ideally be face to face. Mail order or courier services seem to invite shortcuts. Face to face could be digital, but real life is better for communication.

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

The current pharmacy licensing requirements do not create barriers to innovative pharmacist services.

What creates barriers is the lack of funding. Pharmacy income has been dropping since about 2004, and in particular since 2013.

Having an annual DHB contract is close to insane. Each year we are expected to approve or reject a new DHB contract, before our accountants have analysed the previous years financial affairs. This makes it impossible to commit to new services, when it is next to impossible to work out your financial position.

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

I believe a mobile pharmacy may be a step too far; but I could be wrong. The DHB's are giving pharmacy contracts to pharmacies the size of closets. It seems everyone is entitled to a pharmacy contract from your local DHB. Goodness knows how you can get any privacy at your Countdown pharmacy in aisle four.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Pharmacist ownership should result in the best possible health outcomes for the patients.

Across the Tasman in Australia, there are already cases of pharmacists being pressured to sell pharmacist only medicines, even when it is inappropriate.

Detailed questions relating to Option 1

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

Having a pharmacist owner who is interested in health outcomes, means that the dollar does not always come first. You give medicines out when the customer does not have the money or you deliver it to their home. That does not happen when you buy your cough mixture at Countdown.

The risks from Option 1 relate to criminal pharmacists. See C25

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

The current rules regarding ownership should have worked.

Medsafe have known for years that Unichem as a company has been owning Pharmacies illegally, and that East Tamaki Health has owned over twenty five pharmacies illegally.

Medsafe have shown themselves to be weak. There is no point in having pharmacy ownership laws if Medsafe chooses to do nothing. Who disciplines Medsafe??

Perhaps Medsafe should be replaced?

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

Everything

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?:

To really control the pharmacy, the majority shareholder needs to be in face to face contact with the staff each week.

I do not think the responsibilities 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)?:

Perhaps the five pharmacy limit should be reduced to three?

The owner should be able to physically visit each pharmacy each week.

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

I cannot see how an equal partnership would work. I feel that one of the pharmacists needs to have a majority shareholding.

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?:

ONE year at the most. The dodgy pharmacists would just be taking advantage otherwise.

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

I do not understand friendly societies. If they are not dodgy, an exemption would be fine.

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 can see option 2 allowing more pharmacies to go down the free prescription route of The Chemist Warehouse. The goal of driving other pharmacies out of business by selling at below cost, is not inviting to me ; and is illegal in some countries.

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

Only by removing the profit motive.

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?:

If there is a physical pharmacy there needs to be a pharmacist present.

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?:

Prescribers are already owning Pharmacies by dodgy deals, and Medsafe has not done anything about it. To avoid a conflict of interest it is obvious prescribers should not own pharmacies. Allowing Doctors to own pharmacies is quite likely to increase the bill to Pharmac nationwide. I cannot see a benefit of prescribers owning a pharmacy.

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

After a natural disaster or unexpected emergency a permit would be very useful.

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

Depot pharmacies need to be controlled by a full normal pharmacy, so that the remote patients can receive as near to normal service as possible.

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 the above approach is the way to go. Patients initiating overseas supply are often trying to avoid seeing a Doctor. For overall public health, everyone should access their prescriptions through a Doctor. This is obvious really.

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?:

We need to be able to make up Hydrocortisone Ointment ahead, otherwise the customer would be waiting all day. Batch compounding still has its place in pharmacy.

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

Where an expensive rare medicine is needed in small quantities. Pharmacies can move a broken pack onto another pharmacy that needs it . Then there is less

wastage.

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?:

Off label use seems like a buzz word in New Zealand.

Unapproved medicines like Ethambutol are used for every second tuberculosis patient. Off label can also mean "official nonsense".

Setting up a special clinical needs supply authority for unapproved medicines would be a complete disaster. Do you know how many Ethambutol and Melatonin prescriptions are written each week.

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?:

Please reserve this system only for medical practitioners ordering medicines from overseas.

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?:

See previous C18 question. This is a duplicate

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 an emergency only.

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?:

NO . You just know it is not going to be to the same standard of care.

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 think this still needs to go via a Doctor, then pharmacist , then patient.
The patient could organise the importation. But not direct to the patient.

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G415-7

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 19:37:45**

Submitter profile

What is your name?

Name:

helen guy

What is your email address?

Email:

What is your organisation?

Organisation:

rust ave pharmacy

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please comment;:

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

Chapter A (A1 - A5)

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

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

S29 "dispense a medicine". the definition has changed significantly from the Medicine Act.

Under the draft bill, dispensing a medicine is defined as part of manufacturing the medicine, which implies merely supply, rather than the current definition which includes (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

Dispensing as currently carried out by Pharmacists includes clinical checks for appropriateness as well as effective conversation with patients as to how to use 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):

the proposal of 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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues, especially around high cost medicines

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

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

I 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. Overall, I think vending machines would be a very poor substitute for the pharmacy experience, and should only be permitted where no pharmacy service option exists

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):.

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 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, or in Civil Defence Emergency situations, 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 C22 Which option do you support?

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

Question C23 - Why do you support that option?:

I very strongly believe that there is significant and important 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. As a small pharmacy owner, I can confirm that my primary goal is to provide a patient-friendly community pharmacy, with a focus on providing outstanding clinical care in a sustainable and ongoing way. It is my belief that the ongoing outstanding service we provide our patients is what keeps them coming back for more.

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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, however this risk can be partly eliminated by enabling grandparenting provisions for pharmacies operating legitimately under current laws. These provisions could be time-limited to bring them into line if deemed necessary eg. 5 years.

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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

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

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).

Personally, I think the current 5 pharmacy limit is too many - 2 pharmacies per pharmacist owner would be more than enough.

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 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?:

The Act should include provisions for grandparenting the pharmacy businesses that are operating legitimately under current rules. Five years to phase these out should be sufficient.

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.

Non-pharmacist owners, particularly corporate, would likely engage legal teams to effectively cover their risks, to mitigate their responsibility for any adverse outcomes, and structure their business models in ways that would still make Pharmacists responsible for outcomes, whilst demanding maximum profit for shareholders. Pharmacists employed under such conditions would have little incentive to provide any patient care over and above the bare minimum, which would lead to demoralisation of the workforce and subsequent exit to more satisfying professional 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 and practice Pharmacy their way, thus corporatising of Pharmacy services would likely reduce their chances of realising this goal, and likely lead to them exiting the profession also.

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?:

by rewriting it as option 1

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

Other changes to pharmacy licensing requirements

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

All pharmacy activities that require a pharmacy licence need to be conducted either by a pharmacist, or under the supervision of a pharmacist. I do not understand how these activities can be performed safely without the direct in person oversight by a pharmacist. We are concerned that any change in this space could lead to patient safety concerns.

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

I do not support prescribers holding an interest in a pharmacy. In order to remove any conflict of interest it is essential that prescribing and dispensing remain separate.

There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

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

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

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

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

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

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. At my pharmacy, we do not currently do any batch compounding.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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

I am supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

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 I 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?:

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 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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

Personal imports

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

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

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G474-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 19:51:27**

Submitter profile

What is your name?

Name:

Dr Denise Taylor

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Graduate School of Nursing, Midwifery & Health, Faculty of Health, Victoria University of Wellington

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

Pharmacist, Nurse, Midwife

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

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 acknowledge the need for updated regulations which cover a myriad of therapeutic products including those containing human /animal tissue (latter in some of the anti TNF alpha products). However it would also seem reasonable to include natural health products within this framework as many do have evidenced therapeutic effect. It would also then assure good quality of manufacture etc.

We also understand that this will improve the flexibility of responding to new therapeutic products in the future, but the accompanying legislation needs to be explicit so as not to create loopholes for potential commercial misuse.

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).:

This is quite comprehensive. As a registered pharmacist my concerns would be to ensure that pharmacist practitioners are not held to account by non-pharmacist managers/owners who may make it difficult for them to practice in an ethical, safe and moral way. Pharmacists put the patients interest as their primary concern, no matter whether the patient is geographically located. To support this guidance must include the need for safe, appropriate and secure storage and transport of

medicines, with an appropriately qualified and experienced pharmacist to give clinical and medication-related advice.

With respect to point 49, about a prescribers 'scope of practice'. How is that defined? Do clinicians need to request permission when moving from one scope of practice to another? If so how is this mediated? Will it be able to keep up to demand? I am thinking about when medical practitioners (for example) are on their rotation and they move from Cardiology to Rheumatology to Paediatrics to Elderly care to psychiatry to primary care - do they need to register a change in 'scope of practice' for each rotation?

In the UK, Canada and America, pharmacist and nurse prescribers' can start in one area of prescribing and then move to another area of practice (with appropriate CPD and support) dependent on what is needed in their organisation. This is especially important in hospital prescribing services where expertise needs to be covered in times of strike, workforce shortage of medical prescribers or GP prescribers, and epidemic or natural and unnatural disasters.

This layer of bureaucracy seems like it may hinder rather than help in some circumstances. In other countries, registered non-medical prescribers prescribe any medicines within their competence and confidence and that is then monitored via their mandatory re-registration and CPD requirements for an annual practice certificate.

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):

Personally it is unclear to me what is meant by 'parallel import'. In the UK where I have returned home from; this means to import an alternative licensed generic product of the same chemical therapeutic constituency (medication). At present in NZ the controls by Pharmac on what is or is not available for prescribing in NZ seem less than transparent and quite fickle. Pharmacies end up with unused medicines on their shelves which are not re-imbursable because Pharmac changes its mind on suppliers and then payments.

These controls need to be transparent so everyone is clear of what is happening.

Patients are then faced with another medication change; often experiencing adverse events which are often long lasting.

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 fairly comprehensive, but would like to point out that the transport and supply of certain medications (e.g. controlled drugs, vaccines etc) is also a controlled activity to ensure the appropriate safety and storage (cold chain for example) are adhered to.

Subpart 3: Authorisations (ss 56–80)

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

Totally agree with S59 and wholesale supply; this legalises what happens now in emergencies

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

We agree that pharmacist supervision is an important part of a pharmacists' role.

The pharmacists may be completing the clinical check of a prescription and/or then going through the dispensing process; but will also have their eyes and ear alert for what is happening on the shop floor.

For example, ensuring advice given by pharmacy staff is correct; intervening in an emergency situation (for example we had a patient present with early stages of anaphylaxis and escort the patient to the GP next door, rather than an oral antihistamine which may not have worked in time.

Pharmacist supervision and advice on prescriptions and over the counter preparations is clinically important and can be life saving.

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

In terms of 'scope of practice'; do you mean the individuals' job description must explicitly state that they have prescribing qualifications and within this JD they are expected to prescribe as part of their role? Does the prescriber need to state what area? If the area may change over time, this seems unnecessary

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

Category 3 medicines still have the ability to harm patients if the person supplying does not understand the possibilities for interactions with the category 3 product with the patients usual medicines (prescribed or OTC) and /or interactions with their disease. Health practitioner workers generally have little medicines training, unless they are within a pharmacy where that training is mandatory and supervised. And sales are generally supervised. Pharmacy only or Category 3 medicines have been classified as that because of the inherent risk in their supply from inappropriately trained people, whatever their role. Some health professional workers are not members of a registered profession; they do not have a professional body or a mandate to keep up-to-date. This is a potential avenue to open up risk to patients. How will it be monitored for risk and adverse events to members of the public? Where is the training for such members of the workforce to prove they understand when category 3 products are appropriate or not; especially items such as non-steroidal anti-inflammatory agents which are now linked with increased cardiovascular disease (specifically myocardial infarction and/ stroke) and renal impairment (increasingly seen in children).

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

No particular comment here, except one would expect the prescribing, dispensing, procurement, storage and compounding processes to be as stringent as they are for human medicines.

There should be the option for owners of pets receiving veterinary treatment to have generic medicines (with assured product licenses) to reduce costs and ensure pets receive treatment that their owners can afford.

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

People should be able to source the medicines they want, especially if these are not prescribed; for example supplements. The government should review its punitive import tax on such items as it often makes these unaffordable and then negatively impacts health.

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.:

98: Personally believe DTCA should be withdrawn in New Zealand. The general public is generally does not hold the health literacy or background to develop an informed opinion on whether a particular prescribed medication is appropriate. This hen seems an inappropriate background to seek the medication from a prescriber.

What it then also impacts on is the increased prescribing of an advertised medicine due to incentives offered to prescribers; which is basically bribery and unethical. In terms of examples we know that countries with DTCA have higher rates of prescribing of antibiotics and resultant resistance.

Q105. Still believe prescribing business and dispensing business need to be separated; not just due to the potential and observable ethical issues and mis-appropriation of repeat prescribing (which are claimed but never dispensed), but also the need for a clinical consideration of the prescription which is based on patient need rather than monetary gain.

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).:

Product approvals may need to have an expiry date to reflect changes in patents, responses to previously unknown but serious adverse effects and because things should be reviewed to ensure there are not substantial changes which have affected quality of supply, manufacture and safety.

Question B14

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

Conditions to approval could be appropriate as would be at least 5 yearly an update on any factors that affect the authenticity or safety of the product.

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

Question B15

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

None

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

Question B16

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

None, except there would be a need to adequately fund a monitoring system for all therapeutic products via post-market safety reporting and pharmaco-vigilance and surgical vigilance (as needed in the recent and ongoing surgical mesh debacle)

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

Question B17

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

None, but this is increasingly important as generic medicines are often manufactured with different ingredients which patients can be allergic to

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).:

Still agree that a pharmacy needs to be majority owned and effectively controlled by a pharmacist. They have the expert knowledge and training to accomplish these responsibilities plus the professional responsibility to be the advocate for the patient and provide best clinical advice and care. This needs to be free from external pressure from business partners who may only be concerned about financial gain. Pharmacists also have accountability via their registry body the New Zealand Pharmaceutical Council and professionally via the New Zealand Pharmacy Society

Question B19

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

None,

Subpart 2: Permits (ss 131–135)

Question B20

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

None, allows flexibility in times of emergency

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

Question B21

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

None

Question B22

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

None

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

Question B23

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

None

B8 Part 6 of the Bill: Regulator

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

Question B24

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

None really, except who would the regulator be? What would be the requirements of the regulator to be able to assure the government of their capability to do this role?

How will they be governed; how will they maintain impartiality and independence?

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

None really; but will need to be able to defend their cations and recompense people/companies wrongly accused

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

Question B26

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

None

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

Question B27

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

None, although it would be good to understand how the panel will be selected. For example how will people be approached, can people potentially interested in sitting on such committees as experts apply for possible approval/inclusion at a later date?

These people need to be from a wide range of backgrounds and not the usual 'mates of mates'

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

Question B28

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

None at present

B9 Part 7 of the Bill: Enforcement

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

Question B29

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

None similar to present

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).:

Interesting that it is suggested that a person does not need to have particular knowledge to be found negligent. Not sure I agree with this. Sometimes people feel they have the knowledge that is needed, or that the required knowledge is not really necessary and go ahead and do something anyway. That is willful negligence and or ignorance.

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).:

Can the infringement be over turned/wiped clean if the original reason is addressed and rectified and the fine paid?

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

Question B32

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

None

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

Subpart 1: Repeals and revocations (s 275)

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

Question B33

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

None

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

Question B34

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

None, except for customs ability to seize non-prescription items brought into the country by consumers, if they are not available in NZ but have passed other regulatory procedures in another country

B12 - B15, Schedules 1 - 4

Schedules

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

None

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

None

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

Not known

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):

On pint 242; paediatric prescribing is mostly off-label as there is a lack of licensed medicines for use in children as it is now seen as an ethical to perform such research in children.

Therefore this would place a great burden on prescribers for children and should perhaps be seen as an exceptional circumstance.

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

None

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

Pretty hard to comment as its not very transparent at present

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

There needs to be appropriate fundings for post-market surveillance to be sustainable and ensure that all therapeutic products are monitored and not just medicines.

Activity-based controls

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

None

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

None; Not sure hawkers are appropriate to have a wholesale licence unless they fit the requirements of a suitable and responsible person

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, this is an evidenced approach

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

None

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

To be honest I think anything that contains human tissue /cells should be managed in the same way.

In the UK hospitals, manipulated tissue/cell products are prescription only medicines even though they be an oesophageal replacement product for implant into a human. This is because it becomes regulated and then conforms to all cold chain and/or storage chain requirements; it is traceable and linked to the person it was implanted into. This could be an important consideration for NZ

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

Tissue and cell products need stringent post-market controls and vigilance. What needs to be avoided at all costs is the transfer of diseases or cancer cells via these tissue or cell products. The Hepatitis C & HIV disaster via blood products was a major example of how things can go wrong. Often with new products from cells or tissues; there is not the knowledge or experience to understand the actual potential for harm to the recipient in the future.

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

None, except as mentioned previously

Activity-based controls

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

Manufacturing organizations need careful regulation; assurance of patient safety; and clear guidance and/or regulation on how tissue/cells can be harvested from humans and under what conditions and under what consent processes

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?:

Recently completed research into rehabilitative technology devices for people with serious injury in NZ and it would seem that some regulation is necessary to ensure patient safety and to ensure a standard of manufacture for NZ geography.

This would also enable the potential recipient of such equipment to be able to try out equipment before it is purchased to ensure it achieves the intended outcomes.

Product-based controls

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

None known

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

None known

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

None known either way

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

None known

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

Seems robust

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.:

Seems appropriate

C4 Clinical trial sector

Question C16

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

Sounds robust and pragmatic

Question C17

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

None known

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?:

As mentioned earlier I think it infringes human rights if they have a valid prescription

Hawker's licence

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

I do not agree with this. It is now disapproved in the NHS to 'hawk' or give drug samples to prescribers as this bypasses the need for impartial and robust evidence on the medication in questions.

It also then is a way for prescribers to receive extra payments from 'hawkers' by prescribing that product widely, frankly unethical in my belief.

Transition

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

None known as it is a bit sketchy

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?:

As long as a qualified pharmacist is available to give individualized medicines and clinical information alongside the provision of medication and the storage and transport of medicines is safe, secure and conforms to all cold chains or supply chain requirements, then pharmacists from most locations. However mobile systems will be targets for theft and consequently the pharmacist in charge may be more at risk of being harmed.

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 am aware of. Community pharmacists already deliver and supply prescription medicines to rest homes and palliative care premises for example, along with appropriate clinical advice. There are also great examples of pharmacists working alongside and in collaboration with local maraes and psychiatric care facilities, without the need for any changes

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

Any different distribution and supply arrangements need to ensure the safety of the medication and the pharmacist and/or pharmacy worker

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

I would prefer ownership to remain with pharmacists to ensure the clinical needs of all patients (whether they be receiving prescribed; pharmacist only, pharmacy only or general sales medicines) because these services are accompanied by appropriate clinical advice. Without compromising patient care.

I have just returned home to NZ after 30 years working in the UK in pharmacy. The large chains that have established themselves in the UK are generally not pharmacist owned; highly profit oriented and highly abusive of their pharmacist and pharmacy staff. Staff are stressed; wages have fallen from £25-30 per hour in the early 2000's to £20-25. Pressure is out on staff to agree and sign off poor practice with the threats of job loss if they do not and to put pressure on customers to buy multiple products- even if these are inappropriate.

I applied for a Supervisory Pharmacist (pharmacist in charge role) in London, which I then found out was for 3 pharmacies, but I would only work in one but would be responsible for all clinical activity in the three pharmacies. Plus the condition was I was not to monitor controlled drug supplies or use of controlled drugs. The owners were not pharmacists but using the businesses as a front for their illegal activities.

Other non-pharmacist owned pharmacies put pressure on pharmacists to supply all patient repeat medicines that were on a script, even if they were not needed and/or had been stopped. This boosted claims to the government for payment.

There were a small number of GP practices that had a dispensary; but those were reducing in numbers annually because the actual income associated with dispensing alone, is not that great - apart from organizations who write prescriptions for patients who do not exist.

I agree that ownership rules need to be tightened up. When I left NZ in 1984 the pharmacist was only able to have a share in one other pharmacy and that was usually the Night Pharmacy (open 5.30pm to 11pm which worked as a co-operative for all pharmacists who had shares within the business. (I think the share was <10%). To accomplish what is proposed here it needs to be clear that ownership is linked to a controlled level of pharmacy activity/supervision by the pharmacist. The activity could be business and/or HR management. Again when I left in 1984 it was usual to have two pharmacists in the pharmacy; one who was the clinical advisory lead and one who was the business lead. That synergy worked really well.

Detailed questions relating to Option 1

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

Please see above

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

Please see above

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

Business acumen and management

Clinical activity

Supervision of pharmacist internships or pharmacy technician trainees

Providing support to local organizations who use medicines e.g. palliative care, residential homes, schools, public health etc

Merchandise procurement

Advertising and media relations

medicines management services

Vaccination services

Prescribing or clinical activities

Work in or with local health organisations - GP surgeries, maraes,

Linking/liaison with PHOs etc

Research and or audit

Stock management

Controlled drug and OST services

Psychiatric services - supply/administer IM products

HR management etc etc 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?:

These could be separated to suit the individuals' strength. Often the best partnership are complementary ones; where the two individuals are greater than the sum of each alone

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)?:

See points above. Would expect them to be involved in some of the daily running activities of each pharmacy, whatever they may be

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

A written agreement between the pharmacists involved and acknowledgement of their individual responsibilities as part of the ownership agreement

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

None

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

These things take time and negotiation. Will the regulator pay for the inevitable legal fees involved? Knowing how long it can take to organise these agreements in the first place, I would suggest a minimum of 3 to a maximum of 5 years. But there will be costs involved and somehow these need to be kept to a minimum and this would require a Regulator mediated legal advisory system perhaps.

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

No

Detailed questions relating to Option 2

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

See original points; there is a great risk for abuse of pharmacy staff and negligence for the patents

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

Don't do it

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

None have worked so far in UK; am still aware of daily abuse of pharmacy staff by pharmacist owners

Other changes to pharmacy licensing requirements

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

This is a tricky area and especially with NZ's remote population areas where internet access is poor or non-existent. If there are pharmacist only activities going on a pharmacist needs to be physically present.

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 have heard a number of examples where prescribers want to own a pharmacy so they can control the amount of income a pharmacist gets. Pharmacists do not control the level of prescriber pay so why should the reverse happen.

NZ has a very prescriber oriented power balance at present and it needs to be kept separated from pharmacy to ensure there is clear separation of prescribing and dispensing activities. I have mentioned reasons why in numerous other comments.

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

Possibly but I know that there are multiple businesses around the country now thinking they can set up a 'temporary' pharmacy within their business to sell products that are not regulated but which would be taken more seriously if they were sold/recommended by or from a pharmacist. Dangerous

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

Honestly I think it's a gateway to abuse of medicines sales

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 impinges personal freedom and should not be implemented. NZ medicines are controlled by Pharmac and they do not suit all patients. Who exactly are you protecting or giving jobs to, in this scenario?

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?:

Yrs sometimes this is appropriate especially if a product is short dated, but takes some time to compound. It means that continued need could be confirmed with the patient, the product timetabled to be made in anticipation of an agreed time for collection. Some products are complicated to make and need planning into a busy pharmacy day

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

When the pharmacy has run out of supply and needs medicines urgently for a patient
In times of emergency (earthquakes etc when normal supply chains are not working)

C7 Retail sector

Question C42

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

Unknown

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'm unsure why the NZ MoH needs to agree the authority to prescribe of a relevant health practitioner. In the UK and other countries where medical and non-medical practitioners prescribe; this is regulated via their regulatory body with the need to demonstrate mandatory annual CPD in their prescribing area plus having it written into their job description and recognition on their personal professional indemnity insurance arrangements. Each regulatory body then states clearly on its website the practitioners who can legally and professionally prescribe.

With all due respect, how does the Minister of Health have the time or appropriate knowledge to do this?

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?:

See above, as having taught pharmacist prescribers how to prescribe and then assessed them as being suitable prescribers and passed this information to the appropriate regulatory body (as each other non-medical prescribing practitioner group does).

I am not even sure what is meant by 'form and content of prescribing provisions within scopes of practice'. To me scope of practice means elderly care or paediatrics or respiratory or diabetes etc; but it could also mean hospital, retail or primary care or general practice.

As I understand it in NZ non-medical prescribers (e.g. pharmacist and nurse practitioners and registered nurses who prescribe have undertaken special training to do so. Midwives prescribe from a limited list with no extra training; which seems inequitable.

Leaving midwives out of this (as I think postgraduate training is needed); these practitioner prescribers are only allowed to prescribe in the area in which they trained; even though circumstances may change and it means that if the patient has co-morbid conditions the rules are enforcing multiple prescribers; which increases risk of polypharmacy and decreases patient choice in prescribing.

In the UK, America and Canada, non-medical prescribers can do extra CPD and professional practice work to enable practitioner prescribers to move into different areas of prescribing. They do this within their sphere of competence and confidence and are accountable to their employer but also their professional organization, code of ethics and code 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.):

None known

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 it is labourous and unnecessary in some areas especially paediatrics.

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?:

In the UK as a hospital and community pharmacist I was able to complete the necessary paperwork to order a specific medication to be imported from overseas that wasn't yet licensed in the UK but clinically needed for a patient.

Whats the difference here?

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 the third time this question has been asked. I think it infringes on personal freedom if people have a legal prescription and a need for a medicine licensed in another country but not available here. This is draconian and enforces the monopoly that Pharmac has and decides that New Zealanders need. Pharmac is currently years behind in cancer treatment meaning that New Zealanders are being disadvantaged and potentially losing their lives before they need to.

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

When one has run out and a patient is in urgent need

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 imagine so

Health practitioners (non-prescribers)

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

Possibly, but is that supply includes a sale then this is then an organization that needs a pharmacy license.

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, this has been asked before. You end up with receptionists and untrained staff giving medicines to patients when they have no knowledge whether they are appropriate enough and insufficient knowledge and power to question the prescriber on their suitability.

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

Cannot tell if good or bad

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?:

Disagree completely with advertising to patients directly. See earlier comments including lack of health literacy to understand the background to why a particular medicine may or may not be appropriate.

C9 Veterinarians

Question C54

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

Should be the same as for pharmacy staff

C10 Advertising sector

Question C52

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

Can't tell if will be good or bad

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?:

Do not agree with this as have said three times now. It is worse almost than Dr Google. If patients were better informed maybe but they are not. Every other country in the world thinks it's not best practice (except NZ and USA).

In USA it's because big Pharma controls the drug budget and the senate and all within it.

NZ is pretty much ruled by Pharmac and the lack of transparency there is not great

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?:

SCNSA for off-label in pediatrics would apply to about 80% of all medicines prescribed. This is time wasting for busy clinicians

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?:

Any prescriber or pharmacist could do this on behalf of their patient.

Just because it isn't approved in NZ doesn't mean it hasn't been approved elsewhere. Frankly some of the medicines approved in NZ border on the archaic and have been withdrawn from common use elsewhere.

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?:

Infringement on human rights

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

When they're on medication NZ does not have/permit and it is the best thing for them and prevents adverse effects they experience when they are supplied a so-called 'similar' item by Pharmac

Pharmacy licensing

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

See above answers

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

None known

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Because pharmacists are ethically and clinically trained

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

None known

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

Risks of abuse of pharmacy premises and pharmacy staff for monetary gain

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. If there is a charge they are operating as a business and need a pharmacy license

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 or knowledge

Advertising

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

None known

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 be banned see earlier

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, see earlier especially those for people with serious injuries who depend on them for continued life/quality of life

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.:

A lot of this does protect the consumer, but is too complex for many consumers.

Response ID ANON-DPZ8-G42Y-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 20:04:45**

Submitter profile

What is your name?

Name:

Rosie Long

What is your email address?

Email:

What is your organisation?

Organisation:

CCDHB

Submitter Profile (tick all that apply)

Consumer

Pharmacy organisation, District Health Board (DHB)

If you select DHB, please state service area:

Other health practitioner (please comment)

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

Pharmacy Technician

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

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):

Remove the term 'direct' supervision in relation to Pharmacy Technicians. There are occasions where this is not required and is significantly impacting on development of pharmacy services. Pharmacy Technicians are already working in roles and performing activities where they are cannot be directly supervised. Retention of this stipulation for direct supervision will restrict pharmacist activities, compromise patient care and will also interfere with the evolution of the pharmacy sector.

Ensure any accompanying legislation (regulations/rules) allows for professional registration of other pharmacy workers and not just pharmacists.

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

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

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

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

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

Subpart 4: Other offences (ss 81-94)

Question B12

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

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

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

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

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

I do not feel it is necessary for a pharmacist to be a majority owner of a pharmacy business - it is very restrictive. I feel this option would allow for more flexibility.

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?:

I think it would help to increase accessibility to medicines as this would allow more options for the market and establishment of new pharmacies.

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?:

Yes as long as this is properly regulated/monitored e.g regular audits from the regulator.

Other changes to pharmacy licensing requirements

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

I think we should start moving away from the requirement for a pharmacist to be directly supervising every activity. However, I feel a pharmacist should still be available onsite if running a pharmacy business.

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

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

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

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

Pharmacist and pharmacy worker authorisations

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

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

C8 Health practitioners (including pharmacists)

Prescribers

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

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

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

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

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

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

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

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

Health practitioners (non-prescribers)

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

No, this should be left to trained pharmacy workers.

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, this should be left to trained pharmacy workers.

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 do not agree with advertising prescription medicines as I feel this is unethical. The appropriateness of a particular medicine should be determined on consultation with a healthcare practitioner or pharmacy professional.

C10 Advertising sector

Question C52

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

I don't agree with medicines being advertised.

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 agree with advertising prescription medicines as I feel this is unethical. The appropriateness of a particular medicine should be determined on consultation with a healthcare practitioner or pharmacy professional.

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G411-3

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 21:13:17**

Submitter profile

What is your name?

Name:

Nai Park

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Kamo 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

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).:

none

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):

no

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

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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

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

no

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

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):

ni

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–80):

no

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.:

no

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

Question B14

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

no

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

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

Question B16

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

no

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

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).:

no

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):.

no

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

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

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

no

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

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

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

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

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

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

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

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

no

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

no

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

no

Activity-based controls

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

no

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

no

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 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 C22 Which option do you support?

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

Question C23 - Why do you support that option?:

I strongly believe that 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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

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

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 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?:

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 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?:

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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

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?:

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 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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

Personal imports

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

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

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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.

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.:

no

Response ID ANON-DPZ8-G4F1-R

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-17 21:25:43

Submitter profile

What is your name?

Name:

William Peake

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Self

Submitter Profile (tick all that apply)

Consumer

Advertising

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 don't support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

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.:

I do not believe it is necessary to make any changes to the existing advertising processes for any kind of therapeutic 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?:

I submit that direct to consumer advertising of prescription medicines should continue to be permitted in New Zealand under the same conditions that are currently in place.

In summary:

DTCA of prescription medicines has been a well accepted part of the NZ media and advertising landscape for over 25 years. It has caused no harm.

It has been a highly effective primary information source about health conditions and possible remedies.

It has assisted in getting people more engaged in their own health issues and outcomes, often leading to earlier diagnosis & treatment of serious health conditions, and better compliance with treatment regimes.

In today's constantly changing world of the internet, "Dr Google", social media platforms, and more open discussion around health issues, DTCA of prescription medicines is only one source that may be impacting on a person's information gathering, opinions, or influencing the nature of any patient doctor interaction, yet it is probably the most regulated and vetted source in terms of accuracy and consumer safety.

The actual content in the DTCA of prescription medicines is developed with high levels of social responsibility, is truthful and not misleading. The products featuring in DTCA campaigns have all been approved by Medsafe to be marketed in New Zealand.

DTCA of prescription medicines is well regulated in New Zealand. The TAPS (Therapeutic Advertising Pre-vetting Service) peer-review process, introduced in 2000 has successfully ensured that advertiser's content conforms to statutory requirements, and other industry codes.

DTCA of prescription medicines is not a concern to the public of New Zealand. It raises little or no objection, as evidenced in so few complaints to the ASA (Advertising Standards Authority), and there is no substantive evidence of it having caused any harm or any wrongful, or over medication, or having put untoward pressure on prescribers or funding agencies.

The incidence of DTCA of prescription medicines campaigns in NZ is not as prevalent as the opponents of it often like to infer. There are only a small number of campaigns using mass audience media like TV and Radio actually running each year.

DTCA of prescription medicines represents a small percentage of advertising media expenditure for all therapeutic products (around 5-6%) and a tiny percentage or all advertising media expenditure in New Zealand (around 0.2 of 1%).

To remove, or place adverse restrictions on the right to conduct DTCA of Prescription Medicines in NZ is against the public interest

To get rid of, or restrict the rights of an organisation to disseminate a helpful source of accurate information, portrayed in a socially responsible manner, by organisations that have spent vast amounts researching & developing medicines that have been proven beyond doubt to be beneficial to appropriate patients, & been approved for use by regulatory agencies, and whose advertising has been through a rigorous vetting process, seems paradoxical in a world demanding greater access and immediacy of information, and which has relatively unfettered access to absolutely anything via the internet and social media platforms.

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

We live in an ever-changing world for both the Consumer and Medical professionals

It is now nearly 15 years since there was last an open debate around the use of DTCA of prescription medicines in NZ.

A lot has changed in that time.

We live in a more informed, and open society.

We have a more health literate and engaged consumer.

The lines between different sources of information, promotion, or influence have become blurred.

Use of the internet to access information around health issues has grown exponentially over the past 15 years.

The advent of social media, blogging, on-line patient support groups, peer to peer influence, and the normalisation of discussion around many health issues, which were once taboo, or not discussed openly, have also changed the dynamic.

These developments in new digital and social media, & instant access technologies, and the way people interact, have also blurred the boundaries between what is "information or promotion", be it advertising, public relations, public service information, advocacy, endorsement, social influencers, health sector websites, or general peer to peer discussion around the same subject or product. They are all potentially influencers, or promotion, of some description.

What is more important in today's society is accuracy, honesty, relevance, authenticity, and social-responsibility, irrespective of the information or influencer source or material.

Therefore, DTCA of prescription medicines is but one of many sources that may be impacting on a person's information gathering, opinion, or influencing the nature of any patient - doctor interaction. Yet it is most probably the most vetted source in terms of accuracy and consumer safety and compliance with New Zealand regulatory and Industry requirements.

The changing world of the medical professional

Changing consumer / patient demands, and access to new technologies, is also impacting on the medical profession, influencing how they engage with patients, and often how they make decisions around choice of medicines or other remedies.

In a world seeking more convenience, greater immediacy, and "mobile-phone centrality", we are seeing the advent of telemedicine, with virtual home visits, remote or video consultations, and of course medical professionals are becoming mainstream users of social media in how they engage with their peers and patients.

There are now a new group of suppliers & tech consultants that doctors in particular are having to deal with, so no longer just the drug reps!!

The way medical professionals interact with patients will continue to change.

The practice and implications of DTCA of prescription medicines are known.

There are a lot of things that will happen in the future that are unknown.

For example, what will be the implications of medicinal cannabis on the patient- doctor dynamic??

In an article in the NZ Herald dated April 17 2019, citing a research study that indicated that medical professionals are not yet that well informed about medicinal cannabis, the Chairman of the NZ Medical Association, Dr Kate Baddock, said she wasn't surprised that such a high number of GP's reported getting questions about medicinal cannabis. She said: "It's not necessarily that people are saying 'I want it' – it's generally been more of an enquiry than a request".

In the same article, the Medical Director of the Royal College of General Practitioners, Dr Richard Medicott, when asked about increased patient enquiry about medicinal cannabis was quoted as saying: "GP's encourage patients to ask questions and discuss their treatment plans, so its good to be able to have these conversations. However this doesn't necessarily that the GP would be supportive of this type of treatment."

It would therefore be somewhat hypocritical and ironic if some of the opponents of DTCA of prescription medicines cited the argument that such advertising either wastes doctor's time or makes them feel pressured to prescribe that particular medication.

Having "difficult conversations" is part of everyday life in most relationships, not just with doctors and patients.

How will a generational shift of those people who have grown up as "digital natives", in an open forum internet and social media world impact on the doctor - patient interaction in the future?

For example: Today's Millennials as both Medical professionals and as patients becoming increasing users of prescription medications.

This is no longer just a "Baby Boomer" discussion.

The changing prescribing environment:

Today the GP is often only one part of this process.

Of recent years in New Zealand as more drugs have gone off patent and have had a generic substitute, which now reportedly account for 80% of prescription medicines being dispensed, GP's are increasingly just putting the "molecule" name on the script and leaving it to the Pharmacist's discretion to make the final choice of which specific "brand" or generic to dispense.

This can be confusing, and sometimes alarming for the patient, who may well have been used to taking the same "brand" for many years, and then finds themselves being dispensed an alternative, sometimes with unwelcome side effects.

DTCA of prescription medicines has in a number of cases helped to eliminate the confusion and remind the patient that their trusted "brand" is still available even if they may have to pay an additional cost.

Therefore, in today's prescribing environment, the patient even more so requires an accurate and robust knowledge of "all the facts" of what is actually available to them, and sometimes it is only via advertising that this is being delivered.

How DTCA of prescription medicines is actually used in New Zealand.

The majority of recent DTCA of prescription medicines campaigns in NZ have been focused on major public health issues like smoking cessation, diabetes & prevention of cervical cancer, or chronic or debilitating health issues like asthma, arthritis, shingles, or psoriasis.

The purpose of such advertising has been to help people get a better understanding of symptoms, the kinds of treatment options available, or in some cases the availability of vaccines that can prevent the onset of what can become serious conditions.

These privately funded advertising campaigns have often been supporting Government led initiatives.

DTCA of prescription medicines has also been used effectively to help dispel potential patient confusion around drug choice when generic substitutes have entered the market.

These are not trivial subjects, especially if you are a person who suffers from or who is at risk of them.

The actual content in the DTCA of prescription medicines is truthful & not misleading. It has been developed with high levels of social responsibility, objectivity, factual information, unambiguity & contains little or no hyperbole relative to other types of advertising. Many would call it boring!

By choice people don't like taking pills or other medication so to think that advertising results in people racing off to their GP "demanding" what they have seen, is somewhat naïve.

The old adage from my own experience of over 20 years working with the attitudes of consumers with respect to therapeutic products and services is: "If I'm affected I'm interested, if I'm interested tell me all about it, if I'm not bugger off!!"

Therapeutic products & especially prescription medicines is not a category for tyre kickers!!

DTCA of prescription medicines doesn't just happen in isolation.

It's part of an integrated marketing campaign to both consumers & healthcare professionals

DTCA of prescription medicines is expensive. Pharmaceutical companies undertaking these activities therefore want to ensure they are well supported by healthcare professionals, both doctors, pharmacists and other health influencers.

Any DTCA of prescription medicines campaign will be accompanied by an equally rigorous campaign directly to doctors, pharmacists & other relevant healthcare professionals

Section 5.11.9 of The Medicines NZ industry code specifically requires companies to notify doctors and pharmacists at least 7 days before the commencement of any DTCA of prescription medicines campaign.

So therefore it should come as no surprise to GPs if they have some patients presenting themselves or raising comments as a result of these campaigns.

Pharmaceutical companies go to great lengths & expense to ensure there is an integrated approach to bring the consumer and healthcare environments together, with resources available to consumers that can be provided or recommended by healthcare professionals. Where healthcare professionals are time poor these information, education & support resources step in to cover the gap.

The scope & scale of DTCA campaigns in NZ

The incidence of DTCA of prescription medicines campaigns in NZ is not as prevalent as the opponents to it often like to infer.

Over the past 3 years 2016 – 2018 there have in fact only been around 10 brands of prescription medicines actually advertised in mainstream media, like TV and radio, on average each year.

And these have been for treatments for chronic conditions like asthma, diabetes, arthritis and psoriasis, and for vaccines to prevent the likes of shingles or cervical cancer.

These are all major healthcare issues and those people who are either sufferers of these conditions, or concerned about the possibility of contracting them, have every right to access the most current factual information about these treatments or preventions, irrespective of the source of such information.

The amount of actual advertising expenditure on these campaigns is nowhere near the magnitude of the figures often bandied around by the opponents of DTCA.

Best estimates for the years 2016 – 2018 using AC Nielsen data shows annual media expenditure on mainstream media at ratecard value was on average around \$5-6m a year.

This is only around 5-6% of the total expenditure for all therapeutic products where the average ratecard spend is approx. \$100m per annum.

And more significantly given that the ratecard figure for total advertising expenditure in NZ is currently around \$2.5billion, spend on prescription medicines is around 0.2 of 1%!!!

That's right – around two tenths of 1%!!

(Note ratecard media as expressed by AC Nielsen is different to actual expenditure as it does not account for discounts clients receive from media owners, so

actual expenditure may only be 50-60% of reported figures)

Comparisons are sometimes made with the situation in NZ and that of the USA which also allows DTCA of prescription medicines. We cannot fairly compare NZ situation with US where there is a different patient access & funding model and consumers have access to many more options than in NZ, and it has been a very heavily advertised category for a long time.

DTCA of prescription pharmaceuticals is NOT a concern to the general public

Looking at complaints received by the Advertising Standards Authority over the past 5 years, there have in total been only 11 complaints against advertising for prescription medicines, compared with 3587 total advertising complaints over that period.

So that is on average only 2 complaints a year!!

And of those 11 complaints only 1 (one) of them was partially upheld, with the complaint actually being brought against a dentist (ie: a medical professional) for featuring a prescription product in their own advertising without adequate product information. And the complainant was actually an industry representative group, not an individual.

This is also further testament to the fact that there is a high level of social responsibility in the creation of actual advertising content, and a robust self-regulatory process in place with the DTCA of prescription medicines in NZ.

Conclusion:

If a primary role of the new Therapeutics Products Bill is to protect the safety and well being of the public of New Zealand, the focus should be on how to better moderate or contain any adverse impact of ambiguous or unvetted inputs prevalent in a more open and accessible world, rather than seeking to outlaw a method of communication, namely DTCA of prescription medicines, which has been around for over 25 years, is well regulated, has caused no apparent harm, and seems to be universally liked by the public.

Why consider removing DTCA of prescription medicines as an information source, or promotional tool, when the world is being proliferated with more and more information and influencer sources which are way less reliable or moderated in their content.

Regulated DTCA of prescription medicines is a much safer option than the largely unregulated internet or social media platforms.

Those people seeking to prohibit DTCA of prescription medicines are clearly out of touch with how the world is changing and how people now get their news and information.

Response ID ANON-DPZ8-G41Z-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 21:34:04**

Submitter profile

What is your name?

Name:

SIAU, SHUI NGO

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Oceania Healthcare

Submitter Profile (tick all that apply)

Consumer

Industry body

Active ingredients

Medicines

Private hospital

If you select DHB, please state service area:

Other health practitioner (please comment)

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

Activities Coordinator

Medicines (other than cells and tissues)

Other (please comment)

If you selected 'Other' please comment::

residential care

Response ID ANON-DPZ8-G414-6

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 22:01:26**

Submitter profile

What is your name?

Name:

Julie Haggie

What is your email address?

Email:

What is your organisation?

Organisation:

Transparency International NZ

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

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

NGOs

If you selected 'Other' please comment;:

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

Chapter A (A1 - A5)

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

Partially 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):

1. Transparency International NZ submits that 3(b) should include 'adaptation' and 'withdrawal or removal' in the list, to be certain to capture the greyer areas of therapeutic product management, and the areas where a lot of problems seem to occur.

2. Transparency International NZ understands that a weighting of benefits over risks may be to support flexibility and innovation. However this requires balanced wording to ensure that the management of risk is sufficiently dealt with. We do not see that in the wording of ss4, where (b) (i) is somewhat overshadowed by (a). We suggest the inclusion of a clause which will have the direct effect of requiring a more active and dynamic approach to risk (including monitoring and skilled and timely responses) where the detrimental health impact is high, even if those cases are in a minority. For those individuals the result can be catastrophic.

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. Transparency International NZ queries whether the application of medical devices is adequately covered under the draft legislation. Two areas which have generated considerable injury and trauma are the insertion, implantation, and then removal of medical devices through surgery. In the list of controlled activities under 10(2) one assumes removal is included under use. It does not appear to be sufficiently covered in there or in section 53?

2. Ss 22. Transparency International supports the submission of Mesh Down Under' which states that:

"Access restrictions need to be established and applied to BOTH medical devices and medicines. The reasoning and wording in this paragraph is too loose and it

is a clear loophole, "the scheme would enable supply restrictions and/or use restrictions on a device or class of devices". For the regulator to be able to determine a 'safety concern' they need to follow a lengthy complicated process which is extremely convoluted and can last for many years. To substantiate this proof of evidence, the NZ regulator would need to rely on overseas regulatory bodies for 'evidence'. Using the surgical mesh issue as an example, there is clear evidence documented (globally) showing how overseas regulatory bodies have used flawed clinical research to base their decisions on for approving devices. It is understandable that there is a strong pushback from industry to validate the safety of their products, which includes documented conflicts of interest from industry with close links to international regulatory bodies. The surgical mesh issue is the perfect example of how even when serious safety concerns about patient safety are evidenced it takes years for any action to be taken to address serious safety concerns."

...It is important to ensure that a categorisation system be introduced for devices as well as medicines, both need the same level of scrutiny and legislative mechanism.

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:

1. Transparency International NZ comments on DTCA later in this submission but not specifically on the offences.

2. Section 88. Transparency International NZ also agrees with Mesh Down Under in relation to Misrepresenting a therapeutic product (ss 88)- Within the TPGB there have been no provisions made which relate directly to the advertising of procedures, unfortunately only therapeutics products have been included. Consideration regarding the inclusion of procedures is needed. Specifically, the language used in any information which is provided to the public, must be a balanced representation which details all risks as well as the positive impacts and this needs to be extended to information provided in video format or electronic media. There also does not seem to be a clear enough distinction as to what is specifically classed as an advertisement or article. One example of this is the article/advertisement, which was placed in the Listener in 2015, called the Leaky Person Syndrome. It is very unclear as to whether this is an article or advert, but regardless the information should not be misleading. The focus for the advert/article was for women suffering with stress urinary incontinence, sadly only the positives of surgical mesh were highlighted with no mention of any risk at all about the procedure included, nor alternative surgical options provided. At the time of publication, there was plenty of clinical research and evidence which demonstrated serious concerns regarding these procedures and our petition to parliament for an inquiry into the issue had been accepted in parliament and was under review. These devices and procedures were already known as high risk but none of these risks were mentioned. A clear distinction needs to be made as to what constitutes an advertisement or article and we need to ensure that procedures are included in any legislative changes made. Please read this link: <https://www.noted.co.nz/health/health/leaky-person-syndrome/>

3. Section 93. Health practitioner prescriber must not hold interest in a pharmacy business . Transparency International NZ supports the submission of Mesh Down Under where it argues that this clause only applies to pharmacy and medicines. It should also extend to health practitioners who may have a commercial incentive for a medical device, since they have the same potential financial benefits which could lead to basing clinical decisions resulting from a conflict of interest. Strengthening the legislation so it is extended to health practitioners using devices is important- at the very least they should tell the patient that this commercial incentive exists, but, although this is already an expectation this needs to be able to be mandated and included in the legislation.

B6 Part 4 of the Bill: Product approval

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

Question B13

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

Transparency International supports the submission of Mesh Down Under' which also applies to ss 95. How will known loopholes affecting decisions on approval be identified and addressed?

Criteria for approval- "safety and performance of a device to be satisfactorily established"

This is difficult to ascertain if a product has come through the 510k process and is subject to criteria of approval only based on a predicate device. In many cases the predicate device that this new device has received approval through, has also gone through this same process. This 510k approval pathway is not robust enough to ensure the safety of these products and history has shown that the risks cannot be 'satisfactorily established.' As an example, the Protogen Sling made by Boston Scientific in 1996 had a very high complication rate and was recalled in 1999. The FDA stated that "Use of ProteGen in the treatment of female urinary incontinence is associated with higher than expected rate of vaginal erosion and dehiscence and does not appear to function as intended". Ironically the Protegen itself was approved through the same 510k process, yet the predicate devices it was based on were not made of the same material (polypropylene) and the surgical approach to implant this device was completely different. (see second link below) The TVT which is the most commonly used surgical mesh device in NZ currently, is based on the ProtGen predicate device. Of great concern, the FDA have no authority to remove a subsequent device which has been based on a predicate device and has been subject to a level one recall (because of safety concerns). Globally the most serious device related issues and majority of problems that have been associated with medical devices, have come about because of this process. Although the FDA are strengthening their guidelines this 510k process remains.

Question B14

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

1 Transparency International strongly supports the requirement for a register of medical devices to be held by the regulator including those that have been approved and those that have been refused approval.

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):

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):

Transparency International NZ promotes transparency and integrity. We support the regulator promoting openness, ethical behaviour and ethical leadership which will lead to improved public trust and confidence. We strongly support the regulator requiring timely registration of all clinical trials, and reporting of results, not just those that are publicly funded.

It should also be the role of the regulator to apply standards and requirements on relevant random controlled trials.

We strongly promote openness, which means publishing of decisions about declined product approvals, removal of product approvals and results of all trials including those that have negative outcomes.

We strongly support engagement by the regulator with consumers as well as other stakeholders, so that it can be responsive to a range of community voices as well as business and medical professionals.

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):

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

C4 Clinical trial sector

Question C16

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

1. Transparency International NZ joins Mesh Down Under and TranspariMED in their call for the NZ government, via the Ministry of Health to sign the World Health Organisation (WHO) joint statement on public disclosure of results from clinical trials.
2. There are many good reasons for increased transparency of clinical trials, not least that regular and prompt updating of registry data enables patients to locate the trial they are registered on and makes it easier to recruit patients. Whilst there have been significant improvements in the registration of clinical trials there are still big gaps, including around random control trials. We need more effective rules to support industry and regulatory engagement. Another way of increasing transparency is for all NZ trials to be published regardless of whether there is a positive or negative outcome. This is not currently the case. If trial outcomes and summary results are not published, there is a risk that valuable research findings are wasted because they are not available to the scientific and clinical community. This can also result in harmful drugs and devices being marketed which brings patient safety into question.
3. Clinicians and health consumers need to be aware of negative trial outcomes, so that they can make informed decisions about procedures and devices they use or accept to be used on them.
4. Ethics approval should be mandatory for all clinical trials and for most random controlled trials. Although there has been advances in this area, the report from the ANZCTR clinical trial registry notes that "only 50% of trials prospectively registered had ethics approval at the time of registration. (2006-2015)" refer to ANZCTR Clinical Trial Landscape Report. (ss419)-

Question C17

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

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?:

1. Transparency International NZ has a firm view that Direct to consumer advertising should not be permitted. This would bring New Zealand into line with international best practice.
2. We are surprised that a separate and full review including research and independent reviews has not been undertaken. This would complement the general consultation on the Therapeutic Products Bill. The Ministry's pre-stated position on this issue is perplexing given time time lapse since the 2006 report when the Ministry also didn't form an opinion.
3. There is considerable international research available. In the 2006 review the majority of government agencies, educational/research agencies, members of public and consumer groups opposed dtca. Dtca was

unanimously supported by advertising agencies and pharmaceutical companies, and the opinions of health professionals making submissions were divided.

4. We note that since 2017 the Royal NZ College of General Practitioners has supported a full ban on dtca.

Aside from the RNZCGP statement, there are two good relatively recent discussions on the issue:

a) Every-Palmer, Duggal and Menkes in NZMA Journal, 29.8.2014, Vol 127 No 1401

<https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/Position-Statements/2017.03-DTCAPositionStatement.pdf>

b) Helena Jochem 'Direct-to-Consumer advertising for prescription drugs in New Zealand: Time for a Radical Change? LLM Research Paper Laws 432/532, Consumer Law, Victoria University 2015.

5. Considering the changing views in society it would have been useful had the Ministry, in taking its position not to propose a change to the law, provided a more considered paper on the topic, setting out its reasons for its preliminary position, or at least acknowledging gaps in evidence and how they plan to address that.

6. There is certainly international evidence about the failure of dtca to report details about the drug's mechanism of action, success rate, treatment duration, alternative treatments and any behavioural changes that could enhance the health of affected patients. Dtca has also been linked with inappropriate prescribing and overtreatment. Despite the aim for the Bill to make sure the ads were "truthful, not misleading and socially responsible" it is unlikely that in an environment of 'accentuate the positive' an advertiser is unlikely to provide a balanced view.

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Consumers of therapeutic products may be experiencing distress, urgent need, and sometimes in fragile health, when they interface with the products and the people who sell and use them. This generates a power imbalance. They are usually competent and able to understand complexity and to make decisions. This places a particular onus on those who hold power – prescribers, therapeutic product producers, advertisers, medical professionals and regulators – to act with integrity, and particular care, and to provide clear explanations of options and risks, and including alternatives to the use of products. Most medical professionals and therapeutic product producers, and policy makers would benefit from training provided by disabled people that would support their ability to ensure that people with disabilities have informed choice, and receive care of the same quality as others, including on the basis of free and informed consent. This is entirely in keeping with NZ's commitment to the International Convention on the Rights of Persons with Disabilities

Response ID ANON-DPZ8-G4FQ-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 22:13:51**

Submitter profile

What is your name?

Name:

Maria Morley-Bunker

What is your email address?

Email:

What is your organisation?

Organisation:

Community Pharmacy - Unichem Bishopdale

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

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).:

The draft TPB attempts to significantly change the widely accepted definition and understanding of dispensing. I am concerned about this change. Defines dispensing as part of "manufacturing". It also minimises it to just part of the supply chain. 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):

We support this.

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):

We support this.

It will allow one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine requested by a patient. This would greatly benefit patients by giving them timely access to their medications, 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 :

We would be supportive of health practitioners supplying each other with small amounts of medicines in an emergency situation when a pharmacy is either not accessible or cannot provide the medicine in a timely manner. However 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.

Other than in this exception, we oppose this part of the TPB.

Five years of training, and obligations for continuing education, are considered necessary to ensure medicine efficacy, patient safety, and to prevent misuse, overuse, and abuse. Pharmacists are bound by a Code of Ethics that, when it comes to medicine supply, is more stringent than that which applies to other health practitioners.

Pharmacists are the medicines experts for every step of the supply process from storage, transportation, potential for misuse, interactions with other medicines, reporting of harm, and creating systems enabling patient follow-up and product recalls. All pharmacy activity is subject to strict regulations and unannounced inspection audit about every aspect of medicines handling.

If health professionals were regulated to supply Category 3 medicines, they would need to have made the capital and other investments necessary to meet the above requirements, and have their staff supervised by a pharmacist.

To increase access to medicines we would support increased prescribing rights, allowing other health practitioners to prescribe the required medication within their scope of practice. This has the benefit of the patient then being able to access a funded medicine.

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

We oppose this.

For the same reasons described in B7.

In addition to this, the ability for a health practitioner to supervise their staff to supply these medications under direct supervision is limited due to consultations generally occurring behind closed doors.

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

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

We support this.

We agree with the concerns around the importation of counterfeit and substandard medicines. Importation of medicines should only occur through the appropriate regulated channels to ensure patient safety. The safety profile of medicines imported from outside the approved supply chain is unknown. 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.

We believe that section 76 (5)(a) should be amended to only allow the personal

importation of category 4 prescription medicines.

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.

The restriction should also be applied to category 2 (pharmacist-only) and category 3 (pharmacy only) medicines as they should only be supplied with the professional advice provided in a pharmacy setting with a pharmacist oversight.

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

We support this with the qualifications stated below.

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 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).:

We support this partially.

The benefit of a single licence is that it will maintain clinical oversight and transparency over every aspect of pharmacy activity. However, it is difficult to see how medicines can be safely dispensed outside of a pharmacy given the lack of access to equipment, record systems and clinical resources. Section 124 would allow for dispensing and supply at an aged care facility. We do not understand how medicines are able to be dispensed outside of a pharmacy dispensary. 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):.

We support this.

It is important that the system is flexible enough to respond quickly in emergency situations to minimise disruption to patients' access to medicines.

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

Question B21

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

We support this.

I am supportive of increasing the period that licences are valid for. Issuing licences for three years should be the standard period unless quality concerns that have arisen during the licence term have not been promptly rectified. 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):.

We support this.

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.

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):

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:

C5 Wholesale sector (including importers and exporters)

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

Licence to wholesale

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

We support this.

We are supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when the safety profile of medicines imported from outside the approved supply chain is uncertain and 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 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?:

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.

We would welcome and embrace opportunities and arrangements that promote patient

health outcomes provided they do not compromise patient safety or the integrity of the community pharmacy distribution model.

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 wherever possible.

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

This question assumes that the current licensing requirements are barriers to innovation. However, the barriers to innovation that exist are not related to licensing. Innovative Pharmacy and Pharmacist services requires changing the well-identified barriers into enablers - IT systems and processes (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.

We 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.

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

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 can see 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.

We do not, however, see how medicines can be dispensed outside a properly-equipped and staffed pharmacy dispensary.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

The public benefits from a healthy network of community pharmacies owned by pharmacists accountable for their patients' care.

Pharmacists have professional obligations that are in fact higher than those that the Regulator might impose. A non-pharmacist investor owner is more likely to want to meet minimum compliance standards at minimum cost.

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 professionalism, business goodwill and community reputation. The closer a decision-maker (in this case, pharmacy owner) is to accountability and consequence (both professional and financial), the greater incentive there is to do things the best way possible. A pharmacist-owner has twice as much to lose as a pharmacist alone or non-pharmacist owner.

Detailed questions relating to Option 1

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

Community pharmacies, under the current majority pharmacist ownership requirements, deliver many benefits at no cost to patients or the government. They resolve minor health issues quickly in the pharmacy, assist patients to find the right health service, and deal with cost or appointment problems with other primary health services, such as general practice.

Option 2 risks reducing such services because there is no funding to incentivise their 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.

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

Some community pharmacy business ownership arrangements under the Medicines Act could be financially damaged under Option 1.

However, they have not broken the law. No other business sector, including in health, has its licence depending on how its shareholding is arranged. Provided a pharmacist has the operational professional and ethical control of everything done in the pharmacy there is no need for the Regulator to micro-manage where the other shareholders come from, or how they make their investment.

Provided the owner pharmacist has control on all operating decisions that may influence public safety then there is no need for restrictions on how further investment is dealt with.

Young pharmacists are able to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

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

All clinical activities within a community pharmacy setting that require a pharmacy licence, such as the provision of medicines (except general sales medicines).

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

The Act needs to be clear about the definition of effective control. Effective control drives governance and operating decisions. Effective control provisions are grounded in pharmacist owners' obligation as registered health professionals under the Code of Ethics, pharmacists are highly trained medicines experts who must put their patients' interests first, before profits or shareholder value, which are the driving motivations of any normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

We would support the Act to 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 responsible for ensuring compliance with governance and operational obligations.

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

The Bill is unclear 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, so it is difficult to comment on this.

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.

We 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?:

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?:

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 to offset potential financial risks. An immediate change would result in a sell down by private investors which would lead to a loss of value, where investors would no longer see pharmacy as an attractive investment. It would also make it difficult for pharmacists exiting the business on retirement and the introduction of new pharmacist shareholders.

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

Detailed questions relating to Option 2

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

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. By contrast, the non-pharmacy owner is accountable only to their shareholder(s).

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?:

Pharmacy activities requiring a licence need to be conducted by a pharmacist, or under their immediate supervision.

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 essential to avoid conflict of interest by keeping prescribing and dispensing process separate.

There is an incentive for a medical practitioner with a financial interest in a pharmacy to align their prescribing practices to generate more profit from it. Pharmacy revenue is linked to the level of dispensing, so an increased volume of dispensing will result in more income.

We are 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.

We are aware that community pharmacists in other countries have limited rights to prescribe for certain conditions such as minor ailments.

The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

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

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

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

Depots should only be authorised via the licence of a linked full-service pharmacy. This is important to ensure clinical oversight and allows patients access to pharmacists from the full-service pharmacy for clinical advice.

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 bulk for the compounded products that they dispense on a regular basis.

It is safer to produce a larger quantity of a compounded product when there is appropriate staffing and space in the pharmacy to do so in a safe manner.

If pharmacists and pharmacy workers are only able to compound when a request is made this could have significant impact on workload and risk to patient safety.

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

We 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.

The situations where this is appropriate could be governed by the Pharmacists' Code of Ethics where the supply of the medicine would support patient access.

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 support 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?:

Only medical practitioners should be able to issue a SCNSA. Other health practitioner prescribers are generally only able to provide a narrow scope of medicines and it is appropriate that if an unapproved medicine is required that a medical practitioner was consulted.

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?:

We oppose this.

We 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?:

We 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?:

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G4FJ-H

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 22:20:31**

Submitter profile

What is your name?

Name:

Ray Pang

What is your email address?

Email:

What is your organisation?

Organisation:

Global Medical Solutions NZ Ltd.

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medicines

Private hospital

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 don't support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

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. We welcome the regulation on radiopharmaceuticals but wonder what category of medicine will radiopharmaceuticals be put into. Currently all radiopharmaceuticals used in NZ rely on importing and since all reactors making radionuclides are not working 100% (generally 60- 80%), we have to keep at least two different suppliers to back up each other. Too much regulation will make the market lose its flexibility.

Also many radiopharmaceuticals have very low volume sales in NZ and any regulation on them will either drive their prices up dramatically or make them unavailable.

So, we suggest some radiopharmaceuticals be exempted and others categorized into category 4 of medicine.

2. The definition of "prepare a medicine for administration (s 26)", "compound a medicine (s 28)" and "dispense a medicine (s29)" might overlap and be confusing in radiopharmaceutical labelling procedures. During this procedure a pharmaceutical (cold kit) is labelled with a radionuclide (mostly Tc99m), which match all above three definitions. This is currently done by a Nuclear Medicine Technologist with an APC, but if it's defined as the latter two which are "part of manufacturing medicine" and need a pharmacist license, it won't be practical around the country. As far as we understand, there is no radiopharmacist working in any Nuclear Medicine or PETCT centres.

So, we suggest this procedure be defined as "prepare a medicine for administration (s 26)", or a special license or permit issued to Nuclear Medicine Technologist with APC.

3. As the only radiopharmacy in New Zealand, we (GMS NZ) are supplying radiopharmaceuticals for all Sentinel Node Biopsy surgeries in north and south Auckland, as well as some regional centres i.e. Wairau Hospital; we are also supplying Iodine 131 doses to many vet clinics around the country for treating cats' hyperthyroidism. When there is a shortage of Tc99m generators we prepare doses in our radiopharmacy and supply them all over the country. If such activities are defined as "Compound" or "Dispense" and need a pharmacist license, all above services will be unavailable and cause unpredictable losses to the public. So, we suggest a special license or permit for radiopharmaceutical labelling and supplying.

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 :

Nuclear Medicine Technologists are the only group of people who are qualified to compound/dispense radiopharmaceuticals in NZ. If they are defined as Pharmacy Workers then above activities will need a license and general supervision of a pharmacist (s60), which is not practical; if they are defined as Health Practitioners then could only supply Category 3 medicines (s61), this will depend on how radiopharmaceuticals will be categorized.

This seems covered under s71&72 but we are not sure.

We suggest the compounding/dispensing of radiopharmaceuticals be covered by Nuclear Medicine Technologists' scope of practice as they are the only group of people who are qualified to do this in NZ, and as part of the scintigraphy study there are other prescription medicine (i.e. furosemide) will be used which should be under the same scope.

Alternatively, we recommend granting a limited radiopharmacy license to Nuclear Medicine Technologists who are involved in compounding/dispensing radiopharmaceuticals to other practices.

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):

Response ID ANON-DPZ8-G41D-P

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 22:27:14**

Submitter profile

What is your name?

Name:
Simon Alexander

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Unichem Richmond Mall Pharmacy

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please comment;:

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

Chapter A (A1 - A5)

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

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:
For a pharmacist dispensing a medicine involves substantially more than just the supply of the medicine.

B5 Part 3 of the Bill: Dealing with therapeutic products

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

Question B3

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

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

Question B4

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

Subpart 3: Authorisations (ss 56–80)

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

I strongly support one pharmacy being able to supply another pharmacy nearby with medicine to allow timely access for patients to prescribed medicines.

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

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

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 support the mechanism for importation of medicines from overseas and that the importation is managed by a medical practitioner, pharmacist or wholesaler.

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

Vending machines should only be available for use where patients do not have access to a pharmacy or pharmacy depot. Like a depot they should be linked to a pharmacy licence to allow clinical oversight.

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):

Dispensing and supply at an aged care facility should only occur when an aged care facility can meet similar audit requirements necessary for a pharmacy.

Question B19

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

Subpart 2: Permits (ss 131–135)

Question B20

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

I agree that with the introduction of permit for shorter term and urgent situations.

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 support increasing the period that licences are valid for as this would reduce compliance costs and reduce bureaucracy.

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 think this approach is in the best interest of public safety

Hawker's licence

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

Transition

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

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

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

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

Any new supply arrangements need to promote better patient health outcomes without compromising safety. The current community pharmacy service is very effective .

It is important that patients receive advice as well as supply of medicines.

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

Current pharmacy licensing requirements are not a barrier to innovation. Community pharmacy is constantly changing and innovating. We need investment in infrastructure to facilitate innovation.

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

I support the provision of pharmacy services at events such as Fielddays and on maraes as long as dispensing did not occur.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

i believe that the pharmacist-owned model leads to better patient outcomes than alternative models. There is a greater level of accountability.

Pharmacist owners are professionally obliged to operate at high standards.

Detailed questions relating to Option 1

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

Current majority pharmacist ownership has been successful. Pharmacist owners provide many services to the public at little or no cost to the patient or wider health sector. It is unlikely that external investors would support this.

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

I support the strengthening of requirements for owner pharmacists to receive a dividend that is proportional to their shareholding. I don't believe that current way the requirements are being met under the Medicines Act are truly allowing owner pharmacists to have effective control of activities in their pharmacies.

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

All clinical activities within the community pharmacy.

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

The same pharmacist should have both majority ownership and effective control

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 current five-pharmacy limit.

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

I believe effective control can be shared by two pharmacists with an equal share.

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

I believe preventing external investors from having a majority financial share will reduce barriers for pharmacists wanting to own pharmacies.

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

I would imagine we would need a 5 year transition period to allow current pharmacies to meet the new requirements.

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 pharmacies currently run by Friendly Societies should have to comply with the new requirement 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?:

It would be incredibly hard for a pharmacist to have effective control in a pharmacy where they didn't have the majority financial share

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?:

I don't think you can provide oversight of activities 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?:

I support restricting prescribers from taking a financial interest in pharmacies. Dispensing and prescribing activities must remain separate.

It is a clear conflict of interest for a prescriber to have a financial interest in a pharmacy.

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

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

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

Pharmacist and pharmacy worker authorisations

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

Batch compounding should be allowed to continue.

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

Only between pharmacies to allow patients timely access to medicines and to reduce wastage.

C8 Health practitioners (including pharmacists)

Prescribers

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

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

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

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

The SCNSA appears to be a better mechanism than the current S29 system.

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 with this approach.

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

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

Only in emergencies and in small quantities.

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?:

As long as they meet the current audit requirements for pharmacy and show that there is clinical oversight.

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

No, as it would be too hard for the health practitioner to provide effective supervision. I would expect any supplier of category 3 medicines to meet the storage requirements set for pharmacies currently.

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

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

No, I don't believe DTC advertising of prescription medicines should be allowed to occur.

I believe it creates pressure for prescribers to prescribe medicines that are requested by the patient but are not the preferred medicine in the prescribers opinion.

Response ID ANON-DPZ8-G4FR-S

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 22:36:46**

Submitter profile

What is your name?

Name:

Phil Rasmussen

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Phytomed Medicinal Herbs Ltd

Submitter Profile (tick all that apply)

Industry body

Active ingredients

Medicines

Medicines

Professional body (eg, Colleges, Pharmaceutical Society etc), Health service provider (eg, Ambulance, Māori or Pacific health provider etc)

If you select DHB, please state service area:

Pharmacist, Other health practitioner (please comment)

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

Medical Herbalist

Other (please comment)

If you selected 'Other' please comment::

Professional Association representing NZ Medical Herbalists

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):

The Bill should also include Natural Health Products.

As with the other 3 important product groups listed in S3, NZ is seriously out of step with how other developed countries regulate natural health products.

Regulating these through a separate Bill, makes no sense, as most NHPs are designed, recommended and often marketed , for therapeutic purposes

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):.

I agree with these

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):.

There should also be provision for a new category of 'registered natural health practitioner' or 'registered medical herbalist' only medicines (and statutory regulation of this profession under HPCA), as per my previous comments

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 :

Medical Herbalists, who have had an application (re-application, as their initial application was previously accepted by Minister Hodgson during a previous Labour-lead government) for regulation under the HPCA in for 3 years now, should be authorised practitioners able to presc re and dispense a limited number of herbal medicines, that are inappropriate and sometimes unsafe to be made available OTC.

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:.

See my answer to B7 above

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):.

Natural Health Products should also go through a simplified approval process, which could be largely an online notification system, or more in line with how these are regulated in Australia, where product listings are only possible where all ingredients are included on the Permitted Ingredients List, and claims made are selected from a drop down menu. Should the sponsor wish to make therapeutic claims, however, there should be an additional requirement for them to hold a 'Table of Evidence' to be able to justify the claim(s) made, ie that they are in line with the product/ingredient(s) and dosages used in the study(ies) cited by the sponsor in support of such a therapeutic claim(s).

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):

In addition to 121(d) (under Exempt Products), apart from scheduled Pharmacy Only or restricted medicines, individual herbal extracts should be able to be dispensed or compounded extemporaneously, by statutorily registered (HPCA) natural health practitioners, for the use on/by a particular patient, in the context of a one to one consultation. Such a practitioner exemption is a feature of the 1981 Medicines Act, but does not stipulate a practitioner definition or registration requirement, which is essential. It was also a feature of the ANZTPA legislation, and the Natural Health Products Bill.

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

Question B16

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

Clause 124 is important.

New Zealand is way behind the rest of the developed world in the Pharmacovigilance reporting and monitoring requirements it puts on NHP manufacturers and sponsors, and there should be an obligation for a comprehensive system to be in place, and for the regulator (or CARM) to be notified in a timely manner, for all AE's and safety concerns.

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

Question B17

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

C1 Medicines (excluding cells and tissues) sector

Product-based controls

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

Natural Health Products (NHP's) wanting to make therapeutic claims, should go through an Approval process - and it is my personal view, that NHP's should in fact, be regulated under the Therapeutic Products Regulatory Scheme, and not through separate legislation.

The approval process could and probably should be relatively straight forward and involve an online notification system, similar to that in place for 'AUST-L' products by the TGA in Australia.

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

In addition to the 3 groups of therapeutic products listed in A3 (16) as being largely unregulated in NZ, Natural Health Products (NHP's) also urgently require an appropriate form of regulation.

And certain NHP's should be scheduled as 'Practitioner Only', just as many drugs are.

Statutory regulation of Medical Herbalists and Naturopaths under the HPCA, is an ideal mechanism to enable authorisation for these health practitioners to prescribe a small number of NHP's (including specific herbal medicines) that should not be approved for open access/OTC sales.

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:

These proposed changes are good - but as clinical trials are increasingly being conducted involving Natural Health Products (NHP's), a satisfactory definition of a NHP, and the provision for clinical trials involving such products to enable useful product development and commercial outcomes in which an appropriate therapeutic claim can be assigned to such a product that has undergone a successful clinical trial, needs consideration. Currently as there is no definition of a NHP in NZ legislation, the only licencing route available for sponsors wanting to make reasonable therapeutic claims, is as a listed medicine. An intermediary route, as is available through other regulators such as TGA, should be established by this Bill. Regulating these only as 'dietary supplements' or through an entirely separate Bill, makes little sense

Question C17

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

C8 Health practitioners (including pharmacists)

Prescribers

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

As previously commented, statutory regulation of Medical Herbalists (and Naturopaths) under HPCA, would enable arrangements for them to be able to prescribe a limited range of non-OTC products (under a separate Category), in the context of a patient consultation.

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, or at least guidelines and protocols and limitations should be specified

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.:

The TAPS consultation system for NHP's is not working well; inconsistencies occur, and currently compliance with advertising requirements is not being well enforced.

It is also not a level playing field for sponsors/manufacturers producing products that comply with NZ advertising regs (and the limitations on not being able to make therapeutic claims placed on dietary supplements), as many products/brands imported from other countries (eg AUST-L licenced products from Australia), currently breach NZ Medicines Act or Dietary Supplement Regs, but are being sold OTC in NZ, using the country of origin original packaging.

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 believe this should be permitted to continue.

Few other countries allow this, and it encourages over-prescribing and pressures prescribers to potentially make non-best practice decisions

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?:

For certain herbal medicines, degree-trained medical herbalist practitioners are more qualified and appropriate prescribers than medical practitioners, though a more collaborative approach between these and other health practitioners, would have benefits.

Personal imports

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

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

Pharmacy licensing

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

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

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Pharmacies sell and dispense Medicines, and the training, professionalism and clinical judgements of pharmacists aimed primarily at patient wellness and patient outcomes, should not be able to be over-riden, by more commercially motivated interests.

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

As above.

More remuneration for the advisory and clinical inputs by pharmacists, and more emphasis on this element of their practice rather than as medicine or associated product retailers, would have significant pharmacoeconomic benefits.

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-G412-4

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 22:37:23**

Submitter profile

What is your name?

Name:

Kerri Miedema

What is your email address?

Email:

What is your organisation?

Organisation:

Private individual

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?

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

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).:

Defines dispensing as part of "manufacturing" and minimises it to just part of the supply chain

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):

Removes the ability to parallel import a medicine, medical device or type4 product.

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):

S 54 allows for a licence, permit or regulation to be used to authorise supply without a prescription.

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):

Allows for pharmacists to supply, without a wholesale license, to other pharmacists.

This supports patients' timely access to medicines and should reduce wastage, particularly with high-cost medicines

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

Allows for pharmacists to supply, without a wholesale license, to other pharmacists.

This supports patients' timely access to medicines and should reduce wastage, particularly with high-cost medicines

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

This may increase access in rural areas, however in reality this may fall to non-qualified assistants. It also risks fragmenting health records with the increasing use of centralised electronic records. In my opinion, a safer way would be to expand prescribing rights to other health professionals - maintaining a second health professional check and a complete dispensing/medication history. See comment below also.

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

Currently these medicines require a classification change to allow eg physios to supply Voltaren gel. The proposal could put all pharmacy medicines potentially at their disposal, including such items as naproxen (NSAIDs) tablets. Possibly beneficial in terms of access but potentially fragmenting records, serious harms could come to people eg 'triple whammy' combinations if a medicine history is not well taken. The level of involvement of the health professional could be minimal eg reception person making the sale. Wider prescribing rights and provision of medicines through pharmacy is a safer option.

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):

Ensures safety of medicines in NZ

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

Allows for regulations to be used to authorise a pharmacist with specified training to supply a medicine without a prescription in specific circumstances.

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:

no comment

B6 Part 4 of the Bill: Product approval

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

Question B13

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

no comment

Question B14

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

no comment

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

Question B15

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

no comment

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

Question B16

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

no comment

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

Question B17

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

no comment

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

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

Allows for licences to be issued for up to 3 years and circumstances where a licence can be transferred.

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.

Question B19

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

Allows for licences to be issued for up to 3 years and circumstances where a licence can be transferred.

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.

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).:

Allows for permits to be used in short-term emergency situations instead of a licence.

It is important that the system is flexible enough to respond quickly in emergency situations to minimise disruption to patients' access to medicines.

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

Question B22

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

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.

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):

looks reasonable

Subpart 2: Investigative powers (ss 183–196)

Question B25

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

looks reasonable

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

Question B26

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

no further 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):

Looks reasonable

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

Question B28

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

Looks reasonable

B9 Part 7 of the Bill: Enforcement

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

Question B29

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

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):

Looks reasonable

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

Question B34

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

no comment

B12 - B15, Schedules 1 - 4

Schedules

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

no comment

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

no comment

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

no comment

C1 Medicines (excluding cells and tissues) sector

Product-based controls

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

looks reasonable

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

Please retain the Medicines Classification Committee

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:

looks reasonable

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 further 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 further comment

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

no further 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 further comment

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

looks reasonable

C4 Clinical trial sector

Question C16

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

looks reasonable

Question C17

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

looks reasonable

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?:

Allows for medicines not yet approved in New Zealand to be sourced via the issuer of a special needs supply authority, a pharmacy or a wholesaler.

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:

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?:

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.

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

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.

The current restrictions on prescribers having an interest in a pharmacy needs to allow exceptions where they would improve access / retain services in rural areas (ie be in the best interest of the community) - eg if owner pharmacists became prescribers there would need to be provision for prescriptions written by such a pharmacist being dispensed at the pharmacy albeit checked by another pharmacist.

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

Cannot see how a wide range of medicines can be dispensed outside a properly-equipped and staffed pharmacy dispensary. However, supply of eg ECP/contraceptives, advice and other services at a public event would provide opportunity to engage.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

The public benefits when the network of community pharmacies is owned by pharmacists accountable for their patients' care. Community pharmacy is 'of the community'

Pharmacists have professional obligations that are in fact higher than those that the Regulator might impose. A non-pharmacist investor owner is more likely to want to meet minimum compliance standards at minimum cost. But medicines are not a normal item of commerce, and it's appropriate that community pharmacies are owned by pharmacists under Option 1 with 'skin in the game.' That is how every small business owner is incentivised to deliver service by maximising their professionalism and the community reputation.

Detailed questions relating to Option 1

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

Community pharmacies, under the current majority pharmacist ownership requirements, deliver many benefits at no cost to patients or the government. They resolve minor health issues quickly in the pharmacy, assist patients to find the right health service, and deal with cost or appointment problems with other primary health services, such as general practice.

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

Enforce the current provisions and limit pharmacist involvement to five pharmacies

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

Dispensing, supply of pharmacist-only and pharmacy medicines, responding to minor ailments, providing medicines and health advice.

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

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)?:

Continue five pharmacy limit

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

limit involvement 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?:

no

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

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?:

continue to be exempt

Detailed questions relating to Option 2

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

Oppose this option

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

Oppose this option

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

No

Other changes to pharmacy licensing requirements

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

Possibly remote supervision of activities such as compliance packaging preparation by pharmacy technicians when the pharmacy is closed.

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 essential to avoid conflict of interest by keeping prescribing and dispensing process separate. However, if it were in a community's best interest eg to retain or enhance services eg if a pharmacist owner became a prescriber, it should be possible to allow this - providing safeguards were in place to ensure no prescriber took part in the dispensing / checking process of prescriptions generated. In rural areas, the current restrictions could see prescriptions swapped at a central point for dispensing in another town.

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

Support the use of permits in exceptional circumstances but suggest that the range of 'exceptional circumstances' should be sufficiently clear to avoid exploitation by so-called 'pop-up' pharmacies at the expense of the existing licence holders affected by those circumstances

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

Depots should only be authorised via the licence of a linked full-service pharmacy. This is important to ensure clinical oversight and allows patients access to pharmacists from the full-service pharmacy for clinical advice.

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

The 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

Pharmacist and pharmacy worker authorisations

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

It is safer to produce a larger quantity of a compounded product when there is appropriate staffing and space in the pharmacy to do so in a safe manner.

If pharmacists and pharmacy workers are only able to compound when a request is made this could have significant impact on workload and risk to patient safety.

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

The situations where this is appropriate could be governed by the Pharmacists' Code of Ethics where the supply of the medicine would support patient access.

It would also be appropriate for medicines to be supplied between pharmacies for the purpose of reducing wastage or as an emergency response

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

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 at this stage

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

The introduction of a special clinical needs supply authority (SCNSA) is a positive change. It will support patients being given clear advice around what they are being supplied, enabling them to make an informed decision.

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 issue a SCNSA. Other health practitioner prescribers are generally only able to provide a narrow scope of medicines and it is appropriate that if an unapproved medicine is required that a medical practitioner was consulted

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?:

Ensures quality of medicines available in NZ

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

Not sure what the intent of this is - currently medicines are supplied through MPSOs which seems to work effectively. Perhaps in an emergency this would be necessary.

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?:

not sure

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?:

To increase access to medications we would support increased prescribing rights, allowing other health practitioners to prescribe the required medication within their scope of practice. This has the benefit of the patient then being able to access a funded medicine.

Question 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?:

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

Tightening up a good idea

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?:

Personally, I am not a fan. Patients form the idea that they should be able to have the medicine they have seen promoted without question. "Unselling" promoted medicines is very time consuming.

C9 Veterinarians

Question C54

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

Looks reasonable

C10 Advertising sector

Question C52

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

Looks reasonable

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 prefer more subtle advertisements - eg ask about.... condition, rather than stating the product name. Putting a name in mind can lead to 'unselling' or convincing a patient something else is more appropriate.

C11 Patients, consumers and disabled people

Unapproved medicines

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

The introduction of a special clinical needs supply authority (SCNSA) is a positive change. It will support patients being given clear advice around what they are being supplied, enabling them to make an informed decision

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 issue a SCNSA. Other health practitioner prescribers are generally only able to provide a narrow scope of medicines and it is appropriate that if an unapproved medicine is required that a medical practitioner was consulted.

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?:

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.

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

Perhaps in a very small number of circumstances eg if someone had previously used a product overseas and available options proved less satisfactory.

Pharmacy licensing

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

see previous answer to this Q

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

see previous answer to this Q

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

see previous answer to this Q

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

see previous answer to this Q

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

see previous answer to this Q

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?:

See previous answer to this Q

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 previous answer to this Q

Advertising

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

See previous answer to this Q

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

See previous answer to this Q

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.:

looks reasonable

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G41W-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 23:19:20**

Submitter profile

What is your name?

Name:
Jade Heo

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Unichem Kamo 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

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

Chapter A (A1 - A5)

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

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

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):

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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

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 :

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:

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):

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 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 C22 Which option do you support?

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

Question C23 - Why do you support that option?:

Option 1. 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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal

of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

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

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 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?:

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 prescribing and dispensing remain separate.

There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

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

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

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

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

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

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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

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 I 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?:

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

medicine for a patient?:

Personal imports

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

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

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

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Submitted on **2019-04-17 23:29:27**

Submitter profile

What is your name?

Name:

Anna Owles

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Owles Pharmacy

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

New Zealand

Pharmacist

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

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

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

Chapter A (A1 - A5)

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

Support

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

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

Seem to be logical

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).:

Defines dispensing as part of "manufacturing" and minimises it to just part of the supply chain.

I oppose this.

Dispensing includes the preparation of the medicine, advice about its use, and clinical checks and is at the heart of a pharmacist's contribution to primary health care.

It is the clinical check that is important and involves so much.

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):

I support this - it is important that the ability for pharmacists to supply an emergency supply of a medicine to a patient should be maintained. Necessary in everyday life. People go away and forget their meds etc.

Subpart 3: Authorisations (ss 56–80)

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

This is important as it allows for pharmacists to supply, without a wholesale license, to other pharmacists.

This supports patients' timely access to medicines and should reduce wastage, particularly with high-cost medicines.

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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

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

Allows for pharmacists to supply to other pharmacists & compound. This has been done successfully for years. Pharmacists can and should be trusted to continue in this manner for a good outcome for the patient.

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

I do not agree with this.

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.

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):

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

Don't really know enough to comment on this one.

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

I support this -

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.

The restriction should also be applied to category 2 (pharmacist-only) and category 3 (pharmacy only) medicines as they should only be supplied with the professional advice provided in a pharmacy setting with a pharmacist oversight.

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.:

I 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.:

I do not agree with DTCA - not all of the public are in a position to make informed conclusions.

I agree a Health practitioner should not hold an interest in a pharmacy. This would not normally be something they would want to do anyway.

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).:

Nothing to add

Question B14

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

nothing to add

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).:

nothing to add

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

Question B16

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

no comment

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

Question B17

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

No comment.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

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

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.

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 flexible 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

Question B22

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

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

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):

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):

agree

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):

sounds fair

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):

/

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):

makes sense

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:

/

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?:

This is necessary. 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?:

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 C22 Which option do you support?

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

Question C23 - Why do you support that option?:

I strongly believe that 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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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?:

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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal

of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

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

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 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?:

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 prescribing and dispensing remain separate.

There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

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

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

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

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

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

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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

I am supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional.

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

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 I 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?:

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 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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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?:**Question C22 Which option do you support?**

Not Answered

Question C23 - Why do you support that option?:**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:****Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:****Access to pharmacy medicines**

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information**Medical devices that do not have a therapeutic purpose, but may present a health risk**

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

Adverse event monitoring

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

Response ID ANON-DPZ8-G41F-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-17 23:46:13**

Submitter profile

What is your name?

Name:
Justin Ng

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Mangere Bridge 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

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 Section 29 medicines – 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 prescribed medicines, particularly in the case of medicines that are uncommon. It would also allow better continuity of care and ease of access to medications by only having to see their usual community pharmacist to continue smoothly by having one dispenser of medication. Patients prefer to build a relationship with their healthcare providers by their own choice. Not being forced to go elsewhere will foster open clinical relationships. 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 and which medicines.

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. Machines are only as good as the programmes designed for them. Reliance on intuitive or all encompassing programmes have caused issues in many errors ie Boeing Max 8, The debacle with the new pay system for teachers a few years ago etc

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? The same audit standards that current pharmacies are required to meet.?

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).:

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.

Also these patients have no guarantee they are receiving genuine medication.

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 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. At the moment a key drawback to delivery is the lack of infrastructure development in Auckland.

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. These vehicles would require secure premises to ensure OSH requirements are met would increase compliance issues. Resupply of medications (ie out of stock or medication owed) would also be an issue as would restocking.

Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

I strongly believe that 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 and compulsory ethical 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. In many cases community pharmacies exceed required standards as we are acutely aware many of our patients are unaware or unable to understand how the system works. I believe that corporate owners would likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk

these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 (5 years of tertiary training before registration) who must put their patients' interests first, before profits or shareholder value, which are the driving motivations of any normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

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

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 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?:

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 would and will 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.

eg it will be hard for a junior or inexperienced Pharmacist to refuse to dispense a prescribers (who is a financial partner) prescription if they feel that the item in question is clinically unsuitable.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments.

The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

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

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

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

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

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

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

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

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.

Other non pharmacist health practitioners may also be incentivised to provide product that maybe available more economically elsewhere

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?:

C11 Patients, consumers and disabled people

Unapproved medicines

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

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

Personal imports

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

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

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

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

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

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

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

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

Access to pharmacy medicines

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

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

Advertising

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

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

Packaging and labelling and consumer medicine information

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

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

Adverse event monitoring

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

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Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 23:46:57**

Submitter profile

What is your name?

Name:

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What is your email address?

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What is your organisation?

Organisation:

Dentsply Sirona Pty Ltd

Submitter Profile (tick all that apply)

Medical devices, Medicines

Medical devices, Medicines

If you select DHB, please state service area:

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

If you selected 'Other' please comment;:

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

Chapter A (A1 - A5)

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

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):

While the purpose of the Bill is clear, what currently remains unclear are the fees that will be associated with the new scheme - particularly with the introduction of regulation of medical devices. While I understand that this is not part of the Bill, it is essential that there is an understanding, with the introduction of the Bill, that grandfathering of current products should be included/allowed so that the introduction of fees once the new regulatory regime starts does not impact the range of product currently supplied. The addition of grandfathering would not preclude the need to review and provide additional information for medical devices currently entered on WAND. This is important because we currently supply dental products to New Zealand under 518 WAND entries. Even at a nominal fee of \$100 per WAND entry, this would equate to \$51,800 - a significant amount. With the introduction of any fees we would be likely to review and proceed ONLY with what is most profitable, which would mean that dental professionals and patients would have less options to choose from and in some instances, the decision may simply be not to supply product into New Zealand. Grandfathering of products - even if there is a requirement to go through an administrative process - would ensure that New Zealanders can continue to have access to the range of products that they have available to them today. Consideration could also be given to allowing for the potential for supply of medical devices with a fee waiver - this could be explored during further 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):

ss49r. The definitions of manufacture of a medical device and remanufacture of a medical device need to ensure that repairs and associated activities - importantly including upgrades - should be clearly excluded from manufacture - otherwise service technicians become manufacturers. For example, we sell an X-ray machine that is capable of 2D and 3D images at point of sale, but can be purchased (at a lower cost) initially for 2D images - and can be upgraded at a later point in time for 3D. It would be important that the definition of manufacture/remanufacture excludes (and therefore allows) for that upgrade to be done without

having that captured and then having a service technician become the manufacturer. Perhaps there is a need to include some type of reference here to include a reference to allow activities of a service technician that do not alter the purpose of the device-or if you are to move down a similar pathway to Australia - if the Class and GMDN code of the device remains the same after the activity, then this is not considered manufacture.

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):

B5 Subpart 1 - Point 52 (ss 51 and 52). Is the intent to allow only one person to be the Sponsor of any given product supplied in New Zealand? This seems to be the intent. If so, this could be more clearly defined.

Approvals should be granted without an expiry date on the whole - unless there is justification for expiry and re-approval.

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

Question B4

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

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 :

B5 Subpart 3 - Points 72 and 73 (ss62-64). Defines the need for a Special Clinical Needs Supply Authority to supply an unapproved product. It appears that the SCNSA is for a particular patient - but this does not allow a healthcare practitioner e.g. a dentist, to import a product used in their clinical practice on more than one patient. For example, dentists may import a fluoride solution which they may use on numerous patients. A SCNSA per patient will not support this type of use - unless they obtain one for potentially all their patients. Fluoride solutions have been on the market for a number of years and in most instances do not have a dossier that meets currently regulatory requirements, therefore the inability to import this type of product is likely to mean that patients in New Zealand will miss out on these products if the new regulatory regime does not encompass the situation described above. It seems that a type of SCNSA which allows for healthcare practitioner use on their patients should be included in the Bill.

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:

B5 Subpart 3 - Point 89: Consideration should be given to notification of activity of custom-made device manufacture, similar to the scheme in Australia. This ensures that the regulator has a clear picture of who is manufacturing custom-made devices and for what purposes.

Consideration should also be given to ensuring that those manufacturing custom-made devices are using approved materials where appropriate i.e. dental crowns made in New Zealand are made using materials approved by the regulator.

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):

The regulator will need to ensure adequate staff to review the additional wholesale licence applications for medical device suppliers. Section C3, Activity-based controls, Wholesale supply point 408 explains that the licence is intended to authorise the supply of medical devices by wholesale - other than those in the lowest-risk category. Does this mean only Class I devices or anything below a Class III? This will need to be explained and justified.

Question B19

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

Framework for medical devices should ensure that those companies currently engaged in wholesale supply should qualify under the proposed arrangements. Maintenance of the 'status quo' with respect to this was discussed and agreed during the consultation events.

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):

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):

It is entirely appropriate to align notifiable changes with the European and Australian models.

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:

The proposed changes to authorising hawkers as part of the relevant wholesale licence may be appropriate in some circumstances but not all. For example, if one company is employing the sales force and require their hawkers to be authorised, and the medicines are imported and supplied by a second independent company (a third party logistics company) - the proposal will not work. In order to ensure that activity is not restricted, there should be an allowance for an exception, in this instance - to ensure that a hawker can still obtain authorisation independent of a 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?:

Yes - where these products could be used for a therapeutic purpose. This then prevents import and sale for off-label use.

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?:

It is inappropriate to include on the register of medical devices, those that have been refused approval as Commercial-in-Confidence requirements typically mean that the reasons for refusal are not published and it is this information which is of most use to the general public - and the lack of this information can be misleading.

In the affirmative - what would be appropriate: use of GMDN codes for classification of devices; Acceptance and approval of Conformity Assessment (Manufacturer's Evidence) which can then be applied to a range of devices. The Manufacturer's Evidence should be kept current and up to date. Ideally, there would be an alignment with the Australian model where an approval is for a 'kind' of medical device that has the same Class, GMDN Code and Manufacturer. - this would also assist potentially with definitions of manufacture and remanufacture. Statutory timeframes should be established for all device approvals.

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

C3 Changes to approved products: Point 384 (ss 100 and 101). There are problems with the current proposal with respect to major changes as it relates to devices - and in particular, the reference to a change to the name of the manufacturer being a major change - this is not considered a major change as it relates to lower Class devices. A manufacturer name change will impact the manufacturer's evidence, but is unlikely to have an impact on the device per se. It should also be considered that with devices, a single manufacturer can be linked with the manufacture of numerous medical devices. Let's take an example where a medical device manufacturer of Class I and II (low risk) devices undergoes a name change and there are 50 approvals for that manufacturer. It seems counter-intuitive to a risk-based assessment model to consider that this would require the entire range to be re-approved. If we consider how this is managed in Australia - the manufacturer's evidence is varied with appropriate evidence that only the name has changed e.g notified body letter, once the updated (new name) manufacturer's evidence is accepted, the 50 approvals are linked to that new evidence through a variation - thus all approval details remain up to date and the regulation is in line with the risk presented (low). Please ensure that the regulatory scheme appropriately addresses regulatory action that considers lower class (low risk) medical devices as well as high risk devices - and has appropriate definitions for major changes. Accepting a model like Australia does where a kind of medical device is defined to have the same GMDN, Class and Manufacturer (for low risk medical devices) may assist in ensuring appropriate regulation (and not

overkill).

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.:

The six month transition timeframe is insufficient when considering that we currently have 518 WAND entries that would need to be approved. Considering an hour for each approval (based on a smooth on-line submission process, and allowing time for setting up internal files for each approval, preparing appropriate supporting evidence and ensuring necessary supporting documentation is in place) - this is 518 hours of work or approximately 70 days work for one person full time. As all staff members are currently fully occupied, and other activity will need to be modified, if 2 days per week were to be devoted entirely to this project, it would take approximately 35 weeks (for a large company who can shift workload to achieve this; smaller companies would struggle). A 12 month transition would be more realistic and ensure that the burden of the implementation of the regulatory scheme would be minimised. If the regulator wished to expedite the process, then a waiver of any potential fees for the first 6 months may achieve the timeframe - while allowing for companies that may not be able to achieve the deadline to implement within the 12 months without penalty.

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.:

The six month transition timeframe is insufficient when considering that we currently have 518 WAND entries that would need to be approved. Considering an hour for each approval (based on a smooth on-line submission process, and allowing time for setting up internal files for each approval, preparing appropriate supporting evidence and ensuring necessary supporting documentation is in place) - this is 518 hours of work or approximately 70 days work for one person full time. As all staff members are currently fully occupied, and other activity will need to be modified, if 2 days per week were to be devoted entirely to this project, it would take approximately 35 weeks (for a large company who can shift workload to achieve this; smaller companies would struggle). A 12 month transition would be more realistic and ensure that the burden of the implementation of the regulatory scheme would be minimised. If the regulator wished to expedite the process, then a waiver of fees for the first 6 months may achieve the timeframe - while allowing for companies that may not be able to achieve the deadline to implement within the 12 months without penalty.

C4 Clinical trial sector

Question C16

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

Question C17

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

C5 Wholesale sector (including importers and exporters)

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

Licence to wholesale

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

Please ensure that consideration is also given to other issuers of a SCNSA e.g. a dentist or dental healthcare professional and ensure that they are allowed to import and supply to their patients without the need for a wholesale licence.

Hawker's licence

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

Consideration needs to be given to the scenario where the legal entity that holds the wholesale licence is a different legal entity to that which employs the hawkers. For example, where a company employs a sales team that require hawkers licences, but use a third party logistics company to import and supply their products to customers. The scheme should ensure that in these instances, hawkers are still able to obtain a licence independent of a wholesale licence (as they can now).

Transition

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

C8 Health practitioners (including pharmacists)

Prescribers

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

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

Yes

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

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

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

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

The ability to issue a SCNSA should also extend to dental professionals (not just doctors). Further consideration will need to be given to what is required to issue SCNSA for off-label use to ensure that patient's options are not restricted while also considering patient safety. Consideration should be given to whether a SCNSA has to be on a patient by patient basis - or whether it could simply be for a practitioner using a particular product for a particular off-label indication (which would be the preferred option). The costs to doctors and other healthcare professionals - time and money - should also be considered.

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?:

Consideration should be given to products used in the dental surgery and enabling dental healthcare practitioners to prescribe without the involvement of a medical practitioner within their scope of practice.

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

If this is the only way that a dentist could import a medicine that is unapproved for use on their patients, then this should also be allowed.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Dentists should be able to supply pharmacy medicines to their patients. My understanding is that this is in line with current practice and should be allowed to continue.

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?:

Yes - to guard against these products being used for a therapeutic purpose.

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-G41Y-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 00:23:17**

Submitter profile

What is your name?

Name:
Fiona Bradley

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
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

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).:

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).:

Extremely supportive of allowing one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine requested by a patient.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60).:

Question B7 - Please provide any comments on the authorisations for health practitioners :

Section 61(2) and 65

Strongly disagree and not necessarily - "that if a health practitioner has the competencies required to administer these medicines, then they also have the competencies required to safely supply them."

I understand the discussion around timely access to medicines.

My concerns are centered around patient safety which I don't think has been considered or addressed strongly enough with this authorization. For example

interactions with other medications need to be considered and pharmacists have this knowledge and pharmacy workers are trained to refer to a pharmacist in these instances. Coupled with receiving appropriate advice and counselling on how to take the medication. If this provision remains I would expect to see vigorous training, education and competency standards required for those supplying these medicines (ie staff of health practitioners) to ensure patient safety.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

It would be great to be able to have a "special license or permit" to prescribe and provide the medicine eg trimethoprim for UTIs at expanded service sites for one off/ or occasional clinic type set ups, such as a Friday drop in at a Marae, it would be important to be able to supply the medicine at the time of the consultation (as would occur in the pharmacy) to ensure more patients have access to medicines in a timely manner. This could work by a pharmacist being authorized to take off site a small amount of pre-labelled medicine for the purpose of running a clinic at a Marae, for example.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I think it is a shock to hear the way Pharmacists and groups have curtailed the current provisions so yes I support them being retained and strengthened. I have concerns about pressure on pharmacist employees by an owner who is not bound by the same professional and ethical codes and practices (as they are not a pharmacist themselves) - this may put pressure on particularly younger pharmacists who may not be confident to speak up (or know where/to whom to speak to) when patient safety is at risk due to a "business activity".

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)?:

I do like the idea of this taking into account other factors. I prefer having a fixed number though 5 maximum so that it is clear what the expectations are.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

If they jointly share responsibility then that would count as one of their individual 5 pharmacy limit.

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?:

I like the idea of this, especially as the pharmacy workforce is young and as technology increases. I would want to see more detail on how this could look and work to ensure patient safety. I also like this idea to allow more flexibility into the workforce and support different working environments.

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 think this restriction is proving to be a barrier to the Pharmacist Prescribers scope. I would like to see the requirement loosened to be a share or percentage of ownership requirement. As I do not think low level ownership interest for example through shares or investment portfolio is a conflict of interest to Pharmacist Prescribers and any conflict is outweighed by the huge service and potential they can provide within the wider health care system.

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?:

I think this is an extremely practical solution to support workflow, free up pharmacists time and support patients timely access to medicines, as they would not have to wait or return to collect an item, especially for common product like hydrocortisone ointment.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Response ID ANON-DPZ8-G41R-4

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on 2019-04-18 01:12:35

Submitter profile

What is your name?

Name:

lun shen wong

What is your email address?

Email:

What is your organisation?

Organisation:

independent pharmacist

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

Other (please comment)

If you selected 'Other' please comment;:

university tutor

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).:

N/A

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

N/A

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 all seems reasonable

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):

looks good

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.:

s93 Health practitioner prescriber must not hold interest in a pharmacy business ; we should keep this clause as pharmacist prescribers can't from my knowledge prescribe independently on their own accord but rather in a team based environment. Given the nature of this prescribing power, I would imagine it's unlikely that the pharmacist could hold much "power" in this dynamic compared to a prescriber such as a doctor who can prescribe independently on their own without the restriction of being in a team environment. There are other code of ethics which prevent a pharmacist prescriber from abusing commercial interest in a pharmacy; given they can't direct and dispense items they prescribe, I'm not sure there are similar codes for other prescribers so I think its important to keep this wording that independent prescribers and their associated trusts can't hold an interest in a pharmacy business is important in preventing commercial bias.

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):

N/A

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):

N/A

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):

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.

-There is no evidence internally that shows that deregulation was beneficial to health users and if anything, data to date suggest that it increased unethical behavior so not sure that opening up ownership is useful

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

sounds good

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):

How enforceable is this in reality?

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):

N/A

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):

N/A

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):

excellent

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):

expertise in pharmacy matters should require that the expert hold a current APC to be used as an expert, as opposed to just an expert that has experience but isn't registered currently with the regulatory body

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):

N/A

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):

N/A

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):

N/A

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):

N/A

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):

fine but there still needs to be some explicit list of medications that a practitioner can prescribe listed somewhere. We have already had issues in the industry of prescribers prescribing outside their scope and it's difficult to find this information through the regulatory body current. Having it listed in legislation somewhere helps dispensers to pick up on anomaly's quicker for reporting and safety purposes

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):

N/A

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

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:

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 pharmacist services

-mobile pharmacist lead clinics

-mobile pharmacist involvement with clinical trials medication; not confined sole to hospital but also moved into community and managed by a pharmacist

-an easier way for pharmacy to share service provision

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Yes if you want to create a satellite service to rural towns or if your pharmacy is destroyed by a natural disaster and you no longer have a fixed premise, you wouldn't have the ability to operate a pharmacy so having flexibility in these circumstances to open a satellite till you can arrange a fixed premise would be good

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

All seems fine but we just need wording arounds dispensing and counselling services. These 2 things are complements and you can't have one without the other

so they should not be legally split. If you are going to provide a service or activity, you must also provide the counselling too.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

there isn't any evidence to date that I have seen that shows that option 2 would work. the deregulation component of option 2 has been done in other countries and there was no evidence that health consumers benefited, nor that patient safety wasn't compromised in the process. I think option 2 with the supervising pharmacist is harder to enforce and given that with option 1, we already have some issues, I can't imagine that option 2 would make be better. From a patient safety and risk point of view, Option 1 is safer. Option 2 I feel will create more pharmacies, but if those pharmacies are of poor quality and don't provide any level of service as shown in AUCKLAND (re Counties Maunkau), they would simply dilute the level of actual health services consumers receive.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Its hard to enforce at some level and nothing may change, but nothing worse could occur too.

Question C25 - Are there ways in which Option 1 could be improved?:

Pharmacy trades in medicines which aren't items of normal commodity either. there should be a way to prevent family trusts from holding shares in the pharmacy so as to reduce or limit those who are flouting current legislation? I don't even know if that would be easily enforceable..

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

everything that can and could occur in a pharmacy, pretty much everything from dispensing through to counselling through to safe disposal of unused medication.

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, splitting the responsibility means that owners can somewhat enforce through employment how they want things done and effectively control the charge pharmacist through that relationship. It's splitting the responsibility that owners take on when they apply for a license to begin with which is unfair somewhat to the pharmacist in effective control if they disagree with unsafe mandates they are being asked to enforce by owners. Owners need to take responsibility for the services they run and provide alongside the pharmacists they employ.

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)?:

yes and it should be strengthened to excludes trusts or limit them so owners and other health practitioners can't use these to hold interests in pharmacy

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

there is always a charge pharmacist which is one of the owners who takes responsibility for the day to day running so it should be applied to the charge pharmacist in these situations.

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?:

1 year

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

removed

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

lots of risks that include diluting of health services, poor health outcomes, increase hospitalisations, increased unethical behavior for financial gain

Question C34 - Are there ways in which Option 2 could be improved?:

no

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

no

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, especially in rural settings or for resthomes when you can't do visits. It would all fall under innovations in 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?:

YES!!!

again as mentioned earlier, non of the pharmacist prescribers can do it alone, they must be working within particular team environments rather than independently so the risk of financial inducement given they can't refer direct to a particular pharmacy or dispense their own prescriptions is less. Compared with a doctor who can prescribe independently on their own without a team unit, the risk of unethical behavior due to financial inducements is higher.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

not sure

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?:

I think its good

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?:

not sure

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

YES!! when medicines are out of stock or on a stock ration and one pharmacy hold more stock, they should be allowed to sell it to the pharmacy in need!!! given the current climate where there are multiple medications out of stock, it seems silly to not be allowed to purchase excess stock from another pharmacy if they don't require it.

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

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.):

not sure

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

its fine as long as there is information and evidence to support use

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?:

makes sense

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?:

its a good idea but may require more thought

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

rural health setting?

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?:

not sure

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, not if they don't provide the counselling component and aren't working in a team. I don't think this approach supports the intergrated health care clause we are

heading towards. It will create or reinforce patch protection

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.:

N/A

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

N/A

Response ID ANON-DPZ8-G456-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 07:38:44**

Submitter profile

What is your name?

Name:
William Allan

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
Health Quality & Safety Commission (HQSC)

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

Crown entity

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).:

We support the intent of the Bill, its purpose and principles.

We support the enabling nature of the Bill and the flexibility and agility it will provide for updating and keeping the lower instruments in the therapeutic products regulatory framework current and contemporary.

We support the separation of medicines and natural health products, with natural health products being excluded from the TPB. If a natural health product makes a therapeutic claim it becomes a medicine and is covered by the PTC with the necessary protections for the public. However, natural health products still require controls on the manufacture, supply, claims and use, to protect the public. As the risk to the public with therapeutic products is less than that for medicines, the controls for natural health products can be less rigorous than for medicines. Separate legislation for natural health products is therefore appropriate.

We look forward to the consultation on the regulations, rules and notices that will support the Therapeutics Products Act.

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):

s 20 Meaning of AMI (active medicinal ingredient)

Does this include pure powders of active ingredients used in the extemporaneous compounding of medicines by pharmacists? For example, omeprazole powder and phenobarbital sodium powder used to compound oral liquid medicines.

- If these pure powders are AMIs, does this classification affect / restrict their use in the compounding of medicines in a Pharmacy?
- Will these powders still be required to meet the full controls as relate to medicines?

s 37 Meanings of pharmacy worker and qualified

- The classes of potential pharmacy worker have not been defined. Will all classes of potential pharmacy worker be carried forward from the existing regulations (viz, intern pharmacists, pharmacy undergraduate students, pharmacy technicians, PACT, student pharmacy technicians, assistants, after school persons, delivery persons) and any class of worker not yet thought of?
- With the separation of the oversight and control of medicines supply (to come under the TPA) and professional pharmacist services (under the responsible authority/HPCA Act), how will professional activities, which are not controlled activities, be controlled for unregulated pharmacy workers, in particular undergraduate pharmacy students?

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52):

We support the proposed restriction on parallel imports of medicines (and other therapeutic products). The New Zealand medicines supply chain is controlled to protect the public and to ensure the quality and safety of products. It is inappropriate that the controlled supply chain is circumvented through unauthorised persons importing a medicine. Parallel importing risks sub-standard medicines from entering New Zealand's legitimate supply chain. Parallel imported medicines are at risk of originating outside the controlled supply chains in the jurisdiction of origin. Product may be counterfeit, not contain the labelled ingredients or strengths, contain undeclared pharmaceutical ingredients, be contaminated, adulterated or the specific product may not be approved for New Zealand, so will not have been assessed for efficacy and safety in the New Zealand context (eg, appropriate labelling).

Safe administration of oral liquid medicines

We ask that consideration is given to the requirement that appropriate measuring devices (eg, oral syringes) must be provided with all oral liquid medicines, unfunded over the counter (OTC) and funded liquid oral medicines, for all categories of medicine; and that these dosing devices must meet minimum standards (eg, designed specifically for oral / enteral administration with specifically designed syringe tip (hub) to prevent wrong route delivery; metric dosing scale only; of a volume and dosing scale suitable to deliver the required dose volume of medicine, clear-to-read, indelible markings). This requirement should be included in the therapeutic products legislative framework.

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 comment.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

Nil comment.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

Nil comment.

Question B7 - Please provide any comments on the authorisations for health practitioners :

s 61(1) Dispensing medicines for non-wholesale supply by non-pharmacy staff

Dispensing, a controlled activity for a pharmacy business, is controlled under licence.

- What controls, monitoring and audit will be used to ensure compliance by non-pharmacy prescribers and their workers with dispensing requirements? For example, to ensure that dispensing is not delegated to HP workers, that the labelling meets all requirements, and that the containers are appropriate.
- Will these controls be proactive or be reliant on exceptions reporting? We suggest that a reliance on reactive exceptions reporting will put patients at

unnecessary risk of harm. The balance must be for patient safety and the mitigation of harm, and not cost.

- Dispensing is prone to error irrespective of the volume of dispensing undertaken. One could argue that if dispensing is undertaken infrequently the risk of an error and patient harm is greater than when dispensing is a core business. At what volume of dispensing should a HP prescribers authorisation to dispense be replaced by a licence? Will dispensing activity be capped? What is the tipping point, and how will this be decided?
- All dispensing activity must have adequate controls to protect the public from harm.

s 64 Special Clinical Needs Supply Authority (SCNSA)

How will this work in practice?

How is this process envisioned to work in practice? The bureaucracy associated with compliance is likely to be burdensome and not enabling.

a) Off-label medicines use – issuing a SCNSA assumes that the prescriber is aware that the use is non-approved. This is often not the case. Where will the liability rest if a pharmacist dispenses, or a nurse administers, a medicine for an off-label indication, does not have a SCNSA, and is not aware that the use is off-label?

- How practical is this for groups such as paediatrics when nearly all medicines are used off-label?
- How will other HP be notified that a SCNSA exists for a patient's medicine use?
- Will a SCNSA be required for all settings – community, primary care and hospital use?

b) Unapproved medicines use – how will say a pharmacy in Napier know that a SCNSA has been issued by a prescriber in say Auckland (eg, from Starship hospital)?

- How will SCNSAs be communicated if the NZePS is used to transmit a prescription (ultimately becoming paperless)?
- How will situations be handled when an unapproved medicine is required acutely? For example, in theatres, if an unapproved medicine needs to be made available/administered before a patient is identified for a SCNSA to be issued and the medicine obtained (eg, medicines like urokinase, patent blue, thiamine injection, indigo carmine, thiopentone - all currently s 29 medicines)? The proposed flexible approval process may see some of these products approved, but it is likely that not all current s 29 medicines will be approved under the new scheme. Is it possible that a licence or permit could be used to authorise pharmacies to hold unapproved medicines 'just in case'.
- Medicines compounded in a pharmacy are unapproved medicines. Will these require a SCNSA? If they are, this is likely to introduce a delay in supplying the compounded medicine if the prescriber is not aware that the medicine needs to be compounded and therefore requires a SCNSA.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

s 65 Non-wholesale supply of category 3 medicines

We support the supply of category 3 medicines by Health Practitioner (HP) workers, for continuation treatment, if the controls ensure the HP's authorisation of supply in all cases.

What is the level of supervision required for HP workers when supplying category 3 medicines? Activities undertaken in a Pharmacy are controlled through the supervision of a pharmacist.

- What controls will there be on staff in non-pharmacy settings when a HP provides a category 3 medicines to prevent unauthorised supply by a HP worker?
- If the requirement for a category 3 medicine is to be created through a consultation with a HP what mechanisms will be used to ensure compliance, and thereby protect the public from potential harm? What proactive quality systems and audit processes will be implemented? What records or supply will be required?
- What controls will there be to avoid the 'unauthorised' supply of a medicine by a HP worker, for example, controls to ensure that the clinical decision to use a medicine (clinical appropriateness for a client) rest with the HP and is within the HP's scope of practice?
- What minimum standards will be used to control the display, direct access and supply of category 3 medicines to clients?
- Could we see a range of category 3 medicines at the HP's reception with the receptionist selling the medicines without any oversight from the HP? What controls will be in place to prevent the supply to patients cold calling, and what process will be used to proactively monitor compliance?
- Could we see HP workers manipulating medicines (for example dispensing; breaking down bulk packs of a medicine into smaller quantities), or is it envisioned that only original packs could be supplied?

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

Nil comment.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

Nil comment.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

s 80 Vending machines for medicine to be expressly authorised

We support the concept of the supply of medicines through a vending machine in specified situations. An example situation would be remote locations like the Chatham Island where there is no community pharmacy. Prescription medicines are supplied through a collection depot, with no pharmacy workers. Category 3 medicines could be provided through a vending machine (analogous to an automated dispensing cabinet used in some hospitals) following a remote consultation with a pharmacist. The pharmacist would control remotely the supply of the specific medicine for the patient; patient specific labelling could be applied. Fill of the vending machine could be controlled using barcode technology and outer pack dimension measurement verification. The concept could be extended to include the supply of prescription medicines through a vending machine with the control of the supply from a remote location.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

s 93 Health practitioner prescriber must not hold interest in pharmacy business.

Retaining the general ban on HP prescribers holding an interest in a pharmacy business is likely to present barriers to integrated working and the physical

proximity of HP working together in a multidisciplinary team, in integrated premises, with the sharing of resources and expertise. Restricting ownership works against the 'One Team' strategic theme of the New Zealand Health Strategy 2016.

Prohibiting HP prescribers from having an interest in a pharmacy could limit financial investment in a pharmacy business particularly in remote areas or where vulnerable populations are underserved.

The risk of HP prescribers benefitting financially from their prescribing decisions is at best low, and the financial gains slight, if any. HP prescribers are bound by their code of ethics and professional standards to provide appropriate care for their patients. Patients may choose not to obtain their medicines from the community pharmacy in which their HP prescribers holds an interest. Additional controls could be implemented to manage any risk in specific circumstances.

However, there is a risk that HP prescribers holding an interest in a pharmacy could block and stifle new clinical services provided from a community pharmacy they hold an interest in if the new service was seen to be in competition with a general practice (or similar) business. Such barriers would reduce patient choices and be counter to the intent of the Pharmacy Action Plan 2016 to maximise the training skills and knowledge of pharmacists for the benefit of patient care. This is probably a very low risk.

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 comment.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

Nil 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):

Nil comment.

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119):

Nil 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):

Nil 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):

Nil comment.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

Nil 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):

Nil comment.

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):

s 137 Duration

We support the extension of the duration of a licence for up to 3 years, with the regulator's ability to issue an licence for a lesser period if there are safety concerns.

Supply of bronchodilators to schools

Currently bronchodilators can be supplied without a prescription to school principals for the emergency treatment of asthma in school pupils. This is permitted under Medicines Regs, 44(l). Is a similar provision provided for under the Therapeutic Products Bill (or its instruments)? Will this be enabled through the new therapeutic products legislation?

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

Nil 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):

s159 requires a pharmacist to be present whenever a pharmacy activity performed. We believe that the supervision of a pharmacy worker should enable remote supervision – a hub and spoke model - when the pharmacist could undertake a consultation remotely, and the pharmacy worker at the remote site supplies the medicine to the patient.

Other situations where it may be unnecessary to have a pharmacist physically present is where Pharmacy Accuracy Checking Technicians (PACT) are utilised. A possible scenario would be where a pharmacist undertakes a clinical review of the prescription remotely (eg, on a ward, in a general practice, or an ARC facility), the check and validate prescription is then sent to the pharmacy, where it is dispensed by a pharmacy technician and accuracy checked by a PACT. Or the dispensing could be undertaken robotically. The pharmacist would still be available to the pharmacy technician and PACT for advice if necessary, albeit remotely. This type of scenario needs to be enabled by the legislation.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):

Regulator Form

We do not have an opinion on the best form that the regulator should take. When considering the regulator form it is paramount that the regulator has maximum independence from government, government department and industry influence. Whilst it will be important for the regulator to maintain a strong relationship with Health, the regulator must be independent without external control or influence, and make its own decisions and rulings to maximise safety for all New Zealanders.

s 160 Obligations for pharmacovigilance

We note that it is proposed (s160) that the new scheme will require the regulator to have a system to continuously monitor the safety of approved, approval-exempt and lawfully supplied unapproved products and to do so in accordance with requirements to be set in the regulations.

We contend that the regulator's obligations for pharmacovigilance must align with other jurisdictions and include medication error (Directive 2010/84/EU[1]). The requirements under Directive 2010/84/EU include the operation of a pharmacovigilance system

... to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.

Medication error is defined as:

... an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.[2]

1. European Parliament and the council of the European Union. Directive 2010/84/EU, amending amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use of 15 December 2010.

2. European Medicines Agency. Pharmacovigilance Risk Assessment Committee (PRAC). Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014. 23 October 2014.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):

Nil 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):

Nil 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):

Nil 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):

Nil 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):

Nil 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):

Nil 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):

Nil 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):

Nil 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):

We support the separation of matters relating to the provision of medicines (under the TPB) and HP professional practice and competence (under the HPCAA); and the necessary amendment to the HPCAA to ensure alignment.

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 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):

Nil comment.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):

Nil 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?:

Nil 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):

Nil comment.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

Nil comment.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:

Nil comment.

Question C4 - Please provide any comments on the approach to post-market controls:

Nil comment.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions:

Nil comment.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Nil 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?:

We support the restriction on the personal importation of prescription medicines via post or courier.

The New Zealand medicines supply chain is controlled to protect the public. It is inappropriate that the controlled supply chain is circumvented through personal importation of medicines. Personal importation of medicines is open to obtaining medicines that are counterfeit, do not contain the labelled ingredients or strengths, contain undeclared pharmaceutical ingredients, are contaminated, adulterated or may not be approved for New Zealand (so will not have been assessed for efficacy and safety in the New Zealand context). If a prescription medicine is required that is not available in New Zealand (unapproved) it should be procured through the existing controlled supply chain on the prescription of a New Zealand prescriber.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Nil comment.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

Nil 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?:

Nil comment.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Nil comment.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Nil comment.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

We are agnostic on the ownership structure for pharmacy businesses. Whichever structure is adopted patient safety must be paramount.

Option 1

- If the current approach (option 1) is maintained the intent of the legislation must be upheld with control being limited to 5 pharmacies to ensure appropriate control on the day-to-day operations, policies & procedures and maintenance of service delivery standards.
- There is a risk that the option 1 could restrict capital investment to establish pharmacy businesses particularly in underserved remote and high needs areas. This would be undesirable.
- Option 1 would not support the ownership of a pharmacy business by not-for-profit organisations such as NGOs and iwi – organisations that typically service high needs populations.

Option 2

- If open ownership is adopted (option 2) there must be robust pharmacist controls, oversight and protections in place. Controls must be in place to prevent a power imbalance between the pharmacists and non-pharmacist manager(s)/owner(s). To support this model the inclusion of controls such as s155 (Licensee or manager must not induce health practitioner to act unprofessionally), s156 (Responsible person must report non-compliance) and s157 (Protection of responsible person from retaliation) and their associated penalties, are welcomed.
- The Responsible Person must be given control over quality system, the setting of policies and procedures, the allocation of resources, and the day-to-day implementation and monitoring of the quality systems, to ensure patient centred and safe service provision.
- Commercial interest must not come before patients' best interest and safety.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Nil comment.

Question C25 - Are there ways in which Option 1 could be improved?:

Nil comment.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Nil 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?:

Nil comment.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

Nil comment.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Nil comment.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Nil comment.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Nil 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?:

Nil 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?:

Nil comment.

Question C34 - Are there ways in which Option 2 could be improved?:

Nil comment.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Nil comment.

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

s159 requires a pharmacist to be present whenever a pharmacy activity performed. We believe that the supervision of a pharmacy worker should enable remote supervision – a hub and spoke model - when the pharmacist could undertake a consultation remotely, and the pharmacy worker at the remote site supplies the medicine to the patient.

Other situations where it may be unnecessary to have a pharmacist physically present is where Pharmacy Accuracy Checking Technicians (PACT) are utilised. A possible scenario would be where a pharmacist undertakes a clinical review of the prescription remotely (eg, on a ward, in a general practice, or an ARC facility), the prescription is checked and validated by the pharmacist is then sent to the pharmacy, where it is dispensed by a pharmacy technician and accuracy checked by a PACT. Or the dispensing could be undertaken robotically. The pharmacist would still be available to the pharmacy technician and PACT for advice if necessary, albeit remotely. This type of scenario needs to be enabled by the legislation.

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?:

Retaining the general ban on HP prescribers holding an interest in a pharmacy business is likely to present barriers to integrated working and the physical proximity of HP working together in an interdisciplinary team, in integrated premises, with the sharing of resources and expertise. Restricting ownership works against the 'One Team' strategic theme of the New Zealand Health Strategy 2016.

Prohibiting HP prescribers from having an interest in a pharmacy could limit financial investment in a pharmacy business particularly in remote areas or where vulnerable populations are underserved.

The risk of HP prescribers benefitting financially from their prescribing decisions is at best low, with the financial gains slight, if any, particularly now that PHARMAC determines which brands of medicines are funded. HP prescribers are bound by their code of ethics and professional standards to provide appropriate care for their patients. Patients may choose not to obtain their medicines from the community pharmacy in which their HP prescriber holds an interest. Additional controls could be implemented to manage any risk in specific circumstances.

There is a risk that HP prescribers holding an interest in a pharmacy could block and stifle new clinical services provided from a community pharmacy they hold an interest in if the new service was seen to be in competition with a general practice (or similar) business. Such barriers would reduce patient choices and be counter to the intent of the Pharmacy Action Plan 2016 which promotes increased use of pharmacists' skills and knowledge for the benefit of patient. We submit that the risk of any such blocks would be minimal.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Nil comment.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

There is likely to be a continuing need for collection depots in remote areas, for example the Chatham Island. This needs to be provided for under the legislation.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We support this approach. The personal importation of medicines circumvents the controls implemented to protect public safety. With personal importation, the pedigree of the medicine is unknown, there is no guarantee on the quality, safety and efficacy of the medicine. The medicine could be counterfeit, adulterated, contaminated or supra/subtherapeutic. Financial gain must not be allowed to circumvent public safety. If a person wishes to self-fund a medicine that is not publicly funded, this should be obtained through New Zealand's legitimate, established supply chain of licensed wholesalers, pharmacies with an appropriate New Zealand prescription.

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?:

Permitting the compounding (including repackaging, over-labelling of medicines) of a quantity of a medicine in anticipation of a prescription should be allowed. This will facilitate work flow efficiencies and the timely supply of a medicine on presentation of a prescription. However, any anticipatory compounding must have controls to ensure products are safe and of an acceptable and consistent quality, for example:

- The batch size that can be compounded; limiting to a volume/quantity that can reasonably be supplied in, for example, a 4-week (month) period which will vary between pharmacies. Providing a 'use within a time' limitation will provide flexibility over set volume/quantity batch size limits (as are in the current Pharmacy Services Standard).
- The compounded product must have validated stability data (physical and chemical) to cover the pre-dispensing storage period and the in-use period.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Pharmacists should be authorised to undertake wholesale supply of medicines, particularly to other pharmacists/pharmacy businesses. Controls will be necessary (for example, frequency of wholesale supply, quantity of medicine supply, it must not constitute a 'significant' proportion of the pharmacy business's turnover).

If the terminology 'nearby pharmacist' is used, this must be interpreted loosely and not be restrictive, to allow the movement of essential medicines between, for example, DHB hospitals Auckland and Invercargill, when Auckland holds the national stock holding of seldom used but essential medicines (eg, botulism antitoxin (Type A, B, E), diphtheria toxoid injection, Hydroxocobalamin Injection 2.5 g).

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Nil 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)?:

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?:

Competent and responsive prescribers are necessary to ensure safe and effective prescribing, to reduce the likelihood of error and to improve patient safety. There should be consistency in prescribing standards within and between disciplines regardless of a HP's specific scope of practice. We support a consistent and standardised approach to prescribing with the development of a single competency framework for all prescribers in New Zealand as articulated in Implementing Medicines New Zealand 2015-2020. (Ministry of Health. 2015. Implementing Medicines New Zealand 2015 to 2020. Wellington: Ministry of Health). This should include the use of the framework for educational curricula and accreditation (eg, Cornerstone).

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

We support the continued use of standing orders to increase access to medicines when a prescriber is not immediately available.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

See Q B7

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

See Q B7

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?:

See Q B8

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 Q B8

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

Nil comment.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Nil 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?:

We believe that DTCA of prescription medicines undermines the patient-HP therapeutic relationship and potentially limits consideration of all therapeutic options (including to do nothing). New Zealand legislation should be aligned with Europe, Canada and Australia.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G416-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 07:55:07**

Submitter profile

What is your name?

Name:

Michael Syme

What is your email address?

Email:

What is your organisation?

Organisation:

Vitaco Health (NZ) Limited

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;:

Manufacturer, distributor, importer, exporter of Dietary Supplements

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).:

Vitaco Health (NZ) Ltd are pleased to be able to provide a submission for this consultation. Vitaco Health are a nutritional products business that aims to empower healthier lives by developing, manufacturing, distributing and marketing a range of branded products within the nutrition, health and wellness industry. Our product categories include a wide range of dietary supplements, sports nutrition and health and wellness packaged food. We service both the domestic and growing offshore markets with our branded products which include Healtheries, Nutra-Life, Balance, Musashi, Aussie Bodies, Bodytrim and Abundant Earth. Our export markets include China, the Middle East, Asia and Europe.

We note that the government is considering options for the regulation of natural health products and intends to exclude them from the Therapeutic Products Bill, and the definition of 'natural health product' and the mechanism by which they will be excluded from the Bill are yet to be determined. Vitaco supports separating therapeutic products from natural health products under separate and distinct legislation. The current Dietary Supplements Regulations are no longer fit for purpose. The lack of an updated natural health products bill mean the industry is operating in an out-of-date system. Therefore, we support efforts to engage with industry to facilitate the move towards the new legislation.

We would like a clear definition of allowable health claims and permitted ingredients for natural health products. In particular, the interpretation of the regulations must be clear so that the Ministry of Health and industry are consistent regarding the health claims permitted for these products. It is in the industry's and the government's interests that ingredients and products that are supported by an appropriate level of efficacy data are permitted to make health claims consistent with the data.

We look forward to being able to contribute to review the first draft of the natural products legislation when it is released for 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):

The definition of natural health product has not been defined in the draft Therapeutic Products Bill, so although we support the separation of therapeutic products from natural health products, the definition of 'natural health product' and the mechanism by which they will be separated from therapeutic products is of critical importance.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52):

None

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

None

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

None

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

None

Question B7 - Please provide any comments on the authorisations for health practitioners :

None

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

None

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

None

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

None

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

None

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

None

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104):

None

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

None

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):

None

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119):

None

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122):

None

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):

None

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

None

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):

None

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):

None

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

None

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):

None

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):

None

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

None

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

None

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

None

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).:

None

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).:

None

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).:

None

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).:

None

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).:

None

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).:

None

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).:
None

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).:
None

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).:
None

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:
None

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).:
None

Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:
None

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:
None

Question C4 - Please provide any comments on the approach to post-market controls.:
None

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
None

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:
None

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:
None

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:
None

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:
None

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:
None

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:
None

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:
None

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

None

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

None

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

None

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

None

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

None

Question C4 - Please provide any comments on the approach to post-market controls.:

None

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

None

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

None

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

None

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

None

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

None

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

None

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

None

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

None

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

None

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

None

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

None

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

None

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

None

Question C25 - Are there ways in which Option 1 could be improved?:

None

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

None

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?:

None

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)?:

None

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

None

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

None

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

None

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?:

None

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

None

Question C34 - Are there ways in which Option 2 could be improved?:

None

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

None

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?:

None

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?:

None

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

None

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

None

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

None

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?:

None

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

None

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

None

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

None

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?:

None

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

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

None

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?:

None

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

None

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

None

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?:

None

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?:

None

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?:

None

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

None

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?:

Although this question relates specifically to prescription medicines Vitaco has been made aware that there may be some groups that would like DTCA banned for complementary medicines. Therefore, Vitaco would like to take this opportunity to provide our support for the continuance of DTCA for complementary medicines.

DTCA forms a valuable part of overall consumer education, increasing consumer awareness, encouraging consumers to act on undiagnosed or poorly managed conditions, and improving and encouraging communication between doctors/pharmacists and consumers.

DTCA makes consumers more aware of new complementary products and is helpful in consumers opening conversations with healthcare professionals about their health issues. Improved health literacy is part of the current governments' Wellbeing Budget.

Current research done by NZSMI in January of this year showed:

- Patients primarily get their health information from the internet and friends and family
- On seeing advertising through mainstream media, discussions with doctors that resulted were predominantly solutions focused, relating to the condition, problem or ailment, rather than product focused.
- Over half of all New Zealanders would be extremely concerned if DTCA was banned.

Health is the second most searched topic on the internet and a ban on DTCA would have to include internet advertising. There have been numerous reviews of the need and value of DTCA in the last twenty years. Successive governments have found that the benefits have outweighed the risks; and this was in an age when the internet was developing. It is now ubiquitous and the primary source of "the answer to any question".

In summary, Vitaco is concerned that certain groups may be interested in banning DTCA for complementary medicines and we are opposed to this.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

none

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

none

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?:

none

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?:

none

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?:

none

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?:

none

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

none

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

none

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

none

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

none

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

none

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

none

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?:

none

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?:

none

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

none

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?:

none

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?:

none

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.:

none

Response ID ANON-DPZ8-G4ZS-E

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 08:28:22**

Submitter profile

What is your name?

Name:

A/Prof Rhiannon Braund

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

NZPhvC, DSM, University of Otago

Submitter Profile (tick all that apply)

Consumer

Professional body (eg, Colleges, Pharmaceutical Society etc), Pharmacy organisation

If you select DHB, please state service area:

New Zealand

Pharmacist, Other health practitioner (please comment)

If you select 'Other', please comment below;:

Medical Assessor - CARM

If you selected 'Other' please comment;:

University Researcher

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).:

N/A

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

dispense a medicine (s 29): This defines a specific manufacturing activity.

this bill effectively changes the current activity of dispensing, which encompasses clinical appropriateness assessment (inc access to lab results) to a manufacturing process. I strongly disagree with this significant change from the previous Act

S. Pharmacy business. In this section you talk about the supply function as a pharmacy business, however later in the legislation it is clear that ALL prescribes can supply. There needs to be the SAME standard for anyone supplying medication. These are not simple commodities. Why does a Pharmacy have additional rules in this Bill that are not there for others? Would this mean that a midwife or doctor supplying medicines need to have a pharmacy licence? (as per defn of

pharmacy business).

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):

Happy with these

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):

55m - again, a controlled activity is Pharmacy Business, why isn't all supply controlled?

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):

This is a very detailed section of who can supply a medication. Given that this Bill is intended to last, why are these levels of detail not in the regulations? as will occur with other activities.

This is limiting in terms of evolution of training etc. Internationally there are emerging roles for qualified "pharmacy workers" and this precision limits these roles being adopted within NZ

Question B7 - Please provide any comments on the authorisations for health practitioners :

While the "supply" of medication by prescriber is absolutely appropriate in emergency or other access situations, the loss of medication safety checks in the form of another health professional (i.e. pharmacist) reviewing the correctness and appropriateness needs much more consideration. There is a plethora of evidence that prescriber within NZ is sub-optimal, particularly at transition of care points. This is a significant public safety risk.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

health professional staff. Would this mean that a receptionist could issue pharmacy only medications.

When supplying a prescription medication, which staff or "workers" as per previous section can do this? What will be the requirements on training?

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):

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?:

It is of concern that both of the documents referred to above:

[8] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health.

[9] Ministry of Health. 2015. Implementing Medicines New Zealand 2015 to 2020. Wellington: Ministry of Health.

are at the end of their life. Obviously these documents and the current bill need close alignment. Currently there are significant disparities between regions as to the services offered by pharmacy in the access and medication management space.

The Pharmacy Action Plan has failed to deliver on many of the aspirational goals.

the role that pharmacist play in minor ailments, triage and access is vital and superceeds a simple supply role.

While a proportion of the patients may not need additional clinical support, there are still significant concerns with access (geographical and cost). Hub and spoke models can work in some places, but this will increase costs via transport of medications

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

Overseas models that have opened access to health professional business have seen a corresponding in safe and quality service.

While there may have been individuals that have manipulated the system, there should be checks in place to hold these individuals (companies) to account.

By being "firmer" on what effective control means, then we can be confident that a balance between patient and financial considerations are maintained.

Detailed questions relating to Option 1

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

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?:

A pharmacist MUST always be present to intervene or to respond if more information comes to light during the process.

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?:

Pharmacists are health professionals who can face disciplinary actions if they supply medications that are not necessary. Many pharmacists make recommendations (i.e. OTC, p'cist only meds) and this has never been a problem.

The income from actual dispensing is negligible.

If you open up all prescribers to supply, they will have just as much "conflict" as a pharmacist prescriber.

Also we have situations where a pharmacist may be a prescriber in one setting (i.e. MDT, GPs) and not be a prescriber when working in their pharmacy. This should be controlled by "scope of practice" and the professional regulation bodies (i.e. Pharmacy Council)

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Yes, but as an "ad hoc" not instead of.

i.e. ECP providers at music festivals

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Yes, consistency should be key

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?:

If there are "rules" for pharmacy workers, than anyone performing the same tasks, irrespective of practice setting should be held to the same levels of training and regulation

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-G4FN-N

Submitted to Therapeutic Products Regulatory Scheme: Online Consultation
Submitted on 2019-04-18 09:03:59

Submitter profile

What is your name?

Name:
Jennifer Duncan

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).:

d. therapeutic products (s16)

I disagree with classifying sunscreen as a therapeutic product for the following reasons. The biggest issues surrounding sunscreen use are:

- a) Not using sunscreen
- b) Not using enough sunscreen
- c) Not applying sunscreen before going outside
- d) Not reapplying sunscreen after swimming or vigorous exercise

e) Instances of perceived "burn" from using sunscreen that doesn't work, is actually an allergy to an ingredient giving a burn response/appearance
None of these will be reduced by reclassification and higher prices could well increase a) and b)

Australia has used the AS/NZS standard for decades and now has the highest rate of invasive melanoma in the world, overtaking New Zealand. (February 2019). Clearly the Australian standard being mandatory in Australia has not improved the rates of melanoma! QIMR Berghofer Medical Research Institute in Australia states that "New Zealand melanoma rates have stabilised in people aged 60-79 years, with rates continuing to rise only among those aged over 80. In Australia, invasive melanoma rates are still rising in the over 60s." There are issues with different testing labs in Australia giving inconsistent test results which would suggest the AS/NZ Standard should not be the only approved method of testing sunscreen. The focus needs to be on getting people to use sunscreen not putting up more barriers to use through reduced competition and higher prices.

The US Food and Drug Administration (FDA) has announced (February 2019) a new proposal on sunscreen safety that will likely overhaul the entire sunscreen industry. A ruling will be made before 26 November 2019. It has both environmental and health implications and should form part of any consideration for change in New Zealand. Only allowing brands tested against the AS/NZ Standard in the New Zealand market is short-sighted when brands tested against FDA standards from reputable laboratories also provide excellent sun protection and ensure a wide range of products/prices are available. There has been a myth perpetuated by the Australians that the AS/NZ Standard has been developed for conditions in Australasia and no other Standards are acceptable. FDA tested sunscreens are just as effective and should not be excluded from the NZ market. It would be prudent to wait for the FDA review before making any changes and take into account the changes made by the FDA so that world best practices are applied in the NZ market. This is of particular importance in ensuring New Zealand takes positive steps in environmental responsibility in our oceans.

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):

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):

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?:

off-label use should be maintained so that special cases can continue to get last resort treatment

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

About the New Zealand Nurses Organisation

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 52,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements.

NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse.*

EXECUTIVE SUMMARY

1. New Zealand Nurses Organisation *Tōpūtanga Tapuhi Kaitiaki o Aotearoa* (NZNO) welcomes the opportunity to comment on the exposure draft of the Therapeutic Products Bill and Therapeutic Products Regulatory Scheme consultation document.
2. NZNO is supportive of the intent of the draft Bill and regulatory scheme to be principles-based, bench-marked internationally, and sufficiently high level to accommodate 'emergent' technology.
3. The lack of detail in the draft Bill, making it difficult to assess how nurses in the four scopes of practice (Nurse Practitioners, Registered Nurse Prescribers, Registered Nurses and Enrolled Nurses) can function within their scope and the proposed regulatory scheme, needs to be addressed by regulations which must be developed in conjunction with health practitioners who can inform regulation development with the complexities and realities of professional practice.

4. Implementation of the proposed changes are of concern to nurses in some areas of practice where, for example, standing orders are used enabling large numbers of services users to receive care. While acknowledging that much more detail will emerge as the 'regulator' is established and the regulatory scheme is rolled out, it is at this juncture that unintended consequences for the everyday practice of nurses and other health professionals may emerge.
5. NZNO has consulted its members and staff in the preparation of this submission, in particular Nurse Practitioners, RN prescribers, professional nurse advisors and the medico-legal team.
6. NZNO has discussed the proposal with the wider nursing sector including the Nursing Council of New Zealand (NCNZ), College of Nurses Aotearoa (CONA) and Office of the Chief Nursing Officer at the Ministry of Health.
7. Stakeholder consultation sessions with Ministry of Health officials have also been attended and we have had the benefit of reading the submission from the New Zealand Medical Association (NZMA).
8. NZNO does not wish to make an oral submission.

CONSULTATION QUESTIONS

This written submission from NZNO is instead of using the online tool and focuses on the impact on nursing practice of the Bill and proposed Regulatory Scheme. It is anticipated that individual nurses, especially those working in prescribing roles will make submissions online and will seek clarity on if and how the Bill and regulatory scheme if enacted will be enabling of their practice.

1) NZNO welcomes the intent of the Bill to:

align the regulation of therapeutic products with how international partners are managing this complex responsibility;

enable nurses to work to the full breadth of their scope thereby improving access to health services and resources particularly in communities with high needs such as rural Māori communities with limited access to doctors, pharmacists and pharmacies and high health literacy needs; and

offer a principles-based legislation that enables regulation, thereby being more responsive to emerging technologies and healthcare trends.

Practice realities for nurses

- 2) NZNO would like to draw your attention to '*Guidelines for nurses on the administration of medicines*', a comprehensive set of guidelines published by NZNO after wide consultation with the membership and which cover the breadth of situations in which nurses have responsibility for administering and in some cases prescribing medicines. The guidelines include a glossary in which 'standing orders', 'supply' and 'dispense' among other functions are defined (NZNO, 2018). In developing the glossary of definitions, experience tells us that workable definitions are best achieved with health practitioners whose practice is being defined. NZNO expects to be involved in developing these definitions with the regulator.

NZNO members working with '*Guidelines for nurses on the administration of medicines*' include nurse-led clinics, for example eye clinics, and a diabetes service including 4 nurse prescribers with 15 registered nurses working with standing orders. They are seeking clarification on the draft Bill (section 40), 'Meanings of standing order and complying standing order' and are concerned about the impact on their service to care recipients if the way they

use standing orders 'slows' their service delivery and reduces the volume of people they can see in a day.

Nurses working in community palliative care also need reassurance that their ability to access controlled drugs according to the (sudden) changing needs of the terminally ill is not compromised. And members working in appearance medicine who also use standing orders are seeking clarity from legislation on how medicines and medical devices they use routinely will be regulated as they progress the development of standards for the appearance medicine sector which continues to grow significantly.

Legal terminology and interpretation

- 3) A question has been raised by the NZNO medico-legal team about the intent of section 41 of the draft Bill, specifically 41(5) 'a person who is authorised by a complying standing order to do something is taken to be the *agent* of the person who issued the order'. Is the intent that a nurse using a standing order is *liable* as an agent (ie the prescriber) would be? Currently standing orders are widely used so changes to how nurses (prescribers and non-prescribers) work with these in the new regulations needs to carefully consider the complexities and realities of the practice context.

In addition section 38(4) of the exposure draft states '*a prescription may be issued orally, in writing or in any other form.*' Use of '**or**' indicates that a prescription may be issued but not documented. Is this inclusion intentional? NZNO is often contacted by members with questions about their role in administering prescribed medicines and many of these questions are about documentation or lack of, with respect to what has been prescribed and how the nurse should document actions taken, or not taken.

Opportunity to address existing anomalies

- 4) The draft Bill and Regulatory Scheme also present opportunities to address anomalies in the current legislation and regulations. For example, the requirement for Medical Officers of Health to authorise registered nurse vaccinators (Medicines Regulations 1984 clause 44A (2)) are archaic and need to be actively removed at this stage so that 'business as usual' is not an unintended consequence of the principles-based approach being presented. Nurses are responsible and accountable for their practice and currently complete a nationally approved and recognised programme to become an authorised vaccinator. They then need to be certified by a medical officer of health to vaccinate in a particular DHB. The requirements of each Medical Officer of Health can differ and a nurse moving from DHB to DHB has to resubmit an authorisation request for each DHB and then be recertified every two years. NZNO strongly recommends the removal of any requirement for Medical Officers of Health to oversee or approve the practice of nurses. The regulations that will follow this legislation should remove this requirement so that certification of nurses as vaccinators is a responsibility of the nursing profession.

- 5) The timeliness of medicine lists updates also causes concern for members. Recently a drug used in diabetes (vildaglipton) became fully funded but the ability of nurses to prescribe it delayed by the medicines lists maintained by NCNZ, not being updated. With the regulations developed under the Regulatory Scheme enabling regulatory authorities, for example NCNZ, to maintain 'other logical groupings' rather than medicines list, will prescribers and medicines users be sufficiently protected from harm? How will costs of maintaining the 'logical groupings' of medicines and medical devices be split between government and 'industry' which in this case is nursing's regulatory authority?

- 6) NZNO supports the inclusion of access to category 2 and 3 medicines of non-prescribing RNs. For example, members who are school nurses welcome the greater flexibility this will give them to supply medicines they would otherwise be suggesting a young person or family member purchase from a pharmacy or supermarket, reducing the likelihood that the medicine is accessed.

De-prescribing

- 7) Another consideration as the regulations are developed is how *de-prescribing* can be facilitated. Appropriately much focus and energy is on safe prescribing. Equally, de-prescribing needs to be enabled as issues such a poly-pharmacy, anti-microbial resistance and the opioid crisis are addressed. All three scenarios are in part the result of inappropriate practice by a number of parties including health practitioners (prescribers and non-prescribers), regulators, manufacturers and retailers. The new regulatory scheme needs to have sufficient regulatory 'muscle' to require change in practice where this is necessary.
- 8) Direct-to-consumer advertising (DTCA), allowed under the current and proposed legislation, but at odds with the international benchmarking used in the development of the proposals for the regulatory scheme and the Bill, is unlikely to enable de-prescribing. NZNO advocates for the removal of provision for DCTA, primarily because there is no evidence that it improves access to medicines for those individuals and communities with high health and literacy needs.

CONCLUSION

In conclusion, NZNO supports the Bill and has a number of recommendations:

Terms of reference for the regulator should be developed in consultation with those groups, regulatory authorities and professions, including nurses, whose practice will be impacted on a daily basis by the decisions of the regulator.

Groups currently underserved by the current system and legislation resulting in inequitable access to health resources including medicines and medical devices, should be consulted with and then represented in the regulatory scheme.

Anomalies in the current Medicines Act and Regulations, such as the requirement for the Medical Officer of Health to certify nurse vaccinators, should be actively identified and remedied in this process.

Direct-to-consumer-advertising should be discontinued, Aotearoa New Zealand being one of only two developed world jurisdictions that allow this practice for which there is no evidence of benefit to those whose equitable access is already compromised.

Nāku noa, nā

S. E. Gasquoine

Sue Gasquoine

Nursing Policy Adviser/Researcher

REFERENCES

New Zealand Medical Association (2019) *Therapeutic Products Bill Exposure Draft and Proposed Regulatory Scheme*. Wellington: New Zealand Medical Association.

New Zealand Nurses Organisation (2018) *Guidelines for nurses on the administration of medicines*. Wellington: New Zealand Nurses Organisation

Nursing Council of New Zealand (2018) *Medicines list for registered nurse prescribing in primary health and specialty teams*. Wellington: Nursing Council of New Zealand. Retrieved from <http://www.nursingcouncil.org.nz/>



NEW ZEALAND
NURSES
ORGANISATION

TŌPŪTANGA
TAPUHI
KAITIAKI O AOTEAROA

Response ID ANON-DPZ8-G4RH-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 09:42:51**

Submitter profile

What is your name?

Name:

Julie Jones

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

NZACRes

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Medicines (other than cells and tissues), Medical devices, Cells and tissues, Trial ethics

NGOs

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

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).:

cl 32 - definition of manufacturer:

1. To manufacture means (b) - to do anything that is part of the process of (i) producing the medicine.

and:

4. (a) to procure the cells or tissues.

- in the past I have worked on a clinical trial that used the patients own tumour tissue for the production of a personalized vaccine. The tissue was taken directly from the patients in surgery.

Would a situation such as that still fit within the principles of the Bill and allow research to be conducted without undue burden?

Similarly, clause 35, production of a type-4 product. 1 (b)(i) could present issues depending on what the product is manufactured from.

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):

Are there likely to be issues where a product is available over the counter in other countries but not in NZ, which may mean that it is a restricted product in NZ. How would the general public know if they are potentially importing a NZ restricted item?

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).:

151 (1) - This doesn't seem to make sense. If a doctor dies, their family should not become responsible for medical products.

If a license was granted for a clinical trial, and the licensee dies, an unqualified person cannot become responsible for those products.

It would be better to say that it can be temporarily/transferred to a designee of similar or appropriate training or qualification as the person who died, with the supervision of the administrator of their estate.

Similarly for points 2 & 3.

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).:

If a register is maintained and made public, will the information recorded ensure that the IP of products under development are protected? Would the level of information made public be minimal relating to the product or action of product so as not to deter Sponsored studies?

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):

268 - dictating review cycles seems like a good idea. Probably a lot of work but it will allow the wider industry/community an opportunity to effect change as may be necessary.

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 1. 35 & 36 - there doesn't seem to be a provision for the event that all applications cannot be processed within the 12 or 6 month periods. Is there full confidence that resourcing will be available to process all applications in this period?

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

It is a chicken and egg situation regarding regulatory and HDEC approvals. In the new guidelines, the HDEC will have to approve first. The HDEC SOP is due to be updated and I expect they will modify the language to reflect this slight change.

HDEC SOP

12. Where a study involves the administration of a new medicine, HDECs can expect issues of scientific validity to have been satisfactorily addressed as part of that study's being approved by SCOTT under section 30 of the Medicines Act 1981. Accordingly, HDECs may not usually require that additional peer review be carried out in respect of such studies.

Conditions of HDEC approval

126. All HDEC approvals are subject to the following standard conditions.

126.1. Applicants must obtain all necessary regulatory approvals and authorisations before the study commences in New Zealand.

Having the ability to audit and monitor trials is a good idea. Both for ensuring that trials are being run correctly, but also to provide feedback to sites to enable them to identify deficiencies and improve practices. It will put the fear of god into many sites, but at the end of the day, it should be beneficial to sites if approached in the correct way and encourage self improvement and will encourage greater focus on ICH GCP section 5.0 & 5.1 regarding QMS.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

In the main body comments I raised concerns that the transitional period for approval may not be long enough and no contingency appears to be in place in the event that all trials are not approved under the new scheme within the period.

Response ID ANON-DPZ8-G458-E

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 09:58:52**

Submitter profile

What is your name?

Name:
Kelvin Gill

What is your email address?

Email:
[REDACTED]

What is your organisation?

Organisation:
New Zealand Blood Service

Submitter Profile (tick all that apply)

Cells and tissues

Medical devices, Cells and tissues

Medical devices, Medicines

Health service provider (eg, Ambulance, Māori or Pacific health provider etc)

If you select DHB, please state service area:

If you select 'Other', please comment below::

Crown entity

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).:

NZBS supports the purpose and principles of 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):

Dispensing and Supply: please clarify the definition of dispensing. In relation to NZBS activities this is currently not specific enough. In particular, the difference between dispensing and supply is not clear. NZBS and hospital blood banks provide finished blood products and serum eye drops directly to patients. This involves the application of labels to product outer boxes and packing for transport.

Blood is supplied by NZBS to both DHB-managed blood banks and blood banks run by private laboratories contracted by the DHB. Blood banks then provide blood to health care professionals for administration.

Special clinical needs supply authority: see comments under question C47.

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):

Consideration needs to be given to sponsorship of haematopoietic stem cells (HPCs) imported for individually identified patients. Import is currently arranged by the NZ Bone Marrow Donor Registry (NZBMDR) but the product is supplied directly to the hospital. NZBS is rarely involved. NZBMDR would not be in a position to become a product sponsor so some type of exemption for these products may be the best option.

Clarification will also be required for “niche” products, such as platelet rich plasma (PRP) that is manufactured in clinics on an autologous basis for specific patients.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

NZBS has no comments.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

Not applicable to NZBS.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

Not applicable to NZBS.

Question B7 - Please provide any comments on the authorisations for health practitioners :

NZBS expects to be able to obtain authorisation to conduct all relevant controlled activities that it needs to conduct in the course of its business. There is a known anomaly in the current legislation that does not allow Registered Medical Laboratory Scientists or Registered Medical Laboratory Technicians to dispense medicines. This anomaly must be addressed in the new legislation to allow registered laboratory professionals to dispense and supply medicines in order to allow NZBS to operate within the law.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

See answer to B7.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

Not applicable to NZBS.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

Not applicable to NZBS.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

S.80: NZBS assumes that smart fridges (used for red cells) located within secure hospital locations and controlled by NZBS will not be classified as vending machines. For context, smart fridges are used to store unallocated red cell units at locations remote to the blood bank (for example near to operating theatres). Upon request for a named patient, electronic allocation occurs and the units are accessed from the smart fridge by hospital staff.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

NZBS has no comments.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

NZBS has no comments.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

NZBS has 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).:

NZBS has 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).:

NZBS requires clarification as to sponsor obligations for approval-exempt therapeutic products such as cells/tissue sourced from overseas. NZBS currently imports skin from the USA.

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).:

Not applicable to NZBS.

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 NZBS licence(s) will need to permit blood collection conducted at 'mobile' venues without the requirement to list the address of each. Many different venues are used (following assessment for suitability) and these are subject to regular change.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

NZBS has no comments.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

NZBS has no 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).:

NZBS has no comments.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

NZBS has no comments.

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):

NZBS has no comments.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):

NZBS has no comments.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):

NZBS has no comments.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

NZBS has no comments.

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

NZBS has no comments.

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):

NZBS has no 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):

NZBS has no comments.

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):

NZBS has no comments.

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):

NZBS has no comments.

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):

Please clarify the regulatory status of donated and banked human breast milk which is currently not regulated either as a therapeutic product or food. Note that it has a clear therapeutic purpose in some circumstances such as for premature babies with necrotising enterocolitis (s269).

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):

NZBS has no comments.

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):

NZBS has no comments.

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):

NZBS has no comments.

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):

NZBS has no comments.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

No.

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):

NZBS notes that sections 100 and 101 deal only with changes for approved products. NZBS would like clarity on how changes for approval exempt products will be managed but acknowledges that this level of detail may be in the regulations.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

NZBS has no comments.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:

NZBS has no comments.

Question C4 - Please provide any comments on the approach to post-market controls:

NZBS manages a national Haemovigilance system which covers blood components, fractionated blood products and recombinant products. Information from the Haemovigilance system is not provided to the current regulator, NZBS will expect clarity on the information that will need to be provided to the new regulator.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions:

NZBS has no comments.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

NZBS has no comments.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

NZBS supports adoption of the European approach to regulating cells and tissues.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

NZBS notes that sections 100 and 101 deal only with changes for approved products. NZBS would like clarity on how changes for approval exempt products will be managed but acknowledges that this level of detail may be in the regulations.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

NZBS has no comments.

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

NZBS manages a national Haemovigilance system for blood components, fractionated blood products and recombinant products. It is expected that the system will be extended to include other cells and tissue. Information from the Haemovigilance system is not provided to the current regulator, NZBS will expect clarity on the information that will need to be provided to the new regulator.

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

NZBS has no comments.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

s.283 of the consultation document states that manufacturing requirements will continue to be based on the PICS cGMP. NZBS consider this not to be a suitable standard for blood, cells or tissue and has made this clear to the current regulator. The equivalent regulators in Australia and UK are also PICS members but use more applicable standards.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

NZBS has no comments.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Yes, NZBS feels that products with similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated. NZBS has no examples of products that are of concern.

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?:

NZBS will expect clarity on regulation of in-house IVDs as well as IVDs that NZBS manufactures in small volumes and supplies to hospital laboratories.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

NZBS notes that sections 100 and 101 deal only with changes for approved products. NZBS would like clarity on how changes for approval exempt products will be managed but acknowledges that this level of detail may be in the regulations.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

NZBS has no comments.

Question C4 - Please provide any comments on the approach to post-market controls.:

NZBS manages a national Haemovigilance system for blood, it is expected that it will be extended to include other cells and tissue. Information from the Haemovigilance system is not provided to the current regulator, NZBS will expect clarity on the information that will need to be provided to the new regulator.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

NZBS has no comments.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

s.283 of the associated consultation document states that manufacturing requirements will continue to be based on the PICS cGMP. NZBS consider this not to be a suitable standard for blood, cells or tissue and has made this clear to the current regulator. The equivalent regulators in Australia and UK are also PICS members however use more applicable standards.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

NZBS has no comments.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

NZBS has no comments.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

NZBS has no comments.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

NZBS supports this approach.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

NZBS has no comments.

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

NZBS has no comments.

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Not applicable to NZBS.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Not applicable to NZBS.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Not applicable to NZBS.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Not applicable to NZBS.

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 applicable to NZBS.

Question C25 - Are there ways in which Option 1 could be improved?:

Not applicable to NZBS.

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Not applicable to NZBS.

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)?:

Not applicable to NZBS.

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Not applicable to NZBS.

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Not applicable to NZBS.

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Not applicable to NZBS.

Question C34 - Are there ways in which Option 2 could be improved?:

Not applicable to NZBS.

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Not applicable to NZBS.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Not applicable to NZBS.

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?:

NZBS supports 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?:

Not applicable to NZBS.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Not applicable to NZBS.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

Not applicable to NZBS.

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)?:

NZBS has no comments.

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

NZBS has no comments.

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

NZBS has no comments.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

NZBS supplies a small number of approved medicines which are used for off-label indications, for example Intragam P. If off-label use will mean that medicines become unapproved we would like to retain the existing process for unapproved medicines where NZBS obtain agreement from prescribers to issue to a named patient and NZBS / blood bank staff record the issue details (product type and quantity, patient, prescriber, etc.) rather than the prescriber.

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?:

NZBS supplies a small number of unapproved medicines, for example Australian-registered Hepatitis B immunoglobulin. The approach described for the special clinical needs supply authority would be difficult to comply with. We request that NZBS continue to be permitted to import these medicines into the country and manage the overall supply. We would also like to retain the existing process whereby NZBS clinicians obtain agreement from prescribers to issue product for a named patient, with NZBS / blood bank staff recording the issue details (product type and quantity, patient, prescriber, etc.) rather than the prescriber.

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?:

NZBS supports this approach.

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

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 applicable to NZBS.

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 applicable to NZBS.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

C9 Veterinarians

Question C54

What do you think about the approach for veterinarians and veterinary staff?:

Not applicable to NZBS.

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

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?:

NZBS has answered this question in section C8 Health Practitioners.

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?:

NZBS has answered this question in section C8 Health Practitioners.

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?:

NZBS has answered this question in section C8 Health Practitioners.

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

NZBS has no comments.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Not applicable to NZBS.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Not applicable to NZBS.

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Not applicable to NZBS.

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Not applicable to NZBS.

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

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 applicable to NZBS.

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Not applicable to NZBS.

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?:

Not applicable to NZBS.

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?:

NZBS has answered this question in C3 Medical Device sector.

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.:

NZBS has no comments.

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G4US-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 10:08:42**

Submitter profile

What is your name?

Name:

Canterbury District Health Board

What is your email address?

Email:

What is your organisation?

Organisation:

Canterbury District Health Board

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Canterbury District Health Board

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

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).:

Question A1 Comment -

We support the intent and general design of the Therapeutics Product Bill in replacing the Medicines Act and endorse the principles-based update and design. We acknowledge that much of the detail is still to follow – in regulations, rules and notices, and note that without this level of detail it is impossible to know if the right balance has been struck in risk appropriate management.

We oppose the exclusion of Natural health/complementary products (including rongo Māori and dietary supplements) from regulation under this proposed legislation.

We are aware of the history around this but we remain concerned and submit they should be considered for inclusion because they are currently available and are sold to and used by a large proportion of the NZ population with therapeutic intent. These are a group of "therapeutic products" for which there is a great need for regulation. There is a huge amount of misleading advertising, their production is booming and there is a substantial risk of harm.

B1
We agree with the approach to move from set legislative framework to a principles-based legislative framework.
Regarding ss4 a) of the Bill

Please reconsider terminology - we submit that "potential harm" is more accurate than 'likely risk'.

1. The likelihood of harm is a risk.
2. The use of the term "likely" suggests a high probability.
3. Prior to use, medicines have potential effects (beneficial and/or harmful)

"...the potential benefits of therapeutic products should outweigh the potential harms associated with them..."

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):

We support the alignment with international definitions.

Ss14 – Health Practitioner Prescriber – We note this is defined differently to the Medicines Act - Authority to prescribe is to be established in, and bounded by, scopes of practice under the HPCAA (responsibilities of individual scopes of practice for individuals) and not in the regulations.

This is a substantive change. As scopes of practice are defined by each professions regulatory body (e.g. nursing and medical council), inconsistencies may arise. A process for harmonisation or oversight of prescribing roles may be needed.

Is there a legislative instrument to facilitate this if it is needed?

We noted the removal of categories of prescribers (authorised/designated/delegated). See also ss61 and ss276-285

Ss15 - Therapeutic Purpose definition - casts a net that is likely to be wider than intended or is appropriate. The key problem areas are

(a) "compensating for a disease, ailment, defect, injury". This would include many devices in the rehabilitation field that are internationally not generally considered medical/therapeutic devices e.g. corrective glasses, orthotics, hearing aids, speech recognition software (for those who can't type), aids to daily living for those with arthritis e.g. special spoons. Occupational Therapy could provide legions of examples.

(b) "Influencing...a human physiological process". This could inadvertently include all exercise equipment which would be inappropriate

(i) "a purpose connected with a purpose in paragraphs (a) to (h)...". This creates a circular reference that pulls into the net a vast list of support devices. While some of these might be excluded by regulations, others are included by default. e.g. bottles that contain medicines, a computer and computer program used for designing devices or medicines, computer software that supports almost any medical activity, simulation equipment

The definitions of 'therapeutic purpose' and 'intended for use for a therapeutic purpose' in this section of the Bill are applicable to natural/complementary products.

Given the withdrawal of the Natural Products Bill, the exclusion of natural/complementary products is notable.

Ss19 - Categories of medicines – We note the change in terminology. We note the detail for how the categories are applied practically to packaging/labelling etc. will be contained in the rules and regulations to follow, but there is a financial/procedural risk (not clinical) if re-labelling to match the numerical categories supersedes the current labelling of "prescription medicines", "restricted medicines", "pharmacist only medicines" etc.

Ss20 – Active Medicinal Ingredients (AMI) - It is unclear which aspects of current medicines this covers. Presumably rules and regulations around AMIs would mainly apply to manufacturers, but would also apply to pharmacies who manufacture medicines using raw ingredients (e.g. lidocaine powder) to make a batch of product (for many patients and held in stock). We note potential implications for hospital pharmacy compounding and for externally sourced locally compounded products.

Ss21 – Medical device - We welcome the inclusion of software as a medical device, but note that there needs to be extensive clarification around precisely which software is to be included or excluded from regulation. As it stands, the definition appears to include guidelines for clinical decision making (ie HealthPathways), and Electronic Health Records.

a) These types of software meet the definition of therapeutic purposes as they are used for "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury"

b) These types of software also meet the definition of a medical device as they "achieve, or is likely to achieve, its principal intended action by means other than – (A) pharmacological, immunological, or metabolic means; or (B) the action of something that comprises, contains, or is derived from human or animal cells or tissues;"

This is a particularly broad and impractical definition of a medical device, which would require explicit clarification. The absence of standards or regulatory framework for medical software has placed substantial evaluation burden at a local level, and so some degree of regulation would be appropriate.

Ss22 – Supply Restricted and Use Restricted Devices – It would be useful if this section stated principles by which devices will be categorised. Without some state of principle, these sections may create unworkable situations.

Ss34 - Manufacture of device - Manufacture and remanufacture definitions are good and sufficiently flexible to allow limited local customisation by DHBs as is commonly undertaken.

There is a lack of clarity around the implications for software, particularly for any products that have been developed in-house.

Ss39 - Special clinical needs supply authority (SCNSA) - The extension of this approach to include off-label use of medicines that have been approved in NZ is a major change with potentially very high compliance costs and administrative burdens. Off-label use of medicines is common and in most cases is usual clinical care (eg. medication use in children and pregnant women; contraceptive pill for cycle regulation rather than contraceptive purposes; Sildenafil for pulmonary hypertension). SCNSA documentation of all off-label use could be excessively burdensome, even if the requirements were "minimal" compared to SCNSA for unapproved medicines. Even adding a 'tick box' as suggested in the consultation document, would incur development costs within electronic prescribing systems that are already in use.

Use of approved guidelines would be sufficient to cover the off-label use of medicines.

Ss42 – Supply – This section appears to exclude a situation where a District Health Board makes a device for use within the same District Health Board as it doesn't pass from one 'person' to another. It appears that product approval is not required if a product is not being supplied, which simplifies in-house work without adding significant risk. However, we would like to confirm this point. This situation is still picked up in the manufacture part of the Bill (would require a licence as a manufacturer), but good that it is excluded in supply. Selling a device to another District Health Board is rightly included in the definition of Supply. An example of this in-house manufacture is the design and build of an x-ray compatible table for use in the spinal unit. The steps to complete certification for such an item would require destructive testing etc... Which is not appropriate for a one-off build. The table was built by the District Health Board and is used within the District Health Board.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52):

Ss51- Product Approval Requirements - This seems to prohibit parallel importing – which is currently legal in NZ.

Rare conditions may require access to new or seldom used (and unapproved) products that are likely to provide a net benefit to the patient but won't have met the onerous regulatory standards required by the Bill. Supply issues for critical medicines are another example where this provision may be too restrictive. Clear provision of exceptions to cover this need to be included.

We feel this needs clarification and careful thought as to wider implications, particularly around monopolisation of supply and the future cost implications.

It is also unclear how this would apply to the importation of parts of devices, rather than the whole device (ie a new component for repairing an older device, or consumable components for a device).

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

Ss53 Part 2, d) and i) – Authorisation Required for Controlled Activity - Inconsistent terminology; therapeutic product vs 'medicine'

Is it deemed that only "medicines" can be prescribed? This is inconsistent with clinical practice and the definitions of therapeutic products earlier in the Bill e.g. blood products

Overall the list of controlled activities is quite detailed for medicine-based Therapeutic Products but less detailed/incomplete for other products (e.g. devices).

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

Ss57 – Pharmacists- This section refers to medicines. Is it intended that this regulation would cover medical devices, that could be sold (if Category 2) by a pharmacist? If so then a wording change would be required here. Or a statement of exemption for devices.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

We support authorisations for pharmacy workers. This allows delegation and clarity of scope for pharmacy workers by setting out the level of supervision required. For example, this will allow Pharmacy Technicians & others to compound products with "general" supervision of a Pharmacist, rather than "direct" supervision

Question B7 - Please provide any comments on the authorisations for health practitioners :

Ss61 - Health Practitioner Prescriber - Authority to prescribe to be established in, and bounded by, scopes of practice under the HPCAA (responsibilities of individual scopes of practice for individuals) and not in the regulations.

We note this is a change from the Medicines Act. As scopes of practice are defined by each profession's regulatory body (e.g. nursing and medical council), inconsistencies may arise. A process for harmonisation or oversight of prescribing roles may be needed.

Is there a legislative instrument to facilitate this if it is needed?

We noted the removal of categories of prescribers (authorised/designated/delegated). We have not considered the implications of this fully. See also ss14 and ss276-285

Ss61 (2) - Health practitioner Prescriber (e.g. podiatrist, not a prescriber) can "supply" as well as administer category 3 medicines for patients under their care, e.g. for feet and limbs.

We accept this extension from the current provision in the Medicines Act which allows administration but not the supply of these medicines.

We note this has beneficial implications for patients, as they are able to receive full care from one provider, potential benefits of increased independent practice, and allowing practitioners to work at the top of their scope. This could be of benefit in removing the burden from other areas of the health system, potential problems of increased isolation and decreased team practice could be countered through the use of primary care infrastructure such as Primary Health Organisations.

Ss61 (3)(c) - "the patient is in New Zealand or is ordinarily resident in New Zealand";

Our legal team, amongst others, have requested further clarification of the phrase "ordinarily resident", and further discussions about the implications of this clause.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (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):

We submit that more work is needed to clarify the proposals around personal importation of medicines.

Interpretation 1: It appears that these sections were intended to cover people immigrating to New Zealand, returning to New Zealand, or tourists who are passing through. However, if this is the case, then there needs to be a clause that states an end date to someone being able to import medicines. As it stands, it appears that people could move in and out of the country ad infinitum, bringing prescription medications with them each time. Or people could continually access their international prescriber (online type consultations are becoming increasingly common) and have ongoing access to medications via this route.

Oversight of care ought to be transferred to a New Zealand health professional at some point in time if the person is here for more than 12 months. We also note the potential for harm with abuse of some category 2 medicines.

Interpretation 2: Category 1 medicine can be imported if a medical practitioner is satisfied the consumer has a clinical need for medicine that cannot be met by medicine available in NZ. How does this differ from the need for an SCNSA?

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Ss75 – Manufacture of Custom-made devices – Engineering: Good definition and allows for custom manufacturing that currently takes place within the District Health Board. There could be an argument about what constitutes "custom manufacture" but that can be clarified in the regulations.

Laboratories: Many hundreds of in-house in-vitro diagnostics are created and used. The cost implications of a manufacturing licence would be huge. Propose that IANZ accredited laboratories are exempt from this. Supply and manufacture requirements are appropriate if the tests are being used outside of the creating organisation.

Applying the IMDRF Essential Principles to an assay used by a registered laboratory scientist in an accredited laboratory (as is currently the case) would do nothing to enhance patient safety and may only increase the cost of compliance and the administrative burden. Full exemption from further regulation for accredited laboratories is preferred.

Individuals: There is an increase in individuals modifying medical devices to optimise their own health care. ie Diabetic patients and their Insulin pumps. This results in better health management than the off-the-shelf device. Will these modifications be covered? There may be a need to regulate this activity in the future as such technology becomes more available to the public, and the public becomes more tech savvy.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94.:

Ss83 (3) – Direct to Consumer Advertising- There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694-695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system. It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing.

If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised.

If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie Ibuprofen, not Nurofen).

There would also need to be considered that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat, when we have issues with Rheumatic Fever in New Zealand populations.

Ss93 – Health practitioner prescriber must not hold interest in pharmacy business - We acknowledge and agree with the concern about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions and conversely if suppliers owned prescribing businesses.

We submit that the issue of ownership be consistent across the health sector and not be focused solely on pharmacy businesses.

We also note that the definition of a "health practitioner prescriber" has been updated, and this may mean that the provision needs to be reviewed as well. There are queries around the implications of this section for Pharmacist Prescribers owning their own business, and for pharmacies located within General Practice.

B6 Part 4 of the Bill: Product approval

Subpart 1: Approval of products (ss 94–113)

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

Ss113. Therapeutic products register -For medicines, the therapeutic products register must list the active ingredient, we contend that this should be extended to include all ingredients. For example, to determine product suitability for people with allergies. This may be covered "any other information" specified in the regulations?

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

Ss114. Approval-exempt products - Would this allow the small scale manufacture of products in NZ (e.g. Biomed make a number of products under s23, such as fentanyl infusion solutions, where full registration is difficult to meet but safer to manufacture in controlled environment than to prepare in a clinical environments, such as wards, operating theatres etc....)

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

Where possible, having data publicly available would be preferable. Noting that the risk to patients, if the health system cannot independently evaluate information related to therapeutic products, could be high. It is important that the evidence upon which regulatory decisions are made are open to scrutiny by health professionals and patients.

Therapeutic products are used by New Zealanders on the advice of New Zealand health professionals and potentially paid for by New Zealand taxpayers. We submit that full information about active ingredients is essential to the safety and efficacy of medicines use.

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

No matter the system used for granting licences, it should consider patient safety and maintain separation of prescribing and dispensing of advice re medicines/devices.

Whatever system is used should consider separation of ownership responsibilities and clinical responsibilities.

We submit that the issues of independent practice and ownership be consistent across the health sector and not be focused solely on pharmacy.

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):

Ss137 – Duration - Currently Licences are issued for 12 months, new Bill allows Licences for up to 3 years – we support this extension in duration

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

Subpart 4: Obligations of licensees and responsible persons (ss 153–159)

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):

For this to be effective it will be necessary for the Regulator to be appropriately resourced. This is could be difficult for NZ to manage, and close alignment and collaboration with other jurisdictions will be required.

Ss176 - Independent panels- Sufficient expertise to make up these panels may be difficult for NZ to effectively resource.

Ss172 – 176 Oversupplied persons- For persons oversupplied category 1 or 2 medicines (addicted/ abusing, etc.) this places a series of rules in place to limit prescribing and dispensing of these medicines to this person. It is also linked to the Privacy Act 1993/ new Privacy Bill

We note the increase in enforcement options – we support having a greater range of enforcement options to cover a range of infringements. We note this may have significant administrative costs and to be effective will need to be sufficiently resourced.

Ss267 (2) – Consultation – We note concerns that the Regulator is able to determine who is considered “appropriate” for consultation before developing rules, a notice, or an exemption. We also have concerns with Ss267 (3) which notes that despite clause 2 saying that the regulator “must not” make rules etc... a failure to comply with this clause does not affect the validity of any rules or regulations that are created.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):

The regulator can set the fee to make up any cost not covered by government funding. We see this as a potential risk and note that the benefits of regulation are to the taxpayer.

There is a natural tendency for regulators to minimise their risk. To reduce risk regulators have a tendency to increase complexity and potentially costs (increases the risk of bureaucratic overreach).

Conversely, we note that a fee for service system can lead to a culture of customer service, and the risk of putting the customer (applicant) ahead of the citizen (patients).

Financial independence from fees is a necessary component of regulatory independence.

- We submit that an external review process or independent fee setting should be considered.
- We submit that fee setting and revenue collection should be separate from regulation and enforcement to maintain the independence of the Regulator and recognise that the primary customer is the government on behalf of the people of New Zealand.

At the moment, registration of products in NZ is sometimes limited by cost, which has been a barrier. (E.g. section 29). If this becomes applied to devices and software as well we see this as a potential risk.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):

Ss256 - Regulator can set the fee to make up any cost not covered by government funding. We see this as a potential risk of significantly increased costs compared to current. Regulators are inherently risk-averse and there is a tendency for Regulators to increase levels of scrutiny and thus costs. There is a risk this could limit innovation, and/or limit the products available in New Zealand. How will this risk be managed?

Enabling the regulator to charge fees to cover any costs not covered by government funding will likely result in an increase in costs to purchasers of medical devices as these fees will be passed on. Full transparency for any fee proposal with approval from a governing body representing purchasing agencies (including DHBs) would provide a mechanism to transparently manage these additional costs.

At the moment, registration of products in NZ is limited by cost (in some cases), which has been a barrier. (E.g. section 29) If this becomes applied to devices and software as well we see this as a potential risk.

Also, devices are not currently charged – if devices become regulated and fees are charged compared to current (no charge) this would potentially be a big difference and could limit availability and innovation.

Ss267 – Consultation – We note concerns that the Minister and Regulator are able to determine who is considered “appropriate” for consultation before developing regulations, rules, a notice, or an exemption. We also have concerns with Ss267 (3) which notes that despite clause 2 saying that the above people “must not” make rules etc... a failure to comply with this clause does not affect the validity of any rules or regulations that are created.

Given that the regulations, rules, notices and exemptions are going to create the detailed structure of how the Act is applied, and that these regulations and rules need to work for the whole country, and the various ways of working, it is important that a variety of people are consulted, and that may require an independent advisor to determine suitability.

Ss268 – we support 5 yearly reviews of the policy and operation of this Act

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):

We submit that defining roles of health practitioners within the HPCAA act is reasonable. (As per answers in B2 and B7)

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):

We submit that Crown entities should be able to apply for a review in addition to sponsors and license or permit holders. The regulator may make a decision that the health system may disagree with (e.g. DHBs).

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:

Question C4 - Please provide any comments on the approach to post-market controls:

The increasing move to place the responsibility for pharmacovigilance on sponsors is a concern.

- There is a direct and substantial conflict of interest, for example delaying (or not) by seeking greater certainty could have major financial implications for a sponsor.
- Safety issues identified in pharmacovigilance frequently apply to a class (rather than just an individual product) and so a broader view is required.
- Sponsors do not have easy access to the relevant safety data, these are held largely by the public health system.
- It is expensive and difficult to transfer these data to the sponsors, most practitioners want a single point of reporting.
- Large data sets allow for effective pharmacovigilance incorporating multiple variables. This is not possible with sponsor based pharmacovigilance and requires a public health approach.

We submit the primary responsibility for pharmacovigilance remain with the Regulator and the Regulator be given powers to access health data for this purpose. We note that prior to registration the sponsor holds the data and should be responsible for reporting any subsequent data obtained through sponsor generated studies

In order to check reported adverse effects of medicines (and natural medicines) prescribers and pharmacists require ready access to data, ideally from a single source. This source (database) should also include reported adverse effects of all Therapeutic Products, including devices, modified cell lines, etc

For cells and tissues:

We submit that the process for post-market monitoring is aligned with that for pharmacovigilance.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions:

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Any non-medical devices that when used as intended, that has the potential to cause significant harm, should be required to be labelled advising of the risks. If such devices are being used by an operator to provide a service to another person, then the operator should be required to advise person of the risks (i.e. the cosmetic specialist using a high-intensity electromagnetic radiation should have to advise the customer of the potential adverse effects before starting treatment – possibly requiring signed informed consent).

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

General comment on medical devices –

We note difficulties in applying definitions and categorizing with substantial implications. For example electronic records with electronic clinical decision support versus the paper records with paper (and human) clinical decision support (guidance) it replaces.

We note substantive differences in the development cycle of different therapeutic products. For example, new molecular entities in medicines are developed over decades, whereas software might be developed over weeks.

It is not clear to us how the Bill and subsequent Rules and Regulations may impact upon clinical activities. This is a new area and is likely to take many years to develop. It is important the Regulator and consulted parties are given sufficient time and resources to do this.

Many of the same issues raised earlier in our submission for medicines apply to other therapeutic products for example product vigilance and pharmacovigilance. The International Medical Device Regulators Forum (IMDRF) defines software as a medical device (SaMD) as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”. The IMDRF definition is not in the TPB, but we expect NZ to follow this internationally established definition (rather than construct another).

Clarification needed to better understand Post Market Controls. It is proposed in the Bill that MedSafe is the authority for this, with the inclusion of assessment for Software as a Medical Device, more information is needed to understand how MedSafe is appropriate for this based on their expertise.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

Transition: The period of six months seems extremely short, for most medical device manufacturers to obtain the necessary data and submit an application it is likely to take years (as it does for medicines).

This has two potential consequences:

- 1) That multiple devices are no longer available,
- 2) That the regulatory requirements are set low to allow the time frame to be met, such that it becomes an administrative exercise rather than useful regulation.

We submit that an interim regulatory regimen may be required with provision for grandfathering time limited approvals for existing products.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

C16 and C17

Clinical trials are a transnational activity.

Expertise for effective clinical oversight of clinical trials in many areas is scarce.

We submit that the requirements should be such to ensure the regulation of clinical trials is explicitly aligned with Australia and Europe.

We note the existence of Health and Disability requirements for Ethics Committee approval etc. for Clinical Trials currently.

The addition of licensing adds a new administrative hurdle to research – staff have expressed concerns about this.

We note that clinical trials are already constricted and there is a concern within the organisation that further restrictions will make local level studies even more difficult to undertake. It is important in areas such as Point of Care testing to ensure that such devices are tested or validated in NZ or an environment with particular disease prevalence and population characteristics, as these devices can have variations in accuracy according to disease prevalence. Using international test results are often misleading and can result in failure to detect instances of disease. An example has been the Group A Streptococcal point of care tests. In NZ we have more rheumatic fever than most Western countries where the Group A Strep POC rapid test was developed. They were almost entirely developed by companies in resource-rich settings with low GAS prevalence and there are literally dozens available. In the few studies where these tests were trialled on NZ sore throats - they missed GAS positives. This has a big risk when you are in a place with rheumatic fever (I ke south Auckland) so the tests were unable to be recommended for use in the national Heart Foundation Sore Throat guidelines. If these tests are untrials and unregulated we cannot stop practices using them.

We also note that clinical trial regulations ought to be split into categories with differing regulations. Medical Devices (software) would require different regulation to externally applied medical devices (CPAP machines), and yet another set of regulations for trialling internally applied medical devices (joints, implants etc). Medicines would be different again.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

answered in questions B2 and B7

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

C44 - Support in principle but note this is complex and there are substantial differences in both scopes of practice and practice environments as well as in associated training and skills. For example, prescribing in a hospital environment is frequently reviewed, whereas prescribing in a community environment is often only reviewed at the point of dispensing

We suggest regulation should focus on achieving consistent outcomes, rather than consistent process, form and content, as the prescribing environments and requirements vary substantially.

This section also seems to refer only to prescribing medicines, should it apply to all therapeutic products?

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

C45 - We support the approach to standing orders. We envisage that the need will decrease, as scopes of practice change. To issue a Standing Order will be a controlled activity, and can only be done if an individual has this in their scope of practice.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

C46 – off label - This needs clarification as the implications are potentially substantial, see above under question B2

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

C47 - Support and would comment that in the normal course this should be a specialist medical practitioner within their scope of practice. The detailed review undertaken by the Regulator for safety has not happened and hence such prescribing requires an exceptional level of expertise. Consideration as to how these approvals will be documented against the patient such that other health practitioners can then continue to prescribe them is needed. (Will there be a national register?)

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

C50 - We agree health practitioners' should be authorised to supply pharmacy (category 3) medicines to patients. This allows health practitioners to provide full care of the patient, and ensure appropriate ongoing care after the clinic visit. Currently, the health practitioner may make a recommendation that patient purchases the required medicines from a pharmacy (which may/ may not be routinely stocked by the pharmacy), with limited involvement of the pharmacist, and potential for necessary medicines not to be purchased. We note that health care is increasingly multi-disciplinary but aspects of the Bill retain concepts of separate and independent care rather than interconnected care. This has been well advanced in some respects but may need more work. There is a requirement for consideration of applicability to the provision of therapeutic products other than medicines.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

C51 – We agree health practitioners' staff should also be able to supply category 3 (pharmacy) medicines, but only with the approval/ under supervision of the health practitioner. As above, this would help ensure the patient is able to readily obtain medicine to continue treatment initiated by the health practitioner.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694-695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system. It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing. If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised. If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie Ibuprofen, not Nurofen). There would also need to be consideration that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat when we have issues with Rheumatic Fever in New Zealand populations. DTCA of antimicrobial agents may contribute to pressure to use and prescriber be antimicrobial agents. The law currently allows antibiotic advertising to consumers, although to our knowledge it has not occurred yet. The possibility of advertising antibiotics goes against the existing New Zealand Antimicrobial Resistance Action Plan (a Ministry of Health initiative) (<https://www.health.govt.nz/system/files/documents/publications/new-zealand-antimicrobial-resistance-action-plan.pdf>). This is a national plan which specifically highlights the need to review the appropriateness of the regulations around pharmaceutical advertising of human health antimicrobial agents. We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe). We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe).

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?:

There is significant evidence of the negative impacts of DTCA both in New Zealand and overseas (e.g. Toop and Mangin (2007), BMJ, 335: 694-695; Every-Palmer et al (2014), NZMJ, 127: 1401) to support a view that DTCA is counterproductive to our goals as a health system.

It should be noted that DTCA is an issue that requires addressing in a number of areas including pharmaceuticals, cell and tissue therapies, medical devices, laboratory and genetic testing.

If advertising is to continue, we would recommend that natural health products (although excluded from this bill), are subject to the same regulations as other therapeutics, or if a policy change is implemented and advertising is removed, natural health products should also be prevented from being advertised.

If advertising is to continue, we would like to see harsher restrictions – for example, generic drugs are able to be advertised, but not brand names (ie Ibuprofen, not Nurofen).

There would also need to be consideration that DTCA does not contradict Public Health initiatives, such as advertising throat lozenges as an appropriate response to a sore throat when we have issues with Rheumatic Fever in New Zealand populations.

DTCA of antimicrobial agents may contribute to pressure to use and presc be antimicrobial agents. The law currently allows antibiotic advertising to consumers, although to our knowledge it has not occurred yet. The possibility of advertising antibiotics goes against the existing New Zealand Antimicrobial Resistance Action Plan (a Ministry of Health initiative) (<https://www.health.govt.nz/system/files/documents/publications/new-zealand-antimicrobial-resistance-action-plan.pdf>). This is a national plan which specifically highlights the need to review the appropriateness of the regulations around pharmaceutical advertising of human health antimicrobial agents

We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe). We submit that NZ should be consistent with similar regulatory jurisdictions (notably Australia and Europe).

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

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Submitted on **2019-04-18 10:14:17**

Submitter profile

What is your name?

Name:

Aarti Patel

What is your email address?

Email:

What is your organisation?

Organisation:

Canterbury Community Pharmacy Group

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Other health practitioner (please comment)

If you select 'Other', please comment below;:

Unregistered pharmacist working in management

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

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).:

Comments of definitions:

Dispense a medicine (s 29) – the draft proposes a significantly different definition to dispensing which is cause for concern. Current medicines Act states that dispensing, in relation to a medicine, includes without limitation:

- a. The preparation of that medicines 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.

Pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, providing advice to the patient about how to take the medicine safely and effectively; as well as monitoring outcomes.

Under thee draft TPB, dispensing a medicine is defined as part of manufacturing the medicine. This implies dispensing is merely the supply of a medicine, which is misleading. Safety and efficacy of medicines requires the right medication to be prescr bed to the right person, in the right dose, dosage form, the correct quantity and cost with information on how to use, expected outcomes and potential side effects as well as monitor their effects both beneficial and adverse.

Dispensing bridges the process from the prescription/prescriber to the patient/user by checking clinical appropriateness and the provision of information. Dispensing goes beyond a mere supply function.

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):

We are supportive of allowing one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine required by a patient. This enabler benefits patients by giving them quicker access to their prescribed medicines, especially where these are uncommon. It also helps with medicine wastage issues with potential savings to the pharmaceutical budget.

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 :

We would be supportive of health practitioners supplying each other with small amounts of medicines in an emergency situation where a pharmacy is not accessible or cannot provide the medicine in a timely manner. The legislation would need to be clear about the definition/description of health practitioners, what is regarded as small amounts and worded in a manner that does not allow the trading of medicines between health practitioners.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Our approach to the issue of vending machines is to ensure issues of affordable access and patient safety are equally addressed. Vending machines should 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).:

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).:

We support the use of permits for shorter term and urgent situations. The system must be responsive 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).:

We are supportive of increasing the period that licences are valid for, from one year to up to three years, as this would 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).:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

We welcome and embrace opportunities and arrangements that promote patient health outcomes, that do not compromise patient safety; and that do not compromise the integrity of the community pharmacy distribution model. Any alternate distribution model must not undermine the integrity and safety of the current system and current levels of access to community pharmacy services for all New Zealanders.

Dispensing involves a clinical review of appropriateness of the prescription to an individual as well as providing advice on the medicine's safe and effective use. This is very different from the sale of a retail commodity and needs to be provided by a 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?:

To a certain extent, yes in relation to pharmacists prescribing, eg, varenicline to help people to stop smoking. A pharmacist who is also an accredited smoking cessation practitioner, cannot recommend varenicline due to this being classified as a prescription only medicine and can be funded under certain conditions only. The use of pharmacist prescribers in ARC which is struggling to entice GPs to service this rapidly growing group.

Other aspects contributing to innovation in pharmacy services are not directly held back by licensing requirements; rather, here there needs to be more done to support workforce collaboration, IT enablers support integration and aligning policy and funding for all of primary care.

The public good aspects of alternate distribution arrangements must be fully considered against the risk to patient safety and any need for investment in supporting infrastructure and technology.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

We are supportive of service innovations such as providing marae-based services or providing pharmacist services at events such as community cultural events as a way of addressing access, increasing health literacy and encouraging regular contact with a health professional, assuming this would not include dispensing outside of a pharmacy.

We support mobile pharmacy vehicles as an alternate to service rural areas currently serviced by pharmacy depots.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

We believe that there is a 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 that patient care is the focus of community pharmacy.

Pharmacists are under professional obligations 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 costs which will have a negative impact on the range and scope of services the investor owner is prepared to provide.

Medicines are not normal items 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 – resulting in greater accountability.

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 professional relationship between pharmacist and patient, with pharmacists being directly accountable and liable for the services they provide. Employee pharmacists are also held accountable. There is a risk that there could be lower levels 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 voting rights on government and operating decisions impacting public safety.

Question C25 - Are there ways in which Option 1 could be improved?:

Improve option 1 by considering legally mandating the owner pharmacist to have a "veto share" so they are always in control of all voting rights, giving them effective control of all activities, operations and governance matters related to patient safety.

This would allow some flexibility for the owner to seek external funding for investments in pharmacy assets like 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 specifically be tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and not other class of shares 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 (apart from 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' obligations 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 shareholding value, which are driving motivations of normal businesses. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of an ownership stake to effectively exert their professional judgement.

Separation of responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

Consider including a provision in the Act for the effective control pharmacist to have a veto share on governance and operation decisions that affect patient safety. This allows for flexible ownership arrangements while strengthening the requirement for pharmacist ownership, and effective control provision.

Effective control provisions could be shared if two pharmacists have an equal ownership stake (say 26% each), that is, both are legally responsible for ensuring compliance with governance and operational obligations.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

The five pharmacy limit means that pharmacy ownership is spread across a large number of individual pharmacies, it also means that no single pharmacist owner has enough market power to set market prices or contract terms. Essentially current pharmacy ownership rules provide an important public benefit.

We believe appropriate oversight of a pharmacy is effective control – the owners need to demonstrate governance of the business (control the board). The day to day clinical oversight of the pharmacy can be delegated to the 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?:

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 "vet 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's owner's perspective the impacts could 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 were 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 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 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. The transition time needs to consider this.

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?:

We support 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 current rules and regulation

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

We are concerned that the removal of majority pharmacist ownership of a community pharmacy under option 2 will be detrimental to overall quality of care 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. It could 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.

Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. By placing the pharmacist and their professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met.

Owner pharmacists have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so they don't risk loss of registration and loss of value in the pharmacy. Owner pharmacists are accountable to the public through their registration. Non-pharmacist owners would be accountable to 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 requiring a pharmacy licence need to be conducted either by a pharmacist, or under the supervision of a pharmacist to ensure patient safety.

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 essential that prescribing and dispensing remain separate clinical activities to avoid conflicts of interest. This principle needs to be applied across the board even in the existing context with corporate entities that are now operating medical centres and the co-located pharmacies.

There is an 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 currently 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 one way to ensure that this is not an issue.

We are comfortable with the licencing authority continuing to allow for exceptions to prescriber interest in a pharmacy where it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue. This should be extended to allow pharmacist prescribers to work from a pharmacy they have a financial interest in as long as they can show benefits outweigh the risks.

We are aware that community pharmacists in some jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do 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 or need to provide any additional evidence to support the increased benefit over risk.

Overall, we partially support this Bill. However, we are being requested to provide comments to a document with very little detail on the how. We do this in a high trust context. We would expect that we would similarly be involved in the development of the regulations, rules and related instruments that will accompany this Bill.

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-G4UB-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 10:30:27**

Submitter profile

What is your name?

Name:

Leanne Hartge

What is your email address?

Email:

What is your organisation?

Organisation:

3M New Zealand Pty Ltd

Submitter Profile (tick all that apply)

Medical devices, Medicines

If you select DHB, please state service area:

If you select 'Other', please comment below;:

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).:

Agree with the purpose and principles with a risk/benefit approach to support public health and safety. Support the need to align with overseas regulators to ensure an efficient cost effective regulation that enables New Zealand to be supplied with necessary therapeutic goods.

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).:

Definitions should align with harmonised global definitions . API not AMI for active medicines ; There should also be a definition for health care professionals. For Devices legal manufacturer and/or manufacturer should be used instead of responsible manufacturer.

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):

All sponsors should maintain evidence of direct relationship with the manufacturer especially if allowing sponsors of identical products from the same manufacturer to address parallel importing issues. The licence/permit holder should be responsible for post mkt activities if importing without the sponsors consent.

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):

Customer of Veterinarian should be an animal not a patient if this is to be a part of the therapeutic bill, to align terminology . Support MTANZ position on this.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

Support NZSMI position on this for OTC medicines. For Medical Devices there should be a limit for personal use.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Customer made devices definition should align with IMDRF definitions and be included in the Bill.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

Advertising section should specify that it relates to advertising to public not Healthcare Professionals

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):

Support MTANZ position on this section for medical device regulation .For medicines we see no purpose in issuing a new number for every change. This will lead to unnecessary tasks and notifications for tenders and distributors and overload the admin requirements .- also may cause a traceability issue. Regulator Software systems would need to accommodate this . Support NZSMI position on timelines for classification and transparency

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

There should be a process for suspension of medical devices whilst an issue may require a correction and then allowed approval to resume. Cancelling and resubmitting is not a cost/time effective process for necessary therapeutic goods. ; Effect of cancellation requires further description on effect in supply chain on date of cancellation.; Clause 113-2b and c are not acceptable for medical devices may cause breach of commercially sensitive information - a public and non public registry

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):

Approval exempt products should have a clearer definition and be restricted to low volume, special populations or unique technologies/products

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119):

Support MTANZ position on this section for medical devices. Agree with removal of hawkers licence and changes to this process.

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).:

Support this section for medicines but medical devices should not be covered by licences. The approval certificate should stand as sufficient

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

Support NZSML stance on this section.

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).:

Support MTANZ position on this for devices. Support NZSML position on this for medicines

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

Section 136 - split applications needs clarification and intent behind this

Section 137 Agree with MTANZ position on this - although we should not need a licence for a medical device.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

Agree with MTANZ position on 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).:

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 MTANZ position on this in particular public safety announcements should be consulted with the sponsor before publication

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196).:

Agree with MTANZ position on this.

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):

Support MTANZ position on this section and NZSMI position. - Great clarity is needed in this section

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):

Section 212- not necessary for medical devices when they are being approved on conformity assessment certificates.- slow down approval process

The sharing of information to other regulators should align with the chosen regulators this bill supports. - agreements must be in place and sponsor informed of such sharing.

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 MTANZ position on 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):

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):

Any fines collected pursuant to enforcement activities under the bill should go to offset the costs of the regulator

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):

Support MTANZ position on this.

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):

Supports NZSMI position on this section . for medicines This section of the bill should be split to the 4 core categories of therapeutic goods. For Devices there does not need to be new product approval for changes - traceability is achieved through UDI /batch numbers

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

Support NZSMI position on this.

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.:

agree with this position

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?:

We should align with international practice.

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 global model should be adopted wherein the conformity assessment from the approved overseas regulator is adopted fully in its classification and intended use. To this end GMDN codes should not be required as serve no useful purpose and kinds of devices should be grouped according to the classification on the overseas conformity assessment. This will aid in the distinction between devices and medicines if the global classification is adhered too. Will support the cost of obtaining the product for NZ and align with global harmonisation.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Product approval for changes to devices should not require a new approval number unless the change determines it to be a new device.

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.:

Transition time of 6 months is unrealistic. suggest 3 years with stepwise submission process based on risk or need as was globally used for UDI implementation. Approval numbers should be consistent throughout the process due to tender requirements but maybe a traffic light colour scheme approach/ or certificate header to approvals could be adopted to demonstrate status in transition process.

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.:

as for C14

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?:

Chapter D: List of consultation questions

Chapter A Question

Chapter B Questions

Chapter C Questions

Response ID ANON-DPZ8-G43F-T

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 10:37:41**

Submitter profile

What is your name?

Name:

Virak Ream

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

glenfield 7 day pharmacy Ltd

Submitter Profile (tick all that apply)

Health service provider (eg, Ambulance, Māori or Pacific health provider etc), 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?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4):

No comments

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):

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):

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):

Bill covers all relevant controlled activities /supply chain activity controls

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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

no comments

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):

no comments

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

no comments

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

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:

Pharmacist prescriber should not also hold an interest in a pharmacy business

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):

comprehensively covered key areas for product approval

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

comprehensively covered key areas for product approval

Subpart 2: Approval-exempt products (ss 114–115)

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):

No comment

Subpart 3: Obligations of sponsors (ss 116–119)

Question B16

Please provide any comments on the sections covering sponsor obligations (ss 116–119):

no comment

Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

Question B17

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122):

no comment

B7 Part 5 of the Bill: Licences and permits

Subpart 1: Licences (ss 123–130)

Question B18

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):

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):

Very comprehensive and clearly defined

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):

Agreed

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):

Agreed-pharmacy business can still operate in situation where a small pharmacy sole charge pharmacist may find it difficult to get cover by pharmacist if fell ill.

B8 Part 6 of the Bill: Regulator

Subpart 1: Regulatory powers and functions(ss 160–182)

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):.

no comments

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):.

no comments

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):.

no comments

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):.

no comments

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):.

no 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):.

no comments

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):.

no comments

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):.

no comments

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):.

no 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):

no comments

Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):

no comments

B12 - B15, Schedules 1 - 4

Schedules

Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):

no comments

Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):

no comments

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

no comments

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 comments

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

no comments

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

no comments

Question C4 - Please provide any comments on the approach to post-market controls.:

no comments

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

no comments

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

no comments

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

no comments

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

no comments

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

no comments

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

no comments

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

no comments

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

no comments

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

no comments

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

If the products do not have therapeutic purpose it should be exempt from regulation

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

no comments

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

no comments

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

no comments

Question C4 - Please provide any comments on the approach to post-market controls.:

no comments

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

no comments

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

no comments

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

no comments

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

no comments

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

no comments

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

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:

Agreed with amended licence to cover hawkers

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

no comments

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

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 C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I strongly believe that 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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

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 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?:

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?:

no comments

Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

no comments

Other changes to pharmacy licensing requirements

Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

All pharmacy activities that require a pharmacy licence need to be conducted either by a pharmacist, or under the supervision of a pharmacist. I do not understand how these activities can be performed safely without the direct in person oversight by a pharmacist. We are concerned that any change in this space could lead to patient safety concerns.

Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

I do not support prescribers holding an interest in a pharmacy. In order to remove any conflict of interest it is essential that prescribing and dispensing remain separate.

There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being

generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue.

I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments. The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

no comments

Pharmacist and pharmacy worker authorisations

Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

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?:

no comments

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

no comments

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

no comments

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

no comments

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

No comments

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

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?:

No comments

Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

No, 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 I 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.:

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?:

N/A

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?:

NA

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

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?:

NA

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?:

NA

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

NA

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

NA

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

NA

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

NA

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

NA

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

NA

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

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?:

NA

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

NA

Response ID ANON-DPZ8-G419-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 11:00:19**

Submitter profile

What is your name?

Name:

Garry Calder

What is your email address?

Email:

What is your organisation?

Organisation:

Life Pharmacy Meadowbank

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Auckland

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):

I am concerned re the change in the definition of dispensing . The supply of medicine is NOT dispensing . There is no recognition of clinical checks, preparing the product to best suit the patient needs, or our key role in ADVISING the patient on the medication and how to take it properly . For some unknown reason there is a poorly informed belief that the preparation of the medication and the device can be separated . The patient needs re-inforcing on what the Dr has just told them , asap after their consult to help ensure the proper taking of the medication , why and when and what to look out for . These steps need to be at the same time . We have a lot of elderly patients with poor health understanding and need all the support they can get when they come in to us .

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):

Supply of medication between pharmacies to help a patient when there is a shortfall is a great idea . There are real issues with stock levels held in the country at times and we are often waiting " for a boat to arrive " as poor supply for essential medications (and special foods) . If neighbouring pharmacies can work together to get better patient outcomes that is a real benefit to our patients . It would also help the huge wastage we get from stock we hold and the only patient on it changes meds or passes away and we have open bottles that we can't return, that just sit and finally expire at a cost to us and a waste overall to the community.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

Question B7 - Please provide any comments on the authorisations for health practitioners :

ok in small quantities between health practioners but not to be a full scale operation

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):

Should only occur through regulated channels .

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

The use of vending machines should be only for use when patients can't access a 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):

Medicines need to be dispensed in a dispensary.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

Responsible persons is a nightmare of an idea . Just look at the UK and see the people there that are responsible people that own pharmacies . It is a joke . Driven solely by greed and profit , these responsible people put the patient at the very bottom of their concerns .

Subpart 2: Permits (ss 131–135)

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):

Short term and urgent situations is fine . The Waipu situation recently was exactly how not to do it . We must be flexible to look after patient needs in emergencies .

Subpart 3: Provisions applying to licences and permits (ss 136–151)

Question B21

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):

Three years is fine for a license . It should save compliance costs for both parties

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):.

There needs to be some independent ombudsman type system to be able to challenge decisions made by the regulator , if there are wrong decisions made .

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):.

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 . We need to ensure public safety

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

We do not need to change the current community pharmacy model . If technology can help in the future this may be ok as long as the patient- pharmacist interaction is not compromised and the dispensing and advice , there and then is not split up . We can dispense medication to best suit the patient at the time of dispensing . We can access the patient's level of understanding and work with them and their Dr's to get the best outcome with them there and then . There is a major issue with health literacy and we need to be able to act to get the best outcomes .

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

No . A combined co-ordinated approach between all practioners and better IT will get better outcomes . The pharmacy license does not create any barriers.

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Services by a pharmacist at a Fielday, concert, marae etc is ok if it can provide better health outcomes . Not full on dispensing though.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

The best service to the public is by a pharmacy that is owned by a pharmacist . Their whole career is on the line , so they ensure the best they can at all times, to their local community . This is in the public interest .

The alternative allows multinational owners who don't even care about our country let alone the local communities within our country . They are driven by profit solely . They are not there to deliver to the elderly or infirmed that can't get in to get their antibiotics , pain killers etc . They are in overseas head offices .

The supply of medicine is unlike any other normal business and needs to be treated as such . Companies that focus on keeping customers as long as they can , so they buy more products , are not focusing on pateint health outcomes . Dispensing medicines in outlets which sell cigarettes and alcohol is not in the best interest either . They are not driven by giving the best patient care , but solely financial gain . We all need to make a profit to survive but this needs to be balanced .

I have worked overseas in a non-pharmacist controlled pharmacy ownership model and it is a huge step down from the service we offer in NZ . It is an embarrassment to the profession . The patient is never given the level of support and need they require . The owners of the pharmacies do not allow the pharmacist to control the situation as it is needed , despite " regulation" over them . L ke NZ , there is never enough money to audit all what is going on and the level drops significantly once the pharmacy is owned by a non -pharmacist or supermarket etc . I came across many situations of safety risk due to the ownership model . I left the pharmacy ,unpaid in cases, as it was that bad . The community came last , the profit came first.

In my view a pharmacist having control of more than one pharmacy should be made to show they can control the other pharmacy , when they are not there, before being allowed to open another store . Five would be the absolute maximum and would suggest that controlling five would be a huge challenge ,

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 community needs to be protected and huge multinationals driven by shareholder pressures don't care about them . It is socially responsible to have a local pharmacist look after his/her community . An employee in a big chain is never going to care as much as a directly accountable local . The community is looked after by the local pharmacist as it is their obligation , so they go way beyond what is expected of them and at their own expense , as that is what is needed . I am constantly in people 's homes looking after not only their medication needs but all health needs and often even companionship as they sometimes don't have family support or the family are too busy . Social services may call on them once a year , if at all . These people of need are going to be ignored if an open ownership model is allowed . The current overseas pharmacy owners need to be controlled by the current law - just needs enforcing - until the new bill becomes law . They will offer low prices but at what cost to these people in our community . It will put pressure on other health services to try and fill the void . Controlling pharmacy centrally does not work . We rarely get audited and then the follow up can be years later . The respons bilty of the ethics in the pharmacy needs to be by the pharmacy owner . There is no way a central organisation that is always under funded is iver going to control the pharmacy industry .

The third tier of "responsible persons " owning pharmacies is worse than the supermarkets . Their ethics are next to nil . Patient safety becomes an issue as they don't even care about the minimum standards . I worked in a pharmacy that had no fridge,scales,reference books etc . They turned up one day . We were audited and then they went again the next day .

The level of pharmacy in our communities currently is excellent . Any change to the ownership will reduce this and end up costing the government more in the long term as services provided currently will drop off in cost cutting . Access to medicines will decline .

Question C25 - Are there ways in which Option 1 could be improved?:

Pharmacist owners should be shown to prove their dividends match the shareholding of the company , when not 100% owned by a pharmacist/s .

Declarations that Dr's don't have an interest in the pharmacy , should state Dr's or family members of the Dr . The shareholding dividend lines above should help reduce this current issue .

Ownerships of family trusts or other trusts that own share in a pharmacy should be disclosed . Again the tracking of where the dividend goes should be traced . Control must be by the pharmacist 51% owner .

Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

All what a community pharmacy does , that needs a license.

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 - can't 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)?:

Possibly - needs more defining

Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

possibly

Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

Will need time to sort out the incorrectly owned models currently .

Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

A few years

Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

Yes . they should change too

Detailed questions relating to Option 2

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Once you lose control you can't get it back . Look at the UK , a disaster .

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?:

Can't work safely .

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?:

Via skype etc it could work . Would need to have good systems in place

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?:

Independence is essential . I do not support this idea . Prescribing could be based on income/profit vs patient need . Add additional costs onto ur already stretched Health spend.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Civil emergencies and things like fire in the pharmacy.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

Must be licensed and under the direct control of a normal 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?:

Yes

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 if it helps with time saving for busy periods . Helps improve customer service . Needs to be managed correctly .

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Yes , especially when there are high cost medicines that could go to waste otherwise . Between licensed pharmacies .

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 approve the suggested changes . Most patients have no knowledge that they are using unapproved meds at the moment .

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?:

Ok for Doctors still to do this.

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 C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

In emergencies yes

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 .

We need an independent step in this process for patient safety . We see so many errors every day , so if the prescriber doesn't see them , imagine if they dispensed medicines as well . A huge risk . No chance for an independent second opinion on the medication prescribed and its suitability for the patient . We see some nightmares in current prescribing and we are needed as a safety net.

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

No . The Dr's are in closed rooms so have no way they can see what is happening elsewhere in the practice. They are not trained for this . Simply a high risk situation that needs to be avoided .

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 - it drives people into pharmacies and Drs expecting to get medication that is totally unsuitable for them . They only get parts of the message . Companies with big budgets having effect when not necessarily the best alternative.

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?:

No . The wrong people get the wrong message . The patients start telling Drs what they need vs vice versa . This should be stopped .

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 the proposal .Currently many patients unaware of the situation

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?:

Fod Drs yes

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)?:

In emergencies

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4UD-T

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 11:06:08**

Submitter profile

What is your name?

Name:

Michael Thalari

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Botany Junction Pharmacy

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

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):

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 prescribed medicines, particularly in the case of medicines that are uncommon. This allowance could also help with medicine wastage issues and result in pharmaceutical budget savings.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

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:

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):

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 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. Mobile vehicles also create opportunities for medicines theft as vehicles can be stolen and with it all high risk medicines.

Question C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I strongly believe that 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 likely reduce such services as there is no funding to incentivise owners to provide them. There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share

would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

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 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?:

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 prescribing and dispensing remain separate. There is a clear incentive for a medical practitioner who has a direct financial interest in a pharmacy to align their prescribing practices to generate more profit from the pharmacy. Pharmacy revenue is directly linked to the level of dispensing that occurs, an increased volume of dispensing will lead to more income being generated in a pharmacy. The separation of ownership requirements is essential to ensure that this is not an issue. I am comfortable that the licencing authority continue to allow for exceptions to prescriber interest in a pharmacy when it can be clearly demonstrated that the benefits outweigh the risks, and any conflict of interest will not be an issue.

I am aware that community pharmacists in some overseas jurisdictions (such as Alberta, Canada) have limited rights to prescribe for certain conditions, such as minor ailments.

The ability for pharmacists to do a small amount of low-level prescribing to ease the pressure on general practice and other health services should not lead to these pharmacists being considered prescribers, and therefore be prevented from owning pharmacies under this requirement.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

Permits would be useful for urgent situations, such as civil emergencies and unexpected events. Following earthquakes or a more isolated events, such as a pharmacy burning down, permits would allow pharmacies to get back up and running quickly in temporary premises, ensuring access to pharmacy services for the community.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

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?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4F6-W

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 11:12:22**

Submitter profile

What is your name?

Name:

Jeremy Armes

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Countdown / Countdown Pharmacy

Submitter Profile (tick all that apply)

Consumer

Retailer (non-pharmacy)

Medicines

Health service provider (eg, Ambulance, Māori or Pacific health provider etc)

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):

We support the approved product, approval-exempt and unapproved product approach to product classifications.

We support regulation that would see any product that makes a clinical claim automatically included within one of these categorisations, with those who are importing, distributing or selling an unapproved product liable to prosecution by the regulator.

We would support the concept of "retail licenses" being redefined to allow for reputable premises to sell specified category 3 medicines when there are no licensed Pharmacy premises open for trade within a specified distance. An example of a store that carries a retail license currently is the SuperValue supermarket

in Pauanui.

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):

Given New Zealand's small size, we believe there is merit in allowing for products that have been approved for sale in other similarly regulated jurisdictions to be sold in New Zealand - following due diligence from the regulator? .

It is our view, that from a consumer perspective, Kiwis would like access to appropriate "parallel imported" products if they were sourced from trusted and well regulated markets such as the United Kingdom or Australia. The reality is that often New Zealanders are buying such products online already.

There are many examples of medicinal products on retail sale in other jurisdictions at prices that are cheaper than we can purchase them wholesale in New Zealand. We would like to have the ability to source such products and import them into New Zealand to enable us to offer them at lower retail prices to our customers. We note that this could only happen with all MPI requirements, other related legislation and regulation and all customer protection needs being met.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

We would support legislation that made it possible for pharmacies to buy, sell or lend medicines to each other on a small scale, within prescribed limits and parameters. We suggest that the legislation allows this to occur up to specified \$ value per annum and / or % of dispensary turnover. This would allow Pharmacies to borrow or lend prescription items to each other to support patient care and avoid having a patient visit multiple Pharmacies to complete their prescription, or make a return visit to collect an owing item.

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 :

We would support health practitioners being permitted to supply category 3 (pharmacy) medicines to their patients, in addition to administering, for short term use. This would mirror a patient being given a short term dose of medicines when being discharged from hospital in the expectation that they will secure further supplies from their GP and Pharmacist.

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:

We do not support direct to consumer advertising of prescription medicines. We believe the ability to do so presents a potential conflict of interest between the patient and prescriber.

We do support the status quo whereby direct to consumer advertising is allowed for over the counter medicines.

We would be supportive of natural health products being advertised with an amendment to better protect customers. These products currently sit under legislation that applies to food products with little recourse for manufacturers who don't comply with the legislation. We would like to see these come under the Therapeutic Products Bill for action if a product makes clinical claims and starts to masquerade as a medicine.

In our own business, there have been a number of natural health products that we have chosen not to range over the years because we have determined that the supplier can't substantiate claims (as to their product) in New Zealand. Some of these products have been strong sellers in pharmacies elsewhere. Countdown would like to see higher standards consistently enforced via regulation.

We do not support health practitioner prescribers having an interest in pharmacies, nor do we support those with an interest in pharmacies having an interest in GP Practices. Both scenarios do not sit comfortably with professional ethics or (potentially) patient choice

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):.

We agree that it should be an offence for a licensee or manager to induce a health professional to act unprofessionally.

Question B19

Please provide any comments on the criteria for: **granting a licence; licensees; and responsible persons (ss 128–130):.**

We are proud to have brought increased access to, and competitive prices for, pharmacy products and services, to many communities across New Zealand. Countdown Pharmacies now dispense in excess of one million prescription items a year, with our customers benefiting from reduced co-payments at every site.

We feel that more restrictive regulatory settings in relation to the ownership of pharmacies is not in the best interest of the New Zealand public. When the “one pharmacist, one pharmacy” ownership rules were in place it resulted in a lack of competition in the pharmacy market, which ultimately led to higher prices for customers.

The current regulatory settings have allowed for the development of business models which takes advantage of the benefits of economies of scale, with lower prices for customers, without compromising patient safety or the quality of pharmacy services.

There has been some suggestion that the current ownership requirements are necessary to address a risk that commercial interests might override professional judgment. We do not accept that this is a risk that naturally follows from, or is inherent in, more permissive ownership requirements. A pharmacy is a business, and there will be commercial incentives for any pharmacist who owns a pharmacy business - regardless of the ownership model.

In our view, good governance and monitoring systems, coupled with a requirement that pharmacies be operated under the day to day supervision of a registered pharmacist, are sufficient to ensure professional judgment is not compromised.

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):

We support licences no longer being limited to one year where the licensee is capable of demonstrating to the regulator a track record of compliance with licensing requirements.

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):

We would like to see a continued pragmatic approach by the regulator to the requirement for a pharmacist to be present for a Pharmacy to be open. There may be legitimate situations where a Pharmacist very briefly needs to leave the registered premises (e.g. to go to the bathroom) under the security of qualified staff.

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):

With regards to advertising remediation orders we would like to see the regulator having powers to prosecute and fine offenders rather than simply to request a retraction or correction.

In our view, the current consequences of knowingly misleading the public with regard to efficacy or suitability do not reflect the seriousness of the offence. Further, stronger consequences are needed for any product that makes a therapeutic claim, regardless of whether that product is registered as a medicine or not. We also respectfully submit that the regulator might consider a proactive approach in this area, rather than a reactive approach where action is only taken if there is a complaint registered.

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):

We are in favour of civil pecuniary penalties being a regulatory option, particularly where there have been financial gains through a more serious breach of the Act.

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):.

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):.

We are supportive of the classification of medicines proposed. With a similar regulatory approach to the TGA in Australia, and many consumer medicines' packaging "harmonised" (enabling the same packaged product to be sold in both the New Zealand and Australian market), there may be some merit in aligning the nomenclature between the two jurisdictions.

Our view is that it may make more sense in New Zealand to have Schedule 1 (general-sale), Schedule 2 (Pharmacy), Schedule 3 (Pharmacist) and Schedule 4 (Prescription) as the categorisation of medicines to avoid potential confusion in both markets.

In the event that a medicine or active ingredient is reclassified, assuming there are no immediate safety concerns, we would like to see a reasonable notice period given to manufacturers and retailers to enable efficient stock management and communication to customers. An example of this is the recent reclassification of dextromethorphan where we would ideally have liked between six and twelve month notification of the change.

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:.

We support the regulator being required to actively monitor the safety of approved medicines.

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:.

We support "hawking" activity being part of wholesaling license activity when required.

C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

We agree with the proposal to curtail the importation of prescription medicines by post and courier.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:.

We support "hawking" activity being part of wholesaling license activity when required.

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?:

As stated above in B2, we would welcome an alternative approach to "retail-only licences". The regulations at present do not take into account the often limited opening hours of Pharmacies in some neighbourhoods, and the effect that this can have on medicines availability. We propose that limited hours retail only

licenses are made available to retailers in more rural settings so that they may offer a limited range of Pharmacy only medicines when local Pharmacies are closed. The practicality of this proposal may be that a non-Pharmacy retailer can offer Pharmacy medicines for sale only on weekday evenings and at specific times over the weekend to meet the needs of New Zealanders.

As an example, the SuperValue supermarket in Pauanui has such a retail only license, providing a small selection of approved Pharmacy only medicines to their community. The reality for other rural towns is that if the local Pharmacy closes in the evenings or weekends then patients may face a significant to purchase a high needs item such as Pamol or Nurofen for Children.

Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

As stated earlier, we do not support Option 1 as outlined in the Consultation Document. We do not believe that tighter controls over Pharmacy ownership will necessarily improve either standards or patient services. We respectfully invite the Ministry to review recent Medsafe ILA, pre-arranged and unannounced audit data for Countdown Pharmacies and compare these to the average for the Pharmacy sector as a metric for evaluating the professional standards that an organised group can consistently achieve. In multiple audits over the last 12 months, Countdown Pharmacy has achieved a higher percentage of full achievement of audit criteria than the national average, with no critical or high risk issues identified.

Option 1 appears to be designed to protect the interests of existing pharmacy owners in the face of increased competition. Our view is that competition has been very good for New Zealanders in that it has delivered both lower prices and significantly better access to pharmacy products and services across the country.

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?:

We would support a Pharmacist being allowed to provide clinical advice remotely using appropriate technology. For example, this would be appropriate in situations where the patient is unable to visit the dispensing site.

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 stated, we do not support this form of vertical integration in the interests of patients being free to choose when and where they have their prescription dispensed, without undue influence being applied either consciously or subconsciously.

While the vast majority of healthcare professionals will always have their patients best interests at heart, restrictions would remove temptation to benefit

commercially by influencing a patient's choice. For these reasons we are against both Prescribers having a financial interest in Pharmacy and Pharmacies having a financial interest in Prescribers.

Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

We are supportive of permits being used to authorise activities on a short term basis as descr bed.

Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

As stated, we would advocate for an alternative approach to "retail-only licences" being adopted. The regulations at present do not take into account the often limited opening hours of Pharmacies in some neighbourhoods and the effect that this can have on medicines availability. We propose that limited hours retail only licenses are made available to retailers in more rural settings so that they may offer a limited range of Pharmacy only medicines when local Pharmacies are closed. The practicality of this proposal would be that a non-Pharmacy retailer can offer Pharmacy medicines for sale only on weekday evenings and at specific times over the weekend.

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?:

We strongly support changing the definition of prescription to allow increased electronic prescr bing. With an ever growing number of GPs engaging in NZePS it is a logical next step to no longer require a physical signed original prescription at the point of dispensing.

We are supportive of Pharmacies being able to batch compound regularly dispensed items in anticipation of future prescriptions. This will lead to operational efficiencies and I kely reduced waiting times for patients.

Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

We support legislative change that makes it possible for Pharmacies to buy and sell or lend medicines to each other on a small scale. We suggest that the legislation allows this to occur up to specified \$ value per annum and / or % of dispensary turnover.

C7 Retail sector

Question C42

Do you consider the new scheme will have any significant impacts on retailers?:

We do not anticipate that the new scheme will have any significant impact for retailers of General Sale 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?:

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.:

As per our comments in B12, we consider it inappropriate for direct to consumer advertising of prescription medicines to continue due to the potential to create conflict between the patient and prescriber.

We do support direct to consumer advertising for over the counter medicines. The status quo works well and informs customers of their choices.

We also support natural health products being advertised, with an amendment. These products currently sit under legislation that applies to food products with little recourse for manufacturers who don't play by the rules. We would like to see these come under the Therapeutic Products bill for action if a product makes clinical claims and starts to masquerade as a medicine.

In the natural health space we have not ranged a number of products over the years that can't substantiate in NZ the claims they are making on packet, or through advertising. Some of these have been strong sellers in Pharmacies elsewhere. It would like to see a level playing field through enforced regulation.

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-G46F-W

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 11:28:53**

Submitter profile

What is your name?

Name:

Commercial Eyes Pty Ltd

What is your email address?

Email:

What is your organisation?

Organisation:

Commercial Eyes Pty Ltd

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;:

Consultant

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):

We agree with the purpose and principles outlined in ss3 and ss4.

We are supportive of regulation that protects personal and community health, is risk based, supports the timely availability of therapeutic products, is carried out in an open and transparent manner, and that aligns with international standards and obligations and enables co-operation with overseas regulators.

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):

ss 47 and ss 48

The definition for a 'fit and proper person' is broad. It includes person A as well as any person who has been the senior manager of person A or of whom person A is or has been a senior manager. This broad definition does not take into account a specific period in time that the person was in the role. It also does not differentiate if person A is a company or an individual within a company. The broad definition could mean that a large number of employees or organisations could be subject to the 'fit and proper person' assessment. We suggest that this definition be further clarified.

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 agree with the requirements outlined in this section.

ss52 sponsor's consent required to import approved product

We agree with the requirements outlined in this section as this will prohibit parallel importation.

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

We agree with the requirement to have a form of authorisation for the controlled activities.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

No further comments on these sections.

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

No further comments on these sections.

Question B7 - Please provide any comments on the authorisations for health practitioners :

No further comments on these sections.

Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

No further comments on these sections.

Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):

No further comments on these sections.

Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):

We agree with the approach for personal importation of medicines or medical devices. It is noted that there are no provisions for importing a type-4 therapeutic product. It is suggested that provisions for type-4 therapeutic products be included for completeness.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

ss 75 Manufacture of custom-made devices

We support the requirements for custom-made devices. We suggest that the requirements of overseas regulators be taken into consideration in the regulations.

ss78 Authorisation for unapproved product stock in supply chain

We support the requirements outlined in this section and the 'use of current stock' notice.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

No further comments on these sections.

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):

ss 94 - ss 99

We support the requirements outlined in these sections.

ss 100 – Major changes results in new product

We understand the need to be able to identify when major changes have occurred to products. This approach however may not be practical for sponsors if existing products are issued a new TT50 number as there may be product funding implications and additional administrative burden. It is suggested that the sponsor be given the option to retain the existing TT50 number or to move to a new TT50 depending on the specific situation for the product.

ss 101 Sponsor must notify regulator of certain minor changes

We support the requirements outlined for minor changes and suggest a risk based approach for minor changes in line with the requirements in other countries such as Australia, Europe and the US. We anticipate further details regarding these change categories will be included in the regulations.

ss 102 Change of sponsor

We acknowledge that a new sponsor will need to meet the 'fit and proper person' requirements outlined in the TPB. A change in sponsor is often a commercial decision and is notified to the regulator in other jurisdictions. The timing of the 'fit and proper person' assessment by the regulator, the regulator approval time frames and the impact on commercial agreements will need to be taken into consideration as agreements between sponsors are typically finalised prior to submission of the regulatory documentation. If the requirement to undertake a 'fit and proper person' assessment is maintained, further details regarding the timing of this assessment and the regulator timelines will be required.

ss 103 Duration of approval

We agree with product approvals not having an expiry date unless considered necessary. This approach is consistent with the approach in Australia.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

ss 105 - 107, ss 109 - 112

We support the requirements outlined in these sections.

ss 108 Grounds to cancel approval

We support the grounds to cancel an approval. The TPB indicates that a product approval may be cancelled if protected active ingredient information was used when determining whether to grant the approval. In situations where the regulator has been advised to refer to protected active ingredient information, we suggest that this matter be addressed prior to granting approval to avoid confusion in the market if a product was to be supplied and then cancelled.

ss 113 Therapeutic Products Register

We support the proposed therapeutic products register however we propose that there is further clarification around withdrawn or rejected applications, and the circumstances in which these would be publicly available.

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):

ss 114 - 115

Further clarification is required on who will be the sponsor for approval-exempt products. For example, for a custom made device, would there be an expectation for the clinician or the manufacturer to be the sponsor? It is possible that there may be situations where there is no party available fit to be a sponsor or willing to accept sponsor responsibilities.

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

We agree that the sponsor should be responsible for all aspects of the product however we suggest that this be clarified to apply to all aspects that are within the sponsor's control. Once a product is at the end stages of the supply chain, the sponsor may not be in direct control of the product and as such will be reliant on agreements with third parties such as wholesalers and distributors.

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 further comments on these sections.

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 further comments on these sections.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

No further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

No further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

Subpart 2: Investigative powers (ss 183–196)

Question B25

Please provide any comments on the regulator's investigative powers (ss 183-196):

No further comments on these sections.

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 further comments on these sections.

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):

ss 200 – 204 – Subpart 4 – Review of Regulator's decision

We are supportive of the provisions to request a review of the regulator's decision, for an independent review panel to be convened, and for the option to make an appeal to the District Court. We suggest that the timeframe for the applicant to make an application for the decision to be reviewed be extended or that this is an option to apply for the extension. This will enable the applicant more time to consult with internal stakeholders and provide a higher quality response. We also suggest that timeframes for the independent review be specified to ensure the process is transparent.

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):

ss 207 Regulator may rely on recognised authorities

We support the use of recognised authorities to increase the efficiency of regulatory processes.

ss 209 Sharing of information with regulatory agencies

We support sharing of information with regulatory agencies to increase the efficiency of regulatory processes. We anticipate that sharing of information will result in shorter evaluation timeframes and reduced fees.

ss 210 Power of the regulator to act on requests from overseas regulators

We support the provisions in this sections.

ss 211 - 222

We are supportive of these sections. We note that the TPB does not provide details on evaluation timeframes and application categories. We anticipate that further details will be provided in the regulations and rules. We anticipate that the regulatory timeframes will be transparent and that the regulator will be held accountable for meeting timeframes. We also anticipate the opportunity to comment on the

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 further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

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 further comments on these sections.

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

Schedule 2 outlines who may apply for a review and there are some decisions where only the sponsor (not the applicant) will have the ability to request a review, including terms of approval, refusal to vary approval of application, variation of approval and cancellation of approval. It is unclear why there is a distinction between an applicant and the sponsor and how this will impact agents such as consultants working on behalf of the sponsor.

Question B36 - Please provide any comments on the use of regulations, rules or regulator’s notices for particular matters (Schedule 3):

No further comments on this section.

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 further comments on this section.

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):

Refer to response B13. Use of “major” and “minor” change categories including notifications and “consolidated” updates will allow greater flexibility in supply of product, especially in case where there are shared packs with other markets.

ss 100 – Major changes results in new product

We understand the need to be able to identify when major changes have occurred to products. This approach however may not be practical for sponsors if existing products are issued a new TT50 number as there may be product funding implications and additional administrative burden. It is suggested that the sponsor be given the option to retain the existing TT50 number or to move to a new TT50 depending on the specific situation for the product.

ss 101 Sponsor must notify regulator of certain minor changes

We support the requirements outlined for minor changes and suggest a risk based approach for minor changes in line with the requirements in other countries such as Australia, Europe and the US.

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

We support the approach for medicines categorisation however it is currently unclear how controlled drugs will be regulated and the link between the TPB and the Misuse of Drugs Act 1975. In Australia, controlled drugs are classified separately to prescription medicines and have additional controls and requirements.

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:

We are supportive of having transition arrangements to allow sponsors and applicants an opportunity to take the necessary steps in accordance with the new requirements. We note that the transitional timelines are short, especially for medical devices and cell and tissue therapies, which will lead to an increased workload for the regulator. The impact of this increased workload may result in longer evaluation timeframes or delays by the regulator across all of the different activities. Resourcing during the transition period will need to take into account the increased workload and the impact on industry.

Question C4 - Please provide any comments on the approach to post-market controls.:

Refer to B14.

We are supportive of the changes proposed relating to pharmacovigilance requirements.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

We agree with the requirements to have the suitability of manufacturers continue to be assessed during the product approval process and that sponsors would be expected to supply ongoing evidence that approved manufacturing sites continued to meet GMP requirements. We suggest that there be recognition of overseas GMP evidence.

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:

No further comments.

C2 Cell and tissue sector

Product-based controls

Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:

We support the adoption of the European approach to regulating cells and tissues.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

Refer to previous response for C1.

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

No further comments.

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Refer to previous response for C4,

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

Refer to previous response for C9.

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Refer to previous response for C5.

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

No further comments.

C3 Medical device sector

Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

We agree that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated as the risks are the same. These types of products are regulated as devices in some countries due to the risk to consumers. The potential issue will be that products that are not regulated as devices in overseas markets will not have the medical device evidence required. This may result in the products not being distributed to the New Zealand market.

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?:

We have not identified any aspects of the global model for medical devices that we consider inappropriate for New Zealand.

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):

No further comments.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

No further comments.

Question C4 - Please provide any comments on the approach to post-market controls.:

Please refer to previous response for C4.

We are supportive of the changes proposed relating to product vigilance requirements.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Without the rules and regulations that result from the TPB, it is unclear how much work will be required to have a medical device approved. If the application is a form with the EC certificate as evidence the proposed timeframes should be acceptable. If there are greater evidence and submission requirements the transition period may not be achievable. The issue of resourcing by the regulator to address the increased workload will also need to be considered.

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

No further comments.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

The issue of resourcing by the regulator to address the increased workload will need to be considered as this may lead to delays and a backlog of work.

C4 Clinical trial sector

Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

No further comments on these sections.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

No further comments on these sections.

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.:

No further comments.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

We are supportive of direct-to-consumer advertising of prescription medicines. The availability of accurate and factual information is helpful to consumers and enables them to have a more informed discussion with their treatment provider.

Response ID ANON-DPZ8-G4CW-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 11:30:54**

Submitter profile

What is your name?

Name:

Samarina Musaad, Geoff Herd, Melanie Adriaansen, Nicky Beamish (Members of the Northern Region Point of Care Testing Group)

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Labplus, ADHB, WDHB

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Consultant Chemical pathologist, Point Of Care Co-ordinators

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).:

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):.

Re point 83: This is excellent. Who decides/defines a risk associated with a particular device?

Relevance of the question: A device that is deemed risky or not overseas may not be so in New Zealand. Risk is associated with how and why the device (test) is used which is not always consistent between patients or regions. It is important to consider overseas information of course but local expert advice should be sought to confirm or refute.

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):.

It is very important that medical testing devices are validated by International Accreditation New Zealand (IANZ) accredited laboratories. These accredited medical laboratories must have experience in the validation of medical testing devices prior to approval and any funding decisions. For example, the types of medical testing devices which are commonly used by the public and in the community are urine pregnancy test kits and glucose meters.

The New Zealand Point-of-Care Testing (POCT) Advisory Group provides advice and expertise on the validation of POCT devices for both hospital and community use.

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).:

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, because it is the concept of safety that is paramount rather than where the products strictly fits. Examples would include contact lenses.

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?:

Not in principle but by nature of healthcare and diversity in populations and accordingly practices, there would most definitely be the occasional instance when aspects should be modified for New Zealand.

Not all overseas regulators are reliable e.g. FDA is practices on "bear minimum" basis (as attested by practitioners in the US) so a device/test that confirm with the FDA still needs rigorous evaluations.

There should be leeway to allow for local evaluations because of the difference in populations and needs. While a lot of overseas evidence is good and it is silly to re-invent the wheel we have to ensure that our needs and local clinical pathways are tailored for.

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?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

Question C23 - Why do you support that option?:

Pharmacies and pharmacists sell point of care devices. Accordingly there should be a system that ensures that they are proficient at testing, using the device and all aspects of quality control and that they take full responsibility to educate the user when they sell it to the user. Ideally, a written contract between the pharmacists and user would clarify roles and ensure shared responsibility between the user and the pharmacist.

Pharmacist can be taught about using the device by manufacturers of the device BUT their competency should be assessed by a third party that does not have any vested interest. Laboratories in New Zealand have competency schemes for point of care users, many of which are electronic, and would be very suitable for such a purpose. This would also standardize the use of the device throughout the country.

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?:

Too much commercialization. However, if regulatory standards in New Zealand are adequate and well enforced with continuous auditing, this risk can be mitigated.

It would allow better competition and openness to the global market.

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.:

These issues were raised at the consultation meeting on March 19th in Auckland:

1- Adverse event monitoring is critical and is a commendable improvement.

Regulations should allow for withdrawal of the product, without fiscal, or otherwise, penalty to the consumer. This particularly relates to contracts undertaken by PHARMAC with sponsors.

2- Another matter that has concerned many users of devices is the perceived lack of communication between the regulator (Medsafe) and the funder (PHARMAC). PHARMAC should fund a device or test that has not been fully approved by Medsafe because Medsafe is the authority with the responsibility for safety of the device.

3- The WAND database in our view should be fully and totally transparent. This will foster trust towards the regulatory system and trust and accountability towards manufacturers and vendors.

4- With regard to medical testing devices and in particular, point of care testing (POCT) devices, the WAND database should also clearly show which devices have validated for use by IANZ accredited laboratories with expertise in the validation of POCT devices. In other words, the WAND database may list a range of POCT devices from different manufacturers which have been registered on the database. However, this list must clearly distinguish those POCT devices which have been validated for use from those which have not been validated or found unsuitable for clinical use.

Response ID ANON-DPZ8-G4UU-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 11:32:30**

Submitter profile

What is your name?

Name:

Selwan Farhan

What is your email address?

Email:

What is your organisation?

Organisation:

Clendon Pharmacy

Submitter Profile (tick all that apply)

Pharmacy organisation

If you select DHB, please state service area:

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially don't support

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

I find this part to be very confusing and vague. Under the new Bill it defines dispensing as the supply of the medicine, just like a supermarket where you take a box and give it to the customer without any checking, counselling, education or assessment. The aim of dispensing is not just to give a box of medicine but to ensure you provide the medicine along with providing a complete health service.

On many occasions it is the checks and counselling that we do is what improves patient health outcome and prevent harm. Liaising with doctors regarding medication changes or reporting side effects to improve safety and outcomes and to prevent major harm.

The new Bill makes dispensing sound like grab a box and give it to the patient.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):

We need clearer definitions and specific outline of what constitutes a DISPENSING??

The current services which fall under the umbrella of dispensing in terms of

- Checking, Assessment of interactions and side effects, Adherence, missing medications, checking with doctors and updating details as well as follow up!!
- Delivery of medicine, advice, counselling and education??

What covers all the above services and how will they be assessed and by what body????

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52):

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

I am very supportive of the idea of allowing supply of products between pharmacies if requested by a patient. This move can save patient time and reduce wastage both to the pharmacy and to the Ministry.

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 think its a good idea. It will cover supply of medications to practitioners when needed in times of emergency when there is no pharmacy accessible. The legislation must define the circumstances that allow such supply and quantities or periods of supply allowed.

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 need to have better control on importation of counterfeit and substandard medications and devices. I totally support that the importation of a medicine is managed by a health practitioner, pharmacist or wholesaler.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Vending machines should only be available in places where there is no access to a pharmacy and must be connected to an existing pharmacy. There should be clear specifications of these machines and how to prevent items being taken forcefully and taking medications unlawfully.

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):

Most of these aged care facilities are not well managed or maintained and to add medicine dispensing to this kind of environment will lead to major problems and increased risks and incidents.

Unless a complete pharmacy with the appropriate staffing, supply chain, equipment and resources and audits are available then this is a very concerning and dangerous proposal.

Staff at some of these sights change all the time and follow up is a major issue.

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 permits for short term and urgent situations.

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 very supportive of this point. would be good to increase the license period to reduce costs and efforts on both parties.

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?:

very supportive of this move to reduce risk to the public and maintain patient safety.

Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

C6 Pharmacy (and retail-only licence) sector and pharmacists

Pharmacy sector context

Future regulation of pharmacy business activities

Licence to carry out a pharmacy business

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

The legislation must acknowledge that pharmacy is not a retail shop and that the process of dispensing a medicines, counselling, effective use, checking with prescribers and ordering medications must be maintained at a face to face level between health professional and patient or caregiver. opportunities and future models that improve patient outcomes are great as long as they do not destroy or undermine patient safety and the integrity of community pharmacy which has always proven its reliability and efficacy over the 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 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 C22 Which option do you support?

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

Question C23 - Why do you support that option?:

I strongly believe that 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 likely reduce such services as there is no funding to incentivise owners to provide them.

There may be community pharmacy businesses operating legitimately under the Medicines Act that might not be legitimate under the proposed Option 1. There is a risk these pharmacies would be financially impacted, 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 flexibility for an owner to seek external funding for investments in pharmacy assets such as robots while retaining effective control of all pharmacy governance and operational matters. It would also enable young pharmacists to gain a foothold in pharmacy ownership through flexible financing while retaining effective control requirements.

In implementing a veto share provision, the Bill should consider the scope of governance and operations the veto would apply to, and the preferential rights that the veto share would enable the owner pharmacist. This should be specifically tied to the primary goal of ensuring public safety. The transfer of a veto share should only be possible to another pharmacist, and no other class of share should be able to 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 responsibilities must consider who would be ultimately accountable for decisions that relate to the wider operating policies that have an impact on the public.

I suggest that the Act include a provision for the effective control pharmacist to have a 'veto share' on governance and operations 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 responsible for ensuring compliance with governance and operational obligations.

Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

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 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?:

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 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?:

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.

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 prescribers typically only prescribe a very narrow scope of medicines, if an unapproved medicine was required, they would already be expected to consult with a medical practitioner.

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

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.

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

I do not support the personal import of medicines. I believe that medicines imported into the country should not be supplied without the oversight of a pharmacist, medical practitioner or wholesaler. This is to ensure the safety and quality of a medicine, and to ensure the appropriate advice and care is provided with the medicine.

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Packaging and labelling and consumer medicine information

Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

Response ID ANON-DPZ8-G4UM-3

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
Submitted on **2019-04-18 11:37:56**

Submitter profile

What is your name?

Name:

Dr Michael Tatley

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

New Zealand Pharmacovigilance Centre, University of Otago

Submitter Profile (tick all that apply)

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:

Medical practitioner (excluding Surgeons)

If you select 'Other', please comment below;:

Public Health Physician

Other (please comment)

If you selected 'Other' please comment;:

New Zealand Pharmacovigilance Centre

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):

Therapeutic products/therapeutic purpose

S15(1)(a) defines therapeutic purposes to include 'defect'. This then supports the further definition of a therapeutic product in S16(1)(a).

It is not clear whether this act would extend as far as including cosmetics. Cosmetics are intended to alter the visual appearance of a part of a person who either has a defect, or perceives that their appearance is defective in some way. It would seem ludicrous that the/act would make provision to potentially regulate cosmetics. This should be clarified or some provision somewhere included to exclude this category of products

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:

We fully support the wording in the Bill in regard to monitoring. The further elaboration in the consultation document (points 274 – 277) which is presumed to refer

to the content and direction of the rules and regulations also fully supported.

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?:

The products that come to mind that are not classic instrument-type devices include practice management software, drug information databases, patient safety alert systems (within practice management software systems and independently) and diverse apps (smart phone or desktop) that provide health related safety support information and guidance.

There is value in having some form of regulation in regard to such products. However, it may not be possible to specify precise requirements, but it may be possible to specify that they conform to some form of code of practice fundamental to which is the patient safety is not compromised. Would it be possible to develop a code and implement it in such a way that deviations from its provisions could be policed and transgressions dealt with in a manner that either results in improvements that are satisfactory, or removal of the product from widespread use.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C10 Advertising sector

Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

There is no place for Direct to Consumer Advertising in New Zealand. This is a ridiculous system that allows pharmaceutical manufacturers to influence patients who are not in position to adequately consider the relevance of the claims made in their unique or any clinical circumstances. The presentations are delivered in a flashy manner addressing the marketing and action points the company wants to promote. Although the efforts usually include throwaway statements about discussing the decision with their doctor, the choice of product brand (which is usually what the promotional advert is about) is typically outside the control of the prescriber as the funded brand is usually the one that is in use unless the patient is prepared to pay the additional surcharge. This is a cost to the patient that they might be drawn into paying because of the emotional appeal of the advertisement that the promoted product will lead to the best health outcome for them. It is appalling that to address the issue of 'balance', the advertising pitch in audio-visual media runs through the negative features and safety issues at a speed that is barely intelligible.

There is clear evidence from New Zealand that pharmaceutical companies cannot be relied upon to provide balanced information and advertisements. Two recent publications in the New Zealand Medical Journal (one an editorial) [1,2] have provided evidence that in

Advertisements targeting Health Professionals:

'... a high proportion of pharmaceutical advertisements failed to meet the New Zealand regulatory requirements that claims 'valid and have been substantiated'. About a third of claims had no references, only 35% of claims cited at least one RCT, and a very small proportion of those claims were supported by an RCT with low risk of bias.' Whilst in,

Advertisements targeting the general public and patients:

Advertisements to these groups often make claims with terminology such as 'clinically or scientifically proven' with many mistakenly trusting that someone is vetting the information with the patients' interests in mind. The scientifically unwary public are more vulnerable than clinicians to the beguiling effects of partial, exaggerated, misleading and often emotionally charged 'information'.

In short, these findings support the potentially misleading qualities of Direct to Consumer Advertising in New Zealand, it has no value and potentially increase the risk to consumers especially when the products are new to the market and have limited post-approval safety data

There may be a place for a variation of advertising to consumers (which may be a form of Direct to Consumer Advertising). This scenario should include a health practitioner/pharmacy setting where availability or the desirability of health products can be promoted or advised. Examples of this are those for influenza vaccination, emergency contraception availability, or sildenafil, etc. These direct to consumer advertisements should be related to the active component (influenza vaccine, sildenafil et cetera) in a health setting where there is an immediate and direct opportunity to discuss the suitability with a healthcare professional.

1. Ma A, Parkin L. Randomised controlled trials cited in pharmaceutical advertisements targeting professionals: do they support the advertising claims and what is the risk of bias?, NZMJ, 4 September 2015, Vol.128, No 1421, pp22-29
2. Toop L, Mangin D. The art and science of marketing medications, NZMJ, 4 September 2015, Vol.128, No 1421, pp 11-12.

Response ID ANON-DPZ8-G4UH-X

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 12:01:26**

Submitter profile

What is your name?

Name:

Carolyn Armstrong

What is your email address?

Email:

What is your organisation?

Organisation:

Private individual

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;:

I have worked in Regulatory Affairs and maintain an interest in the regulatory environment within in New Zealand.

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):.

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):.

Health practitioner prescriber - will naturopaths/osteopaths/nutritionists/chiropractors be included in this definition?

therapeutic product - is a defined therapeutic product by having a therapeutic purpose/use? eg sunscreen protects skin against UV damage and therefore the potential for skin cancer which is a therapeutic use.

type-4 product - could this cover 'herbal' type products or nutrient based products that can be shown to have definite therapeutic benefit. This is going to become an area of contention as some nutritional type products could potentially provide significant therapeutic benefit but currently cannot make therapeutic claims. Manufacturers of such substances/products will not want to do safety/toxicity studies of the nature required for medicines as their products are derived from foods which are known to be safe. They will likely have data to show efficacy as well as clinical equivalence or benefit and making therapeutic claims would seem to be realistic with such data. How will this be handled? Will these products always fall into the dietary supplements category outside of this bill or could a type-4 product be a suitable place for such a situation?

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):

Category 2-4 products could also present quality and safety issues when parallel imported or brought in by post. There will still be counterfeit or substandard products at this level and this could present serious health consequences for both individuals and the general population. We have seen this with regard to psychoactive substances.

Another issue here is how to handle reclassification when this occurs due to safety or quality issues that have arisen overseas.

Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:

Section 75 may restrict development of custom-made prosthetics and other such devices in development as some of these sorts of devices have been developed in an individual's home workshop for personal use. These people will not necessarily have an understanding of the legality of their actions or how any regulations apply to them, yet their work is quite valuable for themselves and sometimes for the wider population.

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

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):

While I agree with the principle of being able to review a decision made by the regulator I have considerable concern about how this will practically be achieved. Appeal to the District Court level for a decision on a product could present many challenges. District Court judges do not have the scientific knowledge to

determine whether arguments presented by a sponsor or the regulator are valid. The only real grounds a judge might be able to make a decision are on economic fairness, intellectual property issues and reasonableness of a decision. Where indepth scientific/medical evidence is presented an independent expert will be required to give advice and both the regulator and sponsor could argue that the expert is not independent or well enough qualified to provide advice. The current model of an independent standing committee is a good way forward for a district court judge to gain an independent view as long as the standing committee can be flexible enough to encompass the considerable range and depth that is presented in the medicines.

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):.

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:.

How will the current regulator staffing levels cope with these changes? There is a limited pool of pharmacovigilance specialists on both regulator and industry sides.

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?:

Yes. This is a logical approach to regulation of this sector.

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?:

The definition of therapeutic purpose must be rock solid here if this is to be the case. Devices that don't have a clear therapeutic purpose but do pose similar risks should be regulated if they are likely to present an individual with a health concern/complaint through it's use. I don't have any specific examples.

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.:

Restrictions on the use or supply of specific medical devices should be in place. This is similar to the categorization of medicines as category 1-4. Some devices will pose greater risk than others so should have restrictions on use or supply in a similar manner.

Question C4 - Please provide any comments on the approach to post-market controls.:

The proposed approach is in line with the regulation of medicines. We have seen over the past few years the difficulties some individuals have had with various types of devices (breast implants, surgical mesh, hip replacements) the need for post-market controls that are enforceable rather than just recommended. Post-marketing controls would protect consumers where there is evidence from overseas jurisdictions that particular devices present specific issues, in a similar manner to the pharmacovigilance system for medicines.

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.:

This approach is logical. Clinical trials present a situation where the consumer is put at risk in a manner that is currently uncontrolled for devices in particular. While researchers are mindful of risks to trial participants a regulated environment would give participants further protection.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

Response ID ANON-DPZ8-G4UW-D

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-18 12:09:32**

Submitter profile

What is your name?

Name:

Leon Mitchell

What is your email address?

Email:

What is your organisation?

Organisation:

Midwifery Council

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;:

Responsible Authority (regulator)

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).:

The Midwifery Council generally supports the purpose 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).:

The Midwifery Council supports the proposed definitions.

It notes that for health practitioners, their authority to presc be would be established by their scope of practice as opposed to the current situation under the Medicines Act and regulations which list professions with presc bing ability.

The Midwifery Council also notes that the categories of medicines will continue to be classified: category 1 (prescription), category 2 (pharmacist), category 3 (pharmacy), category 4 (general sale).

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 1: Product approval requirements (ss 51 and 52)

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).:

Subpart 2: Controlled activities and supply chain activities (ss 53–55)

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

The Midwifery Council notes that the following common midwifery activities are also listed as controlled activities: prescribing a medicine, administering a category 1 (prescription) medicine to a person or animal.

Subpart 3: Authorisations (ss 56–80)

Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

Question B7 - Please provide any comments on the authorisations for health practitioners :

The Midwifery Council notes that health practitioners would be able to continue to supply, dispense, prescribe and administer approved or approval-exempt medicines, and also the new ability to supply pharmacy medicines to their patients.

This means that midwives will retain the ability they currently have to provide the appropriate health services throughout a woman's pregnancy, labour and birth, and to continue to look after the woman and her baby until the baby is six weeks old.

The Midwifery Council also notes that health practitioners ability to issue standing orders is included in their profession's prescribing authority. More comment on this is included in the response to question C45.

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:

The Midwifery Council supports the proposal allowing for regulations to grant authorisations in 'unusual' circumstances, such as Defence Force medics or visiting groups (sporting, diplomatic, etc.).

Subpart 4: Other offences (ss 81-94)

Question B12

Please provide any comments on the offences created in sections 81–94:

The Midwifery Council supports the section on offences, as these are a necessary part of ensuring the safety of the public, the integrity of the health professional, and the trust in the profession as a whole.

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):.

The Midwifery Council supports the intent of this section, allowing investigation to ensure compliance with legislative requirements. Such actions are required to protect the public from harm, especially where is a risk of harm posed by medicines, products, or health practitioners that do not meet the required standards.

Subpart 3: Offences relating to regulator(ss 197–199)

Question B26

Please provide any comments on the offences relating to the regulator (ss 197-199):

Subpart 4: Review of regulator's decisions (ss 200–204)

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200-204):

Subpart 5: Administrative matters relating to the regulator (ss 205–222)

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):.

B9 Part 7 of the Bill: Enforcement

Subparts 1 and 2: Enforceable undertakings(ss 223–232)

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):

Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):

Subpart 6: Infringement offences (ss 249–255)

Question B31

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):

B10 Part 8 of the Bill: Administrative matters (ss 256–274)

Question B32

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):

B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments

Subpart 1: Repeals and revocations (s 275)

Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):

The Midwifery Council is generally supportive of the proposal for the authority to prescribe to be established under the relevant professional scope of practice, subject to Ministerial approval.

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):

The Midwifery Council notes the lists in Schedule 3 of matters that may be specified in regulations, rules and regulator's notices. The content, while not exhaustive, is a good and appropriate guide.

Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:

C1 Medicines (excluding cells and tissues) sector

Product-based controls

Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):

Question C2 - Please provide any comments on the approach for medicines categorisation (classification):

Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:

Question C4 - Please provide any comments on the approach to post-market controls.:

Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

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?:

The Midwifery Council is not concerned about any specific product; however, it would support products with similar risk features to be regulated in a similar manner to medical devices. This goes back to the need to protect the public from harm or unnecessary risk of harm wherever possible.

Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

C8 Health practitioners (including pharmacists)

Prescribers

Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

The Midwifery Council notes that for health practitioners, their authority to prescribe would be established by their scope of practice, as opposed to the current situation under the Medicines Act and regulations which list professions with prescribing ability.

The Midwifery Council supports this proposal as allowing greater flexibility to be responsive to the needs of the profession in a more timely manner. Any changes (following sector consultation) to a scope of practice proposed by the relevant professional responsible authority would only require approval by the Minister of Health rather than needing a full parliamentary process.

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?:

The Midwifery Council agrees that a degree of consistency in the form and content of prescribing provisions within professional scopes of practice would be beneficial, allowing for easier comparisons between professions, and offering a greater sense of clarity for members of the public who may read these documents.

However, the Midwifery Council would not want to see any regulation put in place that could be overly prescriptive and potentially placing limitations on a responsible authority trying to create its prescribing provisions. The health workforce is varied and not all prescribing provisions can be easily described and formatted in a 'cookie-cutter' fashion to look identical to another prescribing profession.

Perhaps instead of regulation, a better model could be the use of suggested examples, or guidance for minimum standard information. This would then allow a baseline context but still provide the ability individual adaptation as required by that circumstance.

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.):

The Midwifery Council notes that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.

As autonomous health practitioners, midwives do not operate under nor issue standing orders. The Midwifery Council approves of the sentiments of the Ministry of Health officials during the presentations, where comment was made that there was likely to be less use of standing orders in the future.

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

The Midwifery Council notes the intent to authorise health practitioner prescribers to be able issue a special clinical needs supply authority, as long as that

medicine is covered by their scope of practice.

The Midwifery Council is confident that health practitioner prescribers will use their considered clinical judgement, and only undertake this action where they believe it to be safe and reasonable to do so.

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?:

The Midwifery Council believes such actions are likely to be more common where supply options are limited which may occur in remote rural areas. This may also occur in areas of high deprivation, leading to increased demand or even requirement for community-based health practitioners to be seen as more of a public health practitioner than their specific scope would suggest.

In these scenarios, allowing health practitioner prescribers to supply medicines to other health practitioner prescribers would make logistical sense.

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?:

The Midwifery Council believes such actions are likely to be more common where supply options are limited which may occur in remote rural areas. This may also occur in areas of high deprivation, leading to increased demand or even requirement for community-based health practitioners to be seen as more of a public health practitioner than their specific scope would suggest.

In these scenarios, allowing health practitioners to supply medical devices to other health practitioners would make logistical sense.

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?:

When therapeutic products are supplied by a health practitioner, that practitioner will be responsible for the clinical appropriateness of that product as required by their scope of practice. Any liberalisation of patient access to therapeutic products must be done with patient safety as the primary consideration, holding all health practitioners to the same controls and standards.

That said, improving patient access to therapeutic products when it is appropriate can be a significant step in improving patient or even community health. The Midwifery Council is confident that health practitioner prescribers will use their considered clinical judgement, and only undertake this action where they believe it to be safe and reasonable to do so.

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?:

The Midwifery Council notes that direct-to-consumer advertising for prescription medicines occurs in a very limited number of jurisdictions.

Direct-to-consumer advertising can have benefits, such as being a means of educating the public on new or alternative options for medicinal treatments. However, there is risk of misinformation and misinterpretation, often where there are endorsements based on nothing more than celebrity status rather than substantiated by clinical knowledge. This in turn can create patient expectations, leading to pressure on health practitioner prescribers.

The Midwifery Council would welcome more robust investigation and consultation on direct-to-consumer advertising for prescription medicines.

C11 Patients, consumers and disabled people

Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

The Midwifery Council notes the intent to authorise health practitioner prescribers to be able issue a special clinical needs supply authority, as long as that medicine is covered by their scope of practice.

The Midwifery Council is confident that health practitioner prescribers will use their considered clinical judgement, and only undertake this action where they believe it to be safe and reasonable to do so.

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health

practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

When therapeutic products are supplied by a health practitioner, that practitioner will be responsible for the clinical appropriateness of that product as required by their scope of practice. Any liberalisation of patient access to therapeutic products must be done with patient safety as the primary consideration, holding all health practitioners to the same controls and standards.

That said, improving patient access to therapeutic products when it is appropriate can be a significant step in improving patient or even community health. The Midwifery Council is confident that health practitioner prescribers will use their considered clinical judgement, and only undertake this action where they believe it to be safe and reasonable to do so.

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?:

The Midwifery Council notes that direct-to-consumer advertising for prescription medicines occurs in a very limited number of jurisdictions.

Direct-to-consumer advertising can have benefits, such as being a means of educating the public on new or alternative options for medicinal treatments. However, there is risk of misinformation and misinterpretation, often where there are endorsements based on nothing more than celebrity status rather than substantiated by clinical knowledge. This in turn can create patient expectations, leading to pressure on health practitioner prescribers.

The Midwifery Council would welcome more robust investigation and consultation on direct-to-consumer advertising for prescription medicines.

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?:

The Midwifery Council is not concerned about any specific product; however, it would support products with similar risk features to be regulated in a similar manner to medical devices. This goes back to the need to protect the public from harm or unnecessary risk of harm wherever possible.

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.:

The Midwifery Council is aware of the extensive time and effort that has gone into getting the consultation proposal to this point, as it is also aware many of the

details of the proposal have yet to be worked through, and that the subordinate legislative instruments have not yet been developed.

This has resulted in a current proposal that is still big on concept, but insufficient in details, which does not allow for informed submissions from the health sector. The submissions by the health sector serve many purposes, not least being to ensure that any changes proposed do not present any risk to the ongoing safety of the public.