

## Response ID ANON-DPZ8-G4CG-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
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### Submitter profile

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Foetal Anti-Convulsant Syndrome New Zealand

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;:

Charitable organisation

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

#### Chapter A (A1 - A5)

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

Partially support

#### B3 Part 1 of the Bill: Preliminary provisions

##### B3 Part 1 of the Bill: Preliminary provisions

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

No comment, but find it interesting that you are not allowing comment for "Outline of the regulatory scheme" (ss 7-13), as we did want to comment on 9. Product approvals.

#### 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).:

14: Interpretation

"misleading information means information that is false, that is misleading in a material particular, or that it is misleading because of the omission of a material particular" our comment is what if it is the regulatory body that is misleading by omission?

"regulatory entity", all the regulatory entities are funded by the Government, so how can we have a truly independent body?

15: Meaning of therapeutic purpose

(1) (a) "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:" What is happening when a therapeutic product such as sodium valproate is causing defects and injuries? This is in direct violation with what it is meant to be doing.

(2) (a-d) Currently off label prescribing is occurring and our present regulators are not prepared to comment about this prescribing. If medicines are to be used off

label then there needs to be a process that is to be adhered to, which includes, but not limited to, the regulators being able to comment about this off label prescribing, and all off label prescribing to females must include information regarding effects on a fetus during pregnancy.

19: Categories of medicine

(1-4) There needs to be clear clarification of the 4 categories consistent and understood by all prescribers and dispensers. All medicines that are currently on the market will need to be reclassified as well so there is consistency.

## **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):**

51. "Product approval required to import or supply medicine, medical device, or type-4 product."

There are no safety restrictions documented here around the medicines. There should be a criteria that these medicines should be meeting.

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

#### **Question B4**

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

55. Persons in supply chain must comply with regulations

(1) (a-g) The wording is very ambiguous, which we understand that the Bill is trying to be so the specifics can be worked out at the lower levels. However knowing our experiences with having to fight for any changes to go on packaging (and currently knowing required in the packaging) regarding medicine risks to an unborn baby, there is a necessity to remove the ambiguous nature and make wording more rigid. An example would be that there has to be consumer medicine information (CMI) sheets inside original packaging for all medicines. These CMIs must include a segment about pregnancy and lactation, which contains full risks, not just partial information. Additionally the record keeping, auditing, and giving of information to the regulator must include a pregnancy register of harm caused which is not just congenital malformations. In align with this the regulator is to keep its own pregnancy register of medicine which have caused harm to a fetus. Again not just congenital malformations.

(3) What is happening about off label prescribing, particularly when a medicine is contraindicated in pregnancy? There needs to be a full list of warnings around pregnancy, labeling.

### **Subpart 3: Authorisations (ss 56–80)**

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

57. Pharmacists: approved and approval-exempt medicines

Dispensing

There is nothing about warnings around pregnancy. A new section needs to be added which states (c) the medicine has followed the pregnancy warnings and labeling, where applicable. As yet there are no specific pregnancy warnings so these would need to be developed.

**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 :**

61. Health practitioners: approved and approval-exempt medicines

Issuing standing order

(6) Again the language is ambiguous, and there is nothing specific to pregnancy warnings, particularly when the medicine is contraindicated in pregnancy. There needs to be a section which states, the medicine has followed the pregnancy warnings and labeling, where applicable.

64. Health practitioners: special clinical needs supply authority

As above, there is nothing specific to pregnancy warnings, particularly when the medicine is contraindicated in pregnancy. There needs to be a section which states, the medicine has followed the pregnancy warnings and labeling, where applicable.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

### **Subpart 4: Other offences (ss 81-94)**

## Question B12

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

84. Meaning of tamper with and create a risk of harm

Currently pharmacists when dispensing some medicines e.g. sodium valproate are choosing to withhold labeling that should be on boxes, not keeping in original boxes which contain the pregnancy warning on the outside of the box, putting the name sticker over the warning on the box, not distributing booklets that should be given to females on antiepileptic medicines, not giving out CMI, and deliberately x'ing out of warnings that appear on the screen relating to valproate and females, without informing the females. Our concern is how are the regulators going to monitor this? Consumers do not know what is mandatory or regulatory, so are unaware that they should be receiving this information. There needs to be an independent body where consumers can feel comfortable to contact to raise their concerns. Our current regulatory body is not able to action any of these issues or make recommendations mandatory. None is our current system is consumer friendly.

## 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).:

95. Criteria for product approval

There needs to be a (d) the risks of the medicine during pregnancy have been clearly listed on the packaging, datasheet, CMI, and boxes. Where it is contraindicated the stronger pregnancy legislation has been followed (this is something yet to be written). The rationale for the inclusion of (d) is that currently full risks are not being divulged by sponsors, prescribers, and dispensers for antiepileptic medicines.

96. Product standards

(d) "the product's packaging and labelling:" Currently there isn't compulsory labelling on boxes around pregnancy risks, so we are suggesting this changes. Compulsory warnings are necessary for packaging, and that the medicines are dispensed in their original packaging. There also needs to be compulsory labelling for pregnancy risks for medicines.

(e) "the product's product or consumer information". For every medicine available there needs to be compulsory consumer information that is inside every medicine box that is given to the consumer. This consumer information needs to have full pregnancy risks associated with taking the medicine, and also full information risks around lactation. On the datasheet it should be made compulsory to have full information around pregnancy risks and lactation.

98. Content of approval

There needs to be an additional area that has all pregnancy risks to a fetus listed as a compulsory part of getting approval. This includes having a pregnancy register that can monitor the harm that has been caused to a fetus, not just limited to congenital malformations, and that these are reported to the regulator every time a case has been reported.

99. Scope of approval

(2)

Our question is what is happening to the off labelling prescribing that is occurring? Who is monitoring and regulating this?

## Question B14

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

113. Therapeutic products register

(3) "For each approved product, the register must include the following:

We are suggesting that two there should be two more additions to this part which we have labelled (d) and (e)

(d) reason why the product is being used

(e) harm reported from Centre for Adverse Reactions Monitoring

### 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).:

118. Sponsor must comply with regulations

(a) Included in this area needs to be a pregnancy register of harm that has been caused to a fetus, not just congenital malformations, which is reported to and acted upon by the regulator.

(b) There must be a compulsory CMI which is included inside every medicine. Also there must be a compulsory datasheet with full information that is up to date. Who will be reviewing these CMIs and datasheets? The regulators must have the ability to say what can be updated and included in the information sheets. Our current regulator is at the mercy of the sponsor, which is not ideal.

(c) It must be compulsory to have pregnancy warnings on any medicines boxes that are known to cause harm to unborn babies, and that the medicine is given in the original packaging. A pictogram also needs to be on the foil packaging inside the medicine boxes. Labelling needs to be on any package that is known to cause harm to a fetus.

(f) It is absolutely necessary to have accurate information given to the regulator, but the regulator also needs to then follow up on the information given and act upon it so the consumers are informed as well.

There is a necessity for a NZ based pregnancy register around effects on a fetus exposed to any medicines, that is independent from any sponsor. In addition all of this information should be made publicly available.

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

##### **Question B17**

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

No comment.

#### **B7 Part 5 of the Bill: Licences and permits**

##### **Subpart 1: Licences (ss 123–130)**

##### **Question B18**

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

No comment.

##### **Question B19**

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

No comment.

##### **Subpart 2: Permits (ss 131–135)**

##### **Question B20**

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

No comment.

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

##### **Question B21**

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

No comment.

##### **Question B22**

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

No comment.

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

##### **Question B23**

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

No comment.

#### **B8 Part 6 of the Bill: Regulator**

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

##### **Question B24**

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

160. Regulator to monitor safety

It needs to be written that post marketing surveillance will happen to any medicine that is available to the public. Extra post marketing surveillance will occur around medicines that are prescribed to women, particularly if there has already been an indication during clinical trials that is is teratogenic in animals.

161. Public safety announcements

How is the public safety announcements getting to everyone? Will there be monitoring to ensure that it has reached its audience? The current regulators are not doing this in a manner that is empowering the consumers to have the knowledge.

168. Directions order

The directions order needs to be applicable to prescribers, pharmacists, healthcare professionals.

## **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):**

219. Meaning of make publicly available

(2)

The word may needs to be changed to must. Not everyone has access to the internet and some people are not able to use computers due to medical conditions, therefore there must be a variety of methods used to publicise.

## **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):**

267. Consultation

(3) By having this part you are ultimately saying that people and organisation's do not have to be consulted. Instead they must be consulted. People with lived experiences and organisation's that support those people have knowledge that is not found in books, therefore they are vital to the consultation process.

## **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):**

267. Where would specialist only medicines come in? Do they need a separate category? Would Category X medicines also be abandoned?

**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.:**

Throughout this submission we have commented on the need for better post marketing surveillance by the regulators. These need to be particularly focused on adverse effects, but in particular adverse affects to a fetus. Our suggestion is that there is a NZ based pregnancy register set up that monitors any adverse effects to a fetus, not just congenital malformations, to medicines. These adverse effects then need to be followed up through the regulators. This means that the regulators need to put in mandatory action to ensure harm is being prevented. Our current Centre for Adverse Reaction Monitoring forms are not fit for purpose in recording adverse effects to fetus' therefore they need to be updated accordingly.

It can not be just up to the sponsor's to keep up to date records and information, it must to also up to the regulator's and if the regulator's are found not to be providing the full information or following this process they should be held accountable. The Bill needs to show how this accountability can be done.

As part of this post marketing process the regulators need to be inform the consumers about the risks to a fetus.

### **Activity-based controls**

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

No comment.

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

No comment.

## **C2 Cell and tissue sector**

### **Product-based controls**

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

#### **Activity-based controls**

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

No comment.

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

No comment.

### **C3 Medical device sector**

#### **Question C11**

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

No comment.

#### **Product-based controls**

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

#### **Activity-based controls**

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

No comment.

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

No comment.

### **C4 Clinical trial sector**

#### **Question C16**

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

No comment.

#### **Question C17**

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

No comment.

### **C5 Wholesale sector (including importers and exporters)**

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

#### Licence to wholesale

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

No comment.

#### Hawker's licence

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

No comment.

#### Transition

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

No comment.

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

#### Pharmacy sector context

#### Future regulation of pharmacy business activities

#### Licence to carry out a pharmacy business

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

No comment.

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

No comment.

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

No comment.

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comment.

#### Detailed questions relating to Option 1

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

### **Detailed questions relating to Option 2**

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

No comment.

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

No comment.

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

No comment.

### **Other changes to pharmacy licensing requirements**

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

A pharmacist needs to either present or remotely when the dispensing of restricted medicines, and those that have special requirements to them e.g. sodium valproate to females. This is because if the risk benefit discussions need to occur then the pharmacist is the one who should be doing this, then advising the patient where to seek further advice from e.g. neurologist.

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

No comment.

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

No comment.

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

No comment.

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

No comment.

### **Pharmacist and pharmacy worker authorisations**

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

No comment.

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

No comment.

### **C7 Retail sector**

#### **Question C42**

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

No comment.

### **C8 Health practitioners (including pharmacists)**

#### **Prescribers**

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

On any group that is to be formed there must be consumer representation from a person who is not a healthcare professional, but has lived experience. This might mean that within the authority to prescribe group there might be subgroups depending on what the medicine is. On all of these groups there needs to be consumer representation. Also when developing what this might look like have consumer representation and 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, there does need to be a consistent approach, as there is currently inconsistencies between prescribers and the benefits and risks information that they give

to their consumers. As a direct result consumers are having their Health and Disability Consumer Rights stripped away from them.

The regulations will make it mandatory for the correct information to be given. Written in these regulations there must be provisions around females, pregnancy and lactation. Also it is important that all information regarding the medicine be given to the consumer. However all of this information needs to be done in a way that the consumer can understand it. For example a consumer may not know what the word teratogenic means, but might understand a picture with a pregnant woman with a cross through it.

**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.):**

There is going to be a need for very specific regulations particularly when the medicines involved are teratogenic. In addition to this there needs to be a regulatory body that is ensuring that adherence to all the regulations are being followed and if not, then fines need to occur.

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

Our current approach to off label use has been detrimental to the health of our future generations of New Zealanders. An example of this is the off label use of antiepileptic medicines to females. A lot of these females are oblivious to the fact that they are on an antiepileptic medicine, let alone those antiepileptic medicines carry a risk to an unborn baby. The perfect example of this is sodium valproate, which was contraindicated in 2005, yet in 2017 was the second most prescribed antiepileptic medicine for females, and for females in childbearing age.

Our current regulators choose not to discuss the off label use, merely by saying they do not condone it, yet it is occurring and necessary to address it correctly.

If medicines are to be given off label then a mandatory protocol has to be done, particularly around women and pregnancy. If it is found that these are not being followed then the regulator needs the authority to fine these practitioners and ensure they have education around this particular area.

We have babies literally being harmed and dying due to our lax approach to off label prescribing and this needs to change.

We also need an independent body that both healthcare professionals and consumers can go to report such cases. The Health and Disability Commission is not proactive about making systemic changes in this area.

**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?:**

Again all the regulations need to be followed, particularly around pregnancy, and lactation. A pregnancy register still needs to be maintained for this as the information would be pertinent, especially if the product was to become readily available in New Zealand.

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

No comment.

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

No comment.

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

No comment.

#### **Health practitioners (non-prescribers)**

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

This would raise concerns, as currently we are having difficulties with our prescribers and dispensers fully informing our females about the risks to an unborn baby exposed to antiepileptic medicines during pregnancy.

There is going to be a need for very specific regulations particularly when the medicines involved are teratogenic. In addition to this there needs to be a regulatory body that is ensuring that adherence to all the regulations are being followed and if not, then fines need to occur.

**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?:**

This would raise concerns, as currently we are having difficulties with our prescribers and dispensers fully informing our females about the risks to an unborn baby exposed to antiepileptic medicines during pregnancy.

There is going to be a need for very specific regulations particularly when the medicines involved are teratogenic. In addition to this there needs to be a regulatory body that is ensuring that adherence to all the regulations are being followed and if not, then fines need to occur.

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

When advertising any medicine it is essential to disclose all the risks, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

**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?:**

Any medicine needs to disclose all the risks associated with it, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

The healthcare professionals are notorious for not providing full information, particularly around antiepileptic medicines, therefore we need to approach informing our consumers through different avenues, which includes direct-to-consumer.

## **C9 Veterinarians**

### **Question C54**

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

No comment.

## **C10 Advertising sector**

### **Question C52**

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

When advertising any medicine it is essential to disclose all the risks, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

If people are not giving full information whether it be the sponsor, prescriber, dispenser, or regulatory body there needs to be enforcement through fines or other means.

### **Question C53**

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

When advertising any medicine it is essential to disclose all the risks, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

If people are not giving full information whether it be the sponsor, prescriber, dispenser, or regulatory body there needs to be enforcement through fines or other means.

Our views are such because the families we support are the ones who have had their children harmed by exposure to antiepileptic medicines and their healthcare professionals never advised them, or only partially advised them on some of the risks involved. It was not until we started up our charitable organisation that some of the truth has come out. Healthcare professionals are meant to "do no harm" but in our circumstances they have. This is why we are suggesting that the more information the better. In saying that the information needs to be presented in a multitude of ways so different learning styles can be catered for.

## **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?:**

Our current approach to off label use has been detrimental to the health of our future generations of New Zealander's . An example of this is the off label use of antiepileptic medicines to females. A lot of these females are oblivious to the fact that they are on an antiepileptic medicine, let alone those antiepileptic medicines carry a risk to an unborn baby. The perfect example of this is sodium valproate, which was contraindicated in 2005, yet in 2017 was the second most prescribed antiepileptic medicine for females, and for females in childbearing age.

Our current regulators choose not to discuss the off label use, merely by saying they do not condone it, yet it is occurring and necessary to address it correctly.

If medicines are to be given off label then a mandatory protocol has to be done, particularly around women and pregnancy. If it is found that these are not being followed then the regulator needs the authority to fine these practitioners and ensure they have education around this particular area.

We have babies literally being harmed and dying due to our lax approach to off label prescribing and this needs to change.

We also need an independent body that both healthcare professionals and consumers can go to report such cases. The Health and Disability Commission is not proactive about making systemic changes in this area.

**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?:**

Again all the regulations need to be followed, particularly around pregnancy, and lactation. A pregnancy register still needs to be maintained for this as the

information would be pertinent, especially if the product was to become readily available in New Zealand.

## Personal imports

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

No comment.

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

Yes.

## Pharmacy licensing

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

No comment.

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

No comment.

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comment.

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

No comment.

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

No comment.

## Access to pharmacy medicines

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

This would raise concerns, as currently we are having difficulties with our prescribers and dispensers fully informing our females about the risks to an unborn baby exposed to antiepileptic medicines during pregnancy.

There is going to be a need for very specific regulations particularly when the medicines involved are teratogenic. In addition to this there needs to be a regulatory body that is ensuring that adherence to all the regulations are being followed and if not, then fines need to occur.

**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?:**

This would raise concerns, as currently we are having difficulties with our prescribers and dispensers fully informing our females about the risks to an unborn baby exposed to antiepileptic medicines during pregnancy.

There is going to be a need for very specific regulations particularly when the medicines involved are teratogenic. In addition to this there needs to be a regulatory body that is ensuring that adherence to all the regulations are being followed and if not, then fines need to occur.

## Advertising

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

When advertising any medicine it is essential to disclose all the risks, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

If people are not giving full information whether it be the sponsor, prescriber, dispenser, or regulatory body there needs to be enforcement through fines or other means.

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

When advertising any medicine it is essential to disclose all the risks, which include side effects, pregnancy, and lactation. This needs to be made mandatory, particularly with relation to the consumers. The consumers are currently getting diluted information, that does not allow for the Health and Disability Consumer rights to be met.

If people are not giving full information whether it be the sponsor, prescriber, dispenser, or regulatory body there needs to be enforcement through fines or other means.

Our views are such because the families we support are the ones who have had their children harmed by exposure to antiepileptic medicines and their healthcare professionals never advised them, or only partially advised them on some of the risks involved. It was not until we started up our charitable organisation that some of the truth has come out. Healthcare professionals are meant to "do no harm" but in our circumstances they have. This is why we are suggesting that the more information the better. In saying that the information needs to be presented in a multitude of ways so different learning styles can be catered for.

## **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.:**

Before a medicine is even approved onto the market there needs to be research documented about the risks to an unborn baby during pregnancy from a maternalistic and paternalistic perspective. There also needs to be documentation about lactation and side effects. There needs to be pregnancy warnings on the foil covering the medicine and also on the boxes. The medicine needs to be dispensed in the original sponsor packaging, with no labels stuck over the pregnancy warnings. There also needs to be a mandatory consumer medicine information put inside each of the boxes.

When the medicine is on the market prior to being prescribed to the consumer the healthcare professional must outline all the risks and benefits of the medicine. Prior to the medicine being dispensed (or handed over to the consumer) the pharmacist must outline any restrictions, regulations or risks associated with that particular medicine.

The sponsor and the regulatory body MUST have a post marketing surveillance which is mandatory and must include (but not limited to), side effects and effects to a fetus exposed to the medicine during pregnancy (not just congenital malformations). If there are any effects to the fetus then the consumers must be made aware by a public service announcement, which is done in various ways and not just digital.

There is also to be a mandatory pregnancy register both at with the sponsor and an independent one which is reported back to the regulatory body. Again if there is any effects to a fetus then this is to be reported back to the consumers. The consumers need to be at the forefront of all of this.

If it has been noted that the fetus has been affected then support must be immediately forthcoming to the people harmed in the form of a care package for the rest of their life, and the regulatory body need to apologise.

If a medicine is found to be found teratogenic a specific (yet to be designed) mandatory protocol needs to be followed.

There also needs to be an independent body where consumers and healthcare professionals can report to if there is any people not following the regulations, which includes the regulatory body not following the regulations.

The regulatory body needs authority to develop regulations on how a particular medicine can be prescribed, and if these are not followed then the healthcare professional can be fined e.g. mandatory guidelines for the use of sodium valproate for females.

There needs to be consumer representation with any group that is going to be developed from this Bill. There also needs to be consultation with any group.

Reviews need to be done on all medicines new and old, with new regulations put in if they are proving to be teratogenic. With these reviews there needs to be consumer representation.

The CARM forms need revising to include adverse effects to a fetus, not just congenital malformations, or a whole new form developed for a fetus.

## Response ID ANON-DPZ8-G4DJ-F

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-12 17:37:15**

### Submitter profile

#### What is your name?

**Name:**

Jon Mathy

#### What is your email address?

**Email:**

[REDACTED]

#### What is your organisation?

**Organisation:**

Counties Manukau District Health Board

#### Submitter Profile (tick all that apply)

Consumer

Health service provider (eg, Ambulance, Māori or Pacific health provider etc)

**If you select DHB, please state service area:**

Counties Manukau

Surgeon

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

Other (please comment)

**If you selected 'Other' please comment;:**

Clinical Director of Cancer Services, CMDHB

### 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).:

As part of the new regulatory scheme for therapeutic products bill, sunscreen regulation should be specifically addressed.

- In the context of cancer, skin cancer is the most common cancer in NZ, accounting for substantial treatment cost and patient morbidity. The regular use of sunscreen along with other sun protection strategies reduces the incidence of skin cancer.
- In New Zealand, sunscreens are currently classified as cosmetics under the Medicines Act of 1981, despite the claim of therapeutic benefit in providing sun protection. Any substance claiming sun protection (eg listing "SPF") should require MOH evaluation for compliance with relevant regional sunscreen labelling standards, and require MOH consent for distribution.

- A relevant regional guideline is the Australian/New Zealand Sunscreen Standard (AS/NZ 2604:2012), which is mandatory in Australia but voluntary in New Zealand. The AS/NZ standard describes regionally standardised SPF testing and labelling standards. Compliance with the AS/NZ sunscreen standard should be made mandatory in NZ.
- The Commerce Commission of New Zealand, acting on a complaint raised from Consumer NZ, found that a Neutrogena-range of sunscreens (including "Sensitive Skin SPF60+) was significantly less than label claimed. Reference:  
<https://comcom.govt.nz/news-and-media/media-releases/2018/sunscreen-producer-will-meet-nz-standard-for-spf-testing>
- In January 2019 Consumer NZ reported an additional 5 sunscreens that failed to meet advertised SPF labelling in independent testing. Reference:  
<https://www.consumer.org.nz/articles/sunscreens>
- A 2016 study (attached) showed that 27% of audited sunscreens in major NZ stores were not compliant with this standard, and noncompliance may mislead consumers into thinking sunscreens offer more protection than they do.

## **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):**

see comments under Question B1

## **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):**

see comments under Question B1

### **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):**

see comments under Question B1

### **Subpart 3: Authorisations (ss 56–80)**

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

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

see comments under Question B1

## **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).:**

see comments under Question B1

### **Question B14**

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

see comments under Question B1

### **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).:**

see comments under Question B1

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

### **Question B16**

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

see comments under Question B1

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

### **Question B17**

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

see comments under Question B1

## **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).:**

see comments under Question B1

### **Question B19**

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

see comments under Question B1

### **Subpart 2: Permits (ss 131–135)**

### **Question B20**

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

see comments under Question B1

### **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).:**

see comments under Question B1

### **Question B22**

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

see comments under Question B1

### **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):**

see comments under Question B1

## **B8 Part 6 of the Bill: Regulator**

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

#### **Question B24**

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

see comments under Question B1

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

#### **Question B25**

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

see comments under Question B1

### **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):**

see comments under Question B1

### **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):**

see comments under Question B1

### **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):**

see comments under Question B1

## **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):**

see comments under Question B1

### **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):**

see comments under Question B1

### **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):**

see comments under Question B1

## **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):

see comments under Question B1

## **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):

see comments under Question B1

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

### **Question B34**

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

see comments under Question B1

## **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):**

see comments under Question B1

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

see comments under Question B1

**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?:**

see comments under Question B1

## **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):**

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

### **Activity-based controls**

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

see comments under Question B1

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

see comments under Question B1

## **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?:**

see comments under Question B1

## **Hawker's licence**

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

see comments under Question B1

## **Transition**

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

see comments under Question B1

## **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?:**

see comments under Question B1

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

see comments under Question B1

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

see comments under Question B1

##### **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 comments under Question B1

##### **Detailed questions relating to Option 1**

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

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

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

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

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

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

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

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

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

##### **Detailed questions relating to Option 2**

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

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

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

##### **Other changes to pharmacy licensing requirements**

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

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

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

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

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

#### **Pharmacist and pharmacy worker authorisations**

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

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

#### **C7 Retail sector**

##### **Question C42**

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

Yes - see comments under Question B1

#### **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 - see comments under Question B1

**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.:**

see comments under Question B1

**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 comments under Question B1

## **C10 Advertising sector**

### **Question C52**

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

As part of the new regulatory scheme for therapeutic products bill, sunscreen regulation should be specifically addressed.

- In the context of cancer, skin cancer is the most common cancer in NZ, accounting for substantial treatment cost and patient morbidity. The regular use of sunscreen along with other sun protection strategies reduces the incidence of skin cancer.
- In New Zealand, sunscreens are currently classified as cosmetics under the Medicines Act of 1981, despite the claim of therapeutic benefit in providing sun protection. Any substance claiming sun protection (eg listing "SPF") should require MOH evaluation for compliance with relevant regional sunscreen labelling standards, and require MOH consent for distribution.
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- The Commerce Commission of New Zealand, acting on a complaint raised from Consumer NZ, found that a Neutrogena-range of sunscreens (including "Sensitive Skin SPF60+) was significantly less than label claimed. Reference:  
<https://comcom.govt.nz/news-and-media/media-releases/2018/sunscreen-producer-will-meet-nz-standard-for-spf-testing>
- In January 2019 Consumer NZ reported an additional 5 sunscreens that failed to meet advertised SPF labelling in independent testing. Reference:  
<https://www.consumer.org.nz/articles/sunscreens>
- A 2016 study (attached) showed that 27% of audited sunscreens in major NZ stores were not compliant with this standard, and noncompliance may mislead consumers into thinking sunscreens offer more protection than they do.

### **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.:**

As part of the new regulatory scheme for therapeutic products bill, sunscreen regulation should be specifically addressed.

- In the context of cancer, skin cancer is the most common cancer in NZ, accounting for substantial treatment cost and patient morbidity. The regular use of sunscreen along with other sun protection strategies reduces the incidence of skin cancer.
- In New Zealand, sunscreens are currently classified as cosmetics under the Medicines Act of 1981, despite the claim of therapeutic benefit in providing sun protection. Any substance claiming sun protection (eg listing "SPF") should require MOH evaluation for compliance with relevant regional sunscreen labelling standards, and require MOH consent for distribution.
- A relevant regional guideline is the Australian/New Zealand Sunscreen Standard (AS/NZ 2604:2012), which is mandatory in Australia but voluntary in New Zealand. The AS/NZ standard describes regionally standardised SPF testing and labelling standards. Compliance with the AS/NZ sunscreen standard should be made mandatory in NZ.
- The Commerce Commission of New Zealand, acting on a complaint raised from Consumer NZ, found that a Neutrogena-range of sunscreens (including "Sensitive Skin SPF60+) was significantly less than label claimed. Reference:  
<https://comcom.govt.nz/news-and-media/media-releases/2018/sunscreen-producer-will-meet-nz-standard-for-spf-testing>
- In January 2019 Consumer NZ reported an additional 5 sunscreens that failed to meet advertised SPF labelling in independent testing. Reference:  
<https://www.consumer.org.nz/articles/sunscreens>
- A 2016 study (attached) showed that 27% of audited sunscreens in major NZ stores were not compliant with this standard, and noncompliance may mislead consumers into thinking sunscreens offer more protection than they do.  
Reference: Sunscreen Compliance with Regional Practice Guidelines and Standards in NZ - J Prim Health Care 2016

**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-G4DU-T

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-12 20:48:14**

### Submitter profile

**What is your name?**

**Name:**

Graeme Blanchard

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Waitangirua 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;:**

### 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).:**

Dispen a medicine (s29) - the definition of dispensing has changed significantly without any change in ethical expectations. It concerns me greatly. 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 dangerously misleading. Pharmacists know that dispensing includes clinical checks, preparing the medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

If advice has been given suggesting otherwise then that would be a serious error of judgement by that person, or a complete lack of knowledge. Either of which is embarrassing for such an important link in the chain of healthcare.

## **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 uncommon medicines. 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 medicine in a timely manner. The legislation needs to be framed in a way to ensure that it does not allow 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 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 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 NZ 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 and should 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 licenced pharmacy dispensary.

Dispensing at an aged care facility couldn't meet the same requirements to pass a Dispensing 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 up to 3 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 generally not safe for people to import their own medicines due to uncertainty around the medicines credibility.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of medicine.

### 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 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 the current licencing requirements create a barrier to innovation. They simply establish the requirements for safe and effective provision of pharmacist services involving medicines.

Proof of this is the 32 innovative services already available and funded through Community Pharmacy. The only barrier to rolling them out across the country is DHBs agreeing to their funding.

Service innovation requires attention to factors, such as IT systems, and processes as enablers for innovation (eg electronic health record) and achieving alignment of policy and funding settings for primary care.

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.

I believe that the advancement of technology and the community pharmacy workforce over time will lead to the development of new 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.:**

I am supportive of service innovations such as marae-based services or providing pharmacist services at events to improve health equity, as well as increasing health literacy and encouraging regular contact with a health professional, assuming that this would not include dispensing outside of a pharmacy dispensary. I am also supportive of mobile pharmacy vehicles for rural areas but 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 huge public benefit in a health 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 is not.

Medicines are definitely not a normal item of commerce and pharmacies are not like other small businesses in a free market. Requiring pharmacies to be owned by pharmacists under Option 1 means that health professionals with 'skin in the game' focus first and foremost on delivering 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.

there is also a level of accountability 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 of 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 of 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 Option 1. The risk of financial impact on these would be reduced by grandparenting provisions.

The owner Pharmacist could have a veto share so that the owner pharmacist is always in control of all voting rights and operating decisions where public safety is involved.

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

as above with grandparenting and veto rights

**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.

**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' interest first, before profits or shareholder value. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a firm 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 pharmacist owners should have a veto share on governance and operating decisions that affect patient safety to strengthen 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)?:**

The Bill isn't clear around the criteria that would apply in deciding the number, scale and location of other pharmacies would allow oversight to the owner pharmacist.

A five-pharmacy limit may sufficiently spread pharmacy ownership to avoid market dominance thereby providing an important public benefit.

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

I still think a limit of 5 is an appropriate maximum, even if there are two pharmacists sharing the >50% ownership.

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

changes to existing requirements will have a financial impact, affecting current and potential owners. A veto share and a maximum of 5 will provide stability long

term.The A

**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 the 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 Option 1 and think this should apply to all pharmacies. Continuing to grandparent Friendly Societies is a good thing.

**Detailed questions relating to Option 2**

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

My gut feeling, and overseas evidence, is that Option 2 will reduce patient access to services, compromise patient safety, and reduce patient outcomes, compromise professional obligations and affect the profession generally.

Option 2 would likely increase compliance costs due to accountability conflicts and may lead to future workforce issues due to reduced opportunity to progress.

Many young pharmacists are attracted by the opportunity to own their own business. Option 2 would remove that opportunity.

Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so they don't risk losing their registration and therefore their ability to own the pharmacy.

A non-pharmacist owner would be accountable first to their shareholders.

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

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. Any changes to this will likely lead to patient safety concerns.

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

**Other changes to pharmacy licensing requirements**

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

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

I 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.

Future ability of Pharmacists to prescribe funded minor ailment therapy is simply a funded version of what we already do. Which is clearly permitted.

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

yes. For urgent situations such as civil emergencies and unexpected events such as a pharmacy burning down.

**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 to provide appropriate 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?:**

**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 continue for products they regularly dispense.

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

I think it appropriate for pharmacies that do not have a wholesale licence to provide medicines by wholesale where medicines are supplied between pharmacies of common ownership, as well as where they are supplied to other pharmacies to reduce wastage of 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 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, so if an unapproved medicine was required they would already be expected to consult with a medical practitioner.

**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?:**

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.

According to the Medsafe, stored medicines require strict temperature monitoring to ensure they stay within their specified temperature limits.

Pharmacies are audited on monitoring of this.

Pharmacies are also legally expected to have a Pharmacist on site at all times while open and while anyone else is in the building such as builders.

To ensure consistency, any business with medicines on site should be dealt with under the same terms and conditions.

Otherwise the approach to Pharmacies makes no sense.

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

No, I do not.

Typically, these staff will not be in the same room as the health practitioner so will not be working under supervision so unless there was clear and achievable requirements for direct supervision and advice and counselling to be given.

In Pharmacy, store layouts are such that supervision is conducted at all times.

Also, I would 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 importation 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 medicines.

**Pharmacy licensing**

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

sustainable arrangements.

For some years, DHBs have committed to deadlines to deal with the marginal sustainability of distribution of medicines and have failed to meet those commitments.

One has to question if the DHBs are actually adding any value to the Pharmacy services they are funded to manage.

I suggest it is time for Pharmacy services to be managed directly by the Ministry.

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

We are very fortunate to have an incredibly efficient and responsive distribution and supply system.

Don't stuff it up.

**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?:**

Community Pharmacies are so embedded into their communities.

We are an asset that needs to be used rather than torn down.

**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-G4RU-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-13 15:48:05**

### Submitter profile

**What is your name?**

**Name:**

Alexander Browne

**What is your email address?**

**Email:**

[REDACTED]

**What is your organisation?**

**Organisation:**

Nelson Mar borough DHB

**Submitter Profile (tick all that apply)**

Mori

District Health Board (DHB)

**If you select DHB, please state service area:**

Medical practitioner (excluding Surgeons)

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

**If you selected 'Other' please comment;:**

**Next steps after the consultation**

**Executive summary**

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

**Chapter A (A1 - A5)**

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

Support

**B3 Part 1 of the Bill: Preliminary provisions**

**B3 Part 1 of the Bill: Preliminary provisions**

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

**B4 Part 2 of the Bill: Interpretation**

**B4 Part 2 of the Bill: Interpretation**

**Question B2**

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

With specified training and recertification, Registered Nurses within scope of practice can prescribe over the counter medications for the alleviation of pain, specifically paracetamol and bupropfen.

I work in a busy metropolitan Emergency department. We strive to make our patients in pain comfortable as soon as is possible. One way we do this is through the use of standing orders. A trained registered nurse (RN) can give out drugs before the patient has been seen by the doctor to help alleviate pain under a standing order. These orders are signed for by the RN and are then countersigned AFTER the patient has been given the drug by the doctor who sees them.

Standing orders are used commonly in other services such as ambulance.

Often we are asked to countersign orders for patients we have not seen, for over the counter available (OTC) drugs such as paracetamol and bupropion well after the drug was administered. The alternative to signing every drug chart is regular audit, which in the case of a busy ED is an onerous task; this would amount to a weekly audit of 40-50 medication charts (see below standing order document with MoH requirements as part of this).

I propose that for standing orders regarding OTC drugs, we should drop the statutory requirement for MO sign off, so long as the RN dispensing the medication has done training on standing orders, and has regular updated training. Such training is simple via on line modules which are already in place in our hospital. I see very little risk to the patient because:

1. The RN will have completed training for standing orders and will be familiar with them, and will ask the patient about adverse reactions and allergies, and previous dosing prior to giving the drug as a matter of course, regardless of whether it is countersigned at a later date.
2. Countersigning is of no benefit to preventing risk, as the patient has already received the drug.
3. The patient has full access to these drugs in the community in an unregulated fashion. OTC drugs such as paracetamol and ibuprofen can be bought at a supermarket or a petrol station. There are still tight regulations in place for OTC drugs in the hospital.

Countersigning for non OTC or pharmacy only drug standing orders should remain in place.

This would save me about 5 interruptions a shift. In my role as a senior Emergency physician I get interrupted once every 2 minutes whilst working in the Emergency Department on average.

Current countersigning legislation regarding audit:

The authorised medical practitioner, dentist or other practitioner as defined under the Standing Order must either countersign the medication chart within a defined time frame (e.g. within 24 hours of administration) or audit the use of the Standing Order.

If countersigning is not required, or required less frequently than once a month, the issuer(s) must, at least once a month, audit a sample of the records of administration and/or supply, under the standing order.

Audit sample sizes should be as a minimum:

- 50% of administration and/or supply records if there are 20 or fewer in total
- 20-30% of administration and/or supply records if they are in range of 21-100
- 15-20% of administration and/or supply records if there are over 100.

The results of the audit should be recorded along with any required changes or improvements in relation to the standing order documentation, processes or training to be undertaken.

Countersigning

The medication administration must be countersigned by the issuer or another medical practitioner defined within the standing order. The time frame for countersigning will be defined in each standing order. It will normally be:

- 24 hours for the acute hospital setting.

## **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 :**

With training and certification in scope Registered Nurses can prescribe OTC pain medications namely paracetamol or bupropion. I work as a senior physician in a busy metropolitan Emergency department. We strive to make our patients in pain comfortable as soon as is possible. One way we do this is through the use of standing orders. A trained RN can give out drugs before the patient has been seen by the doctor to help alleviate pain under a standing order. These orders are signed for by the RN and are then countersigned AFTER the patient has been given the drug by the Dr who sees them.

Standing orders are used commonly in other services such as ambulance.

Often we are asked to countersign orders for patients we have not seen, for over the counter available (OTC) drugs such as paracetamol and bupropion. The alternative to signing every drug chart is regular audit, which in the case of a busy ED is an onerous task (see below standing order document with MoH requirements as part of this). This would equate to auditing 40-50 charts a week.

I propose that for standing orders regarding OTC drugs, we should drop the statutory requirement for MO sign off, so long as the RN dispensing the medication has done training on standing orders, and has regular updated training. Such training is simple via on line modules which are already in place in our hospital. I see very little risk to the patient because:

1. The RN will have completed training for standing orders and will be familiar with them, and will ask the patient about adverse reactions and allergies, and recent dosing of these OTC medications.
2. Countersigning is of no benefit to preventing risk, as the patient has already received the drug.
3. The patient has full access to these drugs in the community in an unregulated fashion. There are still regulations in place for these in the hospital.

Countersigning for non OTC standing orders should remain in place.

This would save me about 5 interruptions a shift. I get interrupted once every 2 minutes whilst working in the ED on average. Standing order countersigning for OTC pain relief is unnecessary beauracracy that requires a pragmatic solution as that is current practice for ambulance officers.

Kind Regards,

Dr Alexander Browne  
ICU Specialist  
Emergency Medicine Consultant  
Emergency Department,  
Nelson Hospital  
[REDACTED]  
[REDACTED]

#### Countersigning and Audit

The authorised medical practitioner, dentist or other practitioner as defined under the Standing Order must either countersign the medication chart within a defined time frame (e.g. within 24 hours of administration) or audit the use of the Standing Order.

If countersigning is not required, or required less frequently than once a month, the issuer(s) must, at least once a month, audit a sample of the records of administration and/or supply, under the standing order.

Audit sample sizes should be as a minimum:

- 50% of administration and/or supply records if there are 20 or fewer in total
- 20-30% of administration and/or supply records if they are in range of 21-100
- 15-20% of administration and/or supply records if there are over 100.

The results of the audit should be recorded along with any required changes or improvements in relation to the standing order documentation, processes or training to be undertaken.

#### Countersigning

The medication administration must be countersigned by the issuer or another medical practitioner defined within the standing order. The time frame for countersigning will be defined in each standing order. It will normally be:

- 24 hours for the acute hospital setting

**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:**

### **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)?:**

See my previous comments regarding standing orders and the ability of in scope RNs with suitable training and certification to be able to prescribe over the

counter pain relief such as paracetamol and ibuprofen, without the need for Dr or health professional to countersign.

**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.:**

Advertising of medications should be banned. We opened this pandora's box some years ago and it has not added benefit to patients. A drug company sponsored message is not patient education. A similar corollary is found in the advertising of alcohol. It has not provided benefit to the country.

**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. We are an outlier in the world. There is no need for us to be a world leader in advertising for drugs. Patients who want information can find it on the internet without the need for drug company sponsored messages that lead consumers to put pressure on busy clinicians.

## Response ID ANON-DPZ8-G4RD-Q

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

Submitted on **2019-04-13 21:07:08**

### Submitter profile

**What is your name?**

**Name:**

Valerie Hagan-Pratt

**What is your email address?**

**Email:**

**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;:**

### C10 Advertising sector

#### Question C52

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

#### Question C53

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

As a consumer and tax payer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

1. Most consumers lack the knowledge to determine whether any of these drugs might be appropriate or even necessary for them. After all that is what you consult a medical professional to find out; what treatment you need, whether you need medication, particularly to find out how this medication will interact with any drugs you are already taking as well as what side effects the drug or the combination of drugs will cause
2. There is never enough information in an advertisement to allow a potential consumer to make a properly informed choice. It is really just a sales mechanism.
3. The ads promote expectations of what a particular drug, and only that particular drug, will do when perhaps there are other options to achieve the same or better results sometimes even without medication
4. Given that many people expect, and even demand, to walk out of a doctor's surgery with a prescription there is increased potential for over-prescribing, resulting in a waste of drugs and scarce health dollars that could be more usefully spent elsewhere

## Response ID ANON-DPZ8-G4R3-6

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

Submitted on **2019-04-14 11:44:00**

### Submitter profile

**What is your name?**

**Name:**

lesley eley

**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;:**

### 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).:**

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.

### **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?:**

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 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 legal

**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 (

**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 the

## 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

**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?:**

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

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.:**

## Response ID ANON-DPZ8-G4CX-V

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-14 14:02:10**

### Submitter profile

What is your name?

Name:

Fiona Boyd

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Kelston Medical Pharmacy

**Submitter Profile (tick all that apply)**

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;:

**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).:**

I disagree with the definition of dispensing that has been provided here.

Dispensing includes preparation of the medicine for supply, but includes clinical checks, accuracy of prescribing checks, along with providing advice on use,

side-effects and risk of interactions and is at the heart of pharmacist's contribution to primary healthcare

## **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 this as it would improve patient safety by ensuring medicines, devices etc are exactly as labelled and allow for timely response in the event of a 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 as it is important to maintain the ability of pharmacists to provide emergency supply of a medicine

### **Subpart 3: Authorisations (ss 56–80)**

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

I agree as this would allow pharmacists to supply to another pharmacist without the need for a wholesale licence which supports timely access to medicines for patients and may be able to reduce wastage especially of high cost medicines

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

I agree that this should be maintained as it is currently intended

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

To increase access I support an increase in prescribing rights for health practitioners within their scope of practice, so that a funded medicine can be supplied by a pharmacist. If health professionals were regulated to supply Category 3 medicines they would need to meet all of the requirements that pharmacies are held to (included unannounced inspection audits) and have their staff supervised by a pharmacist. Pharmacists have completed five years of training and ongoing education 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 far more stringent than that which applies to other health practitioners. They would also need to invest in ensure they have processes in place for storage, transportation, preventing misuse, ensuring no interactions with other medicines, reporting harm, patient follow up and recalls of medicines.

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

I am opposed to this, it would be inappropriate for staff without the level of training that a pharmacist has to supply medicines, and it is unlikely that a health practitioner would be able to adequately supervise supply as many consultations occur behind closed doors and patients may turn up for supply during this time and would not want to wait until the practitioner was available.

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

No comment

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

I support this as it would limit the ability of consumers to import Category 1 medicines by post which would minimise harm and potential for misuse. It would also help ensure quality as other countries may have different and less stringent checks in place to ensure medicines are supplied as labelled.

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

I support this in part.

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 can increase ease of access to medicines and reduce wider workforce demands on GPs. However, vending machines should only be in locations without access to a pharmacy or pharmacy depot, and should be controlled by a full-service pharmacy to ensure appropriate clinical oversight.

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

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

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):**

I agree with the idea of a single licence to cover multiple activities as it will maintain clinical oversight and transparency over every aspect of pharmacy activity, providing that if needed alterations can be made quickly in special circumstances.

If this includes dispensing away from the main pharmacy then some requirements must be in place around access to patient records and access to appropriate equipment and resources

#### **Question B19**

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

I agree with the need for responsible persons who have met agreed criteria to be needed on the licence

#### **Subpart 2: Permits (ss 131–135)**

#### **Question B20**

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

This system needs to be flexible and quick to allow minimal disruption for 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):**

I support the allowance for licences to be issued for up to 3 years unless there are concerns during this time.

This would help reduce compliance costs on both sides

#### **Question B22**

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

Under certain circumstances licenses should be automatically transferred, to prevent disruption to patients, but not in all circumstances

#### **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

### **C5 Wholesale sector (including importers and exporters)**

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

#### **Licence to wholesale**

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

I support this as the safety profile of medicines imported from outside the approved supply chain is unknown. This restriction would improve patient safety and minimise risk of harm by ensuring medicines etc supplied as exactly as labelled and allow timely response in the event of a product recall.

This would also enable a health professional to be involved in patient care to ensure use of a medicine or device etc is appropriate and safe.

#### **Hawker's licence**

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

#### **Transition**

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

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

#### **Pharmacy sector context**

#### **Future regulation of pharmacy business activities**

#### **Licence to carry out a pharmacy business**

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

I am opposed to hub and spoke distribution models

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

No, but need to ensure that there are checks in place when new services are developed and delivered that there is no reduction in the level of care and clinical advice provided

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

I would like to see that there are systems in place to ensure that any change in distribution and supply do not undermine the current intent, security and integrity of pharmacy services. I do not see how dispensing of medicines can safely occur outside of a properly equipped and staff 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?:**

As a pharmacy owner and former manager I have seen the benefits and risks of an engaged and involved owner vs an owner who is just looking at the financial statements and focussed on the profit margin.

Pharmacies are an integral part of NZ health system and provide a myriad of services to patients that have a significant impact on their health and well being. When the owner is involved in the business and knows the patients and sees the impact of going the extra mile to ensure a patient has the correct medicines and knows how and when to use them and the result of improving their understanding then the question of whether or not to allow profit margins to slide a little changes.

Pharmacist ownership allows for not only legal framework around the way the pharmacy operates but also ethical responsibility to shape the way things are done.

Currently pharmacies deal with a wide range of issues that patients have in connecting with other primary and secondary care providers, prescription issues and provide a lot of advice to assist patients that are not related to pharmacy at all, these are delivered at no cost to the patient or the healthcare system. Under Option 2 these may no longer be provided as there is no financial incentive to provide them.

**Detailed questions relating to Option 1**

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

Benefits:

- owner understands the pharmacy and patient care aspect of the business and is bound by code of ethics personally
- owner is seeing the direct result of choices on patient's health outcomes, prevents patients from becoming a number instead of a person
- better accountability for patient centred care
- many benefits provided at no extra cost to the government or patient
- reduced risk of situations like Boots in UK or other overseas models where pharmacists have lost the capacity to operate in an ethical manner due to the profit driven demands of non-pharmacist owners.

Risks

- some current business arrangements may need to be modified to meet the new requirements, perhaps a time limit could be imposed on when this needs to happen
- May not be the lowest cost model, but will actually provide patient centred care, not a token gesture of the lowest required level of care.

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

I would like to see some location restrictions as there are currently in other parts of the world including some states in Australia whereby before a new pharmacy could open there would need to be evidence of a need or gap analysis showing the benefit to the community. We currently have large overseas owned organisations opening pharmacies a few doors down from existing pharmacies with the seeming intent of shutting down the other pharmacy.

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

I believe the owner should be responsible for meeting all ethical and legal obligations, all owners should share this responsibility regardless of their level of investment.

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

I believe these responsibilities cannot be separated as there is a risk of a separation of focus and it becomes too easy for an owner to hold someone else responsible for ensuring legal and ethical requirements are met, while preventing this by the way they expect the business run in terms of staff numbers and profit margin maintenance demands

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

I think 5 pharmacies should be an absolute upper limit, but struggle to see how a pharmacist can have appropriate oversight of that many pharmacies unless the effective control is shared between 2 or more pharmacist, but would like to see a limit of investment in 5 pharmacies regardless of the level of investment held.

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

A pharmacist or other investor should only be able to have investment in a maximum of 5 pharmacies to prevent the attempt of any one group to control the market or dictate pharmacy behaviour.

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

I believe this would have a positive effect overall, allowing for more individual pharmacists to own and have a stake in how pharmacy operates.

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

I would like to see an immediate halt to any purchases or opening of pharmacies that do not meet the new rules, and a 5 year process of changing any existing arrangements to meet the new stricter 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 think the exemption should 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?:**

**Benefit**

- if cost is the only consideration then this may provide a lower financial cost to the government and perhaps public on the surface (eg no co-payments for patients, government having to provide less financial aid for healthcare in primary care), but I believe there will be a reduced level of care and advice offered which will result in an overall increase in the use of secondary services over time.

**Risks**

- whoever controls the purse strings controls how the pharmacy operates
- this may mean fewer staff, or less qualified staff
- incentives to reduce the amount of time spent with a patient discussing their medicines or health needs as no financial gain
- patients being encouraged to buy OTC products they don't need, or being sold products by non-pharmacist (cheaper) staff without proper questioning and safety checks - sales targets met, but patient safety and trust in the profession suffers
- for most businesses the profit margin is the most important consideration, it cannot be this way in pharmacy, which pharmacists understand and non-pharmacists do not.
- loss of stability in the pharmacy network in NZ as big business chooses to open pharmacies in wealthy and healthy districts instead of rural and poor areas
- inability for small business to compete with large corporates, so small pharmacies who offered better patient care cannot remain viable and close
- loss of many free services currently provided by pharmacy as no financial incentive to provide these.
- increased compliance costs and difficulty in establishing accountability
- employed pharmacists have no good way of reporting non-compliance as risk losing their job, or being made very uncomfortable if they report issues
- focus on increasing product turnover and profit rather than patient health outcomes.
- reduced numbers of pharmacist owners overall, which may result in good people leaving the profession

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

I don't believe there is any way that Option 2 should be considered if the Health Strategy is actually true.

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

NO, and there is no way to make this adequate.

An employed pharmacist will always struggle to report on their employer as it is a conflict of interest if they wish to remain employed.

You can put all the rules in place that you like around preventing any retaliatory action, but they employer still holds the power in the relationship.

**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, except in exceptional circumstances. For example if a patient is unable to come in for a pharmacist only consult but can be spoken to over Skype then this may be ok, but not as a general rule and never for supervision of other staff or dispensing and checking activities

**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 still required, with an ability to provide exemptions for individual, special circumstances.

There is a conflict of interest for a prescriber whereby their actions can influence the income and potential profit.

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

In exceptional circumstances this could be useful, such as earthquakes or natural disasters, but should have restrictions in place to prevent pop up pharmacies exploiting this rule at the expense of existing licence holders

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

These should only be authorised via the licence of a linked full service pharmacy for clinical oversight and to ensure patients still have access to pharmacists for 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?:**

I agree with this as it provides better safety and minimises risks for patients by ensuring imported medicines are legitimate and are supplied as labelled.

**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 should remain as intended by current legislation to allow batch compounding but to restrict the quantities.

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

Yes, where supply will improve patient access. This would also support supply to other pharmacies which could reduce wastage and allow for more timely supply in certain situations

## **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?:**

I agree with the introduction of SCNSA as this will ensure clear advice is given to the patient and better enable 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 provide these. Other health practitioners should have to consult to get one issued

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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 when they are under that practitioners care

**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. They should be allowed to prescribe and funding applied, but supply should be from a pharmacist.

#### **Risks**

- increased compliance costs for practitioner and government as they would need to meet all the requirements that pharmacies and pharmacists must currently meet to ensure safety.

-practitioners may require additional training and capital investment to meet these requirements

- patient would have to wait until practitioner was available to purchase in between appointments

- no real gain, but extra risk especially to patient

**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 are not trained to an appropriate level to do this well or safely.

May not be adequately supervised as health practitioner may be in closed-door consult and feel under pressure to supply as patients may not want to wait for the health practitioner to be available to supervise

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

Advertising should have to meet stricter requirements that puts more emphasis on who it is appropriate for and risks and side effects.

Should not be allowed to mislead or disparage other products/providers

**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-G4R1-4

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

### Submitter profile

What is your name?

Name:

Tania Gluyas

What is your email address?

Email:

What is your organisation?

Organisation:

none

Submitter Profile (tick all that apply)

Consumer

If you select DHB, please state service area:

1072

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

If you selected 'Other' please comment;:

Next steps after the consultation

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

Chapter A (A1 - A5)

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

Neutral

### 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):

### 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.:**

#### **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?:**

These ads downplay safety issues and important details like the side effects.

But most importantly when you have big pharma spending large amounts of money on advertising their products, you are then left with media channels that cannot criticise these products for fear of advertising spend being pulled! And that becomes very dangerous.

## Response ID ANON-DPZ8-G4RV-9

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

Submitted on **2019-04-14 14:52:41**

### Submitter profile

**What is your name?**

**Name:**

Linda Bryant

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Clinical Advisory Pharmacists Association (CAPA)

**Submitter Profile (tick all that apply)**

Professional body (eg, Colleges, Pharmaceutical Society 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?**

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):**

While it is understood that there are reasons for not including complementary medicines and 'dietary supplements' in this Bill, it would be appreciated if the aspect of claims around these products could be addressed. "Help your heart health", "reduce the complications of flu" etc are just a couple of claims made for products.

There are some of the vulnerable people who do have serious health concerns, and perhaps some low health literacy, who are being misled. As under the Code of Rights, and the Consumers Act, people need to be accurately and fully informed of the potential benefits and harms of products.

A tightening of the advertising of complementary products could hopefully be addressed in this Bill.

In particular the dichotomy of needing to be evidence-based to prescribe, provide and sell medicines, but then selling complementary products without the same evidence is problematic. This does extend to non-medicine therapeutic product claims.

### 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):**

Previously, by default due to funding, PHARMAC has provided a safety net for new or expensive medicines. This has meant that medicines have been limited to specialist only or special authority for funding purposes, but also limited access and provided a good safety net while experience with the medicine was gained. An example was isotretinoin, when it was funded only through a dermatologist. As the product became less expensive it became cheaper to get a (non-funded) prescription from a general practitioner and buy the isotretinoin.

In the future new medicines are being marketed more quickly and so safety is not clear (e.g. rosiglitazone) or the use of the medicine is complex, particularly around monitoring, interactions, adverse effects etc. With new technologies - nanotechnology, genetic alteration, CRISPR gene splicing etc, it would be helpful to have a clear indication in the Bill that for some medicines / therapeutic products, there is the potential for a restriction on who is authorised to prescribe / undertake the procedure / activity (e.g. gene splicing, implantations).

This would usually be temporary while more experience was gained for new products, and managed under regulations / rules. It is not intended to be used to advantage one health practitioner over another, but would be available for certain products as an initial safety precaution. currently anyone can prescribe any medicine basically and it have been the environment or cost that has respected this.

Gene therapy, CRISPR gene splicing, nanotechnology and the potential misuse of this / over enthusiasm, would be examples of needing to have some initial control

## **Subpart 3: Authorisations (ss 56–80)**

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

63. Subpart 3:

Although this could cover the comments For Q B4, we think there needs to be a specific section around very new / complex medicines / products and the potential to restrict these to specific health practitioners based on safety concerns and the knowledge and understanding required of the product. There should not be just a reliance on people working within their perceived scope of practice when there is a new treatment concept available

64. Section 57-60

While the Draft Bill is being very clear about the potential for pharmacists to work outside the four walls of a pharmacy, which is excellent, there appears to still be a tendency to focus on the pharmacy environment with dispensing.

Care should be taken that pharmacists can be authorised to undertake controlled activities - including outside a pharmacy.

It is the individual pharmacist who is authorised to undertake the controlled activity, and not just an activity related to within the dispensary.

In the future pharmacies as such may not exist as they disintegrate into retail, remote dispensing, public health hubs that are inter-professional focus on health promotion / public health, and clinical services form within the health care home, or equivalent concept.

There is a need to envisage a future without a pharmacy shop as such.

An example that should be clear (and poss bly is) is that pharmacists may also administer medicines, including IV, and use devices for assessment.

An important area will be the genetic testing and the use of this - it may be too late (the horse has bolted), but genetic testing and basing treatments / selection of medicines / allowing genetic splicing, will need some controls

**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 :**

71. Section 61 (2)

We are in agreement with this, although think that the health practitioner should be the person to provide the medicine after a face-to-face discussion. This may be a virtual discussion, but it needs to be the health practitioner and not a staff member e.g. receptionist, health care assistant, health improvement practitioner etc.

The person may pay for the product at reception, akin to the person purchasing this from the assistant at the counter but the health practitioner needs to have had direct input

75b. Clinical needs supply authority - shouldn't be only a medical practitioner as this may limit access, and in the future that may be a better 'qualified' practitioner who has a better understanding of the product .... but there would be a need to increase accountability for inappropriate and over enthusiastic use i.e. general clinical reviews / monitoring of the use of the product etc

**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):**

Part 41:

Need to be subject to audit and quality processes that pharmacists are

**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.:**

Overseas - Europe, UK, USA, there are vending machines such as MedAvail (previously Pharmatrust) that can store 2000 medicines and can involve a virtual consult. This needs to be allowed for under authorisations e.g. it might be available in a health care home / enhanced general practice environment. Authorisations need to be able to enable these advancements, as well as the remote dispensing and delivery of medicines.

**Subpart 4: Other offences (ss 81-94)**

**Question B12**

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

DTCA targets all levels of society and attempts to persuade individuals that a medicine would alleviate an medical problem. While this could be true for a properly diagnosed and prescribed individual, there is no guarantee that any medicine will work for any patient. The NNT and NNH statistics are never provided with these adverts, which would at the very least enable the public to recognise the potential for benefit and harm.

This is different to normal advertising in that the person themselves are not balancing the cost-effectiveness necessarily, but there is a third party payer (the taxpayer). There is ample information, also nor necessarily accurate, on the internet that is readily available. Searches on the internet will often also provide more valid information though, such as through a validated NZ website eg Health Navigator

While it is recognised that this Bill is not intended to cover complementary medicines / alternative medicines / health supplements, it is important that this Bill includes in its advertising standards tighter control over what can be claimed when advertising these medicines. Statements like "helps heart health"; "prevents the complications of the flu" [ad infinitum, ad nauseum] are misleading, and it is often the vulnerable person with multiple co-morbidities looking for a magic product. Considerable money is spent on products and the recipient needs to be fully informed as per the Consumers Act and also Health and Disability Code of Rights.

Tangential but relevant to this, considering licensing, it is a dichotomy that a health practitioner is evidence-based when prescribing medicines, but can be non-evidence-based when selling complementary/ alternative medicines or supplements.

**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).:**

See Chapter 6 re: pharmacy ownership comments, though as a general comment, to future proof this Bill for 2040, there is a need to envisage that a pharmacy as it now exists is unlikely to exist. the disintegration of a pharmacy (primarily a community pharmacy" and the notion that certain activities are restricted to a

pharmacy will be obsolete. It may be more relevant to consider a 'controlled environment', and also any licensing is of the person, not the environment

## **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):**

As above - consider specific activities that need to be undertaken in a controlled environment - without necessarily a name (which can be limiting to innovation)

## **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):**

Re: Ownership - covered later, but under this section regarding the licensee - the same responsibilities and accountability would be applicable whether a pharmacist or not i.e. potential prison and fines for allowing illegal / unethical practices in the pharmacy

In general, as above, we need to move away from restrictions due to the name 'pharmacy'. There will be many different activities in the future, and a broadened activity such as to a health and well-being hub, public health roles / promotion and this may well be multi-professional and broad spectrum. This would not be a pharmacy as such but incorporate other activities (health coaches, dieticians, physiotherapists etc).

the activities are not pharmacy activities, they will be pharmacist activities within the broader team.

The supply and distribution function may, or may not, occur in this environment. Supply and distribution is likely to occur from a 'controlled environment' but will have different connotations to what pharmacist services may become

## **B8 Part 6 of the Bill: Regulator**

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

#### **Question B24**

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

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

#### **Question B25**

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

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

#### **Question B26**

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

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

#### **Question B27**

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

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

#### **Question B28**

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

## **B9 Part 7 of the Bill: Enforcement**

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

#### **Question B29**

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

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

#### **Question B30**

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

### **Subpart 6: Infringement offences (ss 249–255)**

#### **Question B31**

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

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

#### **Question B32**

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

## **B12 - B15, Schedules 1 - 4**

### **Schedules**

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

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

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

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

### **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):**

With the expanding use of medicines there is a hazard that the 'who and supply ' prescribe what' situation will be cumbersome and difficult to manage / monitor. The individual Council's may decide what standard is required, but multiple complex levels will not be efficient. This is like a nurse prescriber in a specific area who should only prescribe the medicines she is competent to prescribe, but can also prescribe medicines outside her scope because ' it's just a repeat'. This will be management and potentially hazardous.

For the medicines that are pharmacist only - then all pharmacists can do this - the category speaks for itself

Having multiple exemptions for pharmacist to 'prescribe' a product if they have had training is also not feasible - and it is supplying in many situations rather than prescribing as such. This becomes murky and so. The funding (patient pays = selling) or DHB funds is not part of the focus of the Bill. The product really is then just another pharmacist only medicine.

The issue is that the pharmacist does not have to be in a pharmacy - or attached to a pharmacy, in any way in order to supply the product

As per previous comment under B4 - an extra category restricting prescription of some complex new medicines or products to certain health practitioners initially, for safety purposes while obtaining experience, may be helpful to have as a safeguard for future speciality products / medicines

**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.:**

Yes, agree that MedSafe's activities have to be enhanced - and beyond just safety perhaps in light of the new advances regarding medicines and devices / products that are likely in the next 20 years.

## 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?:**

We agree - a pharmacist can be licensed to provide pharmacist services outside a pharmacy but it needs to be clear that that pharmacist does not have to be attached to a pharmacy in any way i.e. not employed by a pharmacy; it is not a satellite pharmacy service, but can be independent

[This away from having to provide pharmacist services from a pharmacy is another reason to consider separating functions and consider dispensing / supply to be from a controlled environment]

NB: dispensing by prescribers - of own or others prescriptions

We disagree with this unless the same regulations / standards apply to all people dispensing.

There is a difference in giving a patient an emergency supply and actually dispensing a medicine for a long term. These two situations should not be confused - there is dispensing according to the rules and regulations; and then there is providing a supply in acute situations.

With the future, and current, potential for medicines to be dispensed and delivered, there is no longer a need for prescriber-dispensing other than an acute situation.

There were good safety (and financial conflict) reasons for separating prescribing and dispensing historically - and these reasons still 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 only issue is around interpretation for funding - needing a licence as a requisite for a service contract with a DHB. The intentions are clearly stated that this is for supply and distribution only, and so there needs to be recognition of this by the DHBs and a de-linking of the supply and distribution functions for other potential pharmacist services for funding [Difficult to encompass in a Bill, we know]

**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?:**

Corporatisation of community pharmacy has already occurred and no one with any knowledge of the industry believes the current legislation is working as originally intended. To unwind the existing roots within the system would be complicated and pharmacists who currently own multiple pharmacies and the corporate owners such as Green Cross, Countdown and Chemist Warehouse, may be unwilling to have their current situation unravelled. The option to have an open ownership model considering the existing model of community pharmacy would not then be very different to the situation that currently exists.

As previously stated, other than a supply and distribution function that is increasingly becoming remote e.g. Zoom in NZ; very common in USA, the concept of a community pharmacy will change considerably in the future.

The model may well morph into a health and well-being hub that may also include dispensing (acute medicines, like the old 24 hour photo drop off facility before i-phones) with many different health care providers / practitioners [physiotherapist, dietitian, nurses, social workers, health improvement coaches, counsellors etc as well as the pharmacist]. There should be no limit on who can own such an enterprise - it is not the prerogative of only a pharmacist to be the owner in this collaborative team concept.

The open ownership model may provide more opportunity to pharmacists to develop new models of professional practice without having to rely on the supply and distribution of medicines as a basis for funding professional services, and improve efficiency of the supply and distribution.

For efficiency - it may also be more cost-effective to have wider ownership.

The question may be - can GP's or other prescribers own or have shares in the pharmacy due to potential financial conflict of interest. This does need discussion because currently a pharmacist (owning the pharmacy next door) may own a general practice.

Looking towards the future, and the efficiencies of remote dispensing and delivery as per Zoom currently, would this matter as the dispensing (the potential conflict of interest area) would be done elsewhere. This would reduce the drive to own a pharmacy that was not predominantly retail. This may be the proviso - not benefiting from the prescription of medicines

### Detailed questions relating to Option 1

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

Benefits

- improved opportunities
- less frustration as people find loop holes
- better access and reduced costs for some products that patients need to purchase (OTC, NSS etc) due to bulk buying
- With the changes to supply and distribution (remote dispensing due to corporate investment) and less pharmacies as a supply outlet required, more pharmacists will be able to move into the general practice environment independent of the supply and distribution role
- Less frustration as loopholes are discovered in the legislation
- no need for grandfathering

Risk

Very little beyond what is already a problem

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

As above - consider prescriber ownership - but this may reduce as the dispensing become off site - remote etc, providing ownership of the remote dispensary wasn't as issue e.g. current corporates having shares in pharmacies and general practices.

Ensure the actual owners are equally responsible for breaches in terms of fines and prison time - very similar to the new Directors' responsibility (no hiding)

Note: Conflict potential is much higher when there is a third party payer for services

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

We disagree with the requirement for pharmacist ownership - but the issue is around ownership of the Supply and Distribution function.

There would be a complication re: licensing of the pharmacist for providing pharmacist only medicines from within a general practice - need to think this one through. As it is not a third party payer - can a general practitioner - or the corporate owning the general practice, be the 'owner' for the pharmacist license [Sorry - messy]

**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?:**

Disagree with the concept of needing to be a pharmacist owner.

Separating control and ownership has led to the current problem. If two different people, both are responsible and accountable

**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)?:**

Too much leeway for interpretation

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

Do not retain this - it is a half way measure that was brought in many years ago to try and legitimise the loopholes that pharmacist owners had already found. There were no good grounds for arriving at a figure of 5.

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

There are only 400 'real' pharmacist owners now, if that - so why is there so much focus on this minority of 10 to 15% of the profession.

The impact of not having pharmacist ownership would be on a minority of pharmacist owners, but the improved efficiencies from a corporate-type owner, presumably looking at efficiencies in the supply and distribution functions to reduce their costs, and hence wages for pharmacists will release pharmacist from the four walls of a pharmacy to do dispensing.

Remote dispensing would be efficient and 'pharmacies' would be a potential outlet for distribution - or couriers / drones / (3D printing) - with pharmacists not required for dispensing and so less required to be employed in the community pharmacy environment. This would provide some opportunities for pharmacists to utilise their pharmacotherapy skills elsewhere (providing the funding didn't compel them to remain attached to a pharmacy)

**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?:**

Yes - as ownership should preferably be open

**Detailed questions relating to Option 2**

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

As above - C24

Corporatisation of community pharmacy has already occurred and no one with any knowledge of the industry believes the current legislation is working as originally intended. To unwind the existing roots within the system would be complicated and pharmacists who currently own multiple pharmacies and the corporate owners such as Green Cross, Countdown and Chemist Warehouse, may be unwilling to have their current situation unravelled. The option to have an open ownership model considering the existing model of community pharmacy would not then be very different to the situation that currently exists.

As previously stated, other than a supply and distribution function that is increasingly becoming remote e.g. Zoom in NZ; very common in USA, the concept of a community pharmacy will change considerably in the future.

The model may well morph into a health and well-being hub that may also include dispensing (acute medicines, like the old 24 hour photo drop off facility before i-phones) with many different health care providers / practitioners [physiotherapist, dietitian, nurses, social workers, health improvement coaches, counsellors etc as well as the pharmacist]. There should be no limit on who can own such an enterprise - it is not the prerogative of only a pharmacist to be the owner in this collaborative team concept.

The open ownership model may provide more opportunity to pharmacists to develop new models of professional practice without having to rely on the supply and distribution of medicines as a basis for funding professional services, and improve efficiency of the supply and distribution.

For efficiency - it may also be more cost-effective to have wider ownership.

Looking towards the future, and the efficiencies of remote dispensing and delivery as per Zoom currently, would this matter as the dispensing (the potential conflict of interest area) would be done elsewhere. This would reduce the drive to own a pharmacy that was not predominantly retail. This may be the proviso - not benefiting from the prescription of medicines

And C30

There are only 400 'real' pharmacist owners now, if that - so why is there so much focus on this minority of 10 to 15% of the profession.

The impact of not having pharmacist ownership would be on a minority of pharmacist owners, but the improved efficiencies from a corporate-type owner, presumably looking at efficiencies in the supply and distribution functions to reduce their costs, and hence wages for pharmacists will release pharmacist from the four walls of a pharmacy to do dispensing.

Remote dispensing would be efficient and 'pharmacies' would be a potential outlet for distribution - or couriers / drones / (3D printing) - with pharmacists not required for dispensing and so less required to be employed in the community pharmacy environment. This would provide some opportunities for pharmacists to utilise their pharmacotherapy skills elsewhere (providing the funding didn't compel them to remain attached to a pharmacy)

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

Very clear responsibility and accountability of the owner, including Directors. They are clearly liable for any breaches - like pharmaceutical manufacturers, companies are responsible and accountable.

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

As above - and looking to the future, and remote dispensing, this is really just like a pharmaceutical manufacturing company and their responsibilities

**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?:**

Looking to the future, the pharmacist in the general practice / health care home / hospital / community health and well being hub could provide the clinical review, advice and counselling. The supply and distribution function is separate to the 'clinical' function beyond the technical checking for interactions, unclear changes in dose / medicine - which would be identified from the dispensary (remote of community pharmacy) and questioned from the dispensary.

The face to face discussion could be from the pharmacist in person or virtually, and still potentially independent of the dispensing function.

See the MedAvail vendor system - a pharmacist is available 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?:**

We need to move away of thinking that the future for pharmacists still revolves around a community pharmacy and that the limitation for pharmacist prescriber is that they are in that environment, when it is more sensible, integrated and less fragmented for them to be integrated in the team - and safer.

Why would the pharmacist prescriber need to be in the pharmacy? This will change with remote dispensing, though there is then the risk of hazardous prescribing with repeat prescribing without adequate safeguards.

We are moving to a future with more complex medicines and hopefully we will reduce drug-related morbidity and mortality. The current pharmacist prescribers who at times do undertaken clinical reviews and prescribe repeat medicines have found that in the integrated environment they are intervening in some way on 70 to 80% of repeat prescriptions.

There are safety and financial conflict of interest issues and there is a need to avoid fragmentation. There is another path for pharmacist prescribers in the future and encouragement to move to the future is required.

There should also not be confusion about what prescribing is involved - it is prescription medicines. Pharmacist only medicines are being supplied.

Other all there are likely to be far more safety concerned with multiple prescribers, and especially prescribers in limited areas. Again, the observation is that prescribers for 'diabetes' focus on this to the detriment of other conditions (CVD, HF etc) and there is fragmented care rather than holistic care, especially around the medicines.

The ability of and health professional to apply for prescribing rights has positives and negatives. Permitting any health practitioner to prescribe medication either from a restricted list or within a defined practice creates a huge potential for medication related health problems. Currently there is no possibility of adding the notification of the supply of prescription to an individual patient, that can be seen by all other potential prescribers. This creates the possibility of duplication of treatments, and the attendant adverse effects. This situation already exists between primary and secondary care, and creating a plethora of unrelated prescribers

can only increase the potential for harm.

We endorse the current system where there is a restriction and only under special circumstances is there an exemption

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

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

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

### **Pharmacist and pharmacy worker authorisations**

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

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

### **C7 Retail sector**

#### **Question C42**

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

### **C8 Health practitioners (including pharmacists)**

#### **Prescribers**

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

The ability of a health professional to apply for prescribing rights has positives and negatives. Permitting any health practitioner to prescribe medication either from a restricted list or within a defined practice creates a huge potential for medication related health problems. Currently there is no possibility of adding the notification of the supply of prescription to an individual patient, that can be seen by all other potential prescribers. This creates the possibility of duplication of treatments, and the attendant adverse effects. This situation already exists between primary and secondary care, and creating a plethora of unrelated prescribers can only increase the potential for harm.

There needs to be a clear integrated / collaborative approach by all Council's to consult and take note.

Due to the imbalance of power (size) and vested interests of professions we believe that this is a function that needs to remain under the Ministry of Health to impart independence and consistency

**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?:**

There is a need for a consistent standard and certainly knowledge and understanding of medicines therapy. Drug-related morbidity and mortality does not appear to be reducing, and nor hospitalisation. Medicines are becoming more complex, and people living longer with co-morbidities.

At a time when so much effort and regulation is put into ensuring the safe product and dispensing / supply, it is ironic that here is an aim to increase prescribing without extensive pharmacotherapy knowledge and understanding, and especially in an increasingly fragmented way.

Access is being less of an issue now and in the future with virtual consults, remote dispensing and courier / drone delivery. We need to avoid the risk of developing a Bill with a focus on improving access over potential quality when access will become less of a from.

Certainly there is a need for consistency in the prescribing standards across all - and simplify. Prescribing of prescription medicines, with the same standard, is by medical practitioners, midwives, nurse practitioners, pharmacist prescribers. There are then specific areas for dentists, physiotherapists, dieticians. 'Half-way' prescribing (i.e. in one area) in a limited area is not safe and would be (modified) understanding orders where necessary to avoid some prescribing beyond their 'specialty'.

Consistency of standard / qualification is an important consideration as there is already 'scope creep' with some prescribing nurses (not nurse practitioners). This will not just relate to nurses but is just an example. Same could be held for community pharmacists. The standard for prescribing is the standard by all, because to limit a broad-based profession to one area risks missing important issues for the patient outside that area

**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.):**

Although it appears to be going backwards, these would be enhanced somewhat to incorporate the nurse prescriber functions to avoid scope creep

**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?:**

Already answered

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

Already answered

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

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

DTCA targets all levels of society and attempts to persuade individuals that a medicine would alleviate an medical problem. While this could be true for a properly diagnosed and prescribed individual, there is no guarantee that any medicine will work for any patient. The NNT and NNH statistics are never provided with these adverts, which would at the very least enable the public to recognise the potential for benefit and harm.

This is different to normal advertising in that the person themselves are not balancing the cost-effectiveness necessarily, but there is a third party payer (the taxpayer). There is ample information, also nor necessarily accurate, on the internet that is readily available. Searches on the internet will often also provide more valid information though, such as through a validated NZ website eg Health Navigator

While it is recognised that this Bill is not intended to cover complementary medicines / alternative medicines / health supplements, it is important that this Bill includes in its advertising standards tighter control over what can be claimed when advertising these medicines. Statements like "helps heart health"; "prevents the complications of the flu" [ad infinitum, ad nauseum] are misleading, and it is often the vulnerable person with multiple co-morbidities looking for a magic product. Considerable money is spent on products and the recipient needs to be fully informed as per the Consumers Act and also Health and Disability Code of Rights.

Tangential but relevant to this, considering licensing, it is a dichotomy that a health practitioner is evidence-based when prescribing medicines, but can be non-evidence-based when selling complementary/ alternative medicines or supplements.

## **C10 Advertising sector**

### **Question C52**

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

### **Question C53**

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

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

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

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

### **Personal imports**

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

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

### **Pharmacy licensing**

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

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

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

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

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

### **Access to pharmacy medicines**

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

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

### **Advertising**

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

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

### **Packaging and labelling and consumer medicine information**

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

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

### **Adverse event monitoring**

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

## Response ID ANON-DPZ8-G4DR-Q

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-14 15:32:59**

### Submitter profile

What is your name?

Name:

Carmel Berry

What is your email address?

Email:

What is your organisation?

Organisation:

Mesh Down Under

Submitter Profile (tick all that apply)

Consumer, Disabled person

Industry body

If you select DHB, please state service area:

Auckland

Other health practitioner (please comment)

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

patient advocate

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).:

Just a comment on Question a1. The diagram doesn't reflect an 'end' of the life cycle of a therapeutic product. Whether it is 'withdrawn for commercial reasons' or made to stop supply as deemed unsafe.

#### 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).:

Clearly defined

#### 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 important thing here is in a situation when a medical professional brings in (imports) a medical device or devices (as we know they do with surgical mesh) - that the safety net of the law must apply in this situation as well.

**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 important thing here is in a situation when a medical professional brings in (imports) a medical device or devices (as we know they do with surgical mesh) - that the safety net of the law must apply in this situation as well.

**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):**

Point 83. 'person or carer can bring in device for own use should be 'own personal use for their own body' ... and carer should be defined as 'not a health professional'.

**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:**

n/a

**B6 Part 4 of the Bill: Product approval**

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

**Question B13**

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

107. How can the safety of a product be satisfactorily established when often they are 'new' or 'innovated' products. This would require pre-market clinical trials yet often medical devices are introduced on the basis that they are 'substantially equivalent' to a previous (or grandfather) device. Without mandatory reporting (by health professionals) of any and all adverse effects AND a register of all implants with follow up in the long term - the safety and indeed efficacy of the devices cannot be established satisfactorily.

**Question B14**

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

Does this replace the section 38 of the old law? 'ie grounds to believe there could be public harm'.

**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):**

124. CRITICAL. post-market safety monitoring and reporting should be mandatory and transparent and timely.

**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):**

short term or exceptional use only.

**Question B19**

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

Short term or exceptional use only.

**Subpart 2: Permits (ss 131–135)**

**Question B20**

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

Agree.

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

**Question B21**

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

n/a

**Question B22**

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

n/a

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

**Question B23**

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

n/a

**B8 Part 6 of the Bill: Regulator**

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

**Question B24**

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

The regulator should have the requirement to answer to the Director General of health and enact recall or prohibition deemed necessary.

**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):**

agreed

### **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):**

Agree that any COI should be declared and all panel members must be independent.

### **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):**

If a manufacturer has been convicted internationally on claims of product safety (civil and federal) they should also be put on notice in New Zealand. 189. Could have a d. clause where the regulator can alert the sponsor that the regulator is aware of international decisions and will be monitoring with vigilance.

### **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):**

n/a

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

## **Question B34**

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

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?:**

agree

## **C1 Medicines (excluding cells and tissues) sector**

### **Product-based controls**

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

n/a

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

n/a

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

n/a

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

n/a

### **Activity-based controls**

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

n/a

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

n/a

## **C2 Cell and tissue sector**

### **Product-based controls**

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

Yes.

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

n/a

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

agree.

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

agree.

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

n/a

### **Activity-based controls**

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

n/a

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

n/a

## **C3 Medical device sector**

## Question C11

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

The question remains - is it the manufacturer or regulator that determines the classification of a device? Case in point is that surgical mesh was previously classified in New Zealand as Class II. FDA and EU have reclassified as Class III (High risk) yet this has not been changed in New Zealand. I anticipate as each device goes through the transition phase they will be reclassified accordingly.

Introduction of the UDI and device traceability can be introduced NOW, without waiting for the entire bill to go through 3 readings.

## 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 question remains - is it the manufacturer or regulator that determines the classification of a device? Case in point is that surgical mesh was previously classified in New Zealand as Class II. FDA and EU have reclassified as Class III (High risk) yet this has not been changed in New Zealand. I anticipate as each device goes through the transition phase they will be reclassified accordingly.

Introduction of the UDI and device traceability can be introduced NOW, without waiting for the entire bill to go through 3 readings.

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

.383. Changes would be categorised as major or minor but this doesn't deal with urgent.

384. About time! 378- public register fully supported, this should include publications of status and results of ALL CLINICAL TRIALS.

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

391. Surgical mesh (Particularly transvaginal mesh) should only be used as a last resort and should have supply restrictions to ensure that it is only used under the management of MDG or in a clinical trial setting.

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

.397 this should be obligatory for health professionals as well as sponsors.

.398 meaning is unclear.

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

.400 wholesalers 'and health professionals' who are obtaining..... (Often surgeons deal direct with sponsors).

## Activity-based controls

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

n/a

**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.:**

n/a

### Question C17

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

n/a

## 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?:**

n/a

## Hawker's licence

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

n/a

## Transition

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

n/a

## C10 Advertising sector

### Question C52

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

582 DTCA should EXCLUDE permanently implantable medical devices like surgical mesh. (EXCEPT Patient information documentation provided by a suitably qualified health professional).

### Question C53

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

n/a

## C11 Patients, consumers and disabled people

### Unapproved medicines

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

n/a

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

n/a

### Personal imports

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

n/a

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

### 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.:**

Full informed consent to use of medical devices is a process not a signature on a page just prior to surgery.

The Bill does not deal with this issue specifically in terms of regulations.

## Response ID ANON-DPZ8-G4RZ-D

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

Submitted on 2019-04-14 17:51:44

### Submitter profile

What is your name?

Name:

Vesna

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Pharmacy

Submitter Profile (tick all that apply)

Consumer

Medicines

District Health Board (DHB)

If you select DHB, please state service area:

Pharmacist

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

If you selected 'Other' please comment;:

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).:

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).:

none

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):

pharmacist should own pharmacy

#### **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

## **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:**

## **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?:**

I disagree

**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

## **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?:**

we should have a system where pharmacy are away from each other 1km or so according to the need of a particular area .

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

none

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

none

**Question C22 Which option do you support?**

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

**Question C23 - Why do you support that option?:**

because I am a pharmacist and I do know how much you have to know to be able to be good and responsible person. Dr that i work with have no idea how the pharmacy work and they are from the same , medical field but have no idea how the pharmacy works.if they don't know how would other professions know?

#### **Detailed questions relating to Option 1**

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

Pharmacy is a multilevel service and if you are not trained or you don't know anything about it it would be very hard for someone else to conduct efficiently and will cause lots of misunderstandings

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

Should be 1 pharmacist 1 pharmacy

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

owner

**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?:**

pharmacist should have majority ownership and responsibility should not 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)?:**

It should be 1 pharmacy 1 owner

**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?:**

no

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

5 years

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

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?:**

huge risk to public

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

Option 2 should not exist

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

supervisory pharmacist should be the owner/pharmacist and should work same as others

#### **Other changes to pharmacy licensing requirements**

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

yes

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

no

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

no

**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?:**

I disagree

#### **Pharmacist and pharmacy worker authorisations**

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

no

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

no

# Therapeutic Products Consultation: Submitter Profile

If you elect not to use the online tool to complete your submission, please ensure you complete the following submitter profile form and send in via email with your submission.

Individual       Organisation

**Name (of individual or organisation):** Skin Cancer College Australasia

**Email address:** info@skincancercollege.org

## Profile (tick all that apply)

### Perspective

Consumer       Disabled person       Māori       Pacific peoples  
 Other [Click here to enter text.](#)

### Industry

Industry body  
 Advertising  
 Retailer (non-pharmacy)

#### **Importer**

Medical devices  
 Medicines  
 Cells and tissues  
 Active ingredients  
 Veterinary medicines

#### **Manufacturer**

Medical devices  
 Medicines  
 Cells and tissues  
 Active ingredients  
 Veterinary medicines

#### **Wholesaler**

Medical devices  
 Medicines

### Health sector

Professional body (eg, Colleges, Pharmaceutical Society etc)  
 Health service provider (eg, Ambulance, Māori or Pacific health provider etc)  
 Private hospital  
 Pharmacy organisation  
 District Health Board (DHB) - please state which service area: [Click here to enter text.](#)

#### **Health practitioner**

Pharmacist       Surgeon  
 Nurse       Optometrist  
 Midwife       Dietician  
 Dentist       Medical practitioner (excluding Surgeons)  
 Other health practitioner (please comment) Primary care skin cancer doctors

### Clinical trials

- Medicines (other than cell and tissue)
- Medical devices
- Cells and tissues
- Trial ethics

### Other

- Government agency
- Crown entity
- NGOs
- Veterinarian
- Other (please comment) [Click here to enter text.](#)

## **Official Information Act statement**

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

10 April 2019

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ABN 47 155 488 467

NZ GST No 119-783-275

Dear Sir/Madam,

## **Therapeutic Products Regulatory Scheme - Consultation Document**

### **1. Introduction**

- 1.1 The board of the Skin Cancer College of Australasia (SCCA) wishes to express its thanks to the Ministry of Health for the opportunity to make a written submission on the proposed Therapeutic Goods Regulatory Scheme.
- 1.2 SCCA is the non-profit peak body for primary care skin cancer health professionals. Our goal is to use education, research, advocacy and standards to improve the availability of high-quality skin cancer diagnosis and management for all New Zealanders. The College has over 1000 members in the Australasian region, 175 are practising in New Zealand.
- 1.3 SCCA strongly supports the Government's aim to protect personal and community health by ensuring that therapeutic products in New Zealand meet acceptable safety, quality and efficacy or performance requirements across their lifecycle.
- 1.4 SCCA gives permission for our contact details to be released under the Official Information Act 1982.

**This submission primarily addresses the following consultation questions:**

**Question B2**

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

**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.

.../2

## **2. Recommendations**

- 2.1 **The Skin Cancer College Australasia (SCCA) strongly recommends that sunscreens be defined as a therapeutic product.**

*Extract from Therapeutic Products Regulatory Scheme – Consultation Document  
Page 12, paragraph 49 (d):* **therapeutic product** (s 16): If it is unclear whether something is covered by the definition of therapeutic product (eg, sunscreens), it will be possible to declare something to be a therapeutic product using regulations.

- 2.2 Consistent with the international approach to regulating such products, sunscreens should be required to comply with pre- and post-market controls that regulate their manufacture, import, promotion, and supply.
- 2.3 Regulation of sunscreens in New Zealand is not a difficult thing to achieve. Standards **already exist** and are applicable for both New Zealand and Australia – i.e. S/NZS 2604:2012. A new [Australian and New Zealand Sunscreen Standard, AS/NZS 2604:2012](#) which replaces the previous Standard AS/NZS 2604:1998 was developed by the Standards Australia and Standards New Zealand in consultation with stakeholders and the public. This was published on 30 May 2012.
- 2.4 The missing element to enable this standard to effectively protect personal and community health is a regulatory framework and supporting legislation to enforce the existing standard.
- 2.5 **Therefore, the Skin Cancer College Australasia (SCCA) strongly supports the proposed Therapeutic Products Bill to replace the Medicines Act 1981 and establish a new regulatory scheme for therapeutic products.**

## **3. Supporting Evidence**

- 3.1 New Zealand and Australia have the highest Melanoma rates in the world. Melanoma is also the fourth most common cancer diagnosed in New Zealand<sup>1</sup>
- 3.2 Patients are consulting their general practitioners to recommend sunscreen products as they are unable to rely on existing product labelling to make informed purchase decisions.
- 3.3 Consumers need to have confidence in the sun protection factor claims made by sunscreen manufacturers. This is especially the case for sunscreens which are used to protect children.
- 3.4 The current situation of classifying sunscreens as cosmetics also means consumers can't have faith in label claims and risk using products that have undergone no testing at all. In Consumer NZ's latest test of sunscreens, only four of the 19 products met SPF label claims.<sup>2</sup>
- 3.5 Any perceived cost to establish and manage regulation of sunscreens is far outweighed by the public health cost of diagnosing and treating skin cancer in New Zealand.

- 3.6 Voluntary compliance with the sunscreen testing standard is not a satisfactory situation for a country with one of the highest incidences of skin cancer in the world.
- 3.7 The clinical evidence in support of quality sunscreens is overwhelming. This evidence is now beyond debate.

*“Skin cancers are predominantly caused by over-exposure to the sun’s UV radiation:*

- (i) During everyday activities which add up over time (e.g. travelling to and from work; doing household chores; shopping etc)*
- (ii) During any planned or prolonged outdoor activities (e.g. doing outdoor work; gardening; playing or watching sport; going to the pool or beach; exercising outdoors etc)*

*When applied correctly and used regularly, sunscreen is effective in reducing the incidence of skin cancer.”<sup>2</sup>*

*“The amassed evidence from epidemiologic and, more recently, genomic studies provides definitive proof that solar ultraviolet (UV) radiation is the principal causal factor for most of these cancers. The fraction of melanoma attributable to solar UV radiation exposure has been estimated at between 65% and 90%; for keratinocyte cancers the population attributable fraction approaches 100%.*

*Of the three approaches to control skin cancer (viz. primary prevention, early detection and better treatment), primary prevention [which includes sunscreen use] is the most cost-effective and the only strategy that can lower the rate at which new cancers arise.”<sup>3</sup>*

If required, we welcome the opportunity to provide further information or answer any questions regarding this submission.

Yours sincerely,



**Ms Lynette Hunt**  
Chief Executive Officer



**Dr Franz Strydom FRNZCGP FSCCA**  
Director

<sup>1</sup>Incidence rates for all cancer and the five most common cancer types 2008 – 2012, Health Quality and Safety commission New Zealand <https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/cancer/>

<sup>2</sup>Consumer NZ, Sunscreens Test Report – December 2018  
<https://www.consumer.org.nz/articles/sunscreens/know-the-issue>

<sup>3</sup>**When to apply sunscreen: a consensus statement for Australia and New Zealand**  
Australian and New Zealand Journal of Public Health - First published: 25 January 2019  
<https://onlinelibrary.wiley.com/doi/full/10.1111/1753-6405.12873>

11 April 2019  
to [therapeuticproducts@moh.govt.nz](mailto:therapeuticproducts@moh.govt.nz)

## Therapeutics Products regulatory scheme consultation

### Introduction

This submission is from the Choosing Wisely campaign – which is coordinated by the Council of Medical Colleges (CMC). The submission from Choosing Wisely only addresses DTCA i.e. **questions C52 and 53** as set out in the online response document.

The Council of Medical Colleges and other Colleges will be making fuller separate submissions on the whole of the Bill.

Choosing Wisely New Zealand is a health professional led, patient focussed, campaign promoting quality care, through better decisions. It is multi professional – engaging doctors, nurses, pharmacists, midwives and other health professional groups – as part of an international community of Choosing Wisely initiatives taking place around the world.

Currently we have projects being implemented in 18 DHBs, several PHOs and GP groups and are working actively with nurses, pharmacists, physiotherapists and occupational therapists.

The campaign aims to promote a culture where low value and inappropriate clinical interventions are avoided, and patients and health professionals have well-informed conversations about their treatment options, leading to better decisions and outcomes.

Choosing Wisely does not support DTCA as it does not align with shared decision making whereby patients and health professionals can discuss tests, treatments and procedures to ensure the patient receives the treatment most suitable for their care.

Choosing Wisely supports the CMC statement on DTCA and considers DTCA can lead to:

- **increased costs and potential harm**
- **inappropriate prescribing**
- **overtreatment, sometimes resulting in harm**
- **iatrogenic harm**
- **putting the doctor-patient relationship at risk.**

Choosing Wisely notes:

DTCA can lead to increased costs to consumers because branded medications may cost significantly more than generic medications or non-drug therapy. The resulting demand from patients for branded medications ultimately imposes a cost on the health-care sector. The pharmaceutical industry invests significantly in marketing and promoting branded products, which may have no efficacy advantage over generic alternatives.

1. **DTCA can lead to inappropriate prescribing** as doctors may feel pressured by patients to prescribe certain medications to the detriment of other non-drug modalities such as lifestyle modifications. There is considerable evidence that patients' requests for a specific product can be a key cause of unnecessary prescribing (i.e. medicinal wastage) with little benefit and often high cost to the patient and health system. DTCA often focusses on particular disorders which can de-stigmatise those disorders but also has the potential for a consumer to self-diagnose.

Recent research by the University of Otago, published in the Australian and NZ Journal of Public Health found that people of ethnic minorities were more likely to ask a pharmacist about an advertised drug than NZ pakeha, some of this results in medicalisation of normal conditions.

2. **DTCA can lead to overtreatment and may lead to iatrogenic harm** as advertisements for pharmaceuticals in New Zealand are not of consistent quality and may cite publications which are inappropriate. Online DTCA and social media can saturate the market and the FDA in the USA has warned several pharmaceutical companies that their sponsored links on search engines were misbranded because they did not provide statements about adverse effects.

It is argued that the benefits of DTCA include disseminating health information about illnesses and treatment, reducing stigma and empowering consumers by providing information and encouraging choice. However, research suggests that information provided to consumers by the pharmaceutical industry is likely to be biased in favour of benefits over potential harms. A study found that only 13% of pharmaceutical advertisements provided any evidence to support their claims about efficacy (Schwartz and Woloshin, 2013). Where evidence is made available, the data tends to exaggerate the magnitude of the benefits (Every-Palmer, Duggal & Menkes, 2014).

DTCA may impact on the doctor-patient relationship in several ways. Most commonly, DTCA prompts consumers to request advertised drugs. While sometimes useful, many doctors (especially general practitioners) find themselves being asked to prescribe medications that they do not consider are clinically indicated (Robinson et al., 2004; Humphreys, 2009). Resisting consumers' requests may place the therapeutic relationship under stress and may lengthen the duration of consultations (Robinson et al., 2004).

In NZ a recent study published in the Australia and NZ Journal of Public Health has noted that people of ethnic minorities were more likely to ask a pharmacist for an advertised drug, than pakeha.

3. **Issues relating to prescribing and potential harm** - Studies conducted in the United States found that consumers exposed to DTCA were more likely to believe that they needed medication, to request products advertised on television, and to receive prescriptions for these products (Gilbody et al., 2005).

There are also examples where significant harm has arisen from under-reporting of safety risks. For example, in 2012, Glaxo Smith Kline promoted the safe use of an antidepressant in a paediatric setting despite established concerns about the risk profile in this population (Bond, 2013). DTCA also encourages health professionals to engage in prescribing off-label uses of pharmaceutical products where the potential to cause consumer harm may increase further (Humphreys, 2009).

4. **Potential cost implications for the consumer and taxpayer** - The pharmaceutical industry invests significantly in marketing and promoting branded products, which often have no efficacy advantage over generic alternatives. Higher costs are passed on to the consumer and tax-payer. In 2011, GSK phased out the asthma inhaler Becotide and replaced it with the more expensive but generally equivalent Flixotide. GSK developed a million-dollar promotional campaign targeted at consumers that generated sales of \$3 million (McMillian, 2011) demonstrating how DTCA can increase pharmaceutical costs.

## References and resources

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Submitted by Sue Ineson, Choosing Wisely Facilitator

████████████████████

On behalf of:

A handwritten signature in blue ink, appearing to read 'Derek Sherwood', with a stylized flourish at the end.

Dr Derek Sherwood  
Clinical Lead  
Choosing Wisely New Zealand



12 April 2019

Ministry of Health  
PO Box 5013  
Wellington 6140

Via Email: [therapeuticproducts@moh.govt.nz](mailto:therapeuticproducts@moh.govt.nz).

Dear Sirs

***RBA RESPONSE TO THE THERAPEUTIC PRODUCTS BILL (TPB)***

We would like to make a short response in regards to:

*Question C53: Do you have a clear view on whether direct to consumer advertising of prescription medicines should continue to be permitted?*

The Radio Broadcasters Association believes that direct to consumer advertising should continue.

We believe all advertising and particularly that around people's health and well-being should be done responsibly.

In the modern world where people are finding information they want on the internet, we believe it is important traditional advertisers who act responsibly have the flexibility to take advertising revenue for products that people use and consume in their everyday lives.

We in no way profess to have any medical knowledge or experience but as a general rule believe consumers who have access to information via editorial or advertising on any platform are able to make better informed decisions.

These products are advertised through our member stations, in an environment where we compete against aggressive and dominant global players like Google. We wish to make the point the principal of regulating traditional media where the digital players are not, is not fair or reasonable in any way.

We thank you for your consideration.

Yours sincerely

A handwritten signature in dark ink, reading "Jana Rangooni". The signature is fluid and cursive, with a long, sweeping underline that extends to the left.

Jana Rangooni  
**CHIEF EXECUTIVE**  
RBA  
P O Box 8049  
Symonds St  
Auckland 1150



13 April 2019

Therapeutic Products Regulatory Scheme Consultation

Ministry of Health

PO Box 5013

Wellington 6140

[therapeuticproducts@moh.govt.nz](mailto:therapeuticproducts@moh.govt.nz)

Submission on **Therapeutic Products consultation**

I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

My reasons for supporting this law change are:

- Advertisements for prescription medicines do not provide all the information needed to make an informed decision about healthcare treatments.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. New Zealand consumers deserve the same protection.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Published New Zealand research also shows people with unhealthier lifestyles are more likely to respond to medicine ads, raising concerns of drugs being used to treat diseases that would otherwise be improved through lifestyle changes.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- There is strong support from doctors, other medical professionals and consumer organisations for a ban on DTCA, as they agree it creates more harm than good.

Yours faithfully

Tony Fowlie



## Response ID ANON-DPZ8-G4RQ-4

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 12:29:30**

### Submitter profile

What is your name?

Name:

Paula Keating

What is your email address?

Email:

What is your organisation?

Organisation:

CDHB

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Other health practitioner (please comment)

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

Clinical Scientist

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).:

The approval of product on a risk based approach is in keeping with international practice and is supported. Risk analysis is not fool proof and there are always the 'black swan' events. Given that most products under this legislation will have approvals under other jurisdictions and satisfied approval criteria of the global harmonisation tools it may be prudent for NZ to adopt a more rigorous post-market approval. Allowing health practitioners to supply adverse event reports would be a much more reactive system to ensure the life-long safety of products.

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

## **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):**

Product approval requirements are considered a key control and it is proposed the regulator will adopt approvals from other jurisdictions e.g. CE marking. It is appreciated that this will help with keeping regulatory cost down.

However, the rate of technological advance is such that most people have access to smart phones with apps that measure their glucose, heart rate etc. These devices are currently unregulated and it may be hard to keep pace with technological advances and control their of in this new legislation.

It is the expertise provided by health practitioners that ultimately protects people and community health. The scope of practice for health practitioners is restricted under the HPCAact. I believe it is the restrictions set out in the HPCAact that is the key control in maintaining the safety of people and communities. To bolster the controls in this TPB legislation it may be worth including an option for health practitioners to feedback to the regulator on approved products to ensure they are safe throughout their lifecycle.

### **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):**

Laboratories with DHB's provide a raft of medical testing that would fall under this legislation as manufactured medical devices. Currently, the use of this testing is legislated for under the HPCAact. All the medical testing of in-house IVD is done by health practitioners regulated under the HPCAact and done according to the standard set by ISO15189 and audited by IANZ regularly. The scope of practice for scientists performing manufacture and use of in-house IVD provides for this activity under research and development. Thus the manufacture and use of in-house IVD testing can be exempted from this bill.

### **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):**

Inclusion of an exemption for custom-made devices manufactured by health practitioners regulated under the HPCAact.

### **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).:

I support the comprehensive post-market monitoring programmes to collect information about the safety and quality of medicines and medical devices after they have been approved. While product sponsors would have explicit obligations in relation to post-market monitoring, reporting and risk management for their products, I believe it is crucial that the regulator has a link to reports from health practitioners on safety aspects of products approved.

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

#### **Question B25**

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

The involvement of sponsors in the post market surveillance is important as is the involvement of health practitioners. Input from both should be provided to the regulator.

**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?:

**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):**

As users of medical devices we find that manufacturers make changes to the product that they deem to be minor whereas we may consider them major in terms of the results obtained. This may be a way for manufacturers to avoid the approval process, thus I support the allowance in the bill for versatile approach to changes in products.

**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.:**

Health practitioners input should be a requirement.

**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.:**

in-house IVD devices

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

## Response ID ANON-DPZ8-G45V-C

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 13:05:04**

### Submitter profile

What is your name?

Name:

Kathy Maxwell

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Hillpark Pharmacy

**Submitter Profile (tick all that apply)**

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;:

### 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).:**

Understand that we need to update the bill but are concerned that trying to use the bill to address problems beyond what the bill covers

##### 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 : This appears be covered as part of manufacturing under the draft TPB. This suggests the dispensing is just a supply function. Pharmacists are qualified staff that consider the dispensing INCLUDES CLINICAL SERVICES to ensure the safe use of medicine by matching the medicine to the patient/person not just a supply function that us about matching a drug to a supply order form.

## **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 for one pharmacy to supply medicines to another nearby pharmacy is beneficial as this will aid in the safe and timely supply of medicine to patients instead of requiring them to return at a later time.

This will also save cost and waste for less common expensive 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 :**

There are benefits for patients if health professionals could supply small amounts of medicines in an emergency situation. The legislation needs to be very clear in the intent of this supply and what determines a small amount.

Need to be very clear that any provider must meet the same Medsafe requirements for the safe storage and supply of medicines - ie labelling - 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):.**

I agree with the concerns around the importation of counterfeit and substandard medicines and that this should only occur through the appropriate regulated channels to ensure patient safety is not compromised. Importation should only be via an appropriate person.

I believe that section 76 should be amended to allow for personal importation of category 4 prescription medicines. Equivalent medicines to those that are available in NZ should be restricted in the same manner 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. Clear definitions of suitable access are important - time and distance from current licenced premises.

Machines should also be linked to a pharmacy licence of a full service pharmacy to ensure appropriate clinical oversight and provision of advice to patients and have to meet all the same level of labelling and storage requirements that licenced premises must. IE Temperature recording.

### **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):.

I do not understand how medicines can be dispensed outside of a pharmacy premise such as in an age care facility. Pharmacies must all all dispensing equipment, access to resources and meet all audit requirements.

For the safety of patients ( and age care facilities) have some of our most vulnerable patients there must be tight rules for the patients benefit and safety.

#### **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 would support timely introduction 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 support increasing the period to 3 years for liciences as this would reduce compliance costs for the regulatory and the provider of service

#### **Question B22**

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

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

#### **Question B23**

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

## **C1 Medicines (excluding cells and tissues) sector**

### **Product-based controls**

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

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?:

Any opportunity that embraces opportunities and arrangements to promote patient outcomes and doesn't compromise patient safety should be welcomed. Community pharmacies are located in the heart of our communities and offer access to health professionals without the need to have an appointment. Any alternative

##### 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 the current licensing requirements create a barrier to innovation. Licensing requirements ensure the safe and effective provision of pharmacist services involving medicines. This is necessary for patient safety.

Service innovation has been limited by the system measures such as IT systems and an electronic healthcare record that means a patient should only have to tell their story once. This will assist better integration of patient care. Also their needs to be alignment between policy and funding for primary care. Innovation needs to look at keeping the patient in the most appropriate environment for that patient.

The future innovation will be enabled by technology and Community pharmacy with a workforce that is available to the public in the heart of our community needs to be central to delivering new services that will lead to better patient care.

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

Improving patient outcomes is not just dependent on the supply of medicines. This needs to be associated with increasing health literacy and ensuring patients have regular contact with a health professional.

Marae based services where collaboration occurs between patients and health care providers may enable better services.

Patients with long term conditions require long term relationships to ensure they receive the maximum benefit from their medicines and supply is only one part.

##### Question C22 Which option do you support?

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

##### Question C23 - Why do you support that option?:

A health network of community pharmacies owned by pharmacists who are in control of, and accountable for, the decisions made in the interests of patients is the best option for public benefit.

Pharmacists have professional obligations under their code of Ethics, and professional development requirements leads to a higher standard of care than that imposed by regulator as the Patient is in the centre of what we do.

Medicines are not a normal item of commerce. Requiring pharmacist ownership means business must first and foremost focus on delivering quality healthcare to maximise 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 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 a pharmacist under their professional obligations being accountable for the service they provide.

Community pharmacies are already delivering many benefits to our local communities by resolving minor health issues quickly and helping patients find the right health services to meet their needs.

##### 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?:

All clinical activities within a community pharmacy setting. This includes but is not limited to the provision of 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 the pharmacist owner's obligations as registered health professionals under the Code of Ethics and require that as medicines experts we must put our patients needs first.

##### 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?:**

I would consider five years a reasonable time to transition, once the Act becomes law.

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

### **Detailed questions relating to Option 2**

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

Owner pharmacists have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally as they have a financial commitment to maintain. Pharmacists have an obligation to their professional body.

I am concerned removal of the majority pharmacist ownership of a community pharmacy will be detrimental to patient access to services, patient safety and patient health outcomes as a non pharmacist owner has obligation would be accountable to its shareholders.

**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?:**

Remote oversight could present a patient safety concern. as it makes delivery health literacy a challenge and any transfer of information through a third medium is a risk

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

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

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

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

### **Pharmacist and pharmacy worker authorisations**

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

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

## Response ID ANON-DPZ8-G47K-3

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

Submitted on **2019-04-15 13:36:23**

### Submitter profile

#### What is your name?

**Name:**

Melanoma Network of New Zealand

#### What is your email address?

**Email:**

[REDACTED]

#### What is your organisation?

**Organisation:**

Melanoma Network of New Zealand

#### 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;:

### 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 Melanoma Network of New Zealand Incorporated (MelNet) recommends that sunscreen be listed as a therapeutic product in the Therapeutic Products Regulatory Scheme. MelNet is a network of over 1200 health professionals committed to reducing the incidence and impact of melanoma in New Zealand.

In 2013 melanoma was the third most commonly registered cancer for both men and women accounting for 10.7% of all registrations, and the fourth most common cause of death from cancer in men and the seventh in women(1). The rates in New Zealand in 2018 stand alongside those of Australia as the highest in the world(2).

Both melanoma and non-melanoma skin cancer represent a major public health issue for New Zealand. While non-melanoma skin cancer has very low mortality, it is the most common cancer and is estimated to account for just over 80% of all new cancers diagnosed annually in New Zealand(1). In 2018, it was projected that over 90,400 New Zealanders would be diagnosed with at least one in situ or invasive non-melanoma skin (Keratinocytic) cancer(3). Non-melanoma skin cancers also represent a significant cost burden on the New Zealand health system.

Exposure to excessive ultraviolet radiation is the principal cause of most skin cancers(4). When applied correctly and used regularly, sunscreen with an SPF of 30 or more and compliant with Australian/New Zealand Sunscreen Standards (AS/NZS 2604:2012) is effective in preventing sunburn, DNA damage and the development of skin cancer(1). Consumers must be able to trust that the sunscreen product they are purchasing will provide adequate sun protection. This is not currently the case in New Zealand, as demonstrated in the latest round of Consumer New Zealand testing which found six out of 10 sunscreen products didn't provide the SPF protection claimed(5). The wide range of sunscreens available on the New Zealand market have varying formulations and ingredients and no requirement to comply with the Standard or have their product tested.

Our position is that effective products which are intended to prevent future harm by disease prevention can reasonably be classified as therapeutic products, particularly when the use of the product represents an active health promoting choice by the user. There are other examples of this risk reducing categorisation within New Zealand such as aspirin use in people over 50 years of age to reduce the risk of cardiovascular and cerebrovascular events. It is also our view that natural products which claim to offer health benefits should be governed under the same regulations as therapeutic products.

In Australia sunscreen must be listed on the Australian Register of Therapeutic Goods (ARTG)(6) and comply with the Standard AS/NZS 2604: 2012 which specifies requirements for labelling of sunscreen characteristics; UVA (broad spectrum) and UVB (Sun Protection Factor) and water resistance. Sunscreens listed on the ARTG must use preapproved ingredients, good manufacturing practice and have low level therapeutic claims. Once a company has listed their sunscreen they must provide evidence that their product has been tested by a registered TGA laboratory and complies with the Standard. The TGA then conducts regular reviews and testing to ensure compliance of sunscreen with requirement(6).

The practical barriers to defining sunscreens as therapeutic products are low. Australia represents a very similar jurisdiction with regards to quality standards, particularly in the field of health. The Australian standards, with the underlying resources, represent an excellent template for the efficient development of robust New Zealand standards.

(1) Health Promotion Agency, MelNet. New Zealand Skin Cancer Primary Prevention and Early Detection Strategy 2017 to 2022. Updated 3 November 2018

(2) World Cancer Research Fund, Skin Cancer Statistics. retrieved from; <https://www.wcrf.org/dietandcancer/cancer-trends/skin-cancer-statistics> 5 April 2019

(3) Sneyd, M.J. and Gray, A. (2018). Expected non melanoma skin (Keratinocytic) cancer incidence in New Zealand for 2018. Wellington. Health Promotion Agency.

(4) Whiteman, D. C., Neale, R. E., Aitken, J. , Gordon, L. , Green, A. C., Janda, M. , Olsen, C. M., Soyer, H. P. and , (2019), When to apply sunscreen: a consensus statement for Australia and New Zealand. Australian and New Zealand Journal of Public Health. doi:10.1111/1753-6405.12873

(5) Consumer NZ. <https://www.consumer.org.nz/articles/sunscreens>. Accessed 22 March 2019.

(6) McRae C. Regulations of sunscreens in Australia

([http://www.assc.org.au/wp-content/uploads/2018/03/McRae\\_Sunscreen-summit-presentation-March-2018.pdf](http://www.assc.org.au/wp-content/uploads/2018/03/McRae_Sunscreen-summit-presentation-March-2018.pdf) ). In: Sunscreen Summit QIMRB. Brisbane, Australia. 16 March 2018.

13 April 2019

Therapeutic Products Regulatory Scheme Consultation  
Ministry of Health  
PO Box 5013  
Wellington 6140

By email: [therapeuticproducts@moh.govt.nz](mailto:therapeuticproducts@moh.govt.nz)

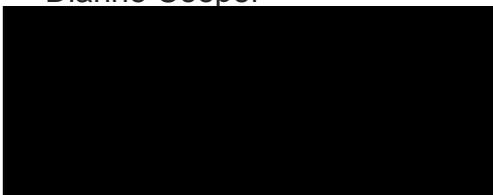
**Submission on: Therapeutic Products consultation**

As a consumer, I strongly support changing the law to ban direct-to-consumer advertising (DTCA) of prescription medicines in New Zealand.

- Advertisements for prescription medicines do not give me all the information I need to make an informed decision about healthcare treatments.
- Research shows DTCA increases the risk of inappropriate prescribing, creating health risks for consumers.
- Unnecessary prescription of medicines leads to increased costs for consumers and the health system.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. Kiwi consumers deserve the same protection.
- There's also strong support from doctors and other medical professionals for a ban on DTCA, as they agree it creates more harm than good.
- Furthermore, I believe there is NO PLACE WHATSOEVER for prescription medicines to be dispensed in a food store (Countdown South Pukekohe or any other supermarket).

Yours sincerely

Dianne Cooper



## Response ID ANON-DPZ8-G43Y-D

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 15:34:32**

### Submitter profile

What is your name?

Name:

Tina Mason

What is your email address?

Email:

What is your organisation?

Organisation:

Arjo New Zealand Limited

Submitter Profile (tick all that apply)

Medical devices

If you select DHB, please state service area:

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

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

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

Chapter A (A1 - A5)

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

Support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

No comments

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

No comments, other than for remanufacturer:

Repairs and maintenance - a person should use approved spare parts and equipment should be maintained to original manufacturer specification.

Reprocessing Single Use Devices: Original manufacturers should approve those that wish to reprocess products.

The Reprocesser becomes the manufacturer and takes full liability for the products and would need to ensure the product is of the same quality, performance and safety as if it was a new device.

We would also expect that they would need to apply appropriate conformity assessment procedures (depending on the class of the product) and demonstrate they meet Essential Requirements/Principles. They would need to keep a technical file detailing all the steps they have taken in the reprocessing of the product, Risk Analysis etc.

## **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):**

To import a product, the products sponsor or the Manufacturer should approve. The Sponsor or Manufacturer should be included in the process where authorisation will be given by a licence, permit or provision in the regulations.

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

#### **Question B4**

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

No comments

### **Subpart 3: Authorisations (ss 56–80)**

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

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

No comments

## **B6 Part 4 of the Bill: Product approval**

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

#### **Question B13**

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

Sponsors: The Manufacturer should approve all local sponsors of their products. This should be part of the product approval process.

#### **Question B14**

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

No comments

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

#### **Question B15**

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

No comments

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

## **Question B16**

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

No comments

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

## **Question B17**

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

No comments.

## **B7 Part 5 of the Bill: Licences and permits**

### **Subpart 1: Licences (ss 123–130)**

## **Question B18**

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

## **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).:

## **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.:**

## Response ID ANON-DPZ8-G4RP-3

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 15:47:37**

### Submitter profile

What is your name?

Name:

Peter Davis

What is your email address?

Email:

What is your organisation?

Organisation:

University of Auckland

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

North Island

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

Other (please comment)

If you selected 'Other' please comment::

Retired research academic with special interest in health policy, particularly pharma.

### 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).:

Three comments. (1) There is not enough here about preventing and reversing the downsides to therapeutic product use. I am thinking in particular of antimicrobial (antimicrobial) resistance. This is not just in the conventionally defined health sector, but also there is increasing evidence that antibiotics are over-used in the agricultural sector. Should there not be a duty of stewardship? This will impact the definition of prescriber roles and obligations. (2) Does safety cover the danger of addiction? As we can see with the opioid epidemic in the US, a therapeutic product can be misused on a large scale with terrible consequences. This needs to be part of the risk profile of any product. (3) There is no mention that decisions made - for example, in administration - must be evidence-based, particularly meeting the highest standards of methodological rigour (such as randomised controlled trials (RCTs) and quasi-experimental designs, which may not be the strong point of subject-matter specialists).

##### 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):**

Two things about the health practitioner prescriber. (1) There is mention of the scope of practice, but not of the quality of practice within that scope. There is plenty of evidence of practitioners who have got into "bad habits" of prescribing too many drugs simultaneously without proper review - polypharmacy - and also continuing prescriptions to patients who are in effect dependent or addicted (the most extreme being pain killers, such as opioids, but also drugs for anxiety and for helping people sleep). (2) What is the equivalent category to a prescriber for a person authorising and administering a therapeutic product that is not a medication, such as a medical device? Surely these people should have a more explicit "scope of practice" and accountability of competence and quality? One further thing. (3) Should not "fit and proper" person be defined? It sounds to me like a subjective value judgement. It is unlikely to be used arbitrarily in the New Zealand context, but it does introduce a rather archaic concept into what is meant to be a modern regulatory framework based on first principles.

## **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):**

What is the supply activity for a medical device that is equivalent to "prescribing a medicine"? Should this not be recognised and defined?

### **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 :**

Should the scope of practice not just for prescribing but also for applying medical devices be stipulated and defined as well?

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

Same comment.

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

Mention should be made of a broader guardianship role given that antibiotics are used in the agricultural sector - e.g. chickens, pigs, cattle - and that this could affect the entire supply chain and through to humans, such as growing antibiotic (antimicrobial) resistance. In other words this is a broader human safety issue that may not be obvious to the veterinarian. Should veterinarians not show a broader sensitivity to the impact of their activities in assisting the administration of antibiotics leading into the food-supply chain? You can add growth hormone to this concern. Growth hormones are increasingly being used with chickens and livestock and this must surely be a long-term danger for humans?

**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:**

How about the application of these regulations to medical devices?

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

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

Control of DTCA has been very weak. This is understandable because commercial interests are at play and the regulatory authority in question has limited resources. There are many examples of advertising for products that have had to be withdrawn because of safety and/or efficacy concerns (e.g. reductil, vioxx) - but these were only well after the event. I am not aware of a single DTCA ad being pulled proactively. There may be some, but not many. The bill should apply a risk-based approach such that advertising is allowed for over-the-counter products because these are seen as available without prescription and hence a consumer can make a judgement. But this does not apply to prescription medicines. The US is a "wild west" which we do not want to follow. The opioid epidemic of deaths has been importantly stoked by commercial advertising to doctors and the public.

## **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):**

It makes a lot of sense to draw on approval decisions by overseas jurisdictions, as long as the agencies involved follow best international practice. Indeed, it

should generally not be the case that New Zealand is at the forefront of, or the only proponent of, a therapeutic product approval process. This was the case with Fenoterol where only New Zealand and West Germany approved this asthma medication, which then had to be withdrawn because of the alleged link to higher death rates in the 1980s. Given that the New Zealand regulatory authority should be relying more on trusted overseas agencies, more resources should be put into pharmacovigilance. In other words, instead of trying to second-guess the major, trusted regulatory authorities overseas by duplicating their work, we should be concentrating resources on monitoring products after release. Special mention should be made of medical devices separately from medicines. These have not been well evaluated and monitored by comparison, either here in New Zealand or overseas. In many cases quite major changes to medical devices - such as the composition materials in hip replacements - have been introduced as minor variations without proper pre-release evaluation, and then been shown after the event to have a poorer performance, efficacy and quality profile. Vaginal meshes is another example where a "medical device" has not been properly evaluated.

#### **Question B14**

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

The New Zealand authorities do not have a good track record on placing restrictions on, and then cancelling approval for, products that are shown to have poor safety profiles. Perhaps this is inevitable given New Zealand's limited resources, but the advertising of these products direct to the public - e.g. Vioxx - and to the medical profession - e.g. Fenoterol - have unnecessarily exacerbated the problem of timely withdrawal decisions.

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

#### **Question B15**

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

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

#### **Question B16**

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

There is a weakness in post-market safety monitoring and reporting. This is left in the hands of the sponsor - who obviously have a vested interest in establishing that there are no difficulties with their product and therefore are not going to be particularly energetic about logging adverse effects. Also, these schemes are too reliant on spontaneous, voluntary reporting, which are notoriously patchy. If clinical trials can be conducted by third parties, and subject to rigorous criteria, then why cannot post-marketing safety monitoring and reporting also be done in this way? In particular, sponsors of a product - either a medicine or medical device - should be required to set up independently governed clinical registries using New Zealand's establishing electronic capture of clinical data, supplementing voluntary reporting by practitioners.

#### **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):**

While obviously New Zealand must not infringe on the intellectual property associated with active ingredients of innovative medicines, this should not be allowed to be used to block access to essential clinical trials information. In the case of Tamiflu (an influenza treatment), the product sponsor - Roche - was able to block access to clinical trials information requested by independent research bodies (e.g. the Cochrane collaboration). Only the most positive trials information was disseminated by Roche. Once independent bodies were able to access the complete set of trials information it was discovered that Tamiflu was much less effective than claimed, but meantime many jurisdictions had invested literally billions into stockpiling the drug in preparation for flu treatment (<https://www.bmj.com/tamiflu>). All clinical trials should meet the requirements of the All Trials initiative, requiring full registration and publication of all results (<https://www.bmj.com/content/346/bmj.f105>). Clinical trials information of course does not infringe on ingredients details, but "commercial sensitivity" has nevertheless been used to block access to this information.

### **B7 Part 5 of the Bill: Licences and permits**

#### **Subpart 1: Licences (ss 123–130)**

#### **Question B18**

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

A rationale needs to be provided for why medical devices are not subject to the same licencing conditions as medicines. This is a parallel issue as to why there is not scope of practice definition and declaration for medical devices in the same way that these exist for prescribing medications. Surely the administration of a medical device, depending on the skill and risk profile, should be subject to similar licencing and scope requirements?

#### **Question B19**

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

The "fit and proper" person requirement reads, to a non-legal, lay person, like a subjective value judgement. How does one enforce this provision? Has it ever been used, and in what circumstances, in a manner that is non-subjective and meets clear evidentiary and relevant evidence-based standards (e.g. proven performance and skills)? This looks like the kind of phrase that was prevalent in the disciplinary regulations for health practitioners before we moved from moral concerns - bringing the profession into disrepute - to issues of competence and performance.

#### **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):

Licensees should be required to keep a public record of the funds they supply to health professionals and health professional organisations in promoting their products (e.g. conferences, inducements, travel), as well as to patient organisations (who then provide "public input" on products of interest to their donors). Also, salesperson of therapeutic products should not be paid on a commission basis since this can tempt them to provide an unbalanced approach in their presentations in order to increase sales.

## 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):

Although the powers look extensive and effective, the New Zealand regulator has not been known for using them in a proactive and timely manner. This is a problem internationally. A recent example is that of vaginal meshes where a product deficiency was long overlooked. Can I suggest two things: (1) that the regulator should be required to follow the "precautionary principle" which is used elsewhere in New Zealand's regulatory framework relating to environmental and safety issues; (2) that there be a "probationary" category of enforcement power that allows the regulator to place a product on a probationary status requiring, for example, special monitoring, short of suspension or cancellation. To reiterate an earlier point - the regulator could make much greater use of the requirement to establish a clinical registry both for post-marketing surveillance and for circumstances where a precautionary approach suggests that a product should be placed on some kind of probationary list. As with clinical trials, these registries should be controlled by independent research and professional agencies, but funded by the product sponsor/licencee. These registries can be established by using New Zealand's existing e-data resources in the health sector, facilitated by linkage. The advertising controls are superficially impressive, but can be ineffective. For example, Nurofen was advertised as if it was able to reach different pain targets, each associated with a different price. Any informed person could see this was blatant dishonesty, and yet the advertisements remained for some time and a court case with a less than punitive fine followed long after the event

([https://comcom.govt.nz/news-and-media/media-releases/2017/\\$1m-penalty-for-misleading-nurofen-specific-pain-range-claims](https://comcom.govt.nz/news-and-media/media-releases/2017/$1m-penalty-for-misleading-nurofen-specific-pain-range-claims)).

### 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):

It is important that the details on the merits review stipulates that at least one member of the panel should have expertise in research methodology where the interpretation of research data is at issue. Many points of dispute revolve around the interpretation of scientific evidence on the safety and efficacy of medicines and medical devices. These points can be highly technical and there is growing debate in the international literature on taking at face value some reported results - in particular, the bias evident in (1) only positive results being published, (2) relying on intermediate endpoints rather than final outcomes (e.g. tumour shrinkage rather than actual longevity of the patient), and (3) inappropriate comparators (for example, placebo rather than existing treatment, and relative rather than absolute measures of success).

### 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):**

It is important that the regulator can work closely with similar agencies overseas. Their resources are much greater, and usually they are overseeing much larger populations that allow side-effects and unwanted outcomes to show up more clearly than in New Zealand's smaller demographic catchment. The important consideration is that such interactions should conform to international best practice. This has not always been the case. For example, a number of international regulators have not enforced the All Trials requirements that clinical trials information and outcomes be fully and publicly reported, including all results not just the positive ones. Similarly with medical devices. The regulatory sector has set a far lower bar for medical devices, and this should not be accepted practice - although there are indications that this gap is being rectified.

## **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):**

Isn't it about time that legislation moved away from identifying explicit monetary values in the legislation when identifying penalties? In the modernising rationale for the approach adopted for this legislation (with which I agree), it was argued that many details would be provided in rules and regulations, rather than being "set in stone" by being inserted in the enabling legislation (which would require an amendment to the Act in order to update them). With inflation, these monetary amounts readily get out of synch, as is clearly evident with the Medicines Act - why repeat the drafting mistake of the Medicines Act? I am not an expert, but there may be several ways to deal with this - (1) have the penalty amounts in regulations which can be updated without needing to change the enabling legislation; and/or (2) relating the fine to the commercial benefit derived by the defendant in their offending, or the penalty stipulated (in statute or regulation), whichever is the higher.

**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):**

See previous comment. Again, the fines for infringement and other offences would be subject to the monetary values established in the legislation, when what would be far preferable is that those monetary values can either easily be updated in rules and regulations and/or set according to the commercial benefit derived by the offender.

**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):**

Unless I am reading these regulations incorrectly, there is no parallel for the administration of a medical device in the definition of scope of practice to that for the prescription of a medicine. The competence requirements of health practitioners need to be related not only to the scope of practice for prescribing medicines but also for the administration/insertion of medical devices.

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

### **Question B34**

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

**B12 - B15, Schedules 1 - 4**

## Schedules

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

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

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

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

### 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):**

Does special mention need to be made about changes made by manufacturers as a product comes close to patent expiry? Some companies make what appear to be reasonably minor changes and then claim the change is sufficiently major to justify the extension of patent time. This seems to be particularly common practice in some overseas jurisdictions as a way to stymie patent expiry and the potential sharp decline in prices; colloquially it is called "evergreening" by critics (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766186/>).

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

Sunscreens need to be brought into the medication category. At present they are treated as cosmetics and many products fail to meet acceptable sun protection standards, and this in a country that has very high skin cancer rates.

**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.:**

It is reassuring to see the importance that the legislation lays on post-market surveillance. A few comments. (1) Presumably a product will have already been released in other jurisdictions or is being so simultaneously (New Zealand should not be a test market, except in exceptional circumstances)? In which case, an important task will be to collect pharmacovigilance information from trusted agencies in other jurisdictions. This may be even more useful, given the likely size of those markets, than spending a lot of time and money on the local market. (2) Spontaneous, voluntary reporting is essential, but such reports are patchy because they rely on practitioners not only identifying adverse effects but then going on to report them. New Zealand should make more of its electronic health data bases and unique patient health number to establish independently-governed clinical registries for nominated new products. More broadly, it might not be hard to establish triggers in the electronic health system that automatically generate alerts for adverse effects across all products. It is also important that post-market controls be applied to medical devices as well as medications.

#### 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.:**

One issue with the marketing of therapeutic products through salespeople is that they can be paid on a commission basis, which places a premium on increasing sales. Payment of mobile salespeople (hawkers) on a commission basis should be banned under the legislation.

### 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:**  
Should there not be a definition of "scope of practice" for medical devices, depending on risk level, similar to that specified for health practitioners prescribing medicines?

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

Could New Zealand not use its ecosystem of electronic health data together with the system of unique health numbering of patients to establish product-specific clinical registries, along with a broader system of surveillance using the same components? This would mean that the system was less reliant on spontaneous, voluntary reporting, which historically has failed to identify the problems with medical devices before the change of policy that prompted Medsafe to introduce more surveillance in this sector. One of the problems is that medical devices could be promoted by practitioners, who then have a conflict of interest because they are less likely to wish to report shortcomings (e.g. re-do rates for the more recent hip replacements with metal parts ([https://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=10838356](https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10838356))).

**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:**

It is important that the regulations require clinical trials to meet the requirements of the All Trials initiative (<http://www.alltrials.net/>). This requires clinical trials to register, to report all results, and to provide trial data to bona fide third parties such as the Cochrane Collaboration.

#### **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?:**

This seems like a sensible precaution. With direct-to-consumer advertising and the emergence of platform e-purchase companies, the sector would really grow in unexpected and unwanted ways. A recent New York Times article shows how, with platform technology companies, direct access to third-party advice and prescribing system, this can easily get to the stage of undermining conventional, professionally-mediated systems of prescribing (<https://www.nytimes.com/2019/04/02/technology/for-him-for-hers-get-roman.html>).

#### **Hawker's licence**

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

It is important that "hawkers" are not permitted to be paid on a commission basis. If they are paid on a commission basis then the incentive is to promote a company's products without necessarily giving the health practitioner a balanced picture giving equal weight to potential downsides as well as positives.

#### **Transition**

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

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

#### **Pharmacy sector context**

#### **Future regulation of pharmacy business activities**

## Licence to carry out a pharmacy business

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

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

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

**Question C22 Which option do you support?**

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

**Question C23 - Why do you support that option?:**

This option is the one that New Zealand is already halfway towards. It seems that it would increase access to pharmacy products. PHARMAC could intervene to ensure that a full range of services were available in rural and other potentially under-served areas. PHARMAC, the DHBs and the Commerce Commission would have to ensure that a degree of competition remained in the market. PHARMAC and the DHBs could also ensure that the quality of pharmacy services remained up to professional standards, even when a company is not under majority pharmacist control.

### Detailed questions relating to Option 1

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

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

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

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

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

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

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

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

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

### Detailed questions relating to Option 2

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

The risks are pursuit of financial goals - for example, after an equity buy-out. However, if a pharmacist was in charge of quality, if competition was effective, and if PHARMAC and the DHBs were vigilant, this might not be a realistic prospect. On the positive side, prices could come down and access should improve with more pharmacies opening.

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

A set of quality and performance criteria could be established for scrutiny, rather like the ERO performs for schools.

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

The supervisory pharmacist could be required to provide standard quality and performance information to PHARMAC and/or the DHBs.

### 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?:**

It is necessary to remove any incentive that prescribers have to manage their patterns of behaviour for financial reasons - such as having a financial interest in a pharmacy dispensing prescriptions.

**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?:**

With the emergence of global retail outfits operating through internet platforms, this area is being transformed and the danger is that approved and unapproved medicines could easily be purchased through the internet without proper professional supervision.

## **Pharmacist and pharmacy worker authorisations**

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

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

## **C7 Retail sector**

**Question C42**

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

## **C8 Health practitioners (including pharmacists)**

### **Prescribers**

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

The scope of practice needs to include reference to medical devices. What medical devices are different health practitioners permitted to administer and after what form of training?

**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. Who could say no to that?! But include reference to medical devices and their administration in the same manner as is proposed for medicines and their prescription.

**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?:**

Is this any medical practitioner, or only a medical practitioner with appropriate specialist qualifications and experience?

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

With the internet and global e-commerce opening rapidly, this seems essential.

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

Certainly not for a potentially addictive substance to a health practitioner as patient. And nothing for pecuniary advantage.

**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 unless that health practitioner is the other person's designated doctor.

### **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?:**

Health practitioners should not have a financial incentive attached in any way to their professional activities when it comes to supplying any medicines. A script does the job.

**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?:**

They likely would be operating under the direction or influence of the health practitioner, so I cannot see the justification for this. See previous comment.

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

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

DTCA has taken us down an unwanted track that could potentially lead to the free-for-all evident in the US where they are suffering disastrous outcomes like the

opioid epidemic that was fostered by regulatory failures amplified by the ability of the industry to influence practitioner and patient behaviours. I am also aware of a recent New York Times article that shows how, with platform technology companies, direct communication of advertising to lay people by pharmaceutical companies can easily get to the stage of undermining conventional, professionally-governed systems of prescribing (<https://www.nytimes.com/2019/04/02/technology/for-him-for-hers-get-roman.html>). We should adopt a risk-based approach where over-the-counter medicines can be advertised because they are subject to normal consumer judgements, but once we get to prescription medicines the risk and cost levels increase. We should follow the EU guidelines. EU provisions on pharmaceutical promotion can be found in this EU Directive on medicinal products (Articles 86 to 100) <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20121116&qid=1472567249742&from=EN>

On DTCA, the Directive says the following:

Article 88

1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only, in accordance with Title VI;

(b) contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971.

2. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 14 of Directive 89/552/EEC (this is what this Article said "Television advertising for medicinal products and medical treatment available only on prescription in the Member State within whose jurisdiction the broadcaster falls shall be prohibited."). It seems that this Article was deleted in a 2007 revision of the Directive, I assume because it became redundant.

6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.

## C9 Veterinarians

### Question C54

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

I think the approach is short-sighted and too narrowly construed. It is not just the potential for diversion of products. This seems a small problem. The major problem is the use of therapeutic products on animals, such as growth hormones and antibiotics. The first could have deleterious effects on human health when the animal is consumed (e.g. chickens, livestock), and the second could be contributing to the growing problem of antibiotic (antimicrobial) resistance which is making it more common for infections to be presented that cannot be treated by the usual armoury of antibiotics available to health professionals. In other words, there is a broader responsibility of stewardship; it is not just diversion of products, but affecting the entire health treatment eco-system.

## C10 Advertising sector

### Question C52

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

The enforcement tools are completely inadequate. The marketing people can run rings around this. I remember a consumer advertisement for Celebrex - a pain relief medicine that was argued to have advantages over standard treatments - that showed elderly people whirling around a dance floor without a care in the world, suggesting that this drug would allow your average elderly person to do just that (but not explicitly saying so) (There is a US example, not necessarily specific to the elderly but which is the closest I could find - <https://www.ispot.tv/ad/7ndD/celebrex-dancing>). All your average elderly person saw was the imagery and the underlying subliminal message, and they would go straight to their doctor asking for a prescription. As it happened this class of drugs was also later shown to have some downsides that were not referred to in the ads or, if they were, were not obvious or sufficient to counter the overall sales pitch.

### 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?:**

This legislation uses a principles-based approach. One of those principles is to adopt a risk-based approach. In other words, a "one size fits all" is not recommended; high-risk devices and activities are treated in an appropriately more regulated way, low-risk less so. The same should apply to advertising. Thus, over-the-counter medicines have been designated as such because they are subject to normal consumer judgements and therefore can be advertised like any other consumer product (subject to accuracy requirements). By the same token, prescription medicines are not sold "over-the-counter" because they have a higher risk and complexity profile, and therefore they should not be advertised as if they were consumer products. The United States has seen a serious amplification of risks and costs with DTCA, the worst being the opioid epidemic. A study by McKinlay et al. of randomised hypothetical doctor decisions showed that doctors were much more likely to prescribe controversial drugs like OxyContin and Celebrex if asked to do so directly by name of the drug than if the patients just asked for pain relief (the McKinlay study is cited in this open access paper <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031617/>)

## 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?:

It is the only approach if the system is to retain the integrity of its approval, regulatory and enforcement processes.

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

See previous comment, although it does seem odd that ANY medical practitioner can action this, rather than a practitioner with special expertise in the area of the product.

## Personal imports

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

This approach is hard to fault. With the opening up of e-commerce there is the potential for a full global prescription medicine market to open up and undermine our carefully constructed regulatory system.

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

Only after recommendation from a specialist in the area.

## Pharmacy licensing

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

These more flexible arrangements would foster greater access.

### 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?:

Greater potential for more flexibility and access, and possibly lower prices.

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

The danger of a closely-held professional model with little place for expansion and innovation. But at least professional values would remain dominant.

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

The potential for greater flexibility, innovation, access, and lower prices, but the danger of commercial values overriding professional ones.

## Access to pharmacy medicines

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

I don't think it is a good principle for medical practitioners to be able to benefit financially from the supply of products as a result of the services they provide.

### 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 comment.

## Advertising

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

The legislative definitions refer only to advertisements. But there is a much wider spectrum of marketing and promotion activities that pharmaceutical companies use. For example, they spend quite a bit of money on conferences, travel and other inducements to prescribers. If the Australian and Canadian examples are any guide, pharmaceutical companies also supply funds to patient organisations, which then advocate on their behalf (for example, <https://europepmc.org/abstract/med/30021681>; <https://journals.plos.org/plosone/article/authors?id=10.1371/journal.pone.0212399>). These are not explicitly covered by the legislation. At the very least pharmaceutical companies should be required to report the funds they deploy to influence practitioner opinion and patient organisations with sufficient detail to identify the recipient organisations.

### 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?:

This is an unnecessary and vexatious complication to the pharmaceutical system that we share only with the US. It is about time we rejoined the mainstream and got rid of DTCA on the grounds of appropriate risk-based regulation - advertising for over-the-counter medications that are subject to ordinary consumer judgement versus higher-risk products that are subject to professional judgement. A patient should go to their doctor with an ailment and then discuss the treatment options with their doctor. What DTCA does is turn the relationship around. A consumer thinks they have found a solution advertised to them and then approaches the doctor to have that solution prescribed for them. In the EU they are very explicit against DTCA, but particularly for medications that are on public

subsidy because otherwise the companies are placing a potentially unnecessary burden on the taxpayer.

## **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?:**

If these products are making health claims and may potentially have deleterious effects on users if misused or because they are not safe in any form, then they should be covered. We are at a stage where manufacturers are making health claims for devices of potentially dubious quality. These could harm users, and also mislead them. One area which is developing rapidly is that of vaping products. These should be recognised as potentially presenting a health risk either now or in the future, and should be regulated.

### **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 Ministry of Health could establish a representative "citizen's jury or assembly" to report back on the legislation, on occasion (say, once a year). To prevent capture by special interest groups, it would be important to be sure that the jury is well selected to be representative but not to be captured by those advocating extreme, or very minority or highly sectional views.

## Response ID ANON-DPZ8-G4R2-5

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 19:15:53**

### Submitter profile

**What is your name?**

**Name:**

Trevor Tillotson

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

The New Zealand College of Podiatric Surgeons

**Submitter Profile (tick all that apply)**

Professional body (eg, Colleges, Pharmaceutical Society etc)

**If you select DHB, please state service area:**

Surgeon

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

Podiatric Surgery as determined under the Podiatrists Board of NZ registered Scope of practice - "Podiatric Surgeon"

**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).:**

The NZCPS supports such a "principle based legislative framework so as to ensure safety for the public regarding the administration/prescribing of therapeutic products relative to a registered health practitioners Regulated Scope/s of Practice.

The Principles around robustly administered prescribing authority performed by suitably qualified practitioners should be fair, non-restrictive of practice, transparent and completed with reference to and collaboration with other overseas/international regulators in order for NZ registered health professionals to practice on a par to their international colleagues, to internationally accepted standards thus allowing NZ practitioners to practice safely and competently within their own registered Scope/s of Practice.

**B4 Part 2 of the Bill: Interpretation**

**B4 Part 2 of the Bill: Interpretation**

## Question B2

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

49a: With regard to s14 definition of "health practitioner prescriber". The NZCPS considers it wholly appropriate and ethically sound that, in the 21st century, registered health practitioners should hold prescribing authority which enables them to practice safely and competently within their regulated scope/s of practice. This is particularly relevant in scopes of practice which deal with infection and severe pain on a daily basis.

In the case of Podiatric Medicine/Podiatric Surgery the current legislation severely prevents this, an unacceptable restriction on scope of practice practice which severely compromises patient safety and competency to practice on a daily basis.

To emphasise the seriousness of this restriction podiatric surgeons who are currently unable to presc be necessary post operative pain relief or possibly prophylactic/post operative antibiotic therapy does not fit with the level of respons bility of invasive treatment allowed by the Podiatrists Board of NZ Scope of Practice for Podiatric Surgeons.

## B5 Part 3 of the Bill: Dealing with therapeutic products

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

#### Question B3

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

Agree

### 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

### Subpart 3: Authorisations (ss 56–80)

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

No comment

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

No comment

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

Agree: Recently a situation occurred whereby podiatric surgeons were restricted from using a particular injectable local anaesthetic which allowed them to undertake surgical procedures utilising smaller, safer doses for the comfort, benefit and safety of the patient. The restricted local anaesthetic is both less toxic and more efficient, yet podiatric surgeons were lawfully unable to administer it and were restricted to the use of a less safe/efficient local anaesthetic until a request for change of categorisation of the more effective anaesthetic could be made - some many months in the process.

The NZCPS considers that in a situation where multiple practitioners are working together that it is appropriate that a practitioner who has prescribing authority should have the authority to authorise a prescription medicine to a patient of a podiatrist where that practitioner does not have prescribing authority if the condition and the health status of the patient in question is known to them and the prescription is authorised in the best interest of the safety, health and comfort of the patient.

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

Agree

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

No comment

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

No comment

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

Agree with most of the proposed regulation in this section.

S.75: With regard to manufacturing Custom Made devices - Podiatrists and Podiatric Surgeons consider the inappropriate prescription and fitting of biomechanically balanced/positionally corrective foot orthoses to be a specialised area of foot mechanics which should be restricted to skilled/biomechanically trained foot orthotists or podiatrists.

### Subpart 4: Other offences (ss 81-94)

#### Question B12

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

Agree

## 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).:

Agree

**Question B19**

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

Agree

**Subpart 2: Permits (ss 131–135)**

**Question B20**

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

Agree

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

**Question B21**

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

Agree

**Question B22**

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

Agree

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

**Question B23**

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

Agree

## **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

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

#### **Question B25**

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

Re: Enforcement Officers - Agree with the proposal of the Regulator's use of the Regulating Authorities as they have knowledge of scopes of practice relevant to their represented area of health care.

### **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):

Wonder whether there should be stronger collaboration with the already existing HPDT in this area?

### **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):

Close liaison and collaboration between the "Regulator" and the various "Regulating Authorities" (at home and internationally) is of paramount importance with regard to the understanding of the various and varied scopes of practice, and what is the presc ribing norm internationally, in each of the registered professions.

## **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):

Wonder whether offence/discipline should be linked, or collaborated with the HPDT?

### **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):

HPDT collaboration necessary/preferred?

### **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):

HPDT process?

## **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):

Agree

## 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 NZCPS considers it imperative that, under the proposed new regulations, any decision to grant prescribing authority to a regulated profession which has not yet been granted prescribing authority, such as podiatric medicine and podiatric surgery, should be made in collaboration with the relevant Registering Authority and seriously take into account the profession's level and type of scope of practice as well as any precedents set by any comparable international regulating authorities for the same profession.

### 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):

The NZCPS welcomes the change in thinking and philosophy centred around clinical practice and clinical need relative to a profession's registered scope of practice, and in collaboration between the Minister of Health and the responsible registration authority under the HPCAA.

The NZCPS does not support the need/concept of prescriber categorisation in the proposed Act when the requirement to prescribe is linked to a practitioner's Scope of Practice.

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

Agree

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

No Comment

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

### C1 Medicines (excluding cells and tissues) sector

#### Product-based controls

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

No comment

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

The NZCPS welcomes the introduction of listing the "class of health practitioner" who has authorisation to perform "specified authorities", again so long as this authorisation for the classifications of medicines is linked to/based upon the practitioner's need to access relative to their registered scope of practice.

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

Agree

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

Agree

#### Activity-based controls

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

No comment

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

No comment

## **C2 Cell and tissue sector**

### **Product-based controls**

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

No comment

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

No comment

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

No comment

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

Agree

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

No comment

### **Activity-based controls**

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

No comment

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

No comment

## **C3 Medical device sector**

### **Question C11**

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

Registered Podiatrists & Podiatric Surgeons prescribe biomechanically balanced foot orthoses which have a therapeutic effect upon the mechanical function of the musculoskeletal system. These products and the issue of these products has never been regulated. The lack of regulation over the supply of this type of foot/lower limb "support/control" has meant that unqualified people are able to portray themselves as "qualified" to prescribe them to the general public, despite the fact that misdiagnosis and inappropriate prescription can result in mechanical dysfunction/injury of the foot/lower limbs and spinal column. The NZCPS would be interested in determining whether anything other than a neutral over the counter cushioning shoe insert (i.e one which is made to prescription following a musculoskeletal examination) falls into the category of a "Therapeutic Medical device". The NZCPS considers this to be the case.

### **Product-based controls**

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

No

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

The NZCPS consider that the processes around product approval by a regulator would be done in collaboration and agreement with the various Regulating Authorities of the different health providers under the HPCAA.

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

Agree if in collaboration with members of the health professions who use the medical devices under their registered scope/s of practice.

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

Agree

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

Agree

### **Activity-based controls**

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

Agree with the draft proposals

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

Agree

## C4 Clinical trial sector

### Question C16

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

No comment

### Question C17

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

No comment

## C5 Wholesale sector (including importers and exporters)

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

### Licence to wholesale

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

No comment

### Hawker's licence

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

Agree, so long as the qualifications of the "hawker" demonstrate that he/she is qualified and competent to promote the medicine samples provided to doctors.

### Transition

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

No comment

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

### Pharmacy sector context

#### Future regulation of pharmacy business activities

#### Licence to carry out a pharmacy business

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

No comment

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

No comment

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

No comment

#### Question C22 Which option do you support?

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

**Question C23 - Why do you support that option?:**

Accountability and responsibility in Option 1 sits with the regulated professional (i.e. the pharmacist). Any issues associated with the regulations or the proposed new Act relating to Pharmacy function are the responsibility of the business owner (i.e. the Pharmacist).

In Option 2 the owner would be a non-pharmacist business person who, due to financial constraints could fail to provide the pharmacist with the stock levels or systems required to run the pharmacy whilst being more interested in the retail operation of the pharmacy. In this business model, if the pharmacist feels restricted or without full control and unable to influence the way the business owner runs the pharmacy business, it could result in compromise which is not in compliance with the Act.

#### Detailed questions relating to Option 1

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

Self ownership promotes ... Accountability, Responsibility, full control of and pride in the service provided.

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

No comment

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

No comment

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

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)?:**

No comment

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

No comment

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

No

**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?:**

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?:**

See earlier 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?:**

See earlier 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?:**

Yes

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

Yes

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

No comment

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

No comment

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

No comment

### **Pharmacist and pharmacy worker authorisations**

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

No comment

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

No comment

## **C7 Retail sector**

**Question C42**

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

No comment

## **C8 Health practitioners (including pharmacists)**

### **Prescribers**

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

Despite the fact that the scope of practice of registered podiatrists and podiatric surgeons requires them to clinically and or surgically manage conditions of the foot, often requiring invasive procedures below the surface of the skin, they do not have prescribing authority which would allow them to practice competently and safely within their scope/s of practice in compliance of the regulations set out in the HPCAA. On a daily basis registered podiatrists are faced with dealing clinically with severe and often chronic bacterial and fungal infections which require a prescription as part of the management of these conditions. Currently podiatrists have to rely on a phone call as well as a close working relationship with their patients GP to obtain a prescription on their behalf. the delay in obtaining the medications increases the risk and expense for their patients.

Whilst all podiatrists/podiatric surgeons holding a current Annual Practicing Certificate are "deemed" competent relative to the HPCAA the lack of prescribing authority prevents podiatrists/podiatric surgeons from fulfilling their obligations to practice competently within their prescribed Scopes of Practice which includes the management and treatment of infections of the foot.

NZCPS considers that linking the authority to prescribe to the health practitioners scope/s of practice is a long overdue implementation with regard to ensuring competence in patient management an treatment by all health care providers.

**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. scopes of practice, whatever the profession under the HPCAA should determine whether a health practitioner should be allowed to prescribe or not as long as the clinical pharmacology educational requirements are consistent across all professions.

**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 continued use of issuing standing orders as indicated in this draft document would still be of benefit but as indicated more discussion would be needed to finally determine their inclusion.

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

Agree

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

Agree

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

Agree

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

When practitioner A (non authorised prescriber) is working in the same premises and has a patient requiring prescription medication to treat a chronic infection, if practitioner B (an authorised prescriber) has access to the patient and the patient notes

**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?:**

In podiatry - not usually required.

### **Health practitioners (non-prescribers)**

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

Yes providing that the education requirements are met. Access would speed up the access to treatment and be less costly/inconvenient for patients.

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

Only under the awareness and physical supervision and direct collaboration of the registered health practitioner. same as C50

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

Prescription medications should not be allowed as DTCA products - could invite financial collaboration between practitioners and drug companies

**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 above answer C52

## C9 Veterinarians

### Question C54

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

No comment

## C10 Advertising sector

### Question C52

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

No comment

### Question C53

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

No comment

## C11 Patients, consumers and disabled people

### Unapproved medicines

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

Agree with the intentions stated in the draft

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

The unapproved medicines should be available to all health practitioners if the medication falls within treatment provided under a health practitioners registered 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?:

Agree with the proposal

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

No comment

### Pharmacy licensing

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

More flexibility provided to pharmacists to prescribe or fill prescriptions whilst working in domiciliary or rest home/retirement village hospitals. security of medications would be of paramount importance requiring compliance to security systems covered by the Act.

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

No comment

### Question C22 Which option do you support?

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

Question C23 - Why do you support that option?:

answered prev

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

answered prev

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

answered prev

## Access to pharmacy medicines

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

no comment

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

No comment

### **Advertising**

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

No comment

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

No comment

### **Packaging and labelling and consumer medicine information**

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

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

No comment

### **Adverse event monitoring**

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

Agree

## Response ID ANON-DPZ8-G4C4-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 19:46:05**

### Submitter profile

#### What is your name?

**Name:**

James Thompson

#### What is your email address?

**Email:**

[REDACTED]

#### What is your organisation?

**Organisation:**

Fisher & Paykel Healthcare

#### Submitter Profile (tick all that apply)

Industry body

Medical devices

Medical devices

#### If you select DHB, please state service area:

North

#### 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

#### 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 intent of the purpose and principles documented. We agree with the intent to co-operate with overseas regulators, and believe it serves the interests of NZ well to align with known respected international regulatory bodies, notably USA (FDA), Australia (TGA), Japan (PMDA), Canada (Health Canada) and European Union via MDD and future MDR. We are concerned with cost implications related to developing a NZ system if there is not substantial leveraging of foreign clearance data.

##### 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):**

There are presently many slight deviations to definitions in existing international medical device regulations. A recommendation is to fully align with a current regulator, of which MDR definitions and Health Canada have particular merits.

Definitions as currently laid out in the document make referencing overly complex, and recommend where possible placing the definition within this section rather than referenced out.

Definitions of Responsible Person and Believe may give rise to future interpretation issues.

Clarification desired as to why 47 (3) (n) refers to Australian law.

## **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):**

As part of the product development process and stay competitive in international marketplace it is valuable to source and reverse engineer competitor products. Means should be provided to ensure this can continue with minimal burden, since such products will not be used on 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):**

No comment.

### **Subpart 3: Authorisations (ss 56–80)**

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

No comment.

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

No comment.

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

No comment.

**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):**

Remain confused over inclusion and terminology of veterinarian here. Is this bill intended to address animal health also? If so, a unique section geared toward animal health would be clearer.

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

No comments

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

78(1)(a)(iii) refers to major changes to approved product. Defining "major", or "significant" as is used by FDA and under the MDR is notoriously difficult and open to interpretation. Clarification is required here, and clarification on what is meant by "significant" is currently being sought by industry per Article 120 of EU MDR.

### **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):**

95(a) - aside from ISO13485/QSR compliance, assessment of complaint files, quality of product as such is not assessed by other regulators. The intent has merits, but the mechanics of establishing product approval by product quality assessment is fraught with challenge.

98(e) - Limit inclusion to statement of Legal Manufacturer.

100(1) (a) - As described previously, interpretation of what is significant or major is open to interpretation. FDA attempt to address with for premarket notifications (510k system) with a change assessment guidance document.

(b) interpret "specified in the rules" to be a future task? Not currently present.

101 - depending on what is defined in the rules with regard to minor changes, this could add considerable unnecessary burden to both manufacturer and regulator. This is not common practice elsewhere and should be duly considered for what value this serves and what resources will be required to administer for value gained.

103 - recommend aligning with either a declaration of Conformity system such as EU, or Canada's annual renewal system rather than fragmented license renewals which become burdensome to maintain and administer.

**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):**

116(1)(c) implies audit requirements however this is not defined, or lacks clarity.

117(1) In other jurisdictions there are typically provisions for products to be acceptable with alternative test methods (for example) to those as defined in product standards. The definitive wording of the clause makes not facility for alternative means for compliance with standards or intent of standards. This is typically addressed via viewing in third party audits e.g, MDSAP audits. This is preferable to what is proposed.

118 (1) Wording "any of the following" is clumsy. Rephrase to "...must comply with requirements specified in the regulations in relation to the following;"

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

**Question B17**

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

No comment.

**B7 Part 5 of the Bill: Licences and permits**

**Subpart 1: Licences (ss 123–130)**

**Question B18**

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

No comments.

**Question B19**

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

128(2) Ability to cross reference definitions not present but valuable here.

**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 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):**

Proposal for licences requiring renewals is out of step with leading regulators i.e., MDSAP markets. Little tangible gain is made from this system in comparison with an audit based MDSAP approach, whereas this system has higher administrative burden for less direct gain from a product and patient safety perspective. Propose this is inefficient and misses the mark intended to introduce a greater level of assurance of product quality and safety to the market.

#### **Question B22**

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

150 In the event of a company acquisition, this proposal introduces costs with not benefit to patient safety or product quality. Means should be provided for transfer of licences in such circumstances.

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

#### **Question B23**

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

No comments.

## **B8 Part 6 of the Bill: Regulator**

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

#### **Question B24**

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

No comments

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

#### **Question B25**

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

185 (1) (a) Do not see need to include request for personal information. Submission of relevant information is sufficient text.

186 (a) Provision for additional testing is reasonable however present text is extremely broad and provides no context around when such investigative testing would be required. This needs to be formally outlined to sponsor with appropriate reasoning provided.

187 Note that local NZ test laboratories are presently very limited in their abilities to perform testing of medical devices. Only very limited external testing is conducted locally at present due to expertise and test equipment availability.

### **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):**

200 (2) (c) a mandatory fee should not be required to review the regulator's decision in all circumstances. This may lead to overly authoritarian regulator and less room to challenge decisions.

201 (2) (d) Lawyer should also have legal experience in a regulated industry, preferably drugs or devices.

### **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):**

208 (5) (b) "reasonable" is vague and requires clarification on meaning. Propose 10 working days.

221 Current certificates provided by Medsafe are not recognised in some markets due to no oversight of manufacturers in NZ. It is hoped that introduction of this legislation will change this situation, and we need to proactively ensure this will be the case by liaising with these markets in advance. (Argentina one example - can confirm others).

## **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):**

Much can be learned from dealings with other regulators. It is important to consider the intent and purpose of the legislation, which should at the core be about ensuring safe and effective products are used on patients. The bureaucracy that may be introduced with product licensing has potential to cloud the intent of the legislation. To this end, systems involving period external audits (e.g. MDSAP auditing) where responsibility is placed on manufacturer to maintain and prove compliance are preferable. The bar is high, yet the administration on licensing is low, and propose it would be less burden for NZ government to maintain. A somewhat middle ground is the Canadian system, a combination of MDSAP with product licensing. NZ is a small country and it is critical that the system is commensurate with the size of the industry.

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

### **Subpart 1: Repeals and revocations (s 275)**

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

#### **Question B33**

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

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):**

Placing this content in a separate schedule makes this challenging to interpret. Incorporate into body of document.

**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?:**

Uncertain. Responsibility of authors to research and document.

## **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?:**

The growth in software apps which purport to have a medical function requires attention for possible impact particularly with regard to advertising and claims.

### **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 of concern that the system leans heavily on the "global model", AKA the IMDRF documents, of which (to my understanding) no country has adopted outright, but particularly concerning when NZ is not represented on the IMDRF. The mechanics of the IMDRF are such that documents are generated at glacial pace, and it would be preferable to align with a market such as EU (MDR) or Canada. Australia in general is overly burdensome for little gain to industry or regulator.

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

Comments placed earlier within this document. Again, this is fraught with challenge unless well defined as to what is a major or significant change, and question the value provided to regulator, and propose notable burden requiring many staff to manage.

**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.:**

In line with other markets introducing regulatory schemes for first time in recent years (e.g. Malaysia), at least a one year transition period is recommended rather than 6 months. This is due to inevitable increased burden on companies on top of other activities.

**Activity-based controls**

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

Comments placed earlier in submission.

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

Transitional period comments noted previously.

**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.:**

It is unclear if ALL existing clinical trials will need to be retrospectively notified.

**C5 Wholesale sector (including importers and exporters)**

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

**Licence to wholesale**

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

No comments

**Hawker's licence**

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

No comments

**Transition**

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

Comments submitted in previous sections. Propose at least 1 year transition.

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

**Pharmacy sector context**

**Future regulation of pharmacy business activities**

**Licence to carry out a pharmacy business**

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

No comments

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

No comments

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

No comments

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comments

**Detailed questions relating to Option 1**

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

**Detailed questions relating to Option 2**

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

No comments

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

No comments

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

No comments

**Other changes to pharmacy licensing requirements**

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

### **Pharmacist and pharmacy worker authorisations**

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

No comments

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

No comments

### **C7 Retail sector**

#### **Question C42**

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

No.

### **C8 Health practitioners (including pharmacists)**

#### **Prescribers**

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

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

No comments

#### **Health practitioners (non-prescribers)**

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

No comments

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

No comments

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

It is important that industry is not unduly penalised due to delays in advertising review and processing.

**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?:**

Experience from other countries should be considered prior to change. It is challenging for a consumer to be adequately informed about a prescription medicine in an advertisement.

## **C9 Veterinarians**

**Question C54**

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

Do not understand the placement of veterinarians in this document.

## **C10 Advertising sector**

**Question C52**

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

Comments as before.

**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?:**

Comments as before.

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

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

No comments

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

No comments

### **Personal imports**

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

No comments

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

No comments

### **Pharmacy licensing**

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

No comments

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

No comments

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comments

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

No comments

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

No comments

### **Access to pharmacy medicines**

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

No comments

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

No comments

### **Advertising**

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

No comments

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

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?:**

No comments

### **Adverse event monitoring**

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

No comments

## Response ID ANON-DPZ8-G42T-7

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 21:09:17**

### Submitter profile

What is your name?

Name:

Tania Bray

What is your email address?

Email:

What is your organisation?

Organisation:

New Zealand Foundation for Mast Cell Activation Disorders

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;:

Trust supporting those in NZ with Mast Cell Activation Disorders

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

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

B5 Part 3 of the Bill: Dealing with therapeutic products

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

Question B3

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

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

Question B4

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

Subpart 3: Authorisations (ss 56–80)

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

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

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

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

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

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

The New Zealand Foundation for Mast Cell Activation Disorders represents the interests of those in New Zealand with Mastocytosis, Mast Cell Activation Syndrome and Hereditary Alpha Trypsinemia. The number of New Zealanders with MCAD's is unknown but the number is likely to exceed 5%. MCADs are chronic, complex and can be extremely disabling if not effectively managed through medications.

In MCAD's mast cells inappropriately degranulate releasing any number of the 200 known mediators (histamine, leukotrienes, prostaglandins, cytokines etc). People with MCAD's frequently take a significant number of medicines to block specific mediators, stabilise the mast cells or control anaphylaxis. In addition to a complex medication regime, it is also normal for the inappropriate immune response to include idiopathic "allergies" to pharmaceuticals, fillers and dyes. Alternative medications to those commonly prescribed or specific medications by specific manufacturers are often required in the management of MCAD diseases. Many basic MCAD medicines cannot be sourced in NZ. For example of the four commonly used H2 blockers, only one can be purchased in New Zealand.

The New Zealand pharmaceutical market is small and unlikely to ever meet the needs of people with MCAD. The lack of access and funding for pharmaceuticals for rare diseases has been identified and discussions with PHAMAC continue regarding this inequity. Until New Zealanders have funding and access to the pharmaceuticals they require then continued access to international pharmaceutical market is critical for the effective management of MCAD's.

We have read the FDA and Medsafe material and understand the concerns with personal imports from international pharmacies. We strongly support the objective to provide safe access to pharmaceuticals from overseas suppliers and we are concerned with the dangers posed by imports. At the most basic level if a person with a MCAD takes a pharmaceutical which contains ingredients other than listed, a mast cell reaction to those ingredients can and does result in anaphylaxis and in extreme circumstances may lead to death. Safety is paramount. However, we believe the proposal to restrict importation to medical practitioners, pharmacists and wholesalers will significantly restrict access to essential pharmaceuticals and increase the cost to the point it may be beyond reach for those having to fund medicines privately. We suggest that other alternatives need to be explored, to keep the community safe. Our reasons are detailed as follows.

Our members experience is that pharmacies are not currently interested in importing medications, if there is not a New Zealand supplier, they will not source it. Pharmacies currently give a flat "No", recommend an alternative medication available in NZ or suggest the patient source it overseas.

Our members experience is also that doctors may be willing to prescribe medications but they are also not interested in sourcing medications from overseas. To do so involves time, is not an easy task and the administration systems often do not readily support purchase, storage, debt collection, finance, sales and dispensing to patients, especially within DHB's.

It is also proposed that wholesalers could import medicines. Many MCAD medications required are not currently being imported into New Zealand e.g. famotidine. The medications required by MCAD patients are often uncommon and specific to a manufacturer, a wholesaler may struggle to find the medicine and profit from the small quantities required.

Unless there is a simple and quick system supporting the sourcing and purchase of a full range of pharmaceuticals then pharmacies and medical practitioners are unlikely to go the extra mile to source pharmaceuticals unavailable in New Zealand. If people cannot source needed medications they will need to go without or shift from legitimate overseas pharmacies (which do exist) to illegitimate ones that don't require prescriptions and disguise the nature of the shipment. Neither of these outcomes is a safe outcome.

People with MCADs often import several medicines including OTC's, from different locations, on top of the costs from subsidised and unsubsidised NZ medicines - the total costs can be significant. The nature of these diseases often renders the patient incapable of working and limited as to means. The requirement for a medical professional to source a medicine from an authorised supplier and dispense it is likely to significantly increase the cost of the medication, for example, one member currently incurs a 30% increase in cost for a personal import that is dispensed by a medical professional, it is expected that when full administrative costs are included then the cost would be even higher. The prescription medicines that MCAD patients import are not nice to have these are essential medications that enable people to function and earn a living.

If the decision is made to proceed with the Section 76 changes then it is suggested that it needs to be made easy and cheap for medical professionals and pharmacies to access the required medicines.

For the above reasons we support the safe provisions of medicines to New Zealanders, but believe the proposed changes are likely to increase the difficulty and cost in accessing essential medicines, unless additional changes are made.

We support Section 77. It is not uncommon for our members to import medical devices. The range of personal medical devices in New Zealand can be limited and it is useful to have continued access to different models.

**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:**

**C1 Medicines (excluding cells and tissues) sector**

## **Product-based controls**

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

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

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

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

## **Activity-based controls**

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

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

## **C3 Medical device sector**

### **Question C11**

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

## **Product-based controls**

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

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

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

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

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

## **Activity-based controls**

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

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

## **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?:**

See the comments in B10. Our experience is that medical practitioners and pharmacies currently are not particularly willing to source medicines on a patient's behalf. Many of the medicines commonly prescribed (internationally) to Mast Cell Activation Disorder patients are not available or funded in New Zealand and need to be sourced overseas. We would welcome the opportunity to collect all needed medications from the local pharmacy, preferably funded.

To prevent the drug reactions which are common in MCAD, patients can have very particular needs for uncommonly prescribed medications, particular brands or medicines without particular fillers, dyes or coatings. For this to work wholesalers would need to be compelled to source small runs of medicines which may need to meet very narrow criteria. As these medications are paid for out of pocket and often required by people of limited means (unable to work) the cost of sourcing these medicines would need to be at least cost, all other things being equal. By way of example a wholesaler filling an order for famotidine would be on charging twice as much if branded "Pepcid" was supplied over a generic. Postage can also be prohibitive when coming from particular countries. Postage can often make up to 50% of the cost of purchase and for this reason often bulk mixed batches are ordered from a single overseas pharmacy. Medications would also need to be imported in a timely fashion. It is acknowledged that wholesalers may be able to acquire pharmaceuticals at a cheaper cost than the current retail market and have them shipped with other products.

For this proposal to work the wholesaler/ pharmacy company would need to be compelled to source and import all medications with a SCNCA. The system would also need to be in place to enable the patient to review the cost prior to purchase.

If New Zealand was able to access the Australian/US prescription pharmaceutical market lawfully then this issue with substandard imports would largely be resolved.

Query – would a SCNCA be required for a medicine which is an OTC overseas but "unapproved" prescription in NZ.

## **Hawker's licence**

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

## **Transition**

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

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

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

We are neutral with regard to the proposal. It should be noted that a number of MCAD medicines e.g. Nalcrom, montelukast, amitriptyline and hydroxyzine were developed, used and researched prior to the recognition of most MCAD's. For that reason there is unlikely to be research into the effectiveness etc of those medicines in treating MCAD's.

This is unlikely to change in the future with the exception of the occasional small scale research into the novel uses use of existing pharmaceuticals. Requiring a SCNSA for off-label use of medicines is unlikely to reduce the number of unapproved medications prescribed for MCAD's and will create additional paperwork. It should be noted that OTC's are also often used off label for MCAD e.g Zantac (ranitidine) is commonly used as a systemic H2 blocker.

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

Support.

A number of MCAD medicines will be unapproved, but would typically be prescribed by a medical practitioner. Enabling other health practitioners to prescribe once the SCNSA has been issued sounds helpful.

### **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?:**

See the comments in B10. Our experience is that medical practitioners and pharmacies currently are not particularly willing to source medicines on a patient's behalf. Many of the medicines commonly prescribed (internationally) to Mast Cell Activation Disorder patients are not available or funded in New Zealand and need to be sourced overseas. We would welcome the opportunity to collect all needed medications from the local pharmacy, preferably funded.

To prevent the drug reactions which are common in MCAD, patients can have very particular needs for uncommonly prescribed medications, particular brands or medicines without particular fillers, dyes or coatings. For this to work wholesalers would need to be compelled to source small runs of medicines which may need to meet very narrow criteria. As these medications are paid for out of pocket and often required by people of limited means (unable to work) the cost of sourcing these medicines would need to be at least cost, all other things being equal. By way of example a wholesaler filling an order for famotidine would be on charging twice as much if branded "Pepcid" was supplied over a generic. Postage can also be prohibitive when coming from particular countries. Postage can often make up to 50% of the cost of purchase and for this reason often bulk mixed batches are ordered from a single overseas pharmacy. Medications would also need to be imported in a timely fashion. It is acknowledged that wholesalers may be able to acquire pharmaceuticals at a cheaper cost than the current retail market and have them shipped with other products.

For this proposal to work the wholesaler/ pharmacy company would need to be compelled to source and import ALL medications with a SCNSA. The system would also need to be in place to enable the patient to review the cost prior to purchase.

If New Zealand was able to access the Australian/US/UK prescription pharmaceutical market lawfully then this issue with substandard imports would largely be resolved.

Query – would a SCNSA be required for a medicine which is an OTC overseas but "unapproved" prescription in NZ.

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

To prevent the drug reactions which are common in Mast cell Activation Disorders, patients can have very particular needs for uncommonly prescribed medications, particular brands or medicines without particular fillers, dyes or coatings. Where a person's needs for a medication are very specific, then it may be appropriate to enable that person to source a particular medication which meets their needs, rather than require a pharmacy or wholesaler to import 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-G42F-S

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-15 21:46:16**

### Submitter profile

**What is your name?**

**Name:**

Claudine Daniel

**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:**

Wellington

Other health practitioner (please comment)

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

Pharmacy Technician

Medicines (other than cells and tissues), Trial ethics

**If you selected 'Other' please comment;:**

**Next steps after the consultation**

**Executive summary**

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

**Chapter A (A1 - A5)**

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

Support

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

**B1 Overview of the draft Bill**

**B2 Tips to help with understanding the draft Bill**

**B3 Part 1 of the Bill: Preliminary provisions**

**B3 Part 1 of the Bill: Preliminary provisions**

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

**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):**

s36 I agree that the pharmacy definition should be expanded to include mobile and limited service pharmacies

s37 Pharmacy worker is vague and encompasses everyone from highly skilled pharmacy technicians to counter assistants. It is simplistic and disrespectful to pharmacy technicians who are required to hold qualifications to work as pharmacy technicians but are not given recognition as a group in their own right.

## **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):**

It should be noted that although the current Medicines Act and Regs state that Pharmacy Technicians undertake activities under the direct supervision of a pharmacist, the reality is that there are very few occasions where this is actually occurring/enforced. Pharmacy is an evolving sector and (thinking about hospital pharmacy particularly) the reality is that pharmacists can't possibly directly supervise many (if indeed any) activities if they are also to undertake the activities that only they are qualified to do (decide on the appropriateness of a medication). Pharmacy Technicians work in all areas of pharmacy and often work alone and in many cases are in charge of departments within pharmacies whereby they supervise pharmacists, make decisions about quality of medication etc. and yet find that legally they are to be supervised by the pharmacist. This concept is hideously outdated and if left in the legislation will leave New Zealand continuing to trail years behind pharmacy practice internationally (as it currently is).

The term direct supervision needs to be removed at least in relation to Pharmacy Technicians and a provision made in the accompanying legislation for other pharmacy workers other than pharmacists to hold professional registration and accountability in their own right.

**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:**

## **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):

## **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.:**

### **C4 Clinical trial sector**

#### **Question C16**

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

I agree that the regulator should be able to audit trial sites and trials.

I believe that any investigational product that is injected, ingested, applied should be classified on the medicines schedule as currently there are many trials in operation which have no pharmacy input.

#### **Question C17**

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

### **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?:**

The identification of pharmacists as being the only pharmacy workers who can deliver innovative services is limiting in itself. Pharmacy Technicians, if regulated, are trained to a level which enables them to give advice. If pharmacy technicians were regulated this would give pharmacists the confidence to allow pharmacy technicians to use their training to give advice (not related to the suitability of the medication for the patient - this remains a pharmacist activity) and not fear that they will be held responsible and accountable for the actions of another pharmacy colleague.

**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 believe that a pharmacy needs to be majority owned by a pharmacist. I feel that if a responsive and effective regulator is in operation any 'supervisory' pharmacist should be able to raise concerns or if necessary 'whistleblow' to the regulator if their owner was not responsive to issues raised.

**Detailed questions relating to Option 1**

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

I feel that this option is restrictive and I am not in favour.

**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 feel that the pharmacy sector is very closed off at the moment and that patients often receive expensive non responsive care and that non-pharmacist owners could bring a fresh approach to the sector whilst retaining the quality that comes with the knowledge of pharmacists and pharmacy technicians.

**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?:**

The regulator needs to be visible, and there needs to be regular and comprehensive audits carried out in order to identify issues.

**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 believe that we need to move away from pharmacists needing to directly supervise activities by allowing Pharmacy Technicians to be regulated independently. It may be worth looking into and defining the activities that can be performed without a pharmacist on 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?:**

In many parts of the world pharmacists are themselves prescribers and at the moment New Zealand is lagging behind in the uptake of these additional duties and having this restriction may dissuade pharmacists from becoming prescribers as they would not be able to own a pharmacy. Also it is not out of the realms of possibility that a doctor/pharmacist/pharmacy technician (if allowed) partnership especially in rural areas would occur and would be appropriate in order to ensure a pharmacy service can be given.

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

Mass casualty, natural disaster etc. would be useful to have this ability. Also shortage due to manufacturing issues (especially with generics).

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

I believe that qualified pharmacy advice (pharmacists/pharmacy technicians) should be available where all medications are sold.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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

**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 appropriate when they are aware that something is regularly required. However, I really believe that the amount of items compounded on-site in what

are realistically variable conditions should as far as possible be halted and a provision be made that items should be sourced from a manufacturer unless the item is needed urgently i.e. harm will come to patient (this is unlikely to be the case with regard to creams/ointments).

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

Yes in the case of from pharmacy to pharmacy only (could include community to hospital also) but I don't believe that a premium should be charged for this as has happened previously in my hospital when supplying other sites in emergency situations. I believe that supply should be made for cost price only and not an activity to generate revenue.

## **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?:**

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?:**

No I believe the advice of a trained pharmacy person is required (pharmacist/pharmacy technician).

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

No I believe the advice of a trained pharmacy person is required (pharmacist/pharmacy technician).

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

I do not believe that medication should be advertised at all.

**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 that medication should be advertised direct to patient as I believe it should be up to the prescriber and pharmacist to decide if a medicine or treatment is 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?:**

I agree

**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

### **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 that imports should be tightly controlled if only for safety reasons

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

Yes, in cases where their normal medication is unavailable here (overseas resident) or where a medication is shown to be effective for a condition but is unapproved/unfunded due to monetary considerations in New Zealand.

### **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?:**

**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?:**

Wider access to pharmacies especially in rural areas

### **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 believe that advice from a trained pharmacy person is required.

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

No, I believe that advice from a trained pharmacy person is required.

### **Advertising**

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

advertising can lead to requests for inappropriate medication and also for medications that come with a premium price.

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

advertising can lead to requests for inappropriate medication and also for medications that come with a premium price.

### **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-G42W-A

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

Submitted on **2019-04-15 22:31:48**

### Submitter profile

**What is your name?**

**Name:**

Richard Barley

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Unichem Taradale Pharmacy

**Submitter Profile (tick all that apply)**

Consumer, Disabled person, Māori, Pacific peoples

**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).:**

##### 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 36

Allowing a pharmacy license to only apply for some pharmacy activities would facilitate IPSCA where supply of medicines and advice about safe use of medicines is separated.

This may lead to inconvenience for the public. Pharmacies may choose to stop services that are not properly funded . eg Bulk foods , cost of freight more than dispensing fees, Compounding mixtures and creams and ointments. Up to Half an hour funded at \$5.30 dispensing fee. Expensive medicines , financial cost of stocking items is too high.

Mixtures for Children take too long to prepare.

This would allow pharmacies to cherry pick the IPSCA contract. Targeting high numbers of LTC patients . Other pharmacies may choose to provide no advice and no clinical interventions ,operating a "factory style" pharmacy .These pharmacies may have a high ratio of dispensary technicians.The public should expect to receive a complete pharmacy service at any pharmacy they choose.

## **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:.

## **B7 Part 5 of the Bill: Licences and permits**

### **Subpart 1: Licences (ss 123–130)**

#### **Question B18**

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

#### **Question B19**

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

### **Subpart 2: Permits (ss 131–135)**

#### **Question B20**

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

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

#### **Question B21**

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

#### **Question B22**

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

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

##### Question B23

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

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

##### Question B32

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

#### B12 - B15, Schedules 1 - 4

##### Schedules

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

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

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

#### C5 Wholesale sector (including importers and exporters)

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

##### Licence to wholesale

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

##### Hawker's licence

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

##### Transition

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

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

##### Pharmacy sector context

##### Future regulation of pharmacy business activities

##### Licence to carry out a pharmacy business

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

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

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

##### Question C22 Which option do you support?

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 would remove the corporate profit driven models where there is reduced staffing ratio's and "difficult customers and prescriptions " are refused

Even though the current ownership model has been twisted by legal constructs . A return to the original intention of the bill would ensure all New Zealanders would have access

to a top quality service where the pharmacist owner takes full responsibility to ensure best outcomes for the public is crucial . This view is supported by Ernst & Young that assesses the Government's proposed changes to pharmacy

ownership regulations, as a part of introducing the Therapeutics Products Bill in 2017 . New Zealand has a number of vulnerable rural areas that would not be financially viable for a corporate model pharmacy business to operate.

### **Detailed questions relating to Option 1**

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

Benefits Higher level of safety with the responsible pharmacist owner much more motivated to provide a top quality service .

Risks . DHB funding via the current IPSCA is low and pharmacist owners may not have the capital to invest in there business especially if the "advice" component of the contract is being performed by a non bricks and mortar pharmacist .

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

Separating funding for supply of medicines and the advice component as provided for in IPSCA and being considered by this bill should be removed as an option.

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

Dispensing , Medicine information and advice , sale of OTC medicines, Pharmacist Only Medicines , Pharmacy Only Medicines ,Pharmacy triage contracts ( yet to be created ) , Vaccination services , Medicine supply to Rest Homes , Medical Centres

#### **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?:**

Operational and financial control of the pharmacy should be shared by all pharmacist share holders. If majority ownership and effective control is separated. We will be back to our current position where majority ownership will fall into the hands of" investor pharmacists "

#### **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)?:**

Each pharmacy could have a maximum FTE ( full time equivalent staff ratio )  
The 5 pharmacies can not have more than 50 FTE staff members employed and cannot be more than 2 hours commute between pharmacies  
This would allow for 2 large pharmacies and 3 smaller pharmacies  
But not so large that effective oversight is lost.

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

Any company formed must have majority pharmacist ownership of both operational and financial control of the pharmacy. As such, any commercial motivations should be tempered by their professional and ethical obligations.  
The company could then own up to 5 pharmacies.

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

The pharmacy profession would be invigorated as opportunities for young well qualified clinical pharmacists to take the lead in primary healthcare delivery ,as our health sector is swamped by the avalanche of health needs created by our ageing population and diabetes epidemic .

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

2 years to allow arrangements to be put in place for majority pharmacy ownership to be put in place, including suitable financial arrangements.  
Green Cross Health advise their majority owned partnership pharmacy stores engage with their local communities more effectively than corporate stores.

#### **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?:**

Exemption should be removed as these friendly societies are struggling to find suitable qualified pharmacists to allow then to provide a quality pharmacy service.

### **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 would quickly allow for corporate foreign ownership of the pharmacy sector.  
The Chemist Warehouse pharmacy has already shown its hand in operating at a loss to force competitors out of the market

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

No Open Ownership will initially see a number of new smaller pharmacies open then the viability of the sector collapse and finally a take over by the corporate stores.  
Resulting in low quality service and then consolidation of outlets and inconvenience for the elderly and frail. This has already occurred in the hardware store market. Building supply chains like Bunnings , Mitre 10 and Placemakers have shut down community hardware operators.

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

No: Supervisory pharmacists would have to be very brave to contradict corporate managers. Job satisfaction would disappear , Mass exodus of our brightest and best clinical pharmacists as the opportunities for ownership disappear.

### **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?:**

Online Pharmacy

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

Pharmac has removed the profit incentive for prescribers to recommend products with the best terms of purchase.

In small communities a combined doctor / pharmacist business could benefit from synergies around a collegial business relationship.

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

Festivals

Emergency disasters

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

Currently Sealeggs a Pharmacy Only Seasickness medication is sold within 10km of a pharmacy by tour boat operators in Kaikoura .

People take a pill that causes drowsiness go on the whale watching expedition then

carry on driving to Queenstown under the influence of the drowsy side effects that can last up to 14 hours. A good example of leniency in licensing rules causing public danger.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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 good , We have residents at a local care facility trying to import viagra off the internet. The medications contained unknown quantities of active ingredient and could be dangerous.

## **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?:**

Rules around compounding for oral medications should remain . But topical creams and ointments should be able to be compounded in anticipation Max 1000g

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

Pharmacies should be able to contract pack another pharmacy's medications using a robotics packing machine. This would make automation more efficient as robotic equipment would not be sitting idle so much. The packing file would be sent electronically between pharmacies that have contractual arrangements.

The commercial arrangements should not be dictated by the IPSCA with the DHB

## **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)?:**

We need to go back to prescribed lists that health practitioner can prescribe from

eg Dental Medications

Mid-Wife medications

**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

The current situation allows prescribers to get out of their depth

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

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

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

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

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

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

**Health practitioners (non-prescribers)**

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

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

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

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

Direct to consumer advertising puts pressure on prescribers to recommend inappropriate medicines . Forcing the prescribers hand.

New medicines should be detailed to the prescribers.

If Pharmac approves new medicines adequate training should be supplied to prescribers.

## **Chapter D: List of consultation questions**

**Chapter A Question**

**Chapter B Questions**

**Chapter C Questions**

## Response ID ANON-DPZ8-G4RN-1

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-16 05:29:29**

### Submitter profile

**What is your name?**

**Name:**  
Angela Heswall

**What is your email address?**

**Email:**  
[REDACTED]

**What is your organisation?**

**Organisation:**  
Kensington Pharmacy

**Submitter Profile (tick all that apply)**

Consumer, Disabled person, Māori, Pacific peoples

Industry body, Advertising

Pharmacy organisation

**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).:**

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).:**

The definition of DISPENSED MEDICINE has changed significantly and this is of serious concern.

Under the new proposed TPB the definition of dispensing is defined as part of manufacturing the medicine. this is very misleading. Dispensing involves clinical checks, preparation, supplying to patient and providing advice to the patient.

A much wider scope which needs to be recognised.

#### 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):

n/a

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

### Question B4

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

n/a

### Subpart 3: Authorisations (ss 56–80)

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

I support this change.

Patient benefits hugely improving access. Wastage issues may be reduced

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 :

This is sensible in emergency situations for small quantities.

Care should be taken not to allow trading of stock between medical practitioners. Clarification in quantity will need to be made very clear.

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:

Concerns about the lack of intervention a vending machine will be able to do that currently happens when a pharmacist dispenses a medicine. These interventions reduce medication errors from happening especially when the prescriber has made a mistake and the pharmacy identifies it. How would a machine identify and manage this.

Patient safety would be at risk.

Vending machines license needs to be linked to the license of a FULL service pharmacy to allow full access to pharmaceutical services that the patient requires.

### 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):.**

How can medicines be dispensed and supplied from a resthome. These should be dispensed from a FULL service pharmacy that has access to All REQUIREMENTS of a pharmacy.

These pharmacies would not meet audit requirements.

#### **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):.**

I agree with permits for Short term and urgent situations. The permits must allow full functionality to happen though. Not partial or create barriers to supplying a FULL pharmacy service.

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

#### **Question B21**

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

This makes sense to increase the time period up to three years.

#### **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?:

I support this. There is too much risk to the patient by importing medicines without the safety of having it clinically checked through a pharmacy.

The patient also does not get the advice from the pharmacists.

Patient safety is a risk currently.

### 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?:

If an alternative model is to be explored then the integrity and the safety of the current system. Access to community pharmacy must remain a priority no matter where they are in the country.

If new systems can improve on the current model or add to it then this should be explored.

When dispensing a medicine consideration of the complexity of the clinical process, advice given on safe and effective use is completely different to a normal retail item. Dispensing and advice MUST be provided face to face to get the best patient outcome.

##### 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 the current licensing requirements creates a barrier to innovation.

Service innovation requires focus on IT systems, improved workforce collaboration and aligning policy and funding models for primary care.

Technology advancement and community pharmacy workforce will lead to innovation over time aligned with the appropriate funding.

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

It is important to keep looking for improvements in reducing the health inequity issues we currently have especially with Maori and Pacifica. It must not compromise the current dispensing model of medicines being dispensed within a pharmacy with FULL 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?:

There are significant public benefits for pharmacies to be owned and operated by pharmacists. They are in control of, accountable for the decisions made in the best interests of their patients care.

The patient care is the focus of the pharmacy.

Pharmacists are under professional obligation to provide services and a standard of care that requires adherence to the highest of standards.

Non pharmacist investors are more likely to focus on meeting minimum compliance standards at minimum cost which then has a negative impact on the patient.

Medicines are not a normal item of commerce and so must be considered differently with patient safety at the forefront of any policy change.

#### Detailed questions relating to Option 1

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

Patient safety is put at the forefront of all decisions. The current model is delivering a high quality at no cost as pharmacy. Pharmacy in its current model are solving patients problems often at no cost to anybody and yet resulting in an improved health outcome to the patient.

Corporate owners would not provide these free services to many of these patients as there is no funding incentive for them. The bottom line dollar is what a corporate model focusses on NOT wanting to maintain a healthy community.

Many pharmacy owners live amongst their communities that they provide services to and are widely trusted. Many of us receive phone calls after hours or weekends from patients that have problems. Would a large corporate chain pharmacy offer this. I think not.

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

I believe option 1 could be improved with grandfathering provisions for pharmacy business that are operating legitimately under the current rules.

An improvement to option one could be by mandating the owner pharmacist to have to vet share so that this pharmacist is always under control of all voting rights, giving them unequivocal control of all activities, operations and governance matters related to the pharmacy. A veto share ensures effective control is in the hands of the pharmacist and replaces the need for re-regulating dividend requirements in proportion to shareholding. This allows flexibility for the owner to seek further funding for investments in pharmacy assets eg robots while retaining effective control of the pharmacy governance and operational matters.

This also allows young pharmacists to gain a foothold in the pharmacy ownership through flexible financing.

Governance and operations should be specifically be related to patient safety and veto share transfer should only happen between pharmacists.

##### 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 medicine except general sale.

##### 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.

The code of Ethics drives effective control through the pharmacist's owners obligation as a registered health professional. They must always put the patient first. A pharmacist who makes judgements on governance and operating decisions and health related investments must have a form of ownership stake to effectively exert their professional judgement.

The act could have a Veto Share ON GOVERNANCE AND OPERATIONS FOR THE EFFECTIVE CONTROL. this ALLOWS FOR flexible ownership and strengthens the effective control obligations.

Possibly if two pharmacists have %26 share.

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

The current model means that ownership is spread over a large number of owners. This prevents market prices and contract terms being controlled by a single or small group of owners. This is a benefit to the public.

The appropriate oversight of a pharmacy is effective control and the owners should demonstrate governance of the business.

The day to day can be delegated to a pharmacy manager whom must be a pharmacist

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

If the pharmacists had an equal share then both would be legally responsible for ensuring compliance with governance and operational matters.

The 5 pharmacy limit could be applied by the pharmacist having a veto shareholding. The pharmacists would then have effective control of up to 5 pharmacies.

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

There is a risk that private investors may sell down their shares and therefore devaluing the pharmacy business. This may make it difficult for pharmacist owners to exit. This may then cause a barrier to entry for pharmacists.

This would be avoidable under option 1 if grandparenting of current legitimate ownership arrangements was implemented or if it was legally mandated that owner pharmacists had a veto share so that the pharmacist is always in control of all voting rights and has effective control.

This allows flexibility for alternate financing arrangements as it replaces the need to regulate any dividend requirements in proportion to shareholding and would maintain current investment value in the sector.

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

Depends on the scale of any impact on the pharmacy sector. A minimum of 5 years to 7 years would be reasonable once the ACT becomes law.

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

Grandparenting of ownership provisions should be maintained for those that are already operating legitimately under the current rules.

**Detailed questions relating to Option 2**

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

This is detrimental to patient access to services, patient safety, their health outcomes, the pharmacist's professional obligations and the pharmacy profession itself. Pharmacists under an investor/corporate owned pharmacy would be under pressure to reach financial performance indicators rather than focus on patient services that improve their health and increase access to services that they may need. If the service does not make a sufficient profit margin then it may not be offered and therefore the patient and local community suffers as they do not have access to services that they require. This is how supermarket food chains work which is not what we want.

Workforce issues are likely to arise as there is a lack of future career advancement. The workforce loses skills.

Pharmacists invest considerably in human and physical capital to operate their businesses which is usually their principle 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 standards are not met, the government effectively raises the stakes for non-performance.

Owner pharmacists have an incentive to conduct themselves and their pharmacies ethically and professionally so they don't risk loss of their registration and therefore loss of the pharmacy.

Owner pharmacists are accountable to the public through their registration. A non-pharmacist owner would be accountable to their shareholders first before the public.

**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?:**

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?:**

How could these activities be performed safely without the direct supervision and oversight of a pharmacist.

A change in this would 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 pharmacy. This is a direct conflict of interest. Prescribing and dispensing should remain separate.

There is a clear incentive for the prescriber who has direct financial gain to align their prescribing practice to generate more profit from the pharmacy.

Pharmacy revenue is directly linked to dispensing volume.

Pharmacists that prescribe for low level minor ailments such as TMP, should not be prevented from owning pharmacies. This level of prescribing is to ease pressure of GP and to improve access to medicines for patients. It does not drive volume.

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

Permits would be excellent for emergency situations eg earthquakes a pharmacy burning down. This would allow a pharmacy to get back up and running quickly in the temporary premise ensuring access to services.

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

These pharmacies should only be linked to a full service pharmacy. They must have appropriate levels of pharmacist supervision and direct 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?:**

I am fully supportive of this approach as it is in the best interest of patient safety.

### **Pharmacist and pharmacy worker authorisations**

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

The ability to Batch compound should still be allowed for in this ACT.

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

Where there is common ownership and to reduce wastage especially high cost and improve access to medicines for the patient.

### **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.):**

no change

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

do not change

**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?:**

Must be prescribed by a medical practitioner and a clinical need must be established.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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 my answer to this previously

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

In emergency situations 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?:**

no comment

### **Health practitioners (non-prescribers)**

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

NO

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

NO

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

NO comment

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

yes as it informs the patients of what is available and offers options for the patients where otherwise they may not be aware.

## **C9 Veterinarians**

### **Question C54**

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

no comment

## **C10 Advertising sector**

### **Question C52**

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

no comment

### **Question C53**

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

yes continue

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

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

See this answer previously

**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 my answer previously

### **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?:**

see my answer previously

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

no Patient safety would be at risk.

### **Pharmacy licensing**

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

see my answer previously

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

see my previous answer

### **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 my reasons previously

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

see my reasons previously

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

see my answer previously

### **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 my answer previously

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

see my answer previously

### **Advertising**

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

no comment

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

Continue

### **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

### **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.:**

consult with the disabled as they have their own and very valuable input.

## Response ID ANON-DPZ8-G42K-X

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

Submitted on **2019-04-16 07:13:45**

### Submitter profile

**What is your name?**

**Name:**

Jane Dawson

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

New Zealand Defence Force

**Submitter Profile (tick all that apply)**

**If you select DHB, please state service area:**

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

Crown entity

**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).:**

NZDF Health believes that the purpose and principles of the Bill are very succinct and clear. The principles are sound, comprehensive and provide good overarching guidelines without being too detailed.

### 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).:**

NZDF Health agrees with the Definitions in their broad context with the exception of the activity 'Dispensing'. To dispense a medicine means to bring the medicine to a state ready for immediate supply to a particular patient in response to a request for that supply.

Issues: Dispensing is a controlled activity. Currently the NZDF repack process is taken as dispensing and the medics then administer the product. Under this definition, the medics would be dispensing as they individualise the product by adding the patient name. Retaining the above definition would mean that non-registered NZDF health personnel (medics) would not be able to administer medicines for patient supply under Standing Orders. This would affect our ability to support operations.

This process also occurs in other areas of practice external to the NZDF.

### 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):**

NZDF Health supports the proposed controls around the management and delivery of the controlled activities and of the supply chain activities.

It is noted that a controlled activity can only be undertaken if the individual has specific authorisation, a licence to undertake the activity, or a permit to undertake the activity.

The NZDF has a unique construct in the management and delivery systems used for medicines and therapeutic products. A significant part of the workforce is composed of non-registered healthcare providers who use standing orders to deliver care in austere environments. These are facilitated by a unique system of repacked medicines.

The Regulations will determine the effect of the proposed legislation on the NZDF operating environment, but it is clear that the NZDF will require special consideration within the Regulations / licensing framework. Failure to achieve that would negatively impact on NZDF capabilities.

**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 NZDF supports the proposed controls around the authorisations for health practitioners. However, the NZDF would require special Regulation or licensure around the importation and use of unapproved / off-licence use of medicines and therapeutic products.

The NZDF use unique products unavailable on the NZ market. Examples: Nerve agent treatments, haemostatic bandages, anti-snake venom, battlefield analgesia

Issues: Under the current proposal the NZDF would require individual approval or individual application for exemption for each medicine. The issues are that:

- Products required for evidence based military medicine practice
- NZDF will never be a sponsor of these products under the meaning of the Bill
- Required ahead of potential need to facilitate operational readiness
- NZDF will need to own the processes for importation and management
- NZDF will be liable for the use of the product.
- Product may be required at very short notice

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

The NZDF uses Standing Orders to provide medicines in this context. The military healthcare providers are not technically staff but are defined as serving under the Defence Act. This provision could be applied to the civilian personnel of the NZDF only.

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

- Veterinary Operating Instructions (VOI) can be written under another piece of legislation. They enable care of animals in the absence of a vet.
- Sect 66 states that vets can only prescribe for a patient of the vet or at request of another vet.
- Sect 67: For the purposes of section 51, a veterinarian may supply an unapproved category 4 medicine or an unapproved medical device by non-wholesale supply if—
  - (a) the medicine or device is supplied—
    - (i) to a patient of the veterinarian; or
    - (ii) for a patient of, and at the request of, another veterinarian; and
  - (b) the patient is in New Zealand or is ordinarily resident in New Zealand; and,
  - (c) there is a complying special clinical needs supply authority for the patient for that medicine or device

The issues that NZDF has are:

- NZDF has military working dogs which are operationally deployed. We do not have vets that deploy with them.
- The dogs are domiciled across NZDF so have different vets.
- There are no clear systems for managing a dog if it is sick or injured.
- We require a system to enable repacked medicines (unapproved products) to be manufactured for the dogs at the Medical Store and for a single vet to be able to create a VOI to cover all the animals. The trainers would then be trained in this care.

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

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

**Subpart 4: Other offences (ss 81-94)**

**Question B12**

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

**B7 Part 5 of the Bill: Licences and permits**

## **Subpart 1: Licences (ss 123–130)**

### **Question B18**

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

NZDF Health supports the use of licences to manage delivery of care in situations that fall outside of routine practice. The proposed legislation is comprehensive and enabling.

Licences are one mechanism that could be used to enable NZDF to practice outside the bounds of practice authorised in the civilian environment. This is the mechanism to use if a Regulation approach for the NZDF is not possible. It would require complex regulatory involvement to manage because of the 3 yearly licence renewal processes.

### **Question B19**

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

NZDF Health considers the criteria to be set at an appropriate level to ensure that the responsibilities, boundaries of practice and quality assurance processes are able to be regulated.

## **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):**

NZDF Health supports the specification of the responsibilities of the licensees and designated responsible persons. It is a significant gap in the current legislation.

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

### **Pharmacy sector context**

#### **Future regulation of pharmacy business activities**

#### **Licence to carry out a pharmacy business**

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

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

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

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

#### **Detailed questions relating to Option 1**

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

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

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

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

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

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

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

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

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

#### **Detailed questions relating to Option 2**

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

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

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

#### **Other changes to pharmacy licensing requirements**

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

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

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

NZDF Health supports the use of permits for enabling short term activities such as emergency management. Within the NZDF environment an example would be:

Pharmacists on deployment. Currently pharmacists who deploy can only work in the pharmacologistics area of practice. The requirement to be in a licensed premises constrains them from dispensing in the deployed clinical environment. This restriction reduces the opportunity to deploy for a potentially valuable member of the clinical team. It would also reduce reliance on the logistics supply system for delivering of repacked medicines.

**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.):**

NZDF Health supports the use of standing orders. Without standing orders the NZDF medics would not be able to provide health care to NZDF personnel in deployed situations. However, the approach under the proposed Bill will not permit the use of the Standing Orders within the NZDF.

Because of the unique activities associated with military activities, the NZDF Medical Treatment Protocols (Standing Orders) are extensive and require special authorising, competence assessment, remote supervision, monitoring and auditing management processes.

The range of care activities includes primary care, occupational care and emergency management. The range of medicines used include controlled drugs, and all classifications of medicines under the current Act. They also include off-licence use and use of unapproved medicines.

This is one area where the NZDF will require either special regulation or licensure to be able to continue operating.

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

NZDF Health supports the approach in general terms. However, the unique nature of military practice means that the NZDF will require special consideration in the form of Regulation or licensure in order to enable off-label use of medicines that are required for operational provision of care.

**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?:**

NZDF Health supports the approach in general terms. However, the unique nature of military practice means that the NZDF will require special consideration in the form of Regulation or licensure in order to use unapproved products that are required for operational provision of care.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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?:**

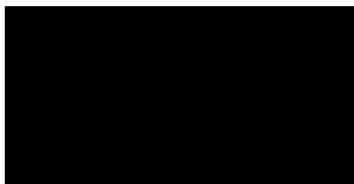
**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

**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?:**

Qualified Pharmacy Technican

Kathryn Rzoska



15 April 2019

**Submission for Therapeutic Products Bill**

Dear Sir/Madam,

I am writing to you regarding my concerns about section 37 (1) for this proposed bill. Definition of a pharmacy worker.

**37 Meanings of pharmacy worker and qualified (1) A pharmacy worker is a person who works in a pharmacy business but is not a pharmacist.**

I think that this definition is too broad and does not recognise the skill that some pharmacy workers have.

I have been a qualified Pharmacy Technician for 20 years. I have a NZ Certificate in Pharmacy Technician Level 5, NZ Certificate in Pharmacy Technician (Specialist) Level 6. NZ Certificate in Adult and Tertiary Teaching Level 5 and I am currently completing a NZ Diploma in Adult and Tertiary Teaching. I was awarded NZ Pharmacy Technician of the Year 2018; I am also a tutor for the Pharmacy Technician Program with NZMA. I have specialised skills, corporate knowledge and considerable experience I deserve more recognition than being referred to as a person who works in a pharmacy but is not a pharmacist.

Pharmacy Technicians newly qualified or with considerable experience provide significant support to the pharmacist. Our qualification is comprehensive and as such, we should be recognised for this. I have been saddened over the years, but even more so in recent times to see our role and qualification minimised and devalued.

As pharmacy technicians we are fully aware of our scope of practice and limitations. I would like to have the Pharmacy Technician recognised as an individual qualification in this document.

If a Pharmacy Technician can own 49% of a pharmacy, then please provide us with the respect that we deserve but rarely are recognised for.

Kind regards

Kathryn Rzoska



## Response ID ANON-DPZ8-G426-9

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-16 10:31:11**

### Submitter profile

What is your name?

Name:

Charon Lessing, PhD

What is your email address?

Email:

What is your organisation?

Organisation:

Auckland University of Technology

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Pharmacist, Other health practitioner (please comment)

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

Lecturer

If you selected 'Other' please comment;:

Next steps after the consultation

Executive summary

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

Chapter A (A1 - A5)

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

Partially don't support

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

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

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

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

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

B5 Part 3 of the Bill: Dealing with therapeutic products

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

### **Question B3**

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

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

### **Question B4**

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

#### **Subpart 3: Authorisations (ss 56–80)**

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

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

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

**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 am concerned at the apparent weakening of the Act with regard to DTCA of prescription preparations.

This is a missed opportunity to bring NZ into line with all other countries (including Australia and excepting the USA), particularly into alignment with WHO recommendations. It is a missed opportunity to improve on requirements for advertising to health professionals.

The self-regulating (sic) practice in NZ undermines PHARMAC activities, erodes the practitioner-patient relationship, has been documented to be unethical in its implementation, seeks to dis-empower and disadvantage people of lower socio-economic status, and arguably is a breach of Te Tiriti o Waitangi (The Treaty).

Category 1 medicines ( i.e. prescription-only) should NOT be advertised to consumers. The Bill does not address this issue adequately, and does not indicate that it will reference the future Regulations - which previously at least had some (abeit minimal) limits on advertising (Part 1 and Part 2 of Schedule 1 of the Act).

### **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):

### **C10 Advertising sector**

### **Question C52**

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

Advertising (ss 82–83): I am concerned at the apparent weakening of the Act with regard to DTCA of prescription preparations. See below.

### **Question C53**

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

Advertising (ss 82–83): I am concerned at the apparent weakening of the Act with regard to DTCA of prescription preparations.

This is a missed opportunity to bring NZ into line with all other countries (including Australia and excepting the USA), particularly into alignment with WHO recommendations. It is a missed opportunity to improve on requirements for advertising to health professionals.

The self-regulating (sic) practice in NZ undermines PHARMAC activities, erodes the practitioner-patient relationship, has been documented to be unethical in its implementation, seeks to dis-empower and disadvantage people of lower socio-economic status, and arguably is a breach of Te Tiriti o Waitangi (The Treaty).

Category 1 medicines ( i.e. prescription-only) should NOT be advertised to consumers. The Bill does not address this issue adequately, and does not indicate that it will reference the future Regulations - which previously at least had some (abeit minimal) limits on advertising (Part 1 and Part 2 of Schedule 1 of the Act).

## **Chapter D: List of consultation questions**

### **Chapter A Question**

### **Chapter B Questions**

### **Chapter C Questions**

## Response ID ANON-DPZ8-G4RA-M

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

Submitted on **2019-04-16 12:00:15**

### Submitter profile

**What is your name?**

**Name:**

Karen Longdill

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

USL Medical

**Submitter Profile (tick all that apply)**

Industry body

Medical devices

Medical devices

Medical devices

**If you select DHB, please state service area:**

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

**If you selected 'Other' please comment;:**

**Next steps after the consultation**

**Executive summary**

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

**Chapter A (A1 - A5)**

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

Partially support

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

**B1 Overview of the draft Bill**

**B2 Tips to help with understanding the draft Bill**

**B3 Part 1 of the Bill: Preliminary provisions**

**B3 Part 1 of the Bill: Preliminary provisions**

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

This Bill appears to be more written for the supply of medicines and seems to be rather complicated for the registration of medical devices.

Medical Devices are not the same as Medicines and we believe they should have their own section(s) in the Bill

We support a Bill which allows for third party recognition to avoid the costs associated with conformity assessments and delayed availability of devices to market in New Zealand

The substantial cost in administering this kind of legislation is of concern and we are keen to understand how this will be funded. .

**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):**

21 The definition of the Devices should align to the harmonised global definition

34 (4) Remanufacture Does this include splitting the original packs to smaller units - this is done often when the original pack size exceeds the clients needs.

43 This definition is confusing as we could be a wholesaler and a non wholesaler as we "own" product for the NZ market and supply to the Health industry and to the general public. This Bill should allow the sponsor to carry out its normal business through their 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):**

There needs to be more than one sponsor for a product range.

Currently in New Zealand there is often more than one supplier of a product - authorised by the manufacturer. Sponsors should have files to support their relationship with the manufacturer.

### **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 reads more for the suppliers of medicines

More information is required to be able to comment further

### **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:**

Custom made devices need to be manufactured to IMDFR definitions which should be included in the Bill

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

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

## **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):

This should apply to medicines only

#### **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):

Any supplier importing product who is not the sponsor should be told to desist.

If this is not the case then the supplier must carry all the obligations of the sponsor including gaining written permission of the manufacturer to supply to the market

#### **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):

Needs further clarification

#### **Question B22**

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

151 should be at least 20 working days

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

#### **Question B23**

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

more aligned to medicines not medical devices?

### **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):

Post marketing monitoring programmes to collect information about the safety, quality and performance of medical devices after they have been approved is supported by us.

161 public announcements re public safety should be made in conjunction with the Sponsor and after consultation with them

162 As above there must be consultation with the sponsor before any recall is initiated

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

### **Question B25**

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

185 Must allow time for sponsor to gather information required

186 Testing of samples for investigative purposes should also be in collaboration with the sponsor

## **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):**

schedule 2 should include any person who is affected by the initial decision

It also specified what decisions are reviewable but does not include approvals

addressing both comments allows all affected to apply to have the decision reviewed

203 timing is also important and there should be a definitive time from the beginning to the end of the process - say 90 days

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

### **Question B28**

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

## **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 industry should not be expected to fund the establishment of the Regulator nor the operational costs.

The split between the costs recovered from the industry and those met by the government has not yet been decided. However it is expected that a large proportion of the costs would be recovered through industry fees or charges . We believe the Regulator should seek funds from the government through normal budgetary process. The protection of the health and welfare of the New Zealand population should be shared responsibility between the Government and the Industry not be the major responsibility of the industry.

The regulator should be responsible for time frames for product approval and their non - performance should incur fines

## **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):**

98 the details of the manufacturer is a challenge as often there is more than one manufacturing facility for devices.  
All sites conform to the same international standards.

100 Changes to medical devices should not need to be notified if the overseas pre-market approval does not change

The NZ regulator should only require notification in relation to elements that make up the content of approval, section 98, and these notifications should not result in a new product approval

113 (2a,b) Therapeutic products register

could breach commercially sensitive information if published on a public website.

This should be deleted from the Bill

#### **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):**

C1 A new product approval for changes to existing product should not be required.

There should be more allowance for variations to current approvals. The changed device is not supplied until regulatory approval is obtained (if applicable). Track and Trace is achieved through batch/serial records and UDI moving forward

##### **Question 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.:**

C4 Annual reports for 3 consecutive years from the date of registration for high risk implantable devices should suffice. No annual report on low-medium risk medical devices unless requested by the Regulator if post - market audit is conducted

#### **Activity-based controls**

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

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

## **C2 Cell and tissue sector**

### **Product-based controls**

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

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

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

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

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

### **Activity-based controls**

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

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

## **C3 Medical device sector**

### **Question C11**

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

### **Product-based controls**

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

C12 It is essential that the proposed Therapeutic products bill supports the growing momentum for global harmonization of medical device regulations

**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.:**

C14 This would exceed resources available to this company to complete in this time frame

There is no benefit in the short term and with the number of devices we currently have on WAND logistically would be impossible for us to achieve.

We reject the need to have licences to supply medical devices .

There should be a specific form of medical device application under the new regulatory framework for products legally supplied to the New Zealand market at the date of commencement

We would require a term of at least 3 years to transition

### **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.:**

see C14

## **C4 Clinical trial sector**

### **Question C16**

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

The expertise for a proposed approval does not reside with the Regulator but in the clinical institution.

Also there is a time frame of 45 working days in which the Ethics committee must complete investigations into the viability of the trial.

This must not be compromised.

### **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.:

## Response ID ANON-DPZ8-G42N-1

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

Submitted on **2019-04-16 12:15:32**

### Submitter profile

**What is your name?**

**Name:**

Vicki Douglas

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Unichem Ker kerri Pharmacy

**Submitter Profile (tick all that apply)**

**If you select DHB, please state service area:**

Pharmacist

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

**If you selected 'Other' please comment;:**

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

#### Chapter A (A1 - A5)

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

Partially support

#### B3 Part 1 of the Bill: Preliminary provisions

##### B3 Part 1 of the Bill: Preliminary provisions

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

#### B4 Part 2 of the Bill: Interpretation

##### B4 Part 2 of the Bill: Interpretation

##### Question B2

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

The definition of dispensing has changed to being "part of manufacturing the medicine". I am concerned about this change as this definition minimises what a pharmacist does to being just a part of a supply chain. With each prescription dispensed, a clinical check is made by a medicines expert - a pharmacist that has spent 5 years training to know about medicines, how they work and how they interact with other medicines, whether prescribed or over-the-counter or natural medicines. Dispensing under its current forms also includes the preparation of the medicine and most importantly, the advice about its use as in how to take the medicine safely and effectively. Dispensing is not merely the supply of a medicine to a patient. It is at the advice step that many potential problems are identified; for example when a patient is being prescribed a sub-optimal dose because of weight; when the patient is taking over-the-counter medicines which could potentially interact. This knowledge is only obtained through face-to-face interaction with patients and this interpretation of dispensing will enable a split of supply and advice which will only lead to poorer patient outcomes. Pharmacists contribute many times a day to a patient's well being within the primary health care by advising while supplying and it would be dangerous to the patient to allow this split

#### B5 Part 3 of the Bill: Dealing with therapeutic products

##### Subpart 1: Product approval requirements (ss 51 and 52)

##### Question B3

**Please provide any comments on the product approval controls (ss 51 and 52):**

I support the removal of the ability to parallel import a medicine, medical device or type-4 product as I believe this will add to patient safety by making sure that anything supplied here in New Zealand is exactly as it has been labelled. I also believe that in the event of a product recall, this would enable a timely response to the 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 ss 54 as it maintains the ability of a pharmacist to supply an emergency supply of a medicine to a patient without a prescription. This is especially important in holiday times when a surprisingly number of people leave home without taking their medications.

**Subpart 3: Authorisations (ss 56–80)**

**Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):**

I support allowing one pharmacy to supply medicine to another nearby pharmacy that is out of stock of a medicine requested by a patient as this supports timely access to medicines by patients especially when medicines are uncommonly prescribed. It would also reduce wastage issues and therefore result in pharmaceutical budgetary savings, particularly with 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 support health practitioners supplying each other with small amounts of medicines (this would need to be clearly defined as to what a "small amount" is) in an emergency situation where a pharmacy is not accessible or can not provide a medicine in a timely manner. Wording should be included to preclude the trade of stock between medical practitioners. However, I don't support blanket authorisation.

I would support an increase in prescribing rights to allow other practitioners to prescribe within their scope of practice to allow patients being able to access funded medicines.

**Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):**

Pharmacists undergo five years of training; have professional development obligations which are strictly audited and are bound by a Code of Ethics. These are considered necessary to ensure medicines and patients are safe and to prevent misuse, overuse and abuse of medicines. Other health practitioners do not have such stringent regulation around their practice in terms of medicine supply and can not be considered to be on a level playing field with a pharmacist who is a medicines expert in every step of the supply process from storage, transportation, interactions, to reporting harm and developing systems enabling patient follow-up and product recalls. If other health professionals were to supply Category 3 medicines, they would need to have made the same capital and other investments to meet the requirements as set down to pharmacists and have their staff supervised by a pharmacist.

The ability of health practitioners to supervise their staff to supply these medications under direct supervision is limited especially as consultations usually happen behind a closed door.

**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):**

Anything which is imported outside of the approved supply chain has an unknown safety profile and its use could compromise patient safety. I think the importation of medicines should only occur through the appropriate regulated channels. I also support the mechanism requiring a SCNSA when obtaining a medicine from overseas, and that the importation is managed by the medical practitioner, pharmacist or wholesaler.

I also believe the restriction should be applied to category 2 (pharmacist-only) and category 3 (pharmacy only) medicines though am happy for the amendment to allow the personal importation of category 4 medicines. This is because category 2 and 3 medicines should only be supplied with the professional advice provided in a pharmacy setting with the oversight of a pharmacist.

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

I support extending the ability of pharmacists to supply prescription medicines in specified circumstances as this will improve access to medicines and will reduce pressure on the demands of General Practitioners.

I do not believe vending machines should become common-place. I do agree that they could be used in locations only where there is no pharmacy or pharmacy depot but that they should 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):**

I do not understand how medicines would be able to be dispensed outside of a pharmacy dispensary as in the example of dispensing and supply at an aged care facility. I don't support this as a pharmacy has all the required dispensary equipment, access to reference resources, record systems and standard operating procedure to ensure patient safety. As in pharmacy, would an aged care facility be able to meet the audit requirements that a pharmacy does and will this dispensing be subject to audit?

**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):**

I support the introduction of permits for shorter-term and urgent situations as long as 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):**

I support issuing licences for up to three years as the norm. The exception to this should be where there has been a quality concern over the period of a licence which has not been rectified. This would be identified by MOH auditing. Going to three years 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):**

I think it would be appropriate for a licence to be automatically transferred in specific circumstances to prevent disruption to patient supply - for example in the case of 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):**

**C5 Wholesale sector (including importers and exporters)**

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

### Licence to wholesale

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

I support this because of public safety - the safety profile of medicines imported from outside the approved chain is unknown. With medicines that have been imported through an approved chain, we know that they are exactly as labelled. This would also ensure timely responses if a product or medicine has been recalled.

As health professionals, pharmacists have a duty to ensure safe and efficacious use of all medicine. Anyone importing their own medicines for personal use will not receive appropriate advice and care around taking that medicine.

### 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; nor should it reduce levels of access to community pharmacy services for all New Zealanders. Dispensing is not just about putting a label on a product - there is a clinical process involved, alongside an advice component about the safe and effective use of medicines and this needs to be provided face-to-face by the pharmacist to the patient. Every day we have multiple examples of interventions which have improved the clinical outcome for the patient. This would not happen in a hub and spoke distribution system.

I

**Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:**

No, the current requirements do not create a barrier to innovation. Licencing is about the safe and effective provision of pharmacist services involving medicines. The advancement of technology (such as electronic health records) and the community pharmacy workforce, alongside improved workforce collaboration and alignment of policy/funding settings for primary care, over time, will lead to the development of new and innovate ways of delivering care to match the community's needs.

Alternate distribution and supply arrangements must be fully considered against the risk to patient safety and the need for investment in supporting technology or infrastructure.

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

I do like the idea of pharmacist services at a marae and major public events, which are examples given in the consultation, as these are great opportunities to engage with patients, address health equity issues, improve health literacy and provide additional services that may not be sought within a community pharmacy environment. I do not support however, the dispensing of medicines outside a properly-equipped and staffed pharmacy dispensary that is subject to quality audits to ensure good standards of practice.

I do support mobile pharmacy vehicles as collection points as an alternate solution to servicing rural areas, but I do not support medicine dispensing from these vehicles

**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 strongly benefits when the network of community pharmacies is owned by pharmacists who are in control of and are 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 rather than a focus on profit.

Pharmacists have professional obligations to provide services and a standard of care that requires adherence to standards that are higher than those a Regulator might impose. A non-pharmacist owner is more likely to want to meet minimum compliance standards at a minimum cost which could have a negative impact on the 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 business in a free market environment. Option 1 is about "skin in the game" with pharmacist owners focusing, above all, on delivering quality health outcomes to maximise their professional and 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?:**

Option 1 ensures the maintenance of the integrity of the professional relationship between the pharmacist and the patient as pharmacists are directly accountable and liable for the services they provide. This also translates to a level of accountability by employee pharmacists. Community pharmacies, under the current majority pharmacist ownership requirements, deliver many benefits at no cost to the patients and wider health sector or the government. This includes resolving minor health issues quickly within the pharmacy setting; assisting patients to find the right health service to meet their needs and to deal with cost or appointment barriers with other primary health services such as GP practice. I believe that corporate owners such as in Option 2 would likely reduce such services as there is no funding to incentivise them as owners to provide these.

A risk of Option 1 is that some community business ownership arrangements under the Medicines Act would be financially impacted. This could be overcome by grandparenting provisions for pharmacies operating legitimately under current laws, which would see a pharmacist having operational professional and ethical control of everything done in the pharmacy which ensures public safety.

**Question C25 - Are there ways in which Option 1 could be improved?:**

It could be improved by legally mandating that the owner pharmacist has a "veto share" so this pharmacist is always in control of all voting rights to ensure effective control is in the hands of a pharmacist. This would replace the need for regulating dividend requirements in proportion to shareholding and allow flexibility for an owner to seek external funding for investments in pharmacy assets such as robots. It would also enable young pharmacists to step into ownership through flexible financing, whilst still retaining control.

Please consider the scope of governance and operations this veto would apply to and the preferential rights that the veto share would enable the owner pharmacist - I believe this should be specifically tied to the goal of ensuring public safety.

**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.

**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 which drives governance and operating decisions. Effective control provisions are grounded in a Pharmacist owners' obligation as a registered health professional, through their Code of Ethics, where patients' interests are put before any profits or shareholder value. This is not normally the case in other businesses. This allows for flexible ownership structures while strengthening the requirement for pharmacist ownership and effective control provisions. Maybe the Act could include "veto shares" on governance and operations for the effective control pharmacist. Those provisions could be shared if two pharmacists have equal ownership (26% each), where both are legally responsible for ensuring compliance with governance and operational obligations.

Separation of responsibilities must consider who would ultimately be accountable for decisions that relate to the wider operating policies that have an impact on the public.

The model in the UK many years ago, with supervising pharmacists overseeing many sites, did not work and it was disestablished and moved back to one pharmacist responsible for one pharmacy.

**Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:**

The Bill is not clear around the decision making on the number, scale and location of other pharmacies allowing appropriate oversight to the owner pharmacist. The five-pharmacy limit means ownership is spread across many individual pharmacists, and it means that no single pharmacist owner has enough market power to set market prices or contract terms. The current model of ownership rules therefore provide an important benefit to the public.

The appropriate model that would achieve effective control is where the owners demonstrate governance of the business (control of the board) with the day-to-day clinical oversight of the pharmacy delegated to a pharmacy manager who is also 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 feel happy that effective control provisions could be shared if two pharmacists have an equal ownership stake (26% each?) where both are 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" which would mean 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?:**

The impact would be a financial one with the risk of investors not seeing pharmacy as an attractive investment and as a consequence, selling down their shareholding in pharmacy, leading to loss in value of the pharmacy business. This could make it difficult for pharmacist owners to exit their businesses on retirement and the introduction of new pharmacist shareholders. This would be avoidable under Option 1 if grandparenting of current legitimate ownership arrangements was implemented or if it was legally mandated that the owner pharmacist had a "veto share" so that this pharmacist is always in control of all voting rights and has effective control. This would allow the Bill to consider flexibility in alternate financing arrangements in community pharmacy, by replacing the need for regulating any dividend requirements 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?:**

This depends on the scale of any impacts on the pharmacy sector. As a minimum, five years would be reasonable.

**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 my support of Option 1 should apply to all pharmacies. Established Friendly Societies however should be able to continue to operate under their current ownership and business arrangement and constitutions, as long as 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?:**

Option 2 would be detrimental to patients' access to services, patient safety, patient health outcomes, the pharmacist's professional obligations and the pharmacy profession generally. Option 2 would see pharmacists working in pharmacy, where there was no pharmacist investor, operating under investor-mandated

sales-related requirements and turnaround time that conflicts with the need for patient engagement and in a way that provides little benefit for the investor owner. These pharmacies would be expected to focus on increasing product turnover and margin rather than focusing on the patient and their health outcomes; similar to some consumer product chains.

Option 2 would lead to compliance cost increases, due to the complexity around accountability conflicts. It may also cause future workforce issues due to the reduced opportunity for pharmacists to progress in their careers to work at the top of their scope. Currently young pharmacists are attracted to Community Pharmacy because of the possibility of someday owning their own business.

Investment in human and physical capital and goodwill are the principal assets of community pharmacy and unless the pharmacist is at the centre of the patient relationship, this is lost and quality standards decline. By placing the pharmacist and his professional reputation at the centre of the distribution relationship, a position 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 both 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 only be accountable to their shareholders.

**Question C34 - Are there ways in which Option 2 could be improved?:**

No, because I don't agree it is the best option

**Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:**

This has not worked overseas in the UK and supervisory pharmacists no longer exist. We should look to the models overseas and learn from their mistakes.

**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. A change could lead to worsening 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?:**

I oppose this - it is a direct conflict of interest and prescribing and dispensing processes should be kept completely separate.

It would be too easy for a GP aligned, by ownership, with a pharmacy to change their prescribing practices to generate more profit from that pharmacy. Pharmacy revenue is linked directly to the prescribing volumes and already the DHBs tell us that the pharmaceutical bill is too high and unsustainable. This move would add to that problem and I feel it is essential to not allow this to happen by keeping separation of ownership requirements.

In other countries such as Canada, as well as (to a certain extent) pharmacists are able to prescribe for minor ailments. This eases pressure on an already overburdened GP system - this type of low level prescribing should not lead to these pharmacists being considered prescribers, and therefore them being 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?:**

I would only support this if permits were used for emergency situations such as fire, earthquakes or other civil emergencies. This would allow pharmacies to re-establish themselves quickly in temporary premises or operating out of other pharmacy premises to continue providing access to pharmacy services in the community. I think there should be clarity around what these exceptional circumstances are to avoid exploitation by "pop-up" pharmacies that could damage existing licence holders affected by those circumstances.

**Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:**

I would support this only if depot pharmacies were authorised via the licence of a linked full-service pharmacy. This would 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?:**

This is paramount for patient safety due to the uncertainty of the source of prescription medicines, and the lack of receipt of 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 continue to be a provision for batch compounding as pharmacies will often compound bulk items that are dispensed 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 without a wholesale licence be able to provide medicines to other pharmacies of common ownership or supplied to other pharmacies to reduce wastage, especially of high cost medicines or as an emergency response. This would support patient access and be governed by the Code of Ethics as to the appropriateness.

**C7 Retail sector**

**Question C42**

**Do you consider the new scheme will have any significant impacts on retailers?:**

**C9 Veterinarians**

## Question C54

What do you think about the approach for veterinarians and veterinary staff?:

## C10 Advertising sector

### Question C52

Please provide any comments on the advertising requirements and enforcement tools.:

### Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

## C11 Patients, consumers and disabled people

### Unapproved medicines

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

I support the addition of SCNSA requirement in authorising the supply of unapproved products. Under the current system GPs are often unaware they are prescribing an unapproved medicine. It will support patients being given clear advice around what they are being supplied, enabling them to make an informed choice.

**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 believe it is appropriate to continue to only allow medical practitioners to access unapproved medicines. As it stands any other health practitioner prescriber would need to consult with a medical practitioner if they wished to prescribe outside of their very narrow scope.

### Personal imports

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

I support this as it is in the best interest of public safety due to the uncertainty around the suitability of the source of medicines. Patients would also lose out on the opportunity to give 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)?:**

No, any medicines imported into the country should be with the oversight of a pharmacist, medical practitioner or wholesale to ensure patient safety, quality of medicine and that 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 support opportunities and arrangements that promote patient health outcomes and which do not compromise patient safety or the integrity of the community pharmacy model. Any alternate model consideration should not undermine the integrity and safety of the current system or current levels of access to community pharmacy services in NZ. It is really important to understand the clinical process of dispensing a prescription medicines and advising patients of the medicines safe and effective use - it needs to be done face to face by the pharmacist to the patient. It can not be separated into two different categories of supply and advice as the two go hand in hand. Supply is not just about slapping a label.....

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:**

I do support initiatives such as marae-based or community services to address health equity issues, increase health literacy and encourage regular contact with a health professional. But I believe this should be done in conjunction with a community pharmacy. I also support mobile pharmacy vehicles, but as a depot model of collection only. I do not believe dispensing should take place from a mobile vehicle.

**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 is 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 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.

The professional obligations and the standard of care by a pharmacist is higher than those that may be imposed by a Regulator. A non pharmacist owner is more likely to focus on meeting minimum compliance standards at a minimum cost - this would negatively impact on the range and scope of services the investor owner is prepared to provide.

Medicines are not an item of commerce and pharmacies are not in a free market environment. - ownership by pharmacists with "skin in the game" means a focus

on delivering quality health outcomes to maximise professional and business goodwill

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

Currently under the majority pharmacist ownership regulations, community pharmacies deliver many benefits at no cost to the patient or the government. For example, we offer a free delivery service within our community and many times go out of our way to visit a patient who we know is struggling. Minor health issues are dealt with quickly, patients are assisted to find the right health service, and deal with cost or appointment problems with other primary health service providers.

Young owners under Option 1 would be able to invest in pharmacy ownership through flexible financing while retaining effective control requirements. Many young pharmacists choose to go into pharmacy as they see a pathway to owning their own business.

**Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

Option 2 risks reducing such services because there is no funding to incentivise the owner to provide them. This would be detrimental to patient access to services, patient safety, patient health outcomes, the pharmacist's professional obligations and the pharmacy profession in general.

Pharmacists under Option 2 would be likely to operate under investor-mandated sales-related requirements and a turn around time that conflicts with the need for patient engagement and in a way that provides little benefit for the investor owner. They would be expected to focus on increasing product turnover and margin rather than concentrating on patient experience and health outcomes.

Option 2 would lead to higher compliance costs due to accountability conflicts.

Option 2 would limit workforce development and the progression of pharmacists within their career.

Community pharmacy assets include human and physical capital and goodwill. Unless the pharmacist is at the core of the patient relationship, this reputation is lost, and quality standards would fall.

Non-pharmacy owners are only accountable to their shareholders and not the public they serve.

**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 don't. Pharmacists undergo five years of training and mandated continuing education to ensure medicines efficacy, patient safety and to prevent misuse, overuse and abuse. They are also bound by the Code of Ethics which is much more stringent than that which applies to other health professionals. They are the medicines experts for every step of the supply process from storage, transportation, interactions with other medicines, reporting of harm and creating systems enabling patient follow-up and product recalls. In addition pharmacies must store medicines within strict temperature ranges, with daily monitoring of both fridge and ambient room temperatures and backup validation. All of this is an auditable process. Pharmacies must also have a pharmacist on site to open their doors and while other pharmacy staff are on the premises to ensure appropriate medicine oversight. If category 3 medicines were open to supply I would expect that the same qualifying requirements that exist in pharmacy would have to be met by other suppliers with the same need for regular audit and that suppliers would have had to make the capital investments to furnish these requirements. I would also expect that these health professional suppliers would have oversight by a pharmacist.

I would support increased prescribing rights to increase access to medications, as long as it was within a specified 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?:**

The ability of a health practitioner to supervise their staff to supply these medications under direct supervision is limited because consultations happen behind closed doors. So I do not support this. There is no provision for advice and counselling to these patients either; something which is provided within a pharmacy setting. Pharmacy staff, outside of the pharmacist role, are trained in product knowledge as well as when to refer patients to a pharmacist, who is readily available in the community pharmacy setting. This provides significant benefits in the ability to provide treatment for minor ailments in a timely manner. I would expect, if this came in, that to safely supply medicines, they would have to be handled and stored to the same level that is required in pharmacy.

**Advertising**

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

**Packaging and labelling and consumer medicine information**

**Medical devices that do not have a therapeutic purpose, but may present a health risk**

**Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:**

**Adverse event monitoring**

**Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:**

**Chapter D: List of consultation questions**

**Chapter A Question**

**Chapter B Questions**

## Chapter C Questions

## Response ID ANON-DPZ8-G42M-Z

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-16 15:10:21**

### Submitter profile

What is your name?

Name:

Colin McArthur

What is your email address?

Email:

What is your organisation?

Organisation:

Auckland District Health Board

Submitter Profile (tick all that apply)

District Health Board (DHB)

If you select DHB, please state service area:

Auckland plus regional and national services

Medical practitioner (excluding Surgeons)

If you select 'Other', please comment below::

Medicines (other than cells and tissues), Medical devices, Cells and tissues, Trial ethics

If you selected 'Other' please comment::

Next steps after the consultation

Executive summary

Chapter A Key features of the new regulatory scheme (A1 - A5)

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4):

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):

The definitions of "therapeutic purpose" and "therapeutic product" are extremely broad, and may capture health-related items which may not have been intended to be brought under the regulatory framework. Examples could include commercial gym equipment (alleviating injury, modifying human physiology), occupational therapy aids (compensating for an ailment, supporting part of human anatomy), and devices / substances used by alternative medicine practitioners such as crystals, massage oils, electromagnetic field protection devices etc.

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 :**

The concept of "off-label use" does not appear to be defined in the Bill, but is crucial to the interpretation of these proposals.

Assuming the current common usage of the term "off-label" (what is stated in the manufacturer's product information sheet), the requirement to issue a SCNSA for every patient use (even if just a box tick) will be unduly burdensome for prescribers, as such uses are extremely common, especially in paediatric and obstetric practices where the evidence base is very limited. The benefits of this requirement vs the regulatory burden have not been justified.

**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):**

Regarding licences for clinical trials, the wording of 128 (1) (g) "...that authorises a person to conduct a clinical trial..." seems to imply that a single person is licenced, but this is inconsistent with other licences which may authorise "persons". Many clinical trials involve multiple sites, and thus multiple persons.

Section 137 only provides for a maximum of 3 years for a licence. This is inadequate for clinical trials which typically run for 5 or occasional up to 10 years with long followup periods.

### **Question B19**

**Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):**

At Auckland DHB, we have over 1400 clinical trials. We strongly recommend that institutional licencing (DHB, University, etc) for clinical trial conduct be used on the basis of the organisation's professional and clinical governance procedures, rather than requiring the licencing (and re-licencing) of individual employees.

With regard to clinical trial licences, the roles of the responsible persons is not clear, although this may be clarified by regulation.

## **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?:

#### Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):.

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply:.

Question C4 - Please provide any comments on the approach to post-market controls:.

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices:.

#### Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions:.

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices:.

## C4 Clinical trial sector

### Question C16

Please provide any comments on the change in approach to regulating clinical trials:.

The definition of clinical trial (s27) has a lot of problems. As general suggestion, I recommend consultation with the Ethics secretariat at the MoH to develop a better definition. Specific issues include:

Limiting the definition to administering a product to individuals, when some clinical trials (cluster and step-wedge designs) intervene at the service level

Excessively broad scope which will include all investigations which collect any additional data point beyond usual clinical practice, such as an additional individual data point (e.g. a pulse rate measurement), but also any additional collection of data at a service level such as infection control assessments. There are a very large number of observational studies, audit and related investigations of current approved treatments and devices used as part of standard treatment which meet this definition, but for which there is minimal or no additional risk to patients, and thus lack any benefit of regulation to outweigh the additional administrative burden. A better approach would be to exclude very low risk studies from the regulatory framework.

The attributes under section 27 (c) do not have clear meanings in clinical practice, and could be much better worded. If I knew what was intended, I would make some suggestions!

Further more, we consider that establishing a additional licensing requirement for clinical trials involving approved therapeutic products used by registered providers and health practitioners offers very little societal benefit, and considerably increased administrative burden. This will be a disincentive to identify inferior or ineffective treatments in current clinical practice, something that should be strongly encouraged. The safety elements for such trials are already appropriate provided by the ethics, site governance and GCP/ICH systems and standards, and this additional regulation would add nothing of value. The inclusion of clinical trials of approved therapeutic products in current clinical use in this regulatory regime does not assist in fulfilling the purpose of the Bill (s3).

However, we do support the need for a regulatory framework for studies involving unapproved therapeutic products, but the move away from the Standing Committee on Therapeutic Trials appears to be a backward step. Despite its line of authority to the HRC, it does function as an independent committee, generally considering studies not funded by the HRC, and it should be retained.

### Question C17

Please provide any comments on the transitional arrangements for clinical trials:.

For currently approved clinical trials, the original applicant for the Section 30 approval, may not be the appropriate person for a licence under the new system. A different applicant should be permitted.

If the definition of a clinical trial is not modified to remove low-risk observational studies, and if comparative effectiveness studies of approved medicines and devices remain included, then there will be a very large number of new applications, for which 6 months will probably not be long enough to ensure applications are submitted for all of them.

## Response ID ANON-DPZ8-G4FV-W

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-16 16:18:26**

### Submitter profile

#### What is your name?

**Name:**

David Mitchell

#### What is your email address?

**Email:**

[REDACTED]

#### What is your organisation?

**Organisation:**

New Zealand Universal List of Medicines

#### 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;:**

The New Zealand Universal List of Medicines is the standard source of commonly-used information about medicines in New Zealand. It is the primary naming and coding database for medicines in the NZ health sector, and is used in most medical and pharmacy software. It includes approved medicines, unapproved medicines, and subsidised special foods, general sales medicines and medical devices. The service is provided under contract to the Ministry of Health. Please note we have only answer the questions relating to advertising of medicines as that is the only section of the draft legislation affecting NZULM.

## C10 Advertising sector

### Question C52

**Please provide any comments on the advertising requirements and enforcement tools.:**

The New Zealand Universal List of Medicines (NZULM) creates electronic listings for individual medicines that are used in clinician software systems to identify individual medicines and record medicine use in patient health records. These listing include records for unapproved medicines that are currently prescribed and dispensed for individual patients under the compassionate access provisions of s29 of the Medicines Act 1981. The provision of listings for unapproved medicines is approved by Medsafe. Under distribution arrangements agreed with the Ministry of Health NZULM listings are also distributed by the New Zealand Formulary (NZF).

We note the Ministry intends to continue to allow patients to access unapproved medicines albeit with tighter restrictions on their use.

The definition of communication in the Therapeutic Products Bill might be construed to cover the provision of listings for medicines by NZULM. If this was the case NZULM and NZF would be unable to provide listings for unapproved therapeutic products.

Removing listings for unapproved products from the NZULM would compromise the Ministry's strategic intent for the NZULM to provide standardised listings and identifiers for all medicines to enable seamless exchange of medicines information amongst care providers, health administrators and others. When this issue was raised with Chris James from Medsafe earlier this year he indicated the Ministry was not changing its policy of enabling medicine information.

The Ministry will need to ensure the NZULM and NZF outputs are recognised as not being an advertisement for therapeutic products to ensure listings for unapproved products continue to be available to clinicians. This could be achieved either by including NZULM and NZF amongst the organisations defined in clause 82 (3) of the Bill or by deeming NZULM and NZF to be exempted communications via regulations made under clause 82 (3) (e).

On balance we believe the the option of an exemption via regulation under clause 82 (3) (e) is preferable because it offers the Ministry greater flexibility.

### Question C53

**Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No comment provided

## Response ID ANON-DPZ8-G4FH-F

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-16 17:21:16**

### Submitter profile

**What is your name?**

**Name:**

Alison Rhodes

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Roche Diagnostics New Zealand Ltd

**Submitter Profile (tick all that apply)**

Medical devices

Medical devices

**If you select DHB, please state service area:**

**If you select 'Other', please comment below;:**

**If you selected 'Other' please comment;:**

### 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).:**

Roche supports the purpose and principles of the Bill and the need for cooperation with overseas regulators. It is practical to align with international standards and practice to support international trade in devices (both import and export) and avoid costly duplication of conformity assessment and delayed availability of devices in New Zealand.

Roche recommends that New Zealand Ministry of Health align, where practical, with Australian TGA regulations for IVDs as they are also focussed primarily on risk-based, tailored classification. This alignment will mean lower compliance costs for Industry, without compromising patient safety, though enabling collaboration and leverage of expertise and regulatory resources across country organisations.

#### 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):**

Definition needs to completely align with the harmonised global definition.

Definition needs to reference In Vitro Diagnostics (IVDs) refer IMDRF definition.

Roche believes that alignment with the Australian TGA regulations for IVDs will be beneficial.

Add more clarity on Type 4 products

Proposal to include Laboratory Developed test (home brew test) and the research use only products

Proposal to include the definition of CATEGORY as this will be important to cluster a set of devices.

**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):**

52 Sponsor's consent required to import an approved product.

(1) (b) import the product without the written consent of the sponsor

While addressing the concerns relating to parallel importing of products, there are situations where there are multiple importers of the same product e.g gloves and dental micro brushes. It is understood that each importer is recognised as a sponsor of the same device.

Add a section to prohibit parallel exporting.

**Subpart 2: Controlled activities and supply chain activities (ss 53–55)**

**Question B4**

**Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):**

55 Persons in supply chain must comply with regulations.

(1) (d) "disposal of therapeutic products"

This will need some detail as to the extent of complying with this requirement for medical device suppliers.

Roche propose to define more specifically a controlled activity for which clinical trials for Medical Devices is needed.

**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):**

68 Veterinarians: wholesale supply

(a) the regulations permit the device to be supplied

Devices approved for humans aren't always approved for animal use

**Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

77 Patient or carer importing a medical device for personal use

There needs to be an additional cause inserted:

"The imported medical device doesn't exceed indicated usage for personal use with limit on volume"

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

No comment

**Subpart 4: Other offences (ss 81-94)**

**Question B12**

**Please provide any comments on the offences created in sections 81–94:**

87 Notifying Regulator of suspicion of tampering

(2) (b) the therapeutic product does not yet exist.

This statement needs better clarification with examples

## **B6 Part 4 of the Bill: Product approval**

### **Subpart 1: Approval of products (ss 94–113)**

#### **Question B13**

**Please provide any comments on the sections covering product approval requirements (ss 94–104):**

Roche is concerned about the timelines of the approval process and specially about new approvals during the transition period. In the Bill changes are addressed very generally. Roche propose to provide better clarification with examples.

96. Product standards

(1) The rules may specify standards for therapeutic products

Roche fully supports the recognition and direct adoption of international standards to demonstrate the safety and performance of medical devices e.g ISO, IEC and includes international recognised symbols especially for packaging and labelling

103 Duration of approval

(2) (a) if the approval specifies an expiry date

This clause needs further clarification to exclude medical devices that have no expiry date for conformity assessment

#### **Question B14**

**Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):**

No comments from Roche.

### **Subpart 2: Approval-exempt products (ss 114–115)**

#### **Question B15**

**Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):**

No comments from Roche.

### **Subpart 3: Obligations of sponsors (ss 116–119)**

#### **Question B16**

**Please provide any comments on the sections covering sponsor obligations (ss 116–119):**

Roche would like to know if international or local product standards are required.

### **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):**

No comment from Roche.

#### **Question B19**

**Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):**

128 Criteria for granting a licence

(1)(g) for a licence that authorises a person to conduct a clinical trial

The criteria required will need to ensure that the Regulator doesn't delay the process to approve a NZ clinical trial and add unacceptable cost to the process.

Please reconsider to put on name of responsible people on the license, names are changing frequently, if not what is the process to update the license?

Fit and Proper person test - same as Company Director, no additional competency required. Liability rests with legal entity not individual.

## **Subpart 2: Permits (ss 131–135)**

### **Question B20**

**Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):**

No comment from Roche.

## **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):**

136 Regulator may split application

This section is too complicated and needs better clarification. Roche recommends to consider to establish a proper change management process rather than asking to renew the licenses.

137 Duration

(1)(b) remains in force for 3 years

In some circumstances, 3 years for a licence could be too short given that clinical trials can take longer to complete and reapplying for an extension of the licence would be counter productive.

### **Question B22**

**Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):**

151 Death, bankruptcy, or insolvency of licence or permit holder

(4) A person to whom the licence or permit is transferred must notify the Regulator within 5 days

Roche thinks that 5 days is too short

## **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 from Roche

## **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 from Roche

### **Subpart 2: Investigative powers (ss 183–196)**

#### **Question B25**

**Please provide any comments on the regulator's investigative powers (ss 183-196):**

No comments from Roche

### **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 from Roche

### **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 from Roche

**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):**

Roche support this section. Roche propose to give more details on the recognition of licenses from recognised authorities, eg. Which authorities are recognised?

**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 from Roche

**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 from Roche

**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 from Roche

**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):**

256 Costs to be recovered

A regulatory scheme must be limited to efficiency costs only.

Roche would appreciate more information about the fee structure

**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 from Roche

**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 from Roche

**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 from Roche

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):**

No comment from Roche

**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 from Roche

## **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).:**

Is pharmaceutical related

**Question C2 - Please provide any comments on the approach for medicines categorisation (classification).:**

No comment from Roche Diagnostics

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:**

Is pharmaceutical related

**Question C4 - Please provide any comments on the approach to post-market controls.:**

No comment from Roche Diagnostics

#### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions.:**

Roche propose to use the IMDRF definitions.

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:**

No comment from Roche Diagnostics

### **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 from Roche Diagnostics

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:**

Is pharmaceutical related

**Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:**

No comment from Roche Diagnostics

**Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:**

No comment from Roche Diagnostics

**Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:**

No comment from Roche Diagnostics

#### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions.:**

Roche propose to use the IMDRF definitions.

**Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:**

No comment from Roche Diagnostics

### **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, devices for cosmetic purposes

#### **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?:**

Roche believes that all global models for medical device are appropriate for New Zealand. Roche recommend to adopt the Australian Medical device model to

assure safe and effective Medical Devices in New Zealand.

Roche believes that the definition of a medical device (including IVDs) needs to be consistent and reflect the GHTF/IMDRF model to capture the same products that are regulated globally as medical devices

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

Is pharmaceutical related

**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 from Roche Diagnostics

**Question C4 - Please provide any comments on the approach to post-market controls.:**

No comment from Roche Diagnostics

**Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:**

Roche recommends thoughtful consideration when determining an appropriate transition period. Roche recognises that during the transition period there will be no disruption to supply of current on market products pending regulatory approval. There is concern however, given the workload expected on the regulator during the transition period, that new product introductions, during the transition period, may be impacted i.e. delays in new product introductions due to registration delays, thereby risking delays in access to innovative diagnostics products that benefit New Zealand patients.

Roche recommend to grant a 5-year period from the commencement date of the scheme for devices, currently being lawfully supplied in NZ, to apply for a product approval to continue supply.

**Activity-based controls**

**Questions C5 - Please provide any comments on the manufacturing-related definitions.:**

Roche propose to use the IMDRF definitions

**Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:**

Roche recommend to grant a 5-year period from the commencement date of the scheme for devices, currently being lawfully supplied in NZ, to apply for a product approval to continue supply.

**C4 Clinical trial sector**

**Question C16**

**Please provide any comments on the change in approach to regulating clinical trials.:**

No comment from Roche Diagnostics

**Question C17**

**Please provide any comments on the transitional arrangements for clinical trials.:**

No comment from Roche Diagnostics

**C5 Wholesale sector (including importers and exporters)**

**To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].**

**Licence to wholesale**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

No comment from Roche Diagnostics

**Hawker's licence**

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

No comment from Roche Diagnostics

**Transition**

**Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:**

Roche recommend to grant a 5-year period from the commencement date of the scheme for devices, currently being lawfully supplied in NZ, to apply for a product approval to continue supply.

**C6 Pharmacy (and retail-only licence) sector and pharmacists**

**Pharmacy sector context**

## **Future regulation of pharmacy business activities**

### **Licence to carry out a pharmacy business**

**Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

No comment from Roche Diagnostics

**Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:**

No comment from Roche Diagnostics

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

No comment from Roche Diagnostics

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comment from Roche Diagnostics

### **Detailed questions relating to Option 1**

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

No comment from Roche Diagnostics

**Question C25 - Are there ways in which Option 1 could be improved?:**

No comment from Roche Diagnostics

**Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:**

No comment from Roche Diagnostics

**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 from Roche Diagnostics

**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 from Roche Diagnostics

**Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:**

No comment from Roche Diagnostics

**Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:**

No comment from Roche Diagnostics

**Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

No comment from Roche Diagnostics

**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 from Roche Diagnostics

### **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 from Roche Diagnostics

**Question C34 - Are there ways in which Option 2 could be improved?:**

No comment from Roche Diagnostics

**Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:**

No comment from Roche Diagnostics

### **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 from Roche Diagnostics

**Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:**

No comment from Roche Diagnostics

**Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:**

No comment from Roche Diagnostics

**Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:**

No comment from Roche Diagnostics

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

No comment from Roche Diagnostics

### **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 from Roche Diagnostics

**Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:**

No comment from Roche Diagnostics

### **C7 Retail sector**

#### **Question C42**

**Do you consider the new scheme will have any significant impacts on retailers?:**

No comment from Roche Diagnostics

### **C8 Health practitioners (including pharmacists)**

#### **Prescribers**

**Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:**

No comment from Roche Diagnostics

**Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:**

No comment from Roche Diagnostics

**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 from Roche Diagnostics

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

No comment from Roche Diagnostics

**Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:**

No comment from Roche Diagnostics

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

No comment from Roche Diagnostics

**Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:**

No comment from Roche Diagnostics

**Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:**

No comment from Roche Diagnostics

### **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 comment from Roche Diagnostics

**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

No comment from Roche Diagnostics

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

No comment from Roche Diagnostics

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No comment from Roche Diagnostics

## **C9 Veterinarians**

### **Question C54**

**What do you think about the approach for veterinarians and veterinary staff?:**

No comment from Roche Diagnostics

## **C10 Advertising sector**

### **Question C52**

**Please provide any comments on the advertising requirements and enforcement tools.:**

No comment from Roche Diagnostics

### **Question C53**

**Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No comment from Roche Diagnostics

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

No comment from Roche Diagnostics

**Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:**

No comment from Roche Diagnostics

### **Personal imports**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

No comment from Roche Diagnostics

**Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:**

No comment from Roche Diagnostics

### **Pharmacy licensing**

**Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

No comment from Roche Diagnostics

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:**

No comment from Roche Diagnostics

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

No comment from Roche Diagnostics

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

No comment from Roche Diagnostics

**Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

No comment from Roche Diagnostics

**Access to pharmacy medicines**

**Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:**

No comment from Roche Diagnostics

**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

No comment from Roche Diagnostics

**Advertising**

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

No comment from Roche Diagnostics

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No comment from Roche Diagnostics

**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, Devices for cosmetic purposes

**Adverse event monitoring**

**Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:**

No comment from Roche Diagnostics

## Response ID ANON-DPZ8-G4FM-M

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-16 17:48:00**

### Submitter profile

What is your name?

Name:

Julia

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;:

### 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):

##### 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.

**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-G4F9-Z

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-16 18:03:24**

### Submitter profile

**What is your name?**

**Name:**

Paul Eley

**What is your email address?**

**Email:**

**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;:**

### 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**

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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?:**

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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.

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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.

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**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?:

### 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?:

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.:**

## Response ID ANON-DPZ8-G4FF-D

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-16 18:13:05**

### Submitter profile

**What is your name?**

**Name:**

Michelle Hooper

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

**Submitter Profile (tick all that apply)**

Consumer

**If you select DHB, please state service area:**

**If you select 'Other', please comment below;:**

**If you selected 'Other' please comment;:**

### Chapter A Key features of the new regulatory scheme (A1 - A5)

#### Chapter A (A1 - A5)

**Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?**

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):**

##### 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.

##### 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?:**

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-G4FY-Z

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-16 19:02:00**

### Submitter profile

What is your name?

Name:

Binit Laxman

What is your email address?

Email:

What is your organisation?

Organisation:

Unichem Kamo Pharmacy

Submitter Profile (tick all that apply)

Consumer

Pharmacy organisation

If you select DHB, please state service area:

Northland

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

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).:**

## **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).:**

## **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 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-G4K9-5

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on 2019-04-16 22:19:13

### Submitter profile

What is your name?

Name:

Clare Hynd

What is your email address?

Email:

What is your organisation?

Organisation:

Self

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

**B4 Part 2 of the Bill: Interpretation**

**B4 Part 2 of the Bill: Interpretation**

**Question B2**

**Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):**

The definition of dispensing a medicine has changed significantly and I am very concerned about this. It has been mixed up with manufacturing of a product. These are two very different procedures. Manufacturing is totally quality focussed and dispensing is patient safety focused on an individual basis.

**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 authorisations of pharmacists and pharmacy workers should be the same as now. But the places that the services could be provided must be more flexible. The authorisations for other healthcare workers providing/dispensing medicines (in a reasonable quantity) should be the same, they must have the same qualifications and quality requirements for patient safety.

**Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):**

They must continue to be recognised as an important part of the pharmacy workforce providing excellent patient care.  
They must be well trained, supported and paid appropriately for their skills.

**Question B7 - Please provide any comments on the authorisations for health practitioners :**

I am happy for healthcare professionals to sell products directly linked to their scope of practice but not their workers. medicines have classifications for a reason and patient safety must never be compromised.  
Standing orders are a great tool and their scope and safety must be broadened and enhanced for better patient access and care.

**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):**

Vets and their staff must always work under their scope of practice .

**Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

Medicines overseas do not have the same quality standards as those enjoyed here and so for patient safety people should not be allowed to import medicines for themselves or others.  
Bringing in 3 month supply of their own prescribed medicine is fine but not for wider distribution or sale.

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

I support these. The use of vending machines has worked well in large cities overseas and should be carefully looked at here.  
Standing order improvement is great

**Subpart 4: Other offences (ss 81-94)**

**Question B12**

**Please provide any comments on the offences created in sections 81–94:**

I support these.

I support the direct advertising of prescription medicines to consumers.

In NZ, with our very generous Pharmac system , we cannot fund all medicines and patients should have the right to know what else is available that they can talk to their doctor about and then pay for it if it is suitable.

**B7 Part 5 of the Bill: Licences and permits**

**Subpart 1: Licences (ss 123–130)**

**Question B18**

**Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):**

I support the flexibility of licences to cover all the new models of care that will develop in the future.

A wholesale license must be carefully controlled so that only small amounts of a medicine can be traded between health care professionals in an urgent situation.

**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):**

Permits must allow more flexibility in an emergency situation not necessarily just a national emergency.

Eg a fire in a pharmacy as opposed to an earthquake.

The quality of the premises for all dispensing of medicines should be similar and subject to the same audit standards for the quality storage of 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):**

I generally agree

**Question B22**

**Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):**

Transfer of licenses should be simpler but also with patient safety and access to medicines as the most important consideration

**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 generally agree

## 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):**

I generally agree with them.

All dispensers of medicines should be treated equally especially with auditing. Pharmacies, general practices and other healthcare professionals, especially if they dispense or sell any class of medicines. And any store selling pharmacy only medicines eg ship terminals and sea sickness tablets.

### Subpart 2: Investigative powers (ss 183–196)

#### Question B25

**Please provide any comments on the regulator's investigative powers (ss 183-196):**

As it is governed by another law, I have no issues with them.

### 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):**

I 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):**

Let's use overseas expertise and advice, We are a very small country and the costs to re look at everything are too great. The advice we use from overseas would of course have to be of a good standard that we would have to audit from time to time.

## 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):**

I believe that people shouldn't be able to import medicines through internet sites, the quality could be dangerous.

However, as we are a small country we need some flex bility to bring in medicines for use in hospitals especially that don't involve a lot of paperwork and cost.

**Question C2 - Please provide any comments on the approach for medicines categorisation (classification):**

Any widening of categories and moving of medicines between classes must be done with patient safety at top of mind.

Widening access doesn't always mean better patient care and safety.

medicines are not normal items of commerce and should be treated with care and respect.

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:**

Sounds like a reasonable idea

**Question C4 - Please provide any comments on the approach to post-market controls:**

I agree with them

### 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?:

Pharmacies that are not in supermarkets. medicines are not normal items of commerce. If people are collecting the prescription medicines they should be in a health related space not a supermarket, so that they focus on their health and medicines for a short period of time, build up a relationship with a pharmacist so that they are part of their healthcare team and medicines (and their good and bad points) are considered carefully and in a supportive environment, this is not a kiosk within a supermarkets.

The ownership needs to be transparent and I think that the maximum should still be 5 as that is the number that someone can reasonably have control over and supervise the day to day workings.

The funding model is not there for a corporate ownership model that has to produce shareholder dividend. The scarce health dollar is not there to improve corporate bottom lines. The present model is driving down staff numbers so that staff are overly stressed and the supportive service is not given 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?:

We need to think wider for a more mobile service by pharmacies in patients homes etc. We need to allow more digital conversations for patients especially those in more remote areas.

There needs to be more depots in rural areas, with well trained staff and digital access to the pharmacist so that consultations can happen and the appropriate medicines sold. It will save a lot of travel by patients to treat minor ailments, allowed by "pharmacist only meds"

###### Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

A patient living 1 hours drive from Gore and needs something to treat vaginal thrush or cold sores. The products can be there to sell at the depot (not the local dairy who access as a drop off point for dispensed meds).

A virtual or phone conversation can happen with the pharmacist in Gore and the patient treated without any travel time.

###### 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 corporate model will put too much stress on the pharmacist trying to run an ethical and safe dispensary, they will be forced to do things against their code of ethics by the managers further up the line. These people are not accountable to the PCNZ or the public of NZ.

Also public money should not be used to pay corporate shareholders dividends. It should be used to pay good wages to the staff providing the safe medicines service. The staff working at the "corporate stores" and working for below average wages, at a very fast rate so that a head office and shareholders can be paid. The fees paid for supply are not sufficient now to provide a safe service and so shouldn't be squeezed more to support a corporate structure. the staff will be under too much pressure and be unable to provide a great patient focused model of care.

##### Detailed questions relating to Option 1

###### Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Good quality patient focused care, well supervised by the pharmacist owner. new models of care will need so dedication and flexibility that a smaller ownership model can easily respond to.

###### Question C25 - Are there ways in which Option 1 could be improved?:

Ensure that the money invested is very transparent as far as the source of funding is concerned. Also how the profits are divided amongst the shareholders. The majority of the profit should go to the majority shareholder who will be taking the most risk and providing a professional oversight to the services being provided.

###### Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

Dispensing, minor ailments advice, prescribed medicines advice. Compounding upon request.

Well trained and resourced staff.

Selling pharmacist and pharmacy only 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?:

Same pharmacists must have majority ownership and 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)?:

5 pharmacy limit should continue

###### Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

Standards are set by the industry and they must be agreed on by all owners/managers. All must be allowed to maintain their professional integrity and competence.

###### 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?:**

2020 (when act is passed by parliament) to 2023 when it is enacted.

**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?:**

Time for them to transition out

**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?:**

It is not an 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?:**

Technology is rapidly developing and so many advice functions could be done remotely.

We must be blue sky thinking here

**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?:**

In interests of integration they can could have a small interest. eg 25% total by all prescribers

**Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:**

In an emergency, fire, flood

**Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:**

I agree that depot pharmacies should only be authorised via the licence of a linked full service pharmacy. This ensures that depot pharmacies will have appropriate pharmacist oversight, with pharmacists at the full service pharmacy able to offer clinical advice to patients collecting their medicines from the depot pharmacy.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

I am supportive of this approach, as it is in the best interest of public safety. It is not safe to allow patients to individually import medicines when there is so much uncertainty around the suitability of their sources.

Pharmacists as health professionals have a duty to ensure the safe and efficacious use of all medicine. Patients that import medicines for personal use miss the opportunity to receive the appropriate advice and care from a health professional

**Pharmacist and pharmacy worker authorisations**

**Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:**

There needs to be a provision to ensure that batch compounding can still continue. Pharmacies typically compound in bulk for the compounded products that they

dispense on a regular basis

**Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:**

I think it is appropriate for pharmacies that do not have a wholesale licence to provide medicines by wholesale where medicines are supplied between pharmacies of common ownership, and where medicines are supplied to other pharmacies to reduce the wastage of medicines, particularly high cost medicines

## **C7 Retail sector**

### **Question C42**

**Do you consider the new scheme will have any significant impacts on retailers?:**

They need to be aware that medicines are not general items of commerce and they need to have safe guards around them and that they need to be treated with care.

But probably little change

## **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 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?:**

I think that it should continue.

Patients are entitled to know about unfunded medicines so that they can discuss this with their prescriber

## Response ID ANON-DPZ8-G4FA-8

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-16 23:10:51**

### Submitter profile

#### What is your name?

**Name:**

Dr Bill Reeder

#### What is your email address?

**Email:**

[REDACTED]

#### What is your organisation?

**Organisation:**

NZSIM (New Zealand Society of Integrative Medicine)

#### 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;:

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):

The Concerns for Excessive and Punitive Regulations - Unintended Consequences.

It is stated correctly that existing regulatory provisions have fallen behind, but it is equally important to understand that the presentation of illnesses especially chronic and multi-system complex disorders is reaching in some expert views, epidemic proportions and poorly managed by the primary and even specialist levels. At best it seems that standard 'approved' medicines are usually symptom control measures where risk-benefits are in many instances unacceptable. Sufferers seek other 'safer' options. These are often 'unapproved medicines' but prescribed by registered medical practitioners.

It is vital that access to these medicines, where regarded as safe and manufactured according to industry standards under the Medicines Act (MA) are not burdened with more complex and unnecessary regulations that will inevitably increase the cost to patient - where already they can be expensive and not subsidised. Perhaps they should be.

NZSIM notes that the new MA proposals appear to be dominated by regulatory language - and passing nuances to assisting patients access to much needed options; which will generally be 'unapproved'.

Just as the Treaty forms a grounding guideline to many NZ laws, so should the needs of sick patients be centrally placed and each proposal under the new MA should ask if their needs are well served not only in safety but unencumbered by yet more compliance costs which will be passed on.

NZSIM doctors have a wealth of experience in these matters. Increasing numbers of sincere medical practitioners have to prescribe specific therapeutic products; often safer, more effective than 'approved' standard pharmaceuticals which have not achieved acceptable outcomes or caused intolerable side-effects - all at patients' significant cost.

### 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?:**

Yes. Compounding pharmacies do have very necessary guidelines and regulations to ensure product purity, safety and continued product safety, content confirmations etc.

Proposed regulations should be sufficient to guarantee highest quality with internal and external QC. Prescribing doctors need to have this assurance. Yet, these compliances must be cost effective as it will always be at the patients costs - already unfunded from tax-payers dollars.

Needless to say, it is no secret that pharmaceutical corporates do not like the competition and certain health professionals do not see why patients cannot all take standard medical drug options. NZSIM medical practitioners have considerable experience because they are sought after by many many patients who choose for reasons outlined previously to request such compounded 'unapproved' options.

NZSIM is of the impression that the officials producing the new MA proposals are in tune with this already and are patient-centric and hopefully neutral.

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

**Question C22 Which option do you support?**

Not Answered

**Question C23 - Why do you support that option?:**

**Detailed questions relating to Option 1**

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

**Question C25 - Are there ways in which Option 1 could be improved?:**

**Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:**

**Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:**

**Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:**

**Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:**

**Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:**

**Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

**Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:**

**Detailed questions relating to Option 2**

**Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

**Question C34 - Are there ways in which Option 2 could be improved?:**

**Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:**

**Other changes to pharmacy licensing requirements**

**Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:**

**Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:**

**Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:**

**Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

## Pharmacist and pharmacy worker authorisations

**Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:**

Absolutely. Again in terms of unapproved TPs, for example, compounding pharmacies do need to hold stocks of these TPs where continued supply is absolutely necessary. And where the product may be so effective and free of adverse reactions that it is sought after. Efficient supply chain is necessary rather than on a prescription first, the compounded and dispensed.

This would be completely disruptive and very uneconomical - thus imposing huge costs on the consumer.

**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)?:**

Yes, there are no regulations at present, This appears to work. Unless there are problems arising from say a dermatologist prescribing antidepressants a lot without an expertise in mental health, as a weak example, then perhaps prescribing according to practice scope would be beneficial to the public good. There may be many unintended consequences and very hard to supervise.

Doctors should be able to voluntarily opt out of certain prescribing rights to enable practice certification to continue when restricting their scope to specific areas not covered under formal sub-specialties. At present any registered GP for example is expected to have full knowledge of all prescribing potential despite never doing so.

**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?:**

Probably not for reasons in C43

**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?:**

Good so long as kept simple - which it seems to be. Regulations are only as good as the ease to which they are followed.

**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?:**

Good

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

Who takes full responsibility here?

Example:

A patient who has not responded to currently available medications or other TPs - and Googles a non-NZ approved imported TP which they wish to trial for an important illness. The doctor does some reasonable research into the TP and cannot see any obvious or significant problem so agrees to sanction the importation.

If it goes wrong should the onus always fall on the GP just because the doctor issued a SCNSN or should the patient also accept responsibility, having signed consent?

It raises the obvious fact that many if not most 'approved' medicines can have side-effects, from minor to severe, some even lethal. With no responsibility on the part of prescriber or supplier? Should be a level playing ground. This does not mean a cavalier prescribing of imported TPs - due diligence is a given, on the part of prescriber and patient. Responsibility needs to be shared - its not a one way street.

**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 the initiator is not the usual patients medical doctor. Providing the prescriber issues reasonable justification for the unapproved TP to the other party, then that party should not simply refuse based on personal preferences - unless there is inherent risks of which the prescriber was unaware.

**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?:**

If that device has approval, the it should go with the device and not the doctor - providing it is used in the way intended.

### 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?:**

NZSIM strongly contends that Medical Practitioners be able to continue to prescribe/supply unapproved compounded medicines to appropriate patients. Not only when other approved medicines are not appropriate but in particular when patient preference is for that compounded product. Patients may request this alternative to standard pharmaceutical medicines for a number of reasons: adverse reactions, personal desire to avoid non-physiological or bio-identical drugs,

susceptibility to incipients, or simply personal choice as a free consumer - in spite of the TP being non-funded.

Unless the unapproved TP has very significant adverse reaction capability, then patient free choice should be upheld without undue hurdles and negativity. It is material fact that pharmaceutical medicines are by no means always the safest and most efficacious option in certain cases. And perhaps should not be the first choice. That is for the doctor-patient relationship and professional trust to decide. Unless hindered by over regulation.

It also needs to be said that the proposed MA has many excellent and well thought through changes and additions.

**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.:**

There needs to be careful distinction between untruthful statements, sales driven marketing hype - and sincere information based reporting, say on websites, informational material etc. It is painfully obvious that pharmaceutical corporates push their marketing to extreme levels where high expected outcomes may be promoted in contrast to the actual evidence-based research. Therefore non-'approved' TPs should equally be allowed exposure on advertising with qualifications - such as non-official unapproved medicine. Not just 'unapproved' which may indicate to the public that it is actually unapproved. The term unapproved is an official term and should not be confused with the public perception of something that is not approved - ie may be dangerous or devoid of effect. Better would be a new term for example 'unregistered'.

**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-G42Z-D

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-17 09:30:00**

### Submitter profile

**What is your name?**

**Name:**

MidCentral District Health Board

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

MidCentral District Health Board

**Submitter Profile (tick all that apply)**

Consumer, Disabled person, Māori, Pacific peoples

District Health Board (DHB)

**If you select DHB, please state service area:**

MidCentral DHB

**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).:**

The purpose and principles are appropriate

**B4 Part 2 of the Bill: Interpretation**

**B4 Part 2 of the Bill: Interpretation**

**Question B2**

**Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:**

The definitions are detailed in the body of the Bill with references made in the definition section - this is difficult to follow in the bill as one has to constantly refer to

the various part of the Bill. It could be made easier if the definitions were provided in the 'definitions' part. In addition, the definition of manufacture is confusing. Likewise, for consistency, an actual testing structure to deeming a 'fit and proper' person needs to be considered. Leaving it up to the 'regulator to determine whether the person is a fit and proper' leaves room for interpretation and inconsistency in approach.

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.

## **B5 Part 3 of the Bill: Dealing with therapeutic products**

### **Subpart 1: Product approval requirements (ss 51 and 52)**

#### **Question B3**

##### **Please provide any comments on the product approval controls (ss 51 and 52):**

The requirement for approvals for medicines is appropriate in principle, however, our experience would suggest that there are many medicines supplied in New Zealand that are not registered by the suppliers because of market constraints. These are vital to patient care and often these medicines are available overseas eg low volume products (currently used under procured under Section 29). The ability of hospitals to procure this through their supply chains for stock (ie without a prescription being issued before procurement) is critical to timely patient care. In the acute stage, it is not practical to wait for a prescription to be issued prior to procuring processes as most of these medicines make take days to weeks to arrive. In addition, while the principle of approval of medical devices is good, this will limit the ability of patients to procure medical devices that they may currently have access to that may not necessarily be available in the NZ market. This limits consumer choice. It is critical that some medical devices are registered, however, the definition of the medical device include almost everything that a patient may use to support themselves. For example, a consumer may be able to procure a blood pressure monitor for home monitoring cheaply in the international market and many of these would be of reasonable quality. The same may apply to equipment that may be used by patients to support activities of daily living. The off label use of medicines requiring an SCNSA could increase administrative burden and how would compliance be assessed? In addition, permits to authorise the import of unapproved products to deal with situations where an approved equivalent is out of stock could result in delays in access to critical products. There needs to a rapid assessment and approval process for this.

We are concerned about the impact that #51 and #52 may have on:

- Provisions for unapproved medicine use (current section 29 of the Medicines Act) - there are some conditions (typically rarer conditions) for which no medicines are approved in New Zealand, and the capacity to access these in specific circumstances is very important.
- Some patients with life-threatening malignancies have been importing life-saving medicines that are not yet PHARMAC funded directly from overseas. It appears this bill intends to prevent this. This is likely to have a major adverse impact on the life expectancy of these individuals.
- Pharmaceutical company-run compassionate access schemes have provided an important way for patients to access life-saving medicines in New Zealand. For example, access schemes for the drug brutinib for patients with relapsed/refractory chronic lymphocytic leukemia. We hope these provisions will not prevent such access schemes.

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):**

It would be sensible that a sponsor can source a product approved for one source then go to another source to obtain the product to market in NZ as long as the product meets the same quality and standards (such as generic medicines) rather than having to seek an additional authorisation.

What does this mean for regulatory requirements specific to rehabilitation equipment Sponsors (suppliers and manufacturers) and any agents potentially involved in the secondary supply, modification, customisation, repairs and maintenance? Will these be required to seek additional authorisation?

We are concerned that 'The controlled activity 'taking overseas in the course of business' is included to avoid a potential loophole. It covers the circumstance where a person takes the product overseas themselves and then supplies it once they are out of New Zealand' will limit armed forces or overseas volunteer/emergency response services. The bill would need to be flexible enough that these services can continue to operate in rapid sequence without unnecessary authorisation requirements.

### **Subpart 3: Authorisations (ss 56–80)**

##### **Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):**

We support Section 59 which outlines the supply of medicines between pharmacies. This will reduce medicine wastage and encourage collaboration in the industry to provide all non-section H medications to the public (generally considered high risk by pharmacists).

**Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):**

These are fine - consideration for the pharmacy technicians that can check dispensed prescriptions should be made in the regulations (or PACTS positions made explicit in the regulations).

**Question B7 - Please provide any comments on the authorisations for health practitioners :**

We are concerned that a health practitioner can prescribe, supply and dispense prescription-only medications. This can lead to unethical behaviours (as it has in the past) - the current system with checks and balances with a pharmacist involvement remains appropriate. It would be better to encourage health practitioners to have a pharmacist as a member of the staff. Category 3 and 'over the counter' non-prescription medications could be appropriate to devolve to health practitioners is supported. However, clarity needs to be provided for example does this mean a nurse and a physiotherapist should be able to provide ibuprofen for pain?

NZBS expects to be able to obtain authorisations 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.

#75(a): Off-label use of approved medicines should not be recorded via a special clinical needs supply authority. Off-label prescription is routine in many areas of clinical medicine, including much of paediatrics and obstetric medicine. Indeed, in some instance, PHARMAC specifically funds medicines outside their label (following clinician-led applications)- examples in haematology are rituximab for hairy cell leukaemia and for autoimmune cytopenias, and erythropoietin alfa for myelodysplasia-related anaemia. Typically, this is already recorded in PHARMAC Special Authority records. Attempting to record all off-label use will be excessively burdensome for all involved, and should be avoided.

Rules vs regulations. Are these the same or different? Consistency in wording needed. Authorisation and supply of medicines is fine but clear accountability in prescribing. Off-label use must remain – most DHBs have a clear process to manage this.

**Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):**

These are appropriate - mentions delegation but needs to ensure clinical oversight is required.

Need clarification if podiatrists (in the example) can prescribe antibiotics and vascular agents. Prescribe vs supply category of medicine, overseas trained practitioners can't prescribe in NZ. To enable wider prescribing Regulatory Bodies must take action to support prescribing uptake an education opportunities.

**Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):**

These are fine, but there appears to be oversight for supply chain needs for veterinary providers. For example who are they authorised to procure medicines from - eg, Can a pharmacy supply a medicine on a prescription for an animal cared by a veterinarian. Many manufacturers will supply both animal and human products, therefore requiring a licence, however, we believe that this needs to be explicit in the regulations.

**Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

From a safety perspective, this makes sense. However, these paragraphs appear to be specifically designed to prevent personal imports of prescription medicines. There are many New Zealanders currently importing life-saving drugs for cancers because they are not yet PHARMAC-funded in New Zealand. This will have a major impact on these individuals' life expectancy. Until the PHARMAC processing timeframes for allowing drugs into the country is significantly reduced, it is difficult to support these clauses in their entirety.

Furthermore, how would you 'police' #80 or any importation of medicine?

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

Another special situation to be accounted for in Section 79 is the importation or purchase of medicines for laboratory research or laboratory quality assurance activities. For example, working in a Medical Research Institute, where they routinely purchase small quantities of prescription medicines for use in laboratory research. In addition, clinical diagnostic labs may require small quantities of prescription medicines for quality assurance (for example, to validate and provide quality assurance assays for therapeutic drug level measurement).

The rules around vending machines may need to be considered for current vending machines for condoms or other 'over the counter' products (paracetamol etc).

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:**

These are largely appropriate. Clarity needs to be provided around the definition of advertising particularly for situations where best practice messages or safety concerns may result in communications that promote one product over the other eg. bulletins from HQSC or BPAC. Additionally, health providers may also provide communications that sometimes result in choosing one product over the other - eg choosing wisely campaigns.

There is also concern over the concept around who can hold interest in pharmacy business. We do not support the view that pharmacist prescribers should not hold interests in a pharmacy. The pharmacist prescriber role is not a core activity that pharmacists do, it is a tool to improve patient care. There would always be a medical practitioner involved in the care of patients as diagnosis is not within the scope of the pharmacist prescriber, hence there is unlikely any negative impact of pharmacist prescriber around conflicts of interest and ability to be impartial if having interests in a pharmacy. Restricting this for pharmacist prescribers would have a negative impact on the ability of pharmacists to work in better ways to improve timely patient care and also restrict access for patients - i.e. enabling them

to prescribe antibiotics as part of an agreed pathway.

#105: A goal of health research investment strategies in NZ has been to preserve intellectual property within New Zealand. Therefore there may be a number of health researchers nationally who conduct clinical trials of devices or pharmaceuticals for which they hold a proprietary interest in the intellectual property or the manufacturing company. It is a conflict of interest, that is reported to human ethics committees and assessed in considering approval of the clinical trial. One should be cautious that this section does not make conducting the type of translational research encouraged in NZ an offence.

## **B6 Part 4 of the Bill: Product approval**

### **Subpart 1: Approval of products (ss 94–113)**

#### **Question B13**

**Please provide any comments on the sections covering product approval requirements (ss 94–104):**

These are appropriate.

#### **Question B14**

**Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):**

#113: We are concerned about the impact of fees or regulatory burden on the approval status for infrequently used medicines. There are many older medicines (e.g.

pentostatin) that are infrequently used in clinical practice because they are reserved for relatively rare conditions. If the fees or regulatory burden to maintain a license are set too high, some sponsors may withdraw from New Zealand, requiring that any future prescription is on an unapproved medicines basis.

### **Subpart 2: Approval-exempt products (ss 114–115)**

#### **Question B15**

**Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):**

These are appropriate.

### **Subpart 3: Obligations of sponsors (ss 116–119)**

#### **Question B16**

**Please provide any comments on the sections covering sponsor obligations (ss 116–119):**

We support this as this would improve accountability and safety - however, 118(a) and (f): are not clear as to how, outside of clinical trials, sponsors can be expected to provide thorough ongoing monitoring of clinical efficacy or of adverse effects. This reporting will rely on feedback to the manufacturer by prescribers and may be incomplete.

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):**

It is unclear what information is withheld. It would appear from the explanation presented that it relates to a product patent. However, as the regulator is required to publish all products that have been approved and declined, how would this be implemented. Are there particular elements of that information that would be withheld? If a medicine is approved then you would expect that the information relating to the active ingredient ie what it is, is available as it will be required for the safe use of that medicine. Some clarity on the intent of this is required.

## **B7 Part 5 of the Bill: Licences and permits**

### **Subpart 1: Licences (ss 123–130)**

#### **Question B18**

**Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):**

This is largely appropriate. The ability of a company to perform activities in behalf for a licenced company would be an enabler, however, it is unclear what checks and balances would be in place to ensure that the subcontractor is operating within reasonable standards.

Regarding clinical trials, we would support the concept of licences however would suggest the cost of these be minimal as there are many trials and organisations that do research that does not have commercial funding and operate with small budgets, as such we would not like to see a reduction in innovation due to the costs of licences. In addition, would medicines dispensed for clinical trails from a pharmacy require a separate licence for the pharmacy to undertake supply for clinical trials? We suggest that the pharmacy licence should be sufficient to allow such supply ie no separate licence is required by pharmacies to supply clinical trial medicines.

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.

It is important that specification of license locations is not burdensome. In clinical trials, it is common for trial sites to be added and removed on numerous occasions during a study. This should not require an update to the license (it already requires notification to the Ethics Committee).

#### **Question B19**

##### **Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):**

These are appropriate. There are 2 considerations however, in large institutions, the senior person such as a CEO may not be the appropriate person to be the holder of a licence, it may be more appropriate that a person with operations responsibilities closer to where the work is done that requires a licence is the person holding the licence - which better aligns with the concept of "fit and proper". What would happen if the person on the licence is under investigation - what impact will this have on the ability to continue delivering a service. We support the concept that a pharmacy to be majority owned and effectively controlled by a pharmacist - transferring ownership to corporate models is not supported.

Medicine prescribing and dispensing must be kept clearly separated by a high legislative fence:

Pharmacy workers in the UK, within a more open pharmacy structure, who are routinely directed by the non-pharmacist owners to sell (products) regardless of the best health advice for the individual patient, pass the blame on "the employer made me do it". The employer hides behind having no professional registration to lose. Only a registered pharmacist can take ultimate responsibility for the running of a pharmacy.

CCSD – licence needed – sterilising for others - will be business contracts between businesses. Ensuring safe sterilisation is imperative but there are many standards already in place to ensure this (usually). Does an Act need to manage this aspect?

Can a DHB department be licenced? Rather than one person? If leave/resigned – what happens then?

We are concerned that the licensing requirement as written could have a chilling effect on NZ participation in international co-operative group trials, including for cancer. The draft prioritisation vehicle for health research in NZ (MoH, March 2019) specifically highlights the value of, "multi-centre trials and those that are undertaken as part of international collaborations" and notes that "funders will work to improve clinical trial networks". Modern investigator-initiated co-operative trials in cancer often include multiple new medicines, to which participants are allocated to on the basis of disease characteristics. Often the trial sponsor is an overseas co-operative trials group and the manufacturer of some or all of the drugs involved may have no NZ presence, so the country Principal Investigator of the trial becomes the sponsor representative in NZ. Thus, this portion of the legislation may require already-burdened clinicians taking on additional roles as licensee for a number of new medicines from multiple manufacturers. It is strongly recommend that any licensee requirements must be kept simple, or the Permit subpart used, and costs low (or waived), for HDEC-approved clinical trials. After all, such trials are essential to collect the key safety and efficacy data that may contribute to a future application for a medicines approval.

#### **Subpart 2: Permits (ss 131–135)**

##### **Question B20**

##### **Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):**

We support the use of pharmacy permits in emergency relocation activities.

Might this Permit subpart offer a more appropriate regulatory framework for clinical trials involving medicines that are not yet (and indeed may never be) approved in New Zealand, and which will only be used for a special purpose (i.e. within a specific ethics committee-approved clinical trial)?

#### **Subpart 3: Provisions applying to licences and permits (ss 136–151)**

##### **Question B21**

##### **Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):**

These are supported - 3 year licencing is appropriate in most circumstances - not for clinical trials.

The 3 year term of licenses (and 2 year term of permits) appears too short for clinical trial purposes. The clinical trials are rarely completed within this time period, once both recruitment and follow-up periods are included. A longer license term of 5 or 10 years may be more appropriate, or at least an option for renewal.

##### **Question B22**

##### **Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):**

While the intent of transfer of licences and permits is great, there may be issues with implementation for example, in DHBs, a pharmacy licence is issued to the pharmacy manager or senior manager and these individuals may change with short notice periods. In addition the new person may not have entered into an employment agreement in time for a new licence to be issued. Some clarity and allowance needs to be available for transition periods - again, potentially to the department rather than the person?

It seems inappropriate to transfer a license or permit to the executor or administrator in the event of the death of a licensee, as the executor or administrator is unlikely to be in a position to assume any of the responsibilities.

#### **Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**

## **Question B23**

### **Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):**

These are largely appropriate. The impact of a law that pharmacists always present when a pharmacy premise is open is currently overly restrictive, including interpretations of this when designing pharmacy premises such as consultation rooms, particularly when our health strategy promotes integrated care. We would like to see allowances that allow premises to remain open of activities during tea breaks and lunch breaks where licences require compliance of with supply of category 1-3 medicines without having to lock parts of the pharmacy. Similar restrictions do not apply in medical practices where a practice may be open without a doctor. The current rules and the proposed bill also do not enable the changing nature of pharmacy and medicines supply options and the people involved in the supply. For example, a pharmacist could be working in an integrated care clinic providing supervision to a pharmacy that operates in that clinic - ie the pharmacist may be involved in the providing services that ensure appropriate medicines are prescribed, but the actual dispensing in checking is led by checking technicians (PACTS). Pharmacy medicines supply and pharmacists medicines supply could be indirectly supervised eg. the pharmacist consults in a consulting room next to the pharmacy or in a clinic but does not have to be in the pharmacy itself for the supply to occur.

## **B8 Part 6 of the Bill: Regulator**

### **Subpart 1: Regulatory powers and functions(ss 160–182)**

#### **Question B24**

### **Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):**

We support this. We suggest that the issues covered in S172-176 needs to have good operational mechanisms to enable health providers to work safely in the context of health information privacy obligations.

In relation to section 160, it should be recognised that GCP-compliant clinical trials already include systems (including Data Safety Monitoring Committees, trial monitors and ethics committees) that monitor the safety of a trial intervention. It is important that this work is not unnecessarily duplicated by the new Regulator.

### **Subpart 2: Investigative powers (ss 183–196)**

#### **Question B25**

### **Please provide any comments on the regulator's investigative powers (ss 183-196):**

We think these are largely legal instruments however, principles seem reasonable.

### **Subpart 3: Offences relating to regulator(ss 197–199)**

#### **Question B26**

### **Please provide any comments on the offences relating to the regulator (ss 197-199):**

These are appropriate.

### **Subpart 4: Review of regulator's decisions (ss 200–204)**

#### **Question B27**

### **Please provide any comments on the review of the regulator's decisions (ss 200-204):**

These are appropriate for approvals of products. The review of decisions licences and permits however may be onerous process, particularly if the decision is to be challenged in the Court setting. This may have consequences on costs of licences and may become a barrier to challenge a decision. Perhaps greater thought needs to be given about the reviews of decisions for licences and consideration to separating large commercial licence process from small businesses or state sector organisations.

### **Subpart 5: Administrative matters relating to the regulator (ss 205–222)**

#### **Question B28**

### **Please provide any comments on the administrative matters relating to the regulator (ss 205–222):**

These are appropriate - approved regulators important.

## **B9 Part 7 of the Bill: Enforcement**

### **Subparts 1 and 2: Enforceable undertakings(ss 223–232)**

#### **Question B29**

### **Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):**

These seem reasonable. We support the use of enforceable undertaking and providing opportunity to improve.

### **Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**

### Question B30

**Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):.**

These seem reasonable.

### Subpart 6: Infringement offences (ss 249–255)

### Question B31

**Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):.**

The concept is reasonable.

### B10 Part 8 of the Bill: Administrative matters (ss 256–274)

### Question B32

**Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):.**

Elements within this are reasonable approaches - the cost of approvals needs to be carefully considered and may need to take a tiered approach so as to allow less commonly used items in the market be able to be access ble. Costs could become a barrier for niche products as well as result increased costs to consumers.

Need to limit costs and not to build bureaucracy costs eventually end up with DHB/public funded. APC costs management.

It is very important that any fee structure draw distinction between investigator-initiated clinical trials (including international co-operative group trials) and commercial trials or applications for medicine approvals. For example, Medsafe, SCOTT and GTAC are able to provide fee waivers in such scenarios, and a similar approach should exist with the new Regulator. Charging new fees for conduct of investigator-initiated clinical trials would discourage New Zealand health research and run contrary to the aims outlined in the consultation document for the prioritisation vehicle for health research (MoH, March 2019).

Please clarify the regulatory status of donated and banked human breast mi k 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):.**

We support this as this will make it easier for a wider range of health practitioners to be considered for prescribing scope.

#### Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)

### Question B34

**Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):.**

These are reasonable - will need education for Customs.

### B12 - B15, Schedules 1 - 4

#### Schedules

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):.**

These are reasonable. However there may be a need to consider review requested by third parties, for example a professional body may want a review of a particular product or medicine due to safety concerns,

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):.**

These we understand are broad areas that would be detailed in the instruments. There would need to be consultation when these instruments are developed. As a specific point, the regulations may need to differentiate between a prescription for dispensing versus an order for administration that currently exists legislation to allow for the unique needs in the acute hospital setting.

**Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:**

We are unable to confirm whether everything that interfaces with Medicines Act is covered. However, the TPB may need to consider interaction with Civil Defence and Emergency Management Act 2002 and Privacy Act 1993.

## **C1 Medicines (excluding cells and tissues) sector**

### **Product-based controls**

#### **Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):**

A process for minor and major changes is welcomed. However, for medicines, the regulations may want to classify changes such as label changes and product packaging as a major, as changes in labels and packaging can have a huge impact on safety, for example, look-alike labels and packages.

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.

#240: Compassionate access schemes where a medicine is licensed in other jurisdictions would be another example where this should be considered.

#241: Speed of obtaining SCNSAs - unapproved medicines can be clinically urgent, and may be required within hours or days. It will be critical that there is a mechanism for rapid approval of clinically-urgent SCNSAs. Also, the SCNSA system appears excessive for off-label use of approved medicines, as this is routine in many areas of clinical practice, not least paediatrics and obstetric medicine, and PHARMAC specifically funds many medicines for unapproved indications, for example in cancer. This could lead to unnecessary duplication of administrative work, prescribers potentially requiring both a PHARMAC Special Authority AND a SCNSA for just one prescription.

#244: Please consider whether the Permit system is more appropriate than the License system for investigator-initiated clinical trials, where the company that produces a medicine may have no New Zealand presence. This may be a particular issue platform trials (increasingly common in oncology studies) or early-phase trials in low-incidence conditions. In this scenario, the therapeutic product would be supplied for a very specific purpose (administration in the context of ethics and SCOTT-approved clinical trial).

#245 product approval – does this cover type 4 products too?

#### **Question C2 - Please provide any comments on the approach for medicines categorisation (classification):**

These are reasonable and the approach taken to enable keeping up with future scopes of prescribing/accessing medicines is good.

#### **Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals.:**

Seeking approvals for patients on unapproved medicines supplied via Section 29 within a 3 month period would create a huge burden on the health system. A grand-parented approach should be adopted. The need to reissue a standing order for an existing standing order within 12 months will also create a significant burden on the system, given that many standing orders may have longer expiry dates and having all renewed in the 12-month timeline could be burdensome (for example St John with standing orders for a 3 year cycle). For medical devices the 6 month period before licences are required for medical devices may also be too short for the range of devices that the TPB covers. This would seem like an unrealistic timeframe for the regulatory body to work to. A longer period such as 12 months may be more achievable. The transition timeframes across the various activities need to be carefully considered. They would appear to be very short and unrealistic given the scale of situations that the transition will apply to

#270: There needs to be clarity in the transitional processes about clinical trials that are in long-term follow-up, but within which the therapeutic product is no longer administered. This is often the case for oncology trials, for example, where a product is given for a short period of time (e.g. weeks or months), then the recipients are followed-up for years. Since no more product is being administered or supplied, such trials should not be required to transition to a new process.

We have some concerns around the risk when staff leave who have the licence in their name – what do we do?

#### **Question C4 - Please provide any comments on the approach to post-market controls.:**

Currently, pharmacovigilance reporting is voluntary. A robust national system would be required as well as consideration given to the implementation of such an activity. A significant change process is required for this to occur, particularly around provider reporting. There is also additional administrative burden. This is a good thing to achieve, however, organisations can't be left on their own to manage this change. It may be that this is enforced via the HPCA act to enable providers to be responsive to the intent of this change

#277: We welcome the suggestion of using NZ's existing pharmacovigilance system (CARM) - duplication of work must be avoided.

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.

### **Activity-based controls**

#### **Question C5 - Please provide any comments on the manufacturing-related definitions.:**

We are pleased to see some recognition of the various activities that are associated with the product life cycle. It still remains unclear whether a contractor who may not be a pharmacist or pharmacy could still compound and what type of licence would be required for this. Additionally, would a hospital pharmacy require a separate licence to pack down products for use on wards as stock?

#280: The process of fee waivers, as currently offered by Medsafe, must be continued for academic and non-profit organisations manufacturing devices and medicines. If not, this will disrupt attempts to develop new medicines and devices in New Zealand, and hamper biomedical research.

#283: Australia's TGA provides an exemption to full GMP requirements for the local manufacture of therapeutic products for first-in-human clinical trials. Please consider providing a similar exemption in this New Zealand law, as this clause has undoubtedly fostered Australian biomedical innovation, and indirectly led to several successful new medicines, vaccines and serological products for international markets, to the benefit of Australia.

#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 C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.:**

This is reasonable and is a good step toward ensuring the quality and safety of work associated with "hawking".

## **C2 Cell and tissue sector**

### **Product-based controls**

**Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:**

NZBS supports adoption of the European approach.

Yes, our understanding is that Medsafe already follows the European approach in licensing cell therapy manufacturers in New Zealand. We are keen to ensure that the law and fee structure continues to distinguish between manufacture for investigator-led clinical trial purposes, and for commercial products. It is important that this new law does not adversely affect current timelines for approvals.

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:**

#333: It is important that this new law does not adversely affect current timelines for approvals.

**Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:**

Unable to comment.

**Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:**

Unable to comment.

**Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:**

Unable to comment.

### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions.:**

#351: Again, note that Australia's TGA provides an exemption to full GMP requirements for the local manufacture of therapeutic products for first-in-human clinical trials. Please consider providing a similar exemption in this New Zealand law, as this clause has undoubtedly fostered Australian biomedical innovation, and helped get several successful new medicines, vaccines and serological products for international markets, to the benefit of the Australian economy.

**Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:**

While in principle this would be a useful thing to do, the scope could be large and may not be the best use of state sector resources.

It should be made clear that the transitional arrangements should only apply to products that are currently being administered to humans - not to clinical trials that are closed to new patient accrual and already in long-term follow-up (of which there may be many more than current trials).

## **C3 Medical device sector**

### **Question C11**

**Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:**

No not required.

#360 (S51) need to define what low-level medical devices are e.g. therapy equipment comes under licence or approval? What is the regulator's notice? How will the management of software updates be managed – those particularly pushed from the Cloud into devices? Those potentially affected e.g. communication devices for aphasic patients, specialised electric wheelchairs, hearing devices etc

### **Product-based controls**

**Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:**

The ability to import approved medical devices from overseas without sponsor approval. This may have an impact on consumers being able to procure devices competitively.

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).:**

As before

**Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:**

These are appropriate

**Question C4 - Please provide any comments on the approach to post-market controls.:**

As before.

**Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:**

The approach is reasonable. Timeframes would be considered reasonable

**Activity-based controls**

**Questions C5 - Please provide any comments on the manufacturing-related definitions.:**

**Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:**

The approach is reasonable. Timeframes would be considered reasonable

**C4 Clinical trial sector**

**Question C16**

**Please provide any comments on the change in approach to regulating clinical trials.:**

Would each trial have to have a separate licence for each site? What would be the costs of obtaining such a licence. There could be a significant number of existing trials and the transition period of 12 months may not be enough for the regulator to issue licences.

The clinical trial definition as it stands (particularly part C(iii)) is too broad, and will draw in many essentially observational clinical studies of standard-of-care therapies. For example, an observational study that uses additional tests (e.g. a blood test or an ECG) to compare outcomes among people receiving approved standard-of-care products would be drawn into the new Regulator's net. Such studies are already reviewed by ethics committees and do not involve exposing participants to additional risk (since the therapeutic products are approved standards of care). Added regulatory burden may inhibit these important studies, which may help detect new benefits or risks of approved medicines that might inform the Regulator's other activities.

It will be very important to ensure these processes are streamlined and run alongside other ethics committee processes, ideally using a shared online portal and shared forms, so the information provided is not duplicated.

**Question C17**

**Please provide any comments on the transitional arrangements for clinical trials.:**

It is important that transitional arrangements apply only to trials within which participants are still receiving the therapeutic product, and not to trials that are in long-term follow-up (where no more therapeutic product is being or will be administered) are excluded.

**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 before - as long as it does not increase costs and does not result in poorer health outcomes due to non-funding of medications.

**Hawker's licence**

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

This is reasonable and is a good step toward ensuring the quality and safety of work associated with "hawking".

**Transition**

**Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:**

The approach is reasonable. Timeframes would be considered reasonable.

**C6 Pharmacy (and retail-only licence) sector and pharmacists**

**Pharmacy sector context**

**Future regulation of pharmacy business activities**

**Licence to carry out a pharmacy business**

**Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

The supply and distribution activities do not necessarily require pharmacist skills and therefore distribution models should not be determined by the pharmacist being present at the point of supply. The supply and distribution must ensure safety not determine how the pharmacist works within the supply and distribution system. Supply via robotics and other supply chain mechanism could be enabled, particularly if access to pharmaceuticals is to be improved.

**Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:**

Yes, the requirement of a pharmacist to directly supervise supply activity is impacting innovation particularly when the pharmacist doesn't necessarily have to be

physically present in the dispensary to provide the expertise. Technicians for example can competently run a pharmacy supply service, with direction from a pharmacist - eg a pharmacist could be working alongside a GP or a doctor to optimise the medicines and check the prescription details, which can then be supplied via robotics or technicians.

#### 4. Innovation:

- a. Community pharmacies are facilitators of safe innovation. Community pharmacies have invested heavily in innovation over the last 5 years, including \$10M+ in automated dispensing systems, and is not a "block" to innovation. Community pharmacists have had to balance the societal constraints of the medicines and pharmacy legislation, are routinely audited to ensure that they do so, and prevent the use of out dated medicines; second hand medicines; the introduction of imported copy medicines into the supply chain.
- b. As health professionals community pharmacies have, until the Supermarkets became involved, not been stockists of alcohol, cigarettes and sought evidence based information regarding vaping. Not all innovation is positive.
- c. Community pharmacies, because they are imbedded within their communities, take responsibility for most of their own medicine deliveries. This means potentially harmful medicines are not left to be accessed by children; are not left out of the fridge, go to the wrong address or left in the sun to degrade.

#### **Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

Dispensing and supply functions could be done by a wider range of professionals as long as their has been pharmacist oversight on prescription appropriateness.

#### **Question C22 Which option do you support?**

Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)

#### **Question C23 - Why do you support that option?:**

The entry of commercial entities does result in a focus on profits with a limited focus on standards of quality of care and outcomes. Pharmacists may better influence the models that would enable different ways of working, innovation and outcome based care.

#### 2. Pharmacist leadership and company control is vital:

- a. Pharmacists are subject to fearsome internal professional peer oversight. The risk to personal reputation within the profession is the very most effective method of controlling aberrant behaviour, on the rare occasion I have felt a more senior pharmacist was in need of a reality check, I have only had to suggest we seek clarity from a local leading colleague and the default position of what is unquestionably right was immediately adopted – no-one ever wants to look bad within the eyes of such a small profession.

#### **Detailed questions relating to Option 1**

#### **Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

Benefits are a health care system that is focused on the patient and not on profit.

Benefits - Interest in professional practice driving models of care - an enabler for integrating care with MDT setting Risks - Limited capacity as the availability of pharmacies would be constrained by pharmacists availability and willingness to operate in certain areas - so may impact access, although this could be enabled by innovative business design eg online services etc

#### **Question C25 - Are there ways in which Option 1 could be improved?:**

Practice audits as part of licencing that would require licencees to demonstrate patient and professional interest over commercial interests. For example independent pharmacist auditors.

#### **Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:**

The responsibility that supply, compounding and distribution of Prescription and Pharmacist Only Medicines are done as per standard set out by regulations. How the service is designed should not be dictated by the legislation. For example - the licencee may decide not to have a pharmacist involved in the physical supply, but decision making on the choice of a product.

#### **Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:**

This does not matter, it could be either or both.

#### **Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:**

Yes it should. Currently, we have an issue with major corporate structures being profit driven rather than patient centric.

#### **Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:**

A responsible person under that act should be appointed. It would be governed by minimum FTE pharmacists on site each day as the duty pharmacist.

Each pharmacist should be able to be afforded 5 - so if there were 2 pharmacists jointly sharing they could run 10.

#### **Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:**

No

#### **Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

We would suggest grandparenting current licence holders and introducing the new rules for any new licences rather than transition.

#### **Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:**

Be able to continue. There needs to be some allowance for situations such as death of a pharmacist owner - perhaps a transition period.

## Detailed questions relating to Option 2

### Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

Benefits - competition in the market and possibly improved access. Risks - Commercial interest over professional and patient centred.

### Question C34 - Are there ways in which Option 2 could be improved?:

Could be through independent governance - example a regulatory board - however this could be a significant undertaking. The fundamental risk is that despite a pharmacist's best efforts they would be 'employed' by the corporate and therefore dictated to 'tow the company line' or risk losing their jobs to someone who will - irrespective of the professional accountabilities.

### Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

Unlikely as there will always be a conflict of interest between employment with needing to perform in a commercial setting vs professional interests.

## Other changes to pharmacy licensing requirements

### Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

Yes most definitely - all circumstances for which a pharmacist is trained or skilled - most technical elements of a pharmacy activity are now successfully completed by technicians.

### Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

No.

### Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

In Civil Defence emergencies.

It could also be used for public health measures, managing communicable disease endemics and vaccination programmes.

### Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

We support this allowance. However consistency of permissions should be achieved in the Bill - for example, a pharmacy licence would require a pharmacist to be present in the pharmacy for a Category 3 medicine to be supplied yet, a retail only licence would not require a pharmacist. The risk to the consumer would be the same so why would one enable supply without pharmacist and the other requires a pharmacist to supervise?

### Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

This would be appropriate as long as consumers are still able to access medicines without additional costs and this does not have a detrimental patient health outcome for those who need to source medications from overseas that PHARMAC do not currently fund.

## Pharmacist and pharmacy worker authorisations

### Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:

Yes, in all hospital settings and other settings where acute care delivery requires medicines to be available immediately. It may also be useful for improving costs and reducing labour costs - however adequate standards must be in place to ensure the safety of the product for such activities

### Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:

Supply to veterinarians, ambulance services, private hospital clinics, NZMAT, Search and Rescue bases. Potentially between pharmacies for continuous stock supply.

## C7 Retail sector

### Question C42

#### Do you consider the new scheme will have any significant impacts on retailers?:

The approach is appropriate. The change may result in an increase in the administrative burden. Processes would need to be relatively simple and responses must be timely. It is unclear whether products already would need every retailer to reapply for approval?

## C8 Health practitioners (including pharmacists)

### Prescribers

#### Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:

This is appropriate.

**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 - via an electronic mechanism rather than continuing to allow paper-based scripts which enables fraud.

**Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):**

It is appropriate to include standing orders in the Bill.

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

While the intent is reasonable, there will be a significant burden on health practitioners. Off label use of medicines is common in many areas and parts of the population eg paediatrics. The off label use of medicines could take a different approach eg a list of medicines that are considered controversial may need approval - others shouldn't.

#569: The SCSNA system for off-label use of approved medicines is highly problematic, as a very large fraction of routine medicines use is off-label. This includes most paediatric and obstetric medicine practice and a large fraction of oncology chemotherapies. Indeed, it is often the case that clinicians won't even know whether a prescribed medicine is being used within its label or not. Older medicines are very frequently used for off-label indications. For example, warfarin is not licensed for stroke prevention in patients with prosthetic heart valves, but this has been routine for decades. Also, PHARMAC specifically funds a number of medicines for off-label indications, so this process could result in clinicians having to complete both a PHARMAC Special Authority and a SCSNA for the same medicine for the same purpose.

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 will 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.

A) no, others who have the authority to prescribe should be able to as well if the patient is being cared for by them.

b) They should be able to apply for this in the first instance.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

#570: This clause will block the ongoing supply of life-saving medicines to a number of patients who are arranging personal imports of drugs not yet PHARMAC-funded in New Zealand, for example for oncology indications.

**Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:**

Already covered in wholesale supply questions.

**Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:**

**Health practitioners (non-prescribers)**

**Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:**

Yes - Do not foresee any risks so long as their professional scopes ensure competency

**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

Yes, Benefits - quick access and knowledge of what the patient will be using. Risks - may result in restricted selection eg they may offer only what they hold.

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

These are appropriate.

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No - the information presented in a DTCA could often result in medicine seeking behaviours without appropriate assessment of options and pressure put on prescribers.

**C9 Veterinarians**

**Question C54**

**What do you think about the approach for veterinarians and veterinary staff?:**

The approach is reasonable - considerations may need to be had with permits for farmers to comply with animal welfare regulations who need access to the medications and do not wish to use a Vet (potentially an accreditation system).

**C10 Advertising sector**

**Question C52**

**Please provide any comments on the advertising requirements and enforcement tools.:**

These are appropriate.

**Question C53**

**Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No - the information presented in DTCA could often result in medicine seeking behaviours without appropriate assessment of options and pressure put on prescribers.

**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?:**

While the intent is reasonable, there will be a significant burden on health practitioners. Off label use of medicines is common in many areas and parts of the population eg paediatrics. The off label use of medicines could take a different approach eg a list of medicines that are considered controversial may need approval - others shouldn't.

**Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:**

As before.

**Personal imports**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

This would be appropriate as long as consumers are still able to access medicines without additional costs or being detrimental to the patient's health.

**Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:**

Yes, when PHARMAC refuse to fund life-saving medications.

There will be individual circumstance and a permit should be able to look at the merits of such application. For example where a personal import would be a more affordable option than going through a pharmacy. A prescription and SCNSA would still apply. The other would be ineligible patients who may be able to seek supply of medicines from their country of origin if visiting.

**Pharmacy licensing**

**Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

The supply and distribution activities do not necessarily require pharmacist skills and therefore distribution models should not be determined by the pharmacist being present at the point of supply. The supply and distribution must ensure safety not determine how the pharmacist works within the supply and distribution system. Supply via robotics and other supply chain mechanism could be enabled, particularly if access to pharmaceuticals is to be improved.

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:**

Dispensing and supply functions could be done by a wider range of professionals as long as there has been pharmacist oversight on prescription appropriateness.

**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?:**

Our reasoning is the entry of commercial entities may result in a focus on profits with a limited focus on standards of quality of care and outcomes. Pharmacists may better influence the models that would enable different ways of working, innovation and outcome-based care.

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

Benefits - Interest in professional practice driving models of care - an enabler for integrating care with MDT setting Risks - Limited capacity as the availability of pharmacies would be constrained by pharmacists availability and willingness to operate in certain areas - so may impact access, although this could be enabled

by innovative business design eg online services etc.

**Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:**

Benefits - competition in the market and possibly improved access Risks - Commercial interest over professional and patient centred.

**Access to pharmacy medicines**

**Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:**

Yes - Do not foresee any risks so long as their professional scopes ensure competency.

**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

Yes, Benefits - quick access and knowledge of what the patient will be using. Risks - may result in restricted selection eg they may offer only what they hold.

**Advertising**

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

These are appropriate

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

No - the information presented in DTCA could often result in medicine seeking behaviours without appropriate assessment of options and pressure put on prescribers.

**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?:**

While in principle this would be a useful thing to do, the scope could be large and may not be the best use of state sector resources.

**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 ability for consumers to access medical devices or products that assist with a disability must not be made harder with any new changes, particularly if they are classed low-risk items. Affordability for the disability sector is a significant challenge so being able to access products (not medicines) that are fit for purpose is important to maintaining choice and control for disabled people. The Bill must take into consideration the impact on disabled people and value the principles within the NZ Disability Strategy.

## Response ID ANON-DPZ8-G46B-S

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-17 09:58:31**

### Submitter profile

What is your name?

Name:

Phillip Graeme Rowe

What is your email address?

Email:

What is your organisation?

Organisation:

Faulkners Pharmacy Te Puke Limited T/A MyPharmacy Te Puke

Submitter Profile (tick all that apply)

If you select DHB, please state service area:

Bay of Plenty

Pharmacist

If you select 'Other', please comment below;:

If you selected 'Other' please comment;:

Next steps after the consultation

### Chapter A Key features of the new regulatory scheme (A1 - A5)

#### Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Partially support

### Chapter B Content of the draft Bill (B1-B2)

#### B1 Overview of the draft Bill

#### B2 Tips to help with understanding the draft Bill

#### B3 Part 1 of the Bill: Preliminary provisions

#### B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

#### B4 Part 2 of the Bill: Interpretation

#### B4 Part 2 of the Bill: Interpretation

#### Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

Dispense a medicine (s 29) – the definition of dispensing has changed significantly. I am concerned about this change.

The Medicines Act states that dispensing, in relation to a medicine, includes, without limitation, —

(a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the

medicine); and

(b) the packaging, labelling, recording, and delivery of that medicine

Under the draft TPB, dispensing a medicine is defined as part of manufacturing the medicine. This implies that dispensing is merely the supply of a medicine, which is misleading. Pharmacists consider dispensing to include clinical checks, preparing a medicine, supplying the medicine to a patient, and providing advice to the patient about how to take the medicine safely and effectively.

## **B5 Part 3 of the Bill: Dealing with therapeutic products**

### **Subpart 1: Product approval requirements (ss 51 and 52)**

#### **Question B3**

**Please provide any comments on the product approval controls (ss 51 and 52):**

### **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.

##### 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?:**

## Response ID ANON-DPZ8-G46S-A

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-17 10:02:06**

### Submitter profile

**What is your name?**

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Brian Day

**What is your email address?**

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**What is your organisation?**

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CARSL Consulting

**Submitter Profile (tick all that apply)**

**If you select DHB, please state service area:**

**If you select 'Other', please comment below;:**

Other (please comment)

**If you selected 'Other' please comment;:**

Regulatory consultancy for medicines, medical devices, clinical trials, natural health products

### Chapter A Key features of the new regulatory scheme (A1 - A5)

#### Chapter A (A1 - A5)

**Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?**

Support

#### B3 Part 1 of the Bill: Preliminary provisions

**B3 Part 1 of the Bill: Preliminary provisions**

**Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:**

No 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).:**

No comment

#### B5 Part 3 of the Bill: Dealing with therapeutic products

**Subpart 1: Product approval requirements (ss 51 and 52)**

**Question B3**

**Please provide any comments on the product approval controls (ss 51 and 52).:**

No comment

**Subpart 2: Controlled activities and supply chain activities (ss 53–55)**

**Question B4**

**Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):**

No comment

### **Subpart 3: Authorisations (ss 56–80)**

**Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):**

No comment

**Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):**

No comment

**Question B7 - Please provide any comments on the authorisations for health practitioners :**

No comment

**Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):**

No comment

**Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):**

No comment

**Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

No comment

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

No comment

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

**Please provide any comments on the offences created in sections 81–94:**

No comment

## **B6 Part 4 of the Bill: Product approval**

### **Subpart 1: Approval of products (ss 94–113)**

#### **Question B13**

**Please provide any comments on the sections covering product approval requirements (ss 94–104):**

No comment

#### **Question B14**

**Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):**

No comment

### **Subpart 2: Approval-exempt products (ss 114–115)**

#### **Question B15**

**Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):**

No comment

### **Subpart 3: Obligations of sponsors (ss 116–119)**

#### **Question B16**

**Please provide any comments on the sections covering sponsor obligations (ss 116–119):**

No comment

### **Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)**

#### **Question B17**

**Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122):**

No comment

## **B7 Part 5 of the Bill: Licences and permits**

## **Subpart 1: Licences (ss 123–130)**

### **Question B18**

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127):

No comment

### **Question B19**

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):

No comment

## **Subpart 2: Permits (ss 131–135)**

### **Question B20**

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):

No comment

## **Subpart 3: Provisions applying to licences and permits (ss 136–151)**

### **Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149):

No comment

### **Question B22**

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):

No comment

## **Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**

### **Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):

No comment

## **B8 Part 6 of the Bill: Regulator**

### **Subpart 1: Regulatory powers and functions(ss 160–182)**

#### **Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):

No comment

### **Subpart 2: Investigative powers (ss 183–196)**

#### **Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196):

No comment

### **Subpart 3: Offences relating to regulator(ss 197–199)**

#### **Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

No comment

### **Subpart 4: Review of regulator's decisions (ss 200–204)**

#### **Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

No comment

**Subpart 5: Administrative matters relating to the regulator (ss 205–222)**

**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):.

No comment

**B9 Part 7 of the Bill: Enforcement**

**Subparts 1 and 2: Enforceable undertakings(ss 223–232)**

**Question B29**

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):.

No comment

**Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**

**Question B30**

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):.

No comment

**Subpart 6: Infringement offences (ss 249–255)**

**Question B31**

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):.

No comment

**B10 Part 8 of the Bill: Administrative matters (ss 256–274)**

**Question B32**

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):.

No comment

**B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments**

**Subpart 1: Repeals and revocations (s 275)**

**Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)**

**Question B33**

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):.

No comment

**Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**

**Question B34**

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):.

No comment

**B12 - B15, Schedules 1 - 4**

**Schedules**

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):.**

No comment

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):.**

No comment

**Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:**

No comment

## **C1 Medicines (excluding cells and tissues) sector**

### **Product-based controls**

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):**

No comment

**Question C2 - Please provide any comments on the approach for medicines categorisation (classification):**

We support this change provided it does not impact on product labelling

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:**

Agree with proposed transition arrangements

**Question C4 - Please provide any comments on the approach to post-market controls:**

No comment

### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions:**

No comment

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

No comment

## **C2 Cell and tissue sector**

### **Product-based controls**

**Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:**

No comment

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

No comment

**Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues:**

No comment

**Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues:**

No comment

**Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products:**

No comment

### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions:**

No comment

**Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products:**

No comment

## **C3 Medical device sector**

### **Question C11**

**Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:**

No they should not be regulated if there is no therapeutic intent with the use of the product

### **Product-based controls**

**Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:**

No

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

The regulatory oversight of changes to medical devices should be risk based and of minimal intervention.

**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.:**

The transition period is far too short. We have over 500 devices from various manufacturers listed on WAND. It would not be possible to make applications for new listings within 6 months. It should also be noted that low risk devices should not be evaluated.

**Activity-based controls**

**Questions C5 - Please provide any comments on the manufacturing-related definitions.:**

No comment

**Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:**

No comment

**C4 Clinical trial sector**

**Question C16**

**Please provide any comments on the change in approach to regulating clinical trials.:**

No comment

**Question C17**

**Please provide any comments on the transitional arrangements for clinical trials.:**

No comment

**C5 Wholesale sector (including importers and exporters)**

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

**Licence to wholesale**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

There needs to be exemptions from personal import restrictions for medicines not available in NZ.

**Hawker's licence**

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

No comment

**Transition**

**Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:**

No comment

**C6 Pharmacy (and retail-only licence) sector and pharmacists**

**Pharmacy sector context**

**Future regulation of pharmacy business activities**

**Licence to carry out a pharmacy business**

**Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:**

No comment

**Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:**

No comment

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

No comment

**Question C22 Which option do you support?**

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?:**

Free market approach

**Detailed questions relating to Option 1**

**Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:**

No comment

**Question C25 - Are there ways in which Option 1 could be improved?:**

No comment

**Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:**

No comment

**Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:**

No comment

**Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:**

Yes

**Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:**

No comment

**Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:**

No comment

**Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

No comment

**Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:**

Exemption 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?:**

No comment

**Question C34 - Are there ways in which Option 2 could be improved?:**

No comment

**Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:**

No comment

**Other changes to pharmacy licensing requirements**

**Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:**

No comment

**Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:**

No comment

**Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:**

No comment

**Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:**

No comment

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply**

**authority, a pharmacy, or a wholesaler?:**

Exemptions should be available

## **Pharmacist and pharmacy worker authorisations**

**Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:**

No comment

**Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:**

No comment

## **C7 Retail sector**

### **Question C42**

**Do you consider the new scheme will have any significant impacts on retailers?:**

No comment

## **C8 Health practitioners (including pharmacists)**

### **Prescribers**

**Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:**

No comment

**Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:**

No comment

**Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):**

No comment

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

As it is currently

**Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:**

This seems to relate only to prescription medicines, the new system needs to be more flexible.

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

Exemptions are needed

**Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:**

No comment

**Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:**

No comment

### **Health practitioners (non-prescribers)**

**Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:**

Yes

**Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:**

Yes

**Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:**

No comment

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

DTCA should be permitted as it improves patient outcomes through greater awareness.

## Response ID ANON-DPZ8-G464-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on **2019-04-17 10:39:47**

### Submitter profile

#### What is your name?

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#### If you select DHB, please state service area:

Auckland

Pharmacist

#### If you select 'Other', please comment below::

Medical writer

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?

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):

### C10 Advertising sector

#### Question C52

#### Please provide any comments on the advertising requirements and enforcement tools.:

#### Question C53

#### Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

Advertising (ss 82–83): I strongly disagree with the advertising of prescription medicines (Category 1 medicines) to consumers. Advertisements of these medicines provide little context for their in a particular condition - what has the consumer tried; what has worked, what hasn't, what other meds are they taking, etc, etc. Years are spent educating health professionals on the step-wise approach to treatment - it would be HARMFUL to not explain this to patients. Patients need to be part of a shared-decision making process - they are meant to be the centre of our health system. Advertisements ARE biased and misleading- this is why ads for smoking are banned. Providing patients with snippets of information without a holistic approach to self-management is HARMFUL.

## Response ID ANON-DPZ8-G4KD-G

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 10:41:49**

### Submitter profile

#### What is your name?

**Name:**

Kate O'Connor

#### What is your email address?

**Email:**

#### What is your organisation?

**Organisation:**

Northern B HDEC

#### Submitter Profile (tick all that apply)

Consumer

Professional body (eg, Colleges, Pharmaceutical Society etc)

If you select DHB, please state service area:

If you select 'Other', please comment below;:

Trial ethics

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).:

I commend the Bill for springing off from some clearly articulated and protective ethical principles, particularly beneficence (do good), and non-maleficence (avoid harm). Alignment with international best practice is also very timely. In practice when ethical approval is being considered, weighing benefits and risks is very hard to do: especially in first in human trials where both are unknown. For trials of commercially sponsored pharmaceuticals, HDECs rely very much on SCOTT for peer review and reporting of adverse events to Medsafe. In the current unregulated environment however, HDECs are in a unenviable position with medical devices where the pool of expertise to provide both sufficiently expert and sufficiently independent peer review is small, while at the same time the commercial imperative is influential. Bringing the device sector into regulation is urgent, however I worry that the availability of expert risk assessment may still be under-powered. For this reason I think that a Precautionary Principle might also be articulated explicitly - essentially the regulator reserves the right to take discretionary decisions in the absence of strong scientific evidence. I also believe that the proportionality expressed in the Principles can flow through to the rules and regulations: higher risk activities need a higher level of scrutiny.

Are there responsibilities under the principles of ToW that should be included? Also Natural Justice?

#### 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):**

27 - Clinical trial. Definition appropriate and allows for emergent research designs such as comparative effectiveness or cluster randomisation designs or research within a Learning Health System.

34 - inclusion of software as a medical device. This is interesting and may have broad implications as we see more Machine Learning and AI. For example, is a patented algorithm that receives GP referrals of individual patients to hospital clinics or specialist services which assign patients to care pathways a medical device? Or is it Type-4? There are significant privacy and consent issues here and I think it may be very helpful indeed to bring medical software into regulation.

## **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):**

Thank you for including clinical trials in the definition of controlled activity

### **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:**

83(3) Advertising - there are likely to be guidelines in the new NEAC Standards for health research about advertising for clinical trials i.e. that a therapeutic benefit cannot be promised, or not exerting undue influence (e.g. of payment for participation). It will continue to be up to HDECs to approve advertisements for trials.

## **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):**

For clinical trials it will be necessary to grant licenses/permits to Principal Investigators but not Sponsors in order to preserve the necessary independence of the research and probity of the findings.

With respect to student/ postgraduate research, students are not "workers" at the University and I do not believe that students should be named as the responsible person (even though they may hold the IP rights, or share them with the commercialisation arm). This is going to cause a bit of confusion, but I think universities are going to have to do a bit more than currently with respect to ensuring that Post Graduate students are 'fit and proper' if they are to be named on the License, or intend doing things (such as taking muscle biopsies or injecting anaesthetic) not in their scope-of-practice. In HDECs currently students can be PIs - this is contrary to the accountability channels in universities in which supervisors are the person responsible.

## **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 confused about whether clinical trials will need a license or a permit as they are mentioned in both. Researchers will take whatever path offers least resistance. Proportionality may apply - permits for low risk activities/devices, Licenses for higher risk (e.g using the TGA risk classification).

## **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):**

HDEC approvals don't expire, but annual reporting required. Somehow we are going to have to link up extensions to licenses/permits to the HDEC approval, and have some way to join reporting of SAEs which indicate that the trial device is too risky to a 'suspension' of the license/permit pending a safety review.

### **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 think this may have an impact on Universities conducting clinical trials, and it will again be necessary to ensure that it is staff members/academics who are named as the responsible person and not post-graduate students.

## **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):**

This section is really good and gives the regulator powers to act in the public interest. Currently Medsafe has invited reporting of SAEs on trial devices, and it will be great to make this compulsory. HDECs can ensure that an SAE reporting pathway through to the regulator is expressed in research protocols.

### **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):**

Good to encompass work done by Recognised Authorities, noting that there may be issues with the way the FDA is approving devices under the 201 pathway.

## **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):**

Seems reasonable to line fees for review of medicine trials (SCOTT) up with the review of device trials. Charging commercial sponsors for HDEC review (cost recovery) has been talked about for a while but no serious work has gone into this yet.

## **B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments**

### **Subpart 1: Repeals and revocations (s 275)**

### **Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)**

#### **Question B33**

**Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):**

### **Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**

#### **Question B34**

**Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):**

## **B12 - B15, Schedules 1 - 4**

### **Schedules**

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):**

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):**

**Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:**

## **C2 Cell and tissue sector**

### **Product-based controls**

**Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:**

Yes

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

There may be a semantic difficulty related to different definitions of "Sponsor" as it is currently applied to the research setting and as it is being used in the TP Bill.

**Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:**

I think there is much to be gained by drawing on the present understandings with respect to the cultural importance of tissue derived from the Tissue Act for research. On the whole researchers 'get it'. HDECs have refined their expectations about tissue research for specified unspecified purposes which may be useful, but the whole approval regime for Tissue Banks is a bit patchy I'm afraid.

**Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:**

**Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:**

### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions.:**

**Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:**

## **C4 Clinical trial sector**

### **Question C16**

**Please provide any comments on the change in approach to regulating clinical trials.:**

HDECs have long awaited the joined-up thinking expressed here and look forward to working together with the regulator to bed the new regime down. Please note that we are currently experiencing a big bump in device trials applications, including first-in-human and permanent implantables, which is likely an attempt to 'get in' in advance of the regulatory regime. This in combination with gaps in injury compensation for commercial trials arising from the ACC Act, no integrated or central body reviewing SAEs (devices), and no independent scientific review like SCOTT means that the situation is deeply troubling for us presently.

I am aware that investigators are very wary of having a regulatory scheme like the TGA for research which will "slow them down", or "put us back 20 years".

Obviously the devil will be in the detail, but taking a proportional approach to risk is sensible so long as safety is the fundamental and underlying regulatory principle.

Please note that my comments are mine alone as an individual HDEC Chair and do not represent the collective HDECs view.

## **Question C17**

**Please provide any comments on the transitional arrangements for clinical trials.:**

## **C11 Patients, consumers and disabled people**

### **Unapproved medicines**

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

I think it's good, and may relieve what occurs occasionally at present whereby doctors get access to unapproved (unfunded) medicines for their patients through a 'research' approval and sometimes with arrangements with the drug company for compassionate continuation. HDECs are very aware that the research pathway is sometimes the only way patients can receive medicine that will help them: it's distressing though when the medicine that works in individual cases will not be available when the "research" is over.

**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**

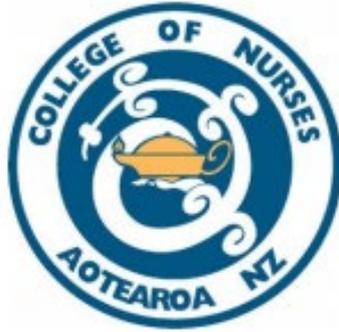
**Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:**

**Chapter D: List of consultation questions**

**Chapter A Question**

**Chapter B Questions**

**Chapter C Questions**



Submission on the Ministry of Health's Therapeutics  
Bill and Therapeutic Products Regulatory Scheme  
Consultation Document

April 2019

The contact person for this submission is:

Professor Jenny Carryer RN PhD FCNA (NZ) MNZM

Executive Director

College of Nurses (Aotearoa) NZ

[REDACTED]

PALMERSTON NORTH

[REDACTED]

# 1. Summary

This submission has been made on behalf of:

Organisation: College of Nurses (Aotearoa) NZ

**Email address:** [REDACTED]

Profile (tick all that apply):

Perspective

- Consumer                       Disabled person                       Māori                       Pacific peoples
- Other Professional Organisation

Health sector

- Professional body (eg, Colleges, Pharmaceutical Society etc)
- Health service provider (eg, Ambulance, Māori or Pacific health provider etc)
- Private hospital
- Pharmacy organisation
- District Health Board (DHB) - please state which service area: [Click here to enter text.](#)

## 2. The College of Nurses (Aotearoa) NZ

The College of Nurses (Aotearoa) NZ – “the College” is a professional organisation of New Zealand nurses from across all regions and specialties which aims for excellence in nursing practice and health care delivery by supporting nurses in their ongoing professional development.

We provide a leading voice for the nursing profession and professional commentary on issues which affect nurses and the health of the community we serve by developing strategic consumer alliances with the aim of creating 100% access and zero disparities in New Zealand health care.

The College was established in 1992, recognising that nurses as key members of the health care team work in diverse community and hospital settings delivering numerous health services to different population groups and cultures. The many challenges and complexities inherent in the current health environment demands a planned and tactical approach. The purpose of the College is to:

- Promote and facilitate professional development in clinical practice, nursing management, nursing education and research
- Monitor, comment and advise on consistency and outcomes of education for nursing practice
- Identify, examine and take action on issues of significance to nursing practice and the health of our community
- Disseminate information on issues of significance to nurses
- Initiate, promote and publish nursing and health related research
- Adopt a collegial relationship with other professional bodies.

One of our key aims is to provide a voice for the nursing profession as a whole, speaking out on issues that affect not only nurses but the health of our community. We monitor and influence policies and legislation and contribute to many committees.

This submission is the result of analysis undertaken by the College, internal consultation, and direct discussions with College members in leadership positions across the health sector. College members have also attended workshops facilitated by the Ministry of Health.

## 2. Submission

### 2.1 *General*

The Ministry of Health is seeking feedback on the draft Therapeutic Products Bill (the Bill) and the Therapeutic Products Regulatory Scheme which proposes to repeal and replace the Medicines Act 1981 to provide modern, comprehensive, and cost-effective regulation of therapeutic products in New Zealand.

Feedback from the College largely relates to:

- Interpretations and definitions which require clarification
- Scopes of practice and medicines lists

### 2.2 *Interpretation and definitions*

The College has a number of concerns about the definitions and meanings set out in section B4, Part 4 in relation to definitions and meanings. All definitions used in the Bill should have the meaning set

out in the *Interpretation* section even if the same definition or meaning is repeated in other sections of the Bill. The current approach is confusing for readers. In addition, some of the definitions provided lack clarity and are confusing. In particular:

- S38(4): *a prescription may be issued orally, in writing, or in any other form* – this is unclear. The responsibilities of prescriber and administrator would require close attention particularly for oral orders (does this mean verbal orders) and other forms of prescription.
- S41: Clarity is required in relation to standing orders and liability. If a registered nurse is the agent of the person who issues the standing order, are they also liable as an agent. Attribution of liability is explained at s239-241 but it is extremely difficult to follow the explanation.
- S43: the use of the term ‘non-wholesale’ is confusing. We understand the intention is to differentiate between wholesale and non-wholesale supply to enable the application of different controls. The College supports replacing the term ‘non-wholesale’ with the term *retail* since this is less confusing.
- The use of the term health practitioner worker is confusing and may be interpreted as including unregulated categories such as health support worker or health care assistant. The College proposes that the term ‘health practitioner worker’ be replaced with *health practitioner employee/contractor*.

### 2.3 *Scopes of practice and medicines lists*

The College supports the Bill’s intent to link prescribing authority to scopes of practice, rather than by regulation. We also support that responsibility for ensuring the competence of prescribers rests with the relevant responsible authority.

#### Medicines lists

In regard to medicines lists, registered nurses working in specialist roles find the lists are increasingly not fit for purpose as evidence and practice evolve over time. There are two distinct levels of prescriber within the registered nurse scope of practice which when updated will require reference to two distinct medicine lists. A preferred approach to medicine lists is for nurse prescribers to nominate medicines relevant to their specialty area that are within their knowledge and competence. Responsibility for ensuring the competence of registered nurses would sit with the Nursing Council of New Zealand.

Should the decision to be made to retain medicines list, the proposal for ‘logical groupings’ of medicines for the lists is not practical for registered nurse prescribing lists. The Nursing Council of New Zealand consulted extensively on medicines lists when they were introduced and the current restrictions in relation to route, dose, and preparation would make class grouping extremely challenging.

#### Access to category 2 and 3 medicines for registered nurses without prescribing authority

Enabling registered nurses without prescribing authority to supply to category 3 medicines to their patients is a welcome move, particularly for nurses working in schools (for example).

Similarly, the College supports the enabling of registered nurses without prescribing authority to supply category 2 medicines, provided they meet any requirements as determined by the Nursing Council of New Zealand.

To be useful, provision for a nurse to place a [Rural] Practitioner Supply Order for relevant category 2 and 3 medicines will be needed.

#### Registered nurse vaccinators

The College notes that the Bill provides an opportunity to remove outdated requirements in relation to nurse vaccinators. At present, Medical Officers of Health are required to authorise registered nurse vaccinators who have already completed a nationally approved programme to become an authorised vaccinator. We support the removal of the requirement for Medical Officer authorisation. Registered nurses practice independently and in collaboration with other disciplines and it is not appropriate for another discipline to oversee or approve the practice of nurses.

#### Unapproved medicines

The proposal to restrict the issue of special clinical needs authority for unapproved products to medical practitioners is inappropriate and should be extended to include nurse practitioners. Restricting this activity to medical practitioners, even for the initial consultation, is an unnecessary additional consultation for a patient when nurse practitioners have the same legal prescriptive authority as their medical colleagues. Nurse Practitioners therefore have equivalent ability in weighing the risks and benefits of products that are unapproved.

Other health practitioner prescribers should be able to prescribe unapproved products once a medical or nurse practitioner has issued a special clinical needs supply authority for that medicine for a patient.

#### At the request of another health practitioner prescriber

The College finds this phrase found mostly in section 61 confusing and it is unclear how this would work in practice. The phrase refers to the prescription of a medicine that is 'at the request of another health practitioner prescriber'. In general, this is an unusual provision since all prescribers should complete their own examination and assessment of a patient before making a clinical decision that includes provision of a prescription.

For registered nurses who are prescribers, the phrase is problematic. At present, registered nurse prescribers are able to provide a continuation prescription to a patient only if they have assessed the patient themselves and are satisfied that the patient requires continuation of the medication initially prescribed. However, 'at the request of another practitioner prescriber' the registered nurse may be required to issue repeat prescriptions to patients they have not assessed themselves. We are concerned that this provision could be used inappropriately. We are also concerned about the risk for registered nurses in relation to the issue of a prescription that is based on the clinical decision making of another practitioner. This appears to contradict safe practice.

#### Impact on the Nursing Council of New Zealand

While we acknowledge that the operational detail relating to most of the issues raised will arise in the regulations, the College notes the need to be mindful of the impact that extending monitoring requirements of registered nurse prescribing will have on the Nursing Council of New Zealand. Inevitably the cost of increased monitoring would need to be met by the profession via increased annual practising certificate fees that apply to all nurses whether or not they have prescribing rights.

### 3. Summary

The College looks forward to engaging further with the Ministry of Health on the development of the Bill and the regulations arising consequent to the Bill.

A handwritten signature in blue ink, reading "Jennifer B. Carryer". The signature is written in a cursive style with a large initial 'J'.

Professor Jenny Carryer RN PhD FCNA(NZ) MNZM  
Executive Director  
College of Nurses Aotearoa (NZ)

## Response ID ANON-DPZ8-G46Z-H

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 10:58:35**

### Submitter profile

#### What is your name?

**Name:**

Helen Hamer

#### What is your email address?

**Email:**

#### What is your organisation?

**Organisation:**

Helen Hamer & Associates Ltd.

#### Submitter Profile (tick all that apply)

Consumer

#### If you select DHB, please state service area:

Nurse, Other health practitioner (please comment)

#### If you select 'Other', please comment below;:

Peer support - a person with lived experience of Mental health and addiction

NGOs, Other (please comment)

#### If you selected 'Other' please comment;:

Joint submission on behalf of Changing Minds NGO & Helen Hamer Nurse Consultant and contractor in Mental health and addictions area

## C10 Advertising sector

### Question C52

#### Please provide any comments on the advertising requirements and enforcement tools.:

DTCA of psychotropic prescription medicines continues to be a contentious issue:

Impact of Advertising:

- The pharmaceutical industry spends hundreds of millions of dollars each year for a return on profit margins and invest heavily in DTCA because they know consumers exert huge and effective pressure on prescribers. When prescribers feel pressured to support the patient's choice, this may limit full disclosure about the best treatment options available e.g. a cheaper generic version of the advertiser's product, or alternatives such as 'prescribing' a talking therapy approach. The risk to the patient is that they will be given medicines they don't need at that time.
- Pharmaceutical advertisers' interest is in promoting health worries or risks amongst the population, yet reluctant, for commercial reasons, to confront any misconceptions about their products yet promote presumptions about their products based on uncritical biases in the claims they make in their adverts.
- Commercially-driven advertisements employ the architecture of marketing strategies that carefully crafts the message to sell their products. This strategy can perpetuate false or misleading information in an advertisement, such as misrepresentation or misunderstandings about the origin and cause of mental distress/illness (i.e. depression is a chemical imbalance in the brain that can be corrected with drugs).
- Recently in New Zealand, a second-generation anti-psychotic medication in injectable form was advertised in the mainstream media e.g. television, non-medical journals and magazines, and at bus stops. The advertisements did not depict any additional or alternative therapy. These advertisements include on-screen endorsements by healthcare professionals. The life-size posters at bus stops made emotional depictions in their caption 'When you have schizophrenia, people may nag you to take your pills and that can lead to conflict'. Risks and side effects required readers to go to a website of the pharmaceutical company.

Impact on the patient

- As consumers we enjoy free-expression, choice and rely on openness about products available. However pharmaceutical products are different from food or clothing. Proper or improper use of pharmaceuticals can lead to harm and the safety of the patient therefore relies upon the strong relationship between patient and prescriber.
- With persuasion by adverts, people may seek access to the medication from other unreliable and risky sources e.g. order on the internet. Drugs acquired through alternate means raises concerns about whether the medication is what it is purported to be or a dangerous substitute; whether it is appropriate for the consumer even if it is as advertised (as there is no prescription involved); the dangers of injecting it incorrectly; the risk of overdose; polypharmacy; and where and how the person disposes their used needles. This increases a service user's risk of harm exponentially.

Impact on the therapeutic relationship:

- Traditionally, health practitioners' decisions about treatment were accepted by patients without question or discussion. The rise of the knowledgeable consumer-citizen and a democratisation of how information about medicines is available has resulted in patient's expectations that they will be informed of uncertainties about products marketed in the media and what the alternatives may be. Further, both and/or prescriber and patient may believe that they will have to rely on psychotropic medication long-term (often in long acting injectable form). Also, individuals can become dependent on the medications as the only treatment alternative, have difficulty reducing or stopping the medication or are too daunted or defeated by the idea, usually due to the side effects themselves.
- The risks associated with DTCA (as above) are amplified when dealing with vulnerable populations, for example people with serious psychotic disorders such as schizophrenia and concerns for the overprescribing of this medication for Maaori and Pacifica.
- Such direct marketing further relies on the health practitioner/prescribers to give a full account of all side effects etc. particularly psychotropics, whose side effects are toxic and known to reduce life expectancy. Therefore, in practice some prescribers are reluctant give a full disclosure of the risks and therefore informed consent is limited. However, when positive results have been the emphasis of the advertising it provides conflicting views that have the potential to rupture the therapeutic alliance between the patient and health practitioner in the face of the promises of good health outcomes by the commercial drug companies.

In summary, pharmaceutical advertising is strictly for profit: The argument for DTCA pharmaceutical advertising is that it provides helpful and empowering information to consumers, but the intent of any advertiser is to sell something, not to charitably educate their audience. For accurate, unbiased information on medication, consumers and physicians can turn to peer-reviewed literature and international clinical guidelines. If New Zealand is unable to repeal DTCA, we have made some suggestions to make it a fairer and safer process in section C53.

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#### 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 power and sophistication of the pharmaceutical industry cannot be underestimated. Those who seek to counter it in the public interest need more than commitment and energy... In the absence of strong advocacy in the public interest, the pharmaceutical industry will continue to set the tone of public debate." (Rt Hon Helen Clark, Minister of Health 1989 -1990)

The above warning about DTCA and Big Pharma is ever present - DTCA of prescription-only medication is permitted only in the United States and New Zealand. In 2008 the European Parliament opposed DTCA, in accordance with the 'precautionary principle' with most countries citing public safety as their rationale for banning the practice. The UK had previously prepared contingencies for the adoption of DTCA; we believe that New Zealand can take some lessons and recommendations from the UK rationale and build in the following safeguards for DTCA of selected items, specifically psychotropic medication:

- That New Zealand develop a non-partisan organisation that has no vested interest for or against DTCA of prescription medicines. This agency will have a neutral interest in promoting the honesty, reliability and transparency of claims that drug manufacturers make to people who are "ill... or who may be persuaded they are ill".
- If we do not ban DTCA in New Zealand, then we can expect that the pharmaceutical companies will increase their opportunity to market their products even more aggressively and create more costly advertising that is persuasive and emotive. If so, a non-partisan agency can provide balanced information to allow

patients and prescribers to make reasonable judgments and health decisions about the products advertised

- That all advertisements are vetted before distribution to the population such as the quality of the description of the product; that it includes an honest disclosure of adverse effects; provides information about the relative efficacy of the product and consideration of, and price evaluations for, alternative cost of generic products

- Adverts need to be explanatory rather than purely slogans, and linked to the NZ Clinical Guidelines/NICE guidelines (UK) to promote unbiased information on the prescribing of pharmaceutical products for both patients and prescribers

In summary, this submission supports the following recommendations by Toop, et al. (2003) Report to the Minister of Health supporting the case for a ban on DTCA -

- There is convincing evidence, supported by public and professional opinion, to justify a ban of direct-to-consumer advertising of prescription-only medicines in New Zealand.

- There is an urgent need for increased provision of comprehensive and readily accessible independent consumer information.

- Recommendations That the New Zealand government introduce regulations and /or legislation to prohibit the advertising of prescription medicines directly to the public, through print and broadcast media or any other means.

- That the Government establishes an independent medicine and health information service free of commercial interests

# Response ID ANON-DPZ8-G4FZ-1

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 11:33:25**

## Submitter profile

### What is your name?

**Name:**

Teresa Taylor

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[REDACTED]

### What is your organisation?

**Organisation:**

Pharmaco NZ 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?

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).:

Pharmaco supports the introduction of replacement legislation for the Medicines Act 1981.

Pharmaco is supportive of the general design of the new regulatory scheme. We acknowledge that it must manage risk, be efficient and cost effective, be flexible, sustainable, supporting of New Zealand's trade and economic objectives and encourage safe consumer access to medicines.

We support the inclusion of medical devices and cell and tissue therapies and also support the inclusion of Type 4 products to futureproof the Act. We also support a 5 yearly review of the Act and the suggestion that the Audit Office is likely to audit the new Regulator.

More information is required around the governance of the new Regulator and the entity form of the Regulator. We understand that there will be no consultation on the entity form and that there are a number of principles that need to be taken into consideration when deciding on the particular form but the final form of the entity will have a huge impact on the Industry in regards to accountability, performance and financial implications. It is important for the industry to understand what KPIs the Regulator will be measured against.

We do not support the form being a Crown entity but would support the Regulator being part of the Ministry of Health or a department of.

We are also conscious that this bill gives the new Regulator substantial new areas of responsibility and are concerned that regardless of the form that it is

considerably better resourced than the current regulator to enable it to deliver the content of the bill.

Pharmaco supports the separating out of natural products and the development of a new Natural Products Bill. There is a need to have a clear delineation between natural health products, OTC medicines and prescription medicines and the provision of allowable claims for natural health products.

Pharmaco agrees with the purpose and principles of the Bill.

## **B4 Part 2 of the Bill: Interpretation**

### **B4 Part 2 of the Bill: Interpretation**

#### **Question B2**

**Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50):**

Categorisation

We request that categorisation be harmonised along the lines of the Australian scheduling, being Schedule 1 for general sale, Schedule 2 for pharmacy only, Schedule 3 for pharmacist only and Schedule 4 for prescriptions. It is possible that there needs to be a new category created for controlled drugs.

MODA

There are still some rub points between MODA and the current Meds Act which could continue to be an issue with this new scheme eg; scheduling of Controlled Drugs eg; C5, B3 which differs from the scheduling in Australia and means that labelling cannot be completely harmonised between AU and NZ and will require local overlabelling.

Also the requirements around the Controlled Drugs register in MODR are completely outdated and should enable more up to date methods of recording of transactions.

AMI v API:

There is no need to create a new acronym here when there is a globally accepted term for usage and we suggest that all references in the bill to AMI be replaced with the globally used API.

## **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):**

Authorisation for importation of an approved product

Section 52

Although prevention of parallel importation is intended by the Act it needs to be clear under what circumstances someone could get authorisation to import an approved product (when the sponsor does not give their permission) and what the responsibilities of that person will be in respect to the imported product ie; safety issues, recalls. PV etc.

An example of this is the current situation where wholesalers are importing approved products which have been removed from the NZ market due to a change to funding status and yet the sponsor company is unaware of these products being imported by a third party.

Medical device regulation

We note that substantial change is proposed to the way medical devices will be regulated. We are keen to hear how the Regulator will resource for all of this new work and we are also keen to ensure that costs associated with the regulation of medical devices are not transferred to the cost silo relating to the regulation of medicines.

Fees for service, Regulator accountability and key performance indicators need to have a higher priority than has currently been given, in our opinion, in this proposed legislation.

Device and medicine delineation

We are keen to see legislation that clearly defines medical devices and medicines, and are not satisfied that the current draft will resolve the issues that occur on a regular basis around this. We would like to suggest that where there is a discrepancy or disagreement over device/medicine delineation that international standards apply.

### **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):**

Importation of unapproved medicines

Health professionals should be the only ones allowed to import unapproved medicines and should do so by an SCNSA. We also agree that medical practitioners

should be the only ones allowed to issue a SCNSA and that ongoing prescribing for that patient should remain with that or another medical practitioner to ensure that the continued use of the product is appropriate.

We would however like some clarity on how SCNSAs will be managed and controlled.

1. The consultation document states that:

- Unapproved medicines must be listed on licences to import – will this be product specific or will this activity be allowed for any medicine and medical device?
  - Stockpiling will be allowed in appropriate places. How will this be managed?
2. How will the Regulator know what is being imported and in what quantities?
  3. What is the responsibility of the importer in relation to safety aspects ie; recalls, PV, overseas safety issues?
  4. Who will be responsible for the ongoing monitoring for standing orders and SCNSAs?

We feel that there needs to be further discussion and clarity around how the importation of unapproved medicines is to be managed and controlled. Otherwise we could see an influx of unapproved medicines with few or no controls in place.

### **Subpart 3: Authorisations (ss 56–80)**

#### **Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):**

Importation of unapproved medicines

1. What is the responsibility of the importer in relation to safety aspects ie; recalls, PV, overseas safety issues?
2. How will the Regulator know about what unapproved medicines/devices have been imported into NZ?
3. Will there be a need to report imported unapproved products to the Regulator as is the current case for S29s?
4. What about the company who owns the medicine/device – there will be no visibility for them and no means of traceability.

Section 59

What would be the circumstances for pharmacists to provide wholesale supply?

#### **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 :**

Importation of unapproved medicines

1. What is the responsibility of the importer in relation to safety aspects ie; recalls, PV, overseas safety issues?
2. How will the Regulator know about what unapproved medicines/devices have been imported into NZ?
3. Will there be a need to report imported unapproved products to the Regulator as is the current case for S29s?
4. What about the company who owns the medicine/device – there will be no visibility for them and no means of traceability.

SCNSA

What form will this take? Will Regulator have any visibility as to how often SCNSAs are being issued and therefore how often unapproved products are being prescribed and imported?

Off label use is problematic and difficult to control. Encouragement of off-label use will increase PV requirements for the sponsor if the off label use is reported to the company?

#### **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):**

Importation of unapproved medicines

1. What is the responsibility of the importer in relation to safety aspects ie; recalls, PV, overseas safety issues?
2. How will the Regulator know about what unapproved medicines/devices have been imported into NZ?
3. Will there be a need to report imported unapproved products to the Regulator as is the current case for S29s?
4. What about the company who owns the medicine/device – there will be no visibility for them and no means of traceability.

Reference to an animal as a patient could be confusing.

Medicines and devices approved for humans may not necessarily be approved for use in animals.

#### **Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

Personal Importation

We applaud the Regulator's intent to severely address the issue of parallel importing of approved product and also the desire to clamp down on counterfeit product entering New Zealand.

Pharmaco supports regulation to stop the personal importation of prescription medicines by post and/or courier. We also believe that this restriction should apply to over the counter medicines. Personal importation by post of OTC medicines will not prevent importation of unadulterated, counterfeit or unapproved medicines.

It is unreasonable to assume that consumers will be able to understand product categorisation and investigate whether products are registered in New Zealand or not. This is compounded by the fact that many foreign medicines are labelled non-prescription and are in fact prescription in New Zealand.

It is also unreasonable to believe that customs and border authorities will have the resource or in-depth knowledge to distinguish between foreign OTC labelled medicines and items that are prescription only in New Zealand, many of which could come in the same package.

We accept and agree that people visiting New Zealand should be allowed to bring in their own medication prescribed by doctors in their home country or products that they have purchased in their own country and for their personal use only, not exceeding 3 month's supply.

A more robust, enforceable regulation would be to publicise the fact that all medicines for personal use must be brought in to New Zealand in person, otherwise they must come through regular channels where a sponsor is known and can be made to take responsibility for the quality and recall of their product should this become an issue.

**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).:**

Transition of products already in the process

We feel that any approvals started under the existing regulations should continue to be completed under those regulations. We also feel strongly that the existing fee structure should apply for all product applications started under the existing legislation.

If this is not practical or possible, then we would seek a credit of fees paid under the old regulations against fees charged for the new regulations.

#### Major and minor changes

Pharmaco supports the concept of major and minor changes, but wishes to make comment on the proposed process for self-assessable changes. We support annual or 6-monthly reporting of self-assessable changes, however we believe that a dual option is preferred with manufacturers choosing to submit either ongoing notifications or a compulsory 12 month notification. The 12 month notification may be more desirable where manufacturers have a wide range of products and can schedule notification updates.

#### Numbering of majors

We have a real concern that every change will require the issue of a new number. We believe this could result in substantial confusion and unworkable situations.

We see no advantage in giving every change a new number as there is no link back to the original and a potentially impossible traceability situation.

We also foresee considerable problems when three or four majors may come onto the market at the same time and there is variable approval and numbers will no longer be in numeric order.

It is also important that there is clear definition given to what constitutes a major change.

We feel that the current system is mostly working well and the proposed changes are retrograde for all parties concerned. Obviously there will need to be very clear definition around what constitutes a major and what constitutes a new registration, but essentially replication of the existing system would appear to be the most pragmatic and workable solution.

There is no desire in this instance to replicate the Australian model, which is fraught compared to ours.

#### Fees

Annual licensing fees could severely restrict the availability of medicines in New Zealand given the costs/market size ratio. If fees are to be annualised, we would suggest an exemption for any product that is not being sold. This allows sponsors the flexibility to prepare for a market with a wide range of variance and get registration for a wide range of variants, but not be debilitated by large annual fees for the range when a very small number of that selection may ever get to market. This issue applies to both prescription and non-prescription medicines. This is particularly pertinent when sponsors wish to bring product in or register product with the idea of putting it up for PHARMAC tender.

#### Timelines for approvals

We believe there should be legislated timeframes for product approvals and this should be mentioned in the Act. The detail could be in the Regulations but accountability for the Regulator to have clear timeframes around product approvals should be mentioned in the Act.

All parties will benefit from total transparency around the timeline required for regulatory processes. We would suggest the adoption of the European system of declared maximum timeframes, with a mutually agreeable "clock stop" by either party to make the registration process as transparent as possible.

We believe that since the fee model to be chosen will most likely be full cost recovery, it is imperative the bill includes sections on the consequences of poor performance for the Regulator, including compensation.

#### Transparency

Pharmaco approves of increased transparency that will lead to improved patient safety and quality. We do have a concern however, that the publication of approvals in some detail has a number of attendant problems.

The first of these is that it sets an expectation of supply and companies are often put under considerable pressure by practitioners and, in some cases, the public,

when news breaks of a new entity approval. It is understood in New Zealand that supply is dependent on numerous factors, including commercial viability, PHARMAC funding, ability to provide adequate pharmacovigilance and monitoring and simply the size of the available market. More discussion is required around the rules regarding blanket publication of all data.

The second major concern is the protection of intellectual property and sensitive business information. It appears the Regulator has in the past been put under pressure with Official Information Act requests. There needs to be consideration given to developing a more robust process around these types of requests.

#### Transitional arrangements

Any approvals started under the existing regulations should continue to be completed under those regulations. This comment also extends to the fees.

We do not support transitional fees. If the application was submitted before the new legislation is implemented than the application should continue to be assessed under this fee.

We would suggest that following royal ascent and in the early part of the 2 year transition phase, that all sponsors be required to update the status of their approved medicines. This would prompt sponsors to remove products from the database which are about to lapse or for which there is no intention to continue to maintain registration.

#### Question B14

##### **Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):**

108 Grounds to cancel approval

(a) the quality, safety, or efficacy or performance of the product for the purposes for which it is used is unacceptable should read "becomes unacceptable"

We note that this section allows the Regulator to notify a sponsor that an application or a registration has been cancelled, but does not require them to consult. We feel this is unjust and would request an addition that says prior to notification the Regulator and sponsor will discuss any proposed cancellation.

#### 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):**

Licence for Importation of unapproved medicines

Clarification is sought around wholesale permits allowing blanket importation of unapproved product (essentially as currently exists under S29 and S25). It may be overly cumbersome to have the permit list each individual instance of importation of an unapproved medicine, however there needs to be full traceability of imported unapproved medicines by the Regulator for safety reasons, particularly should a recall be necessary.

We would appreciate further clarification on exactly how the Regulator intends to manage this form of permit. One solution may be to use technology and for the importer to record in a database details of their importations, such that all importations can be traced if necessary.

#### Subpart 3: Obligations of sponsors (ss 116–119)

#### Question B16

##### **Please provide any comments on the sections covering sponsor obligations (ss 116–119):**

119 Sponsor not responsible for approved products imported without consent

This should include and extend to, products imported for personal use.

Pharmaco is supportive of the new responsibilities which have been added to sponsors in this draft bill. We also support the removal of a separate hawkers' licence requirement.

#### Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)

#### Question B17

##### **Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122):**

We suggest the removal of the word "declined" from 121:3 because there should not be protection for a declined application.

We do not agree with Section 122 (A) unless the regulator has undergone consultation with the sponsor giving a reason for the disclosure, a timeframe for the disclosure and an opportunity to appeal against the disclosure.

We do not agree with Section 122 (c) if the information in the public domain has entered without the sponsor's permission.

### **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 fully support the move to ensure that sponsors, licensees and responsible persons must be New Zealand-based and must have knowledge of the industry (no

longer suitable to have lawyers and accountants as licensees).

#### **Question B19**

**Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):**

We would like further clarification around the issues of mergers and acquisitions between companies and the effect of this on licensing. We also seek clarity on what happens if a “responsible person” leaves the company. Is the licence transferable?

We are concerned that there is a blanket ability of the Regulator to cancel an approval under “any other criteria”. We feel that this principle should be qualified in the bill.

#### **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):**

Importation of approved products

Pharmaco has concerns about the proposal for an approved product to be imported into NZ without the sponsor's knowledge. Although according to the proposed legislation the sponsor would not be responsible (s119) when an approved product is imported by another “authorised” party, the sponsor should be made aware of the availability of the product in the country so they can record batch numbers for safety reasons.

Patient information

There is an opportunity to improve patient access to medicines information using QR codes and reference URLs far more extensively than is currently encouraged by the regulator. We would encourage in-depth discussion around the regulations underneath the technology principle that give the industry the opportunity to safely and efficiently improve customer education.

#### **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):**

We believe there should be more clarification/discussion in the Bill as to who are considered to be senior managers within a company.

The definition of a senior manager seems to be based on their ability to exercise significant influence over the management or administration of another person, whether it be directly or through 1 or more interposed entities.

Considering the penalties that can be imposed on a senior manager there are obvious concerns about personal liability which could impact on a large number of “managers” within the industry.

### **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 Form of the Regulator

Pharmaco does not support the establishment of a Crown health entity. Whilst we recognise that there are obvious challenges to the current form of the regulator, we believe that some modification to the current model that allows a somewhat higher degree of autonomy would be the preferred option.

The key elements to be considered for the form of the Regulator are cost, resourcing, flexibility, capability and review processes. We feel strongly that there would be considerable increase in cost to establish a Crown health entity and to run it on an ongoing basis. There is also major concern about the ability to review processes, particularly when there is a high degree of separation from democratically elected officials.

Pharmaco supports the move for the Regulator to provide a comprehensive post-marketing monitoring programme to collect information about the safety and quality of medicines and medical devices. However this should not come as a high cost to the industry.

Any requirements for this programme should be aligned to current international practice.

Recall orders should apply to Pharmacists also to ensure they are “motivated” to respond to recalls.

## **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):**

Pharmaco believes strongly that reviews of not only process, but content should be available to persons and sponsors.

Pharmaco also believes the District Court is an entirely inadequate adjudicator for all decisions and that persons must have the ability to appeal to the High Court given the broad powers of the bill and the substantial penalties it seeks to impose.

The merits review process

Pharmaco does not believe it is acceptable for the Regulator to appoint all members of any review committee. We do agree with the "expertise" parameter suggested in the bill and also the inclusion of a lawyer. We contend, however, that a three person committee in many cases will be inadequate to get a broad range of skills necessary in many instances. Again we reiterate that the District Court is not a suitable endpoint for an appeal and strongly believe the High Court to be appropriate in this instance.

There should be a timeframe identified from the application for review until the panel's decision ie; perhaps 90 working days?

TGA appeals process and section 60

We believe there are many elements of the TGA appeals process which could be incorporated into the New Zealand bill. These include persons being given 90 days to give notice in writing to the Minister to request reconsideration of a decision and that the Minister has 60 days to respond in writing, including a statement of reasons (findings, reference to evidence and reasons for the decision) to the person whose interests are affected. It is important to note that if the Minister upholds his decision there is then the opportunity to have that decision reviewed by the administrator of an appeals tribunal.

## **Subpart 5: Administrative matters relating to the regulator (ss 205–222)**

### **Question B28**

**Please provide any comments on the administrative matters relating to the regulator (ss 205–222):**

We accept the need for the Regulator to be able to share information with overseas regulators but believe these provisions need to be supplemented with stronger safeguards regarding distribution of shared information, particularly in relation to confidential information, intellectual property, patent information and in some cases, copyright. We are concerned that s209-4 refers only to "appropriate protections" without detailing what these are and no consequence or appeal process should these provisions be abused or inadequate.

Resourcing for Technology

We do wish to express considerable concern about the technological resourcing of the current Regulator and believe that substantial investment will be needed, particularly given the broader scope of the new Regulator, if they are to meet the aspirations of the new bill. We do not believe that the current systems are capable of being simply scaled up and would support a more modern, more easily accessible, more easily interrogated data platform that will allow improved patient safety and monitoring of medicines.

## **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 would suggest that the words "wilfully" and "recklessly" be added to the definitions list at the beginning of the bill with the appropriate legal definition attached.

We are concerned that the Regulator may not be adequately resourced to carry out and prosecute offenders under the new legislation. We would like to see a structure proposed as to how the Regulator intends to administer this part of the bill – for instance will there be a division or department set up that deals with prosecutions and warnings?

### **Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**

#### **Question B30**

**Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):**

**Subpart 6: Infringement offences (ss 249–255)**

**Question B31**

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):.

**B10 Part 8 of the Bill: Administrative matters (ss 256–274)**

**Question B32**

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):.

**B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments**

**Subpart 1: Repeals and revocations (s 275)**

**Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)**

**Question B33**

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):.

**Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**

**Question B34**

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):.

**B12 - B15, Schedules 1 - 4**

**Schedules**

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):.**

Please refer to my comments under B27.

**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?:**

## Response ID ANON-DPZ8-G46T-B

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on 2019-04-17 11:53:13

### Submitter profile

What is your name?

Name:

Catherine Orr

What is your email address?

Email:

What is your organisation?

Organisation:

St John

**Submitter Profile (tick all that apply)**

Health service provider (eg, Ambulance, Māori or Pacific health provider etc)

If you select DHB, please state service area:

Other health practitioner (please comment)

If you select 'Other', please comment below;:

Paramedic

NGOs

If you selected 'Other' please comment;:

**Next steps after the consultation**

**Executive summary**

**Chapter A Key features of the new regulatory scheme (A1 - A5)**

Chapter A (A1 - A5)

Question A1 - Do you support the general design of the new regulatory scheme for therapeutic products?

Support

**B3 Part 1 of the Bill: Preliminary provisions**

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

**B4 Part 2 of the Bill: Interpretation**

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

**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 :**

St John supports health practitioner prescribers supplying, prescribing, administering and dispensing medicines and issuing standing orders. St John also supports changes to the Health Practitioners Competence Assurance Act (HPCA Act) which would specify that scopes of practice may include the authority to prescribe and supply medicines, and supports the simplification of the process to add or change a health practitioners' authority to prescribe.

Currently certain paramedic qualifications include training to administer and supply medications in the community, for example the post-graduate Community and Remote Paramedicine paper (PARA 808) offered by Auckland University of Technology. St John is currently working on a strategy to formalise the Extended Care Paramedic (ECP) scope of practice, which would enable specific paramedics with post-graduate education to manage patients with low acuity conditions in the community, with the aim of enabling patients to access care closer to home, minimising unnecessary transports/referrals to emergency departments and supporting primary care services in rural areas with known workforce gaps.

It is envisaged that prior to, and shortly following the registration of paramedics under the HPCA Act, Extended Care Paramedics would administer specific medicines to patients with low acuity conditions under standing orders issued by medical practitioners employed by ambulance services. St John strongly supports personnel who use standing orders being permitted to supply (as well as administer) medicines contained within standing orders. The ability for Extended Care Paramedics (as an example) to supply specific medications included in standing orders would be highly beneficial in removing some of the barriers to accessing appropriate care for patients.

St John supports health practitioners being able to supply category 3 (pharmacy) medicines that are within the practitioner's scope of practice.

St John supports the proposed approach for establishing a new or changed authority to prescribe. Following the registration of paramedics, St John would support a scope of practice being developed for specially-trained paramedics (for example, Extended Care Paramedics), which includes the ability to prescribe. The ability of paramedics with specific training to prescribe a limited number of medicines relevant to out-of-hospital and urgent primary care would even further reduce barriers to care which some patients experience, especially patients who do not have access to transport, cannot afford to see their usual health professional or who live rurally and thus find it difficult to access primary care or pharmacy.

Provision for specially trained paramedics to prescribe would also be helpful in the aged care context. Currently, registered nurses and other health workers in aged care facilities can only administer a limited number of medicines. As a result, an ambulance is frequently called to treat the patient and while paramedics can administer some medicines using standing orders, paramedics cannot supply or prescribe medicines for health workers in aged care to subsequently administer to the patient.

**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:**

St John personnel currently administer medicines under standing orders issued by the St John Medical Director. Should further consultation occur on regulations around the requirements for standing orders, St John would appreciate the opportunity to provide feedback.

St John supports section 71, which gives personnel working under standing orders the ability to supply a prescription medicine under an authorised standing order. Because ambulance personnel already administer medicines under standing orders, St John strongly supports the ability for personnel working under standing orders to also supply medicines. Section 71 would be particularly helpful to the proposed establishment of Extended Care Paramedics within the ambulance/health sector, whereby Extended Care Paramedics would be required to supply short courses of medicines under standing orders.

**Subpart 4: Other offences (ss 81-94)**

**Question B12**

**Please provide any comments on the offences created in sections 81–94:**

**B6 Part 4 of the Bill: Product approval**

**Subpart 1: Approval of products (ss 94–113)**

**Question B13**

Please provide any comments on the sections covering product approval requirements (ss 94–104).:

**Question B14**

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).:

**Subpart 2: Approval-exempt products (ss 114–115)**

**Question B15**

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).:

**Subpart 3: Obligations of sponsors (ss 116–119)**

**Question B16**

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:

**Subpart 4: Protection of active ingredient information about innovative medicines(ss 120–122)**

**Question B17**

Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).:

**B7 Part 5 of the Bill: Licences and permits**

**Subpart 1: Licences (ss 123–130)**

**Question B18**

Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).:

**Question B19**

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).:

**Subpart 2: Permits (ss 131–135)**

**Question B20**

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).:

**Subpart 3: Provisions applying to licences and permits (ss 136–151)**

**Question B21**

Please provide any comments on the sections applying to licences and permits (eg, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).:

**Question B22**

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).:

**Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**

**Question B23**

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).:

**B8 Part 6 of the Bill: Regulator**

**Subpart 1: Regulatory powers and functions(ss 160–182)**

**Question B24**

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

**Subpart 2: Investigative powers (ss 183–196)**

**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196):.

**Subpart 3: Offences relating to regulator(ss 197–199)**

**Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

**Subpart 4: Review of regulator's decisions (ss 200–204)**

**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

**Subpart 5: Administrative matters relating to the regulator (ss 205–222)**

**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):.

**B9 Part 7 of the Bill: Enforcement**

**Subparts 1 and 2: Enforceable undertakings(ss 223–232)**

**Question B29**

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):.

**Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**

**Question B30**

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):.

**Subpart 6: Infringement offences (ss 249–255)**

**Question B31**

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):.

**B10 Part 8 of the Bill: Administrative matters (ss 256–274)**

**Question B32**

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):.

**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 per question B7 (ss 61-64), St John supports the proposed changes to the Health Practitioners Competence Assurance Act to include prescribing rights within a scope of practice.

**Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**

**Question B34**

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):.

## **B12 - B15, Schedules 1 - 4**

### **Schedules**

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):**

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):**

**Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:**

## **C1 Medicines (excluding cells and tissues) sector**

### **Product-based controls**

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):**

**Question C2 - Please provide any comments on the approach for medicines categorisation (classification):**

St John supports a classification system that enables wider access to specified medicines, particularly in the out-of-hospital setting, and clarification on which classes of health practitioner can perform specified activities for each medicine.

Current legislation does not adequately cover the practical medicines requirements of providing emergency ambulance services. For example, there is a subgroup of medicines that we need to access and cannot, because they need to be individually prescribed. An example is 100ml sodium bicarbonate, used for the treatment of release syndrome following a person being trapped under a weight. We cannot access the 100ml solution at present because it is not a registered medicine, therefore it cannot be supplied to St John without a doctor writing a prescription for an individual patient. As a result, we carry ten 10ml ampoules and draw them up individually.

As part of the Therapeutic Products Bill to facilitate the use of medicines in the emergency ambulance setting St John would advocate for provision in legislation that enables:

- Small volumes of controlled drugs to be carried on the person of, vehicle of or first aid kit of a contracted provider of road emergency ambulance, or air emergency ambulance services, for the purpose of providing immediate access to those drugs to enable the management of life-threatening conditions, and conditions that create distress (for example pain).
- Small volumes of prescription medicines to be carried on the person of, vehicle of or first aid kit of a contracted provider of road emergency ambulance, or air emergency ambulance services, for the purpose of providing immediate access to those drugs to enable the management of life-threatening conditions, and conditions that create distress (for example nausea).
- Non-registered medicines to be supplied to a contracted provider of road emergency ambulance, or air emergency ambulance services, on the request of a registered medical practitioner.
- Small volumes of non-registered medicines to be carried in the vehicle of or first aid kit of a contracted provider of road emergency ambulance, or air emergency ambulance services, for the purpose of providing immediate access to those medicines to enable the management of life-threatening conditions.

While the hospital schedule of pharmaceuticals does not fall under the regulatory scheme for medicines and is a mechanism administered by Pharmac, we ask that this be considered alongside the classification of medicines.

St John is currently implementing the National STEMI pathway, where paramedics can administer fibrinolysis in the community setting. This means that these clot-busting medications can be given up to 60 minutes sooner than if the patient was first transported to hospital, significantly improving patient outcomes. Currently one of the key fibrinolytic medicines, tenecteplase, is classified as a hospital schedule pharmaceutical, which creates regulatory challenges for DHB pharmacists and requires special Ministry permission to be used in the out-of-hospital setting.

St John recommends doing away with the hospital schedule. If a medication is safe to be administered in hospital, it is safe to be administered by trained paramedics in the community.

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:**

**Question C4 - Please provide any comments on the approach to post-market controls:**

### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions:**

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

## **C2 Cell and tissue sector**

### **Product-based controls**

**Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:**

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.:

Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues.:

Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.:

#### Activity-based controls

Question C5 - Please provide any comments on the manufacturing-related definitions.:

Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:

### C3 Medical device sector

#### Question C11

Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

#### Product-based controls

Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:

Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:

Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:

Question C4 - Please provide any comments on the approach to post-market controls.:

Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:

#### Activity-based controls

Questions C5 - Please provide any comments on the manufacturing-related definitions.:

Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:

### C4 Clinical trial sector

#### Question C16

Please provide any comments on the change in approach to regulating clinical trials.:

#### Question C17

Please provide any comments on the transitional arrangements for clinical trials.:

### C5 Wholesale sector (including importers and exporters)

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].

#### Licence to wholesale

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

#### Hawker's licence

Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:

#### Transition

Question C15 - Please provide any comments on the transition arrangements for regulated activities involving medical devices.:

### C6 Pharmacy (and retail-only licence) sector and pharmacists

#### Pharmacy sector context

#### Future regulation of pharmacy business activities

## Licence to carry out a pharmacy business

### Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

St John would like to see greater flexibility around wholesale supply of medications. As an example, Wa kato DHB currently will not supply St John with tenecteplase for STEMI patients in the community as we are an external, third party organisation and they don't have a wholesale licence. Allowing pharmacies (such as hospital pharmacies) that do not have a wholesale licence to supply medicines to other health organisations (such as ambulance services) for administration in the community, without having to apply to the Director General of Health for an exemption will be highly beneficial.

### Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:

As well as the challenges posed by wholesale licensing arrangements above in Question C19, St John would appreciate a review of the classification of hospital schedule pharmaceuticals, which could be amended to include use by St John in the community in keeping with current national patient pathways and best practice.

### Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:

St John supports service innovation in pharmacy by broadening the locations that a pharmacist can practice and the type of services they can provide. This supports our work in developing models of care which include multidisciplinary teams based in the community.

### Question C22 Which option do you support?

Not Answered

### Question C23 - Why do you support that option?:

#### Detailed questions relating to Option 1

#### Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

#### Question C25 - Are there ways in which Option 1 could be improved?:

#### Question C26 - What activities do you consider a pharmacist ownership requirement should cover?:

#### Question C27 - For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?:

#### Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:

#### Question C29 - If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?:

#### Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:

#### Question C31 - What transition time do you consider would be required if Option 1 was implemented?:

#### Question C32 - Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?:

#### Detailed questions relating to Option 2

#### Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

#### Question C34 - Are there ways in which Option 2 could be improved?:

#### Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:

#### Other changes to pharmacy licensing requirements

#### Question C36 - Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?:

#### Question C37 - Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?:

#### Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:

#### Question C39 - Please provide any comments on the intended approach to depots and/or retail-only licences.:

#### Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

## Pharmacist and pharmacy worker authorisations

**Question C40 - Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?:**

**Question C41 - Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?:**

St John would support regulations that allow pharmacies to supply medicines to other health practitioners (for example, within St John) for the purpose of administration in the community. St John would also support pharmacies supplying other health organisations that do not have registered health practitioners (for example paramedics currently), where standing orders are utilised.

## 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)?:**

St John agrees it is sensible to refer to health practitioner prescriber in the Act instead of listing each individual health practitioner group. This will enable groups of health practitioners to be able to prescribe without having to change the legislation. St John also agrees with the simpler process to seek a new/change in prescribing authority.

**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.):**

There is currently no legislation that specifically enables controlled medicines to be carried for easy access in the pre-hospital setting and emergency ambulance services are not specifically considered, mentioned, or catered for in any legislation. Essentially the modern ambulance service has evolved out of necessity without legislation to enable it.

The result is that by definition, we are not adhering to legislation. Instead, we have agreed broadly with the medicines control office that we can do what we need to do to meet the needs of patients, provided it is governed by a standing order.

St John would like to see the specific, practical requirements of providing medicines in an emergency ambulance service outlined and catered for in any new legislation. We would be happy to provide further input and be part of a working group to facilitate this.

This should be considered over and above any potential future changes to prescribing rights of paramedics, as the right to prescribe will only apply to a certain subsection of paramedics with advanced qualifications.

**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?:**

St John would see it as beneficial to be able to provide category 3 medicines to patients where appropriate and within the 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?:**

**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-G46X-F

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 12:27:21**

### Submitter profile

**What is your name?**

**Name:**

michelle du Preez

**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

registered nurse

**Submitter Profile (tick all that apply)**

Medical devices

**If you select DHB, please state service area:**

north

Nurse

**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?**

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):**

Has the livelihood of existing registered cosmetic professionals, -and yes there is alot of us, with existing businesses been taken into account, registered nurses such as myself that practice in a safe manner, but dont necessarily use the highly dominant eg; allergan or galderma brands? if our source and scope is limited it is going to potentially give us less and less control over time of our own businesses and increase prices as we are less accessible to fair trading, therefore consumer prices will increase as a result of ours. Nurses at present also have to give doctors a pretty hefty percentage of our income to source prescription medicine and "cover costs" of standing orders,- now to thwart our access to the medical devices we utilise in our business also. It is beauticians and untrained professionals that are of the concern, not registered nurses and other medical professionals who spend thousands of dollars on ongoing training and maintenance of practising certificates etc who are going to cop the brunt of this, especially if there is going to have to be an extra oversight on delivery which may potentially change the course of our services also? Of course we want the public to be safe, but there is alot of us registered nurses whom this industry it is our vocation and bread and butter, that are extremely concerned that are going to lose more control of our practices that we have worked extremely hard for , and the access bility to do so.

**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):**

have any nursing bodies such as NZNO been allocated to represent nurses decisions?

## **B5 Part 3 of the Bill: Dealing with therapeutic products**

### **Subpart 1: Product approval requirements (ss 51 and 52)**

#### **Question B3**

**Please provide any comments on the product approval controls (ss 51 and 52):**

so the unavailability to parallel import or practitioners been able to access products wholesale from wholesalers overseas who have permission to sell from the original sponsor is going to have horrific effect on price and trade with overseas. higher cost and less access bility to health professionals,- higher price for consumer. what is wrong with trading overseas if the product has the CE standard trademark in europe and is a reputable wholesaler?

### **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):**

how much are all these extra licences permits etc going to cost our country?

### **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):**

What is the limit for personal use medical devices?

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

should a doctor be making profit off a standing order ?

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

**Please provide any comments on the offences created in sections 81–94:**

in regards to S91, so we can still remain to get our supplies from an authorised sponsor from the original sponsor?

## **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):**

so basically we are going to cut accessibility right down, even if it is KFDA approved or carries the CE mark? so we are going to narrow the market right down which takes the accessibility of numerous products away from health professionals, - less competition - higher prices

#### **Question B14**

**Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):**

will have devastating affects on parallel importing and accessibility and costs.

### **Subpart 2: Approval-exempt products (ss 114–115)**

#### **Question B15**

**Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115):**

would exempt products be ones that have already been sold and utilised in this country for quite sometime?

### **Subpart 3: Obligations of sponsors (ss 116–119)**

#### **Question B16**

Please provide any comments on the sections covering sponsor obligations (ss 116–119).:  
who is to fit these costs?

### **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).:

### **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?:**

Are these licences going to be attainable to professionals such as nurses who have already been bringing specific devices into the country.?

### **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)?:

Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:

Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C48 - In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?:

Question 49 - Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?:

## Health practitioners (non-prescribers)

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

## Response ID ANON-DPZ8-G4F4-U

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**  
Submitted on 2019-04-17 12:37:51

### Submitter profile

What is your name?

Name:

Richard Turnbull

What is your email address?

Email:

[REDACTED]

What is your organisation?

Organisation:

Walls&Roche 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?

Neutral

Chapter B Content of the draft Bill (B1-B2)

B1 Overview of the draft Bill

B2 Tips to help with understanding the draft Bill

B3 Part 1 of the Bill: Preliminary provisions

B3 Part 1 of the Bill: Preliminary provisions

Question B1 - Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).:

No comment

B4 Part 2 of the Bill: Interpretation

B4 Part 2 of the Bill: Interpretation

Question B2

Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

I don't agree with the assumption that dispensing is part of manufacturing. Dispensing is part of a process involving not only dispensing but also clinical checks,

liaison with other health professionals and patient advice. This whole process is vital to primary health care. It is not supply.

## **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 this. Good for patient safety and allows tracking.

### **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. Important to maintain pharmacists ability to emergency supply medication for a strictly limited time.

### **Subpart 3: Authorisations (ss 56–80)**

**Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):**

Agree that pharmacies should be able to supply other pharmacies. Should help patient supply as well as reduce wastage.

**Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):**

Pharmacists need to control this

**Question B7 - Please provide any comments on the authorisations for health practitioners :**

Do not agree with this. Pharmacists are the correct persons to supply these medicines. Other health practitioners do not have the training or expertise around medicine efficacy nor are they bound by a strict code of ethics in regard to sale of medicines. Pharmacists are the medicine experts.

**Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):**

The sale of these medicines would effectively be by health practitioner staff as they are normally consulting behind closed doors. These staff would have very limited knowledge on these products.

**Question B9 - Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70):**

Should only be related to animal medication.

**Question B10 - Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77):**

I agree that prescription medicine should not be able to be imported unless under special circumstances. ie. NZ prescriber writes a prescription for a medication not available here. Even this needs checks and balances. It is important to control importation as agree with the problems stated such as counterfeit. Category 2 and 3 medicines should have the same restrictions to ensure pharmacist oversight.

**Question B11 - Please provide any comments on the authorisations created in sections 71–75 and sections 78–80:**

Generally support this section

### **Subpart 4: Other offences (ss 81-94)**

#### **Question B12**

**Please provide any comments on the offences created in sections 81–94:**

I do not believe that there should be any direct to consumer advertising of prescription medicines. It creates an expectation from patients that a GP will prescribe it to them if they want it.

## **B6 Part 4 of the Bill: Product approval**

### **Subpart 1: Approval of products (ss 94–113)**

#### **Question B13**

**Please provide any comments on the sections covering product approval requirements (ss 94–104):**

I support these comments

#### **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):**

I support the single licence as long as it is specified that all the activities are carried out by a pharmacy business including dispensing to both walk in patients but also facilities such as Aged Care or Community Care or Mental Health etc. This makes sure that medicines are safely dispensed in a suitable environment.

#### **Question B19**

**Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130):**

Can only be to a pharmacist for a pharmacy for safety etc

### **Subpart 2: Permits (ss 131–135)**

#### **Question B20**

**Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135):**

Support this especially in cases of fire, earthquake and other natural disasters.

### **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):**

Would make a lot of sense to issue a pharmacy licence for longer than a year. 3 years would be suitable. Would reduce costs for both pharmacy and regulators. It would be easy to reduce the time for pharmacies with compliance issues.

#### **Question B22**

**Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151):**

Agree that they should be transferable in certain situations

### **Subpart 4: Obligations of licensees and responsible persons (ss 153–159)**

#### **Question B23**

**Please provide any comments on the obligations of licensees and responsible persons (ss 153–159):**

Agree with this. The licensee must be a pharmacist to understand true control.

## **B8 Part 6 of the Bill: Regulator**

### **Subpart 1: Regulatory powers and functions(ss 160–182)**

#### **Question B24**

**Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182):**

No comment

**Subpart 2: Investigative powers (ss 183–196)**

**Question B25**

Please provide any comments on the regulator's investigative powers (ss 183-196):

No comment

**Subpart 3: Offences relating to regulator(ss 197–199)**

**Question B26**

Please provide any comments on the offences relating to the regulator (ss 197-199):

No comment

**Subpart 4: Review of regulator's decisions (ss 200–204)**

**Question B27**

Please provide any comments on the review of the regulator's decisions (ss 200-204):

No comment

**Subpart 5: Administrative matters relating to the regulator (ss 205–222)**

**Question B28**

Please provide any comments on the administrative matters relating to the regulator (ss 205–222):

No comment

**B9 Part 7 of the Bill: Enforcement**

**Subparts 1 and 2: Enforceable undertakings(ss 223–232)**

**Question B29**

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232):

No comment

**Subparts 3, 4 and 5: Offences, attribution of liability and defences, and evidentiary matters (ss 233–248)**

**Question B30**

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248):

No comment

**Subpart 6: Infringement offences (ss 249–255)**

**Question B31**

Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255):

No comment

**B10 Part 8 of the Bill: Administrative matters (ss 256–274)**

**Question B32**

Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274):

No comment

**B11 Part 9 of the Bill: Repeals, revocations and amendments to other enactments**

**Subpart 1: Repeals and revocations (s 275)**

**Subpart 2: Amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)**

**Question B33**

**Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285):**

No comment

**Subparts 3, 4 and 5: Amendments to the Search and Surveillance Act 2012, Customs and Excise Act 2018 and other enactments (ss 286–290)**

#### **Question B34**

**Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289):**

No comment

### **B12 - B15, Schedules 1 - 4**

#### **Schedules**

**Question B35 - Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2):**

No comment

**Question B36 - Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3):**

No comment

**Question B37 - Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?:**

No comment

### **C1 Medicines (excluding cells and tissues) sector**

#### **Product-based controls**

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (s 100 and 101):**

No comment

**Question C2 - Please provide any comments on the approach for medicines categorisation (classification):**

No comment

**Question C3 - Please provide any comments on the transition arrangements for existing medicine product approvals:**

No comment

**Question C4 - Please provide any comments on the approach to post-market controls:**

No comment

#### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions:**

No comment

**Question C6 - Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence:**

No comment

### **C2 Cell and tissue sector**

#### **Product-based controls**

**Question C7 - Do you support adoption of the European approach to regulating cells and tissues, which distinguishes between cells and tissues that are subject to minimal manipulation and those that are engineered?:**

No comment

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101):**

No comment

**Question C8 - Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues:**

No comment

**Question C4 - Please provide any comments on the approach to post-market controls for cells and tissues:**

No comment

**Question C9 - Please provide any comments on the transition arrangements for product approval controls for cell and tissue products:**

No comment

#### **Activity-based controls**

**Question C5 - Please provide any comments on the manufacturing-related definitions.:**

No comment

**Question C10 - Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.:**

No comment

### **C3 Medical device sector**

#### **Question C11**

**Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:**

No comment

#### **Product-based controls**

**Question C12 - Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?:**

No comment

**Question C1 - Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).:**

No comment

**Question C13 - Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.:**

No comment

**Question C4 - Please provide any comments on the approach to post-market controls.:**

No comment

**Question C14 - Please provide any comments on the transition arrangements for product approval controls for medical devices.:**

No comment

#### **Activity-based controls**

**Questions C5 - Please provide any comments on the manufacturing-related definitions.:**

No comment

**Question C15 - Please provide any comments on the transition arrangements for regulating activities involving medical devices.:**

No comment

### **C4 Clinical trial sector**

#### **Question C16**

**Please provide any comments on the change in approach to regulating clinical trials.:**

No comment

#### **Question C17**

**Please provide any comments on the transitional arrangements for clinical trials.:**

No comment

### **C5 Wholesale sector (including importers and exporters)**

**To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16 [in chapters B5 and B6].**

#### **Licence to wholesale**

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:**

Already discussed

#### **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 don't agree with this. Allowing a supply only function would be of detriment to patients and their safety. As concluded in IPSCA discussions last year the pharmacist role in dispensing a prescription including clinical evaluation, health professional consultation, actual dispensing and patient advice cannot be separated without major risk to the patient.

I think that the public are well served by the current arrangements.

**Question C20 - Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?:**

No I don't believe so. Innovation is happening. The main barriers are MOH and Pharmac policies. Such as not allowing Original Pack dispensing which has stoooped full automation in dispensaries.

**Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.:**

Great care needs to be taken here as pharmacy supply could become greatly reduced with an Amazon type model. Currently we have 1000 or so pharmacies who cover the majority of the country ready to supply primary health care to NZ. This could disappear very quickly to patient detriment

**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?:**

Public safety must be the main consideration here. Community Pharmacies majority owned by Pharmacists ensure accountability. Pharmacists also have a very high level of professional obligation under their code of ethics. A non-pharmacist owner would not have this.

#### 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 delivers many benefits to patients which add to the primary health care net work overall. Pharmacy is often the first stop for patients who resolve them often at no cost to the patient or DHB. This is all part of what owning a pharmacy and caring for your patients is all about. Non -pharmacist owners who are only interested in profit and ROI would take a different view on this under Option 2

**Question C25 - Are there ways in which Option 1 could be improved?:**

I think the ownership laws should be strengthened to ensure that a pharmacist must own 51% of a pharmacy in both voting (control) and shareholding (profit) shares. Maintain a max of 5 pharmacies.

**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?:**

Yes. Separation especially to non-pharmacists creates different levers. Profit vs professionalism.

**Question C28 - Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?:**

The 5 pharmacy limit is about right as enables some scale and size for investment.

I think appropriate oversight of a pharmacy is effective control by a pharmacist– 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?:**

As long as the pharmacists shares add up to 51% then I think that between them they share responsibility.

**Question C30 - Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?:**

There would be some impact if non-pharmacist owners had to sell down quickly to conform with the law.

**Question C31 - What transition time do you consider would be required if Option 1 was implemented?:**

A year minimum

**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?:**

As they are historic they should probably be allowed to continue.

#### 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 is detrimental to patient safety, patient health outcomes and patient access to services. Non-pharmacist owners will expect increasing returns and margin at the expense of professionalism.

An example of this. When I worked in England (with open ownership) I locum-ed in a pharmacy. I was presented with a prescription for Amoxil. On asking the non-pharmacist owner who was present where the Amoxil was he pointed to a large bag of capsules with Greek writing on and said that's the Amoxil. I refused to dispense the prescription. Now if a pharmacist was for example married, with children and under financial pressure, a non-pharmacist owner can put enormous pressure on the pharmacist to weigh up between their hungry children or the code of ethics. There are hundreds of different scenarios along this line. Profit becomes an underlying factor.

Currently I don't think any NZ Pharmacist is doing this solely for profit. Otherwise they would choose another profession.

**Question C34 - Are there ways in which Option 2 could be improved?:**

It should not be an option

**Question C35 - Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?:**

It wouldn't matter what requirements are applied there will always be some non-pharmacist owners that would look to try and coerce or divert them from the supervisory function of patient safety over investor profit.

**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. All pharmacy activities 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?:**

Yes. Massive conflict of interest. Increased volume of prescribing leads to an increased level of prescriptions.

**Question C38 - Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?:**

Only for emergency situations such as fire, civil defense emergencies etc

**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?:**

As discussed earlier. I agree with curtailing. Any importation should only apply with a NZ prescribers prescription for a medicine not available in NZ

**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?:**

It seems relatively consistent with what happens now

**C8 Health practitioners (including pharmacists)**

**Prescribers**

**Question C43 - Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?:**

No comment

**Question C44 - Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?:**

No comment

**Question C45 - Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.):**

No comment

**Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:**

Support this to allow supply of unapproved medicines with the necessary controls

**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?:**

Should be restricted to medical practitioners

**Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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 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 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?:**

As above

#### **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. Huge risks here. Pharmacies and pharmacists are set up to do this job with all the necessary training.

**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.:**

I do not think DTC advertising should be allowed. Allows patients to exert pressure on GP's.

**Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:**

As above

#### **C10 Advertising sector**

##### **Question C52**

**Please provide any comments on the advertising requirements and enforcement tools.:**

## Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

## C11 Patients, consumers and disabled people

### Unapproved medicines

Question C46 - What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?:

Question C47 - What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that: a) only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product? b) other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?:

### Personal imports

Question C18 - What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?:

Question C55 - Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?:

### Pharmacy licensing

Question C19 - What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?:

Question C21 - Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities?:

Question C22 Which option do you support?

Not Answered

Question C23 - Why do you support that option?:

Question C24 - What do you consider are the benefits and/or risks that could result from Option 1?:

Question C33 - What do you consider are the benefits and/or risks that could result from Option 2?:

### Access to pharmacy medicines

Question C50 - Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?:

Question C51 - Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?:

### Advertising

Question C52 - Please provide any comments on the advertising requirements and enforcement tools.:

Question C53 - Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

### Packaging and labelling and consumer medicine information

#### Medical devices that do not have a therapeutic purpose, but may present a health risk

Question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?:

### Adverse event monitoring

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

## Response ID ANON-DPZ8-G46A-R

Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**

Submitted on **2019-04-17 13:09:38**

### Submitter profile

**What is your name?**

**Name:**

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**What is your email address?**

**Email:**

**What is your organisation?**

**Organisation:**

Immunisation Advisory Centre

**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?**

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):**

31. Under the current Act, regulatory and associated administrative powers are held by the Minister of Health and the Director-General of Health. Under the new scheme, the regulator would hold such accountability and powers, independent of the Minister of Health. These proposed changes largely reflect current practice because most regulatory powers have been delegated to Ministry of Health staff and are aligned with modern regulatory schemes.

32. A decision on the form of the regulator has not yet been made

Our comment is that if at all possible at the same time we address the "Authorisation of Vaccinators" vs how we have reclassification of vaccines for Pharmacists

Also need to check and understand the Health Professional prescriber ? is this a RN and currently under scope of practice with Nursing Council the road to become a prescriber is a barrier for RNs

#### 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 clarification of the Health practitioner prescriber. For vaccines this need to be an RN who has done training, please do not use the Nursing Council nurse prescriber road, it is too time consuming, the comparison is a pharmacist who can give vaccines

#### 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):

b. many activities conducted by health practitioners would be authorised via the Act (or by regulation for specific circumstances). These include: prescribing a medicine; issuing a special clinical needs supply authority; administering a category 1 medicine; possessing a category 1 medicine and issuing a standing order.

Need to ensure that vaccines are included for registered nurses

### Subpart 2: Controlled activities and supply chain activities (ss 53–55)

### Question B4

#### Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55):

60. There would be additional requirements for the supply of a prescription medicine (s 54). While generally a prescription issued by an authorised prescriber would be required, it would be possible to use a licence, permit or regulations to authorise supply without a prescription. Situations where we expect this would be used include supply of vaccines for use in approved immunisation programmes and emergency supply by a pharmacist for a patient who has gone on holiday without their prescribed medicine(s). We also envisage it being used in future to authorise the supply, by pharmacists, of prescription medicines such as trimethoprim and the emergency contraceptive pill in specified circumstances.

Yes Vaccines need to fit in here

### Subpart 3: Authorisations (ss 56–80)

#### Question B5 - Please provide any comments on the authorisations for pharmacists (ss 57–59):

63. Subpart 3 would provide authorisations that apply generally to all members of each profession (subject to their scope of practice).

If authorisations for pharmacy then ? authorisations for RNs, need discussion on processes for vaccines

#### Question B6 - Please provide any comments on the authorisations for pharmacy workers (s 60):

as above

#### Question B7 - Please provide any comments on the authorisations for health practitioners :

69. 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

As above need clarification on this again this fits well for vaccines and RNs

#### Question B8 - Please provide any comments on the authorisations for health practitioners' staff (s 65):

154. In keeping with current international practice, the new scheme would have active and comprehensive post-market monitoring programmes to collect information about the safety and quality of medicines and medical devices after they have been approved

Very supportive of any post market pharmacovigilance esp in vaccine programmes

#### 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:

Agree need very clear and simple processes in place for standing orders

### 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):

**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):

218. In the new scheme, the authorisation to prescribe would be established via the relevant profession's scope of practice, but subject to the Minister of Health's approval. To implement this change, the Health Practitioners Competence Assurance Act 2003 would be amended to :

Please make sure consideration is given to all RNs to be able to prescribe and give vaccines on the National Schedule

**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):**

277. Medsafe currently runs and oversees important pharmacovigilance initiatives such as a spontaneous reporting scheme for adverse events, an early warning scheme and a publicly accessible database of suspected adverse reactions. These initiatives would be continued, and potentially enhanced, under the new scheme. The regulator would also be able to establish a committee to provide expert advice on pharmacovigilance matters .

We think this would be helpful and any post surveillance would be helpful

**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?:**