

Therapeutic Products Regulatory Scheme

Consultation document

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Consultation

A Therapeutic Products Bill (the Bill) is being developed to replace the Medicines Act 1981 (and its associated regulations) and establish a new regulatory scheme for therapeutic products. This consultation document is intended to be read alongside an exposure draft of the Bill. It provides information on the policy and details contained in the exposure draft to help inform submissions on the draft Bill.

The purpose of this consultation document

Together with the exposure draft of the Bill, this document provides detail on the proposed regulatory scheme for therapeutic products that is; principles-based, risk-proportionate, reflects international norms, and is designed to be responsive to the challenges of emerging technologies and changes in the health care settings in which therapeutic products are used.

Even adopting a principles-based approach, the Bill is still long and technical. For this reason, the Government has agreed to release a draft of the Bill to get input from the sector before it is introduced to Parliament. We would like you to help us ensure this Bill is fit for purpose both now and into the future.

The three main purposes of this companion paper to the exposure draft of the Therapeutic Products Bill are to:

- a. provide an overview of the draft Bill and describe in broad terms the regulatory scheme that would be established by regulations, rules and notices – while noting the detail of these instruments will be developed and consulted on later
- b. obtain feedback on the draft Bill
- c. collect information from the sector on key policy issues.

Layout of the consultation paper

This consultation paper is divided into three main chapters:

- a. **Chapter A: Key features of the new regulatory scheme** – describing the rationale for the Bill, what it covers and the main types of controls
- b. **Chapter B: Content of the draft Bill** – describing the parts within the Bill, providing additional explanation of particular provisions to assist understanding and highlighting the provisions that are different from the current regulatory approach

- c. **Chapter C: What the new scheme would mean for different sectors and health practitioner groups** – outlining how the regulatory tools within the Bill are intended to apply to different products, sectors or professions and what the relevant regulations, rules or notices are expected to cover. This includes a section focussed on the aspects of the Bill that are particularly relevant from a consumer perspective.

While these chapters overlap somewhat, we are aiming to cater both to those with an interest in the whole scheme and those with a specific area of interest.

Chapter B contains questions covering the sections (grouped by topic) in the draft Bill and provides an opportunity to comment on the policy, practical implications or detail of those sections. These are grouped by topic.

To avoid repetition, Chapter C refers back to the questions in Chapter B when relevant. Chapter C then contains additional questions focused on particular policy issues where we are seeking feedback and also questions on specific issues that are only relevant for particular sectors. Each question is numbered once, so if the same question is asked in two topics within Chapter C, the question number is repeated. For example, question C6 is asked in both the topics for medicines and the wholesalers sectors. As such, the numbering of questions in Chapter C is often not sequential.

How to provide feedback

You can provide feedback by:

- a. using our online tool at <https://consult.health.govt.nz/medsafe/therapeutic-products-exposure-draft-consultation>. This is our preferred way to get feedback; or
- b. sending an electronic submission to [email: therapeuticproducts@moh.govt.nz]

The closing date for submissions is 18 April 2019. We are also holding consultation sessions to provide richer information, and you are welcome to register your interest in attending - go to our website <https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation-document>

Your feedback is important because it will help shape the final proposals, ensuring they are workable and that the purpose of the legislation is achieved. We appreciate you taking the time to make a submission.

If you elect not to use the online tool for your submission, please:

- ensure your electronic (email) submission includes the mandatory submitter information in the Therapeutic Products Consultation submitter form found on the website <https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation-document>
- note that, 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.

Next steps after the consultation

The Ministry will analyse the feedback and publish a summary of this analysis on its website.

The Ministry will provide advice to the Government on the overall outcomes of the consultation and seek approval for any major changes in policy identified. Then we will work with the Parliamentary Counsel Office to amend the Bill, as necessary. The Bill would then be introduced to Parliament.

Once introduced, the Bill would follow the standard parliamentary process. Following the first reading, it would be referred to a select committee (expected to be the Health Select Committee). The select committee normally invites public submissions on a Bill. It then holds public hearings to listen to some of the individuals or groups that have made submissions. After hearing submissions it works through the issues raised and decides what changes, if any, should be made to the Bill.

The Bill would then have second and third readings in the House. Then, after receiving the royal assent, it is referred to as an Act.

The Therapeutic Products Act would come into force on a specific date to be appointed by the Governor-General by Order in Council, or at the latest by a backstop date that would be inserted in the Bill. That date is likely to be around two years after royal assent. On the commencement date the new regulatory scheme would replace the current scheme in the Medicines Act 1981. For some aspects of the scheme, the Bill will include transition provisions to provide additional time for the sector to meet the new requirements. The transition period starts on the commencement date.

The regulations, rules and notices required to implement the scheme will need to have been developed before the commencement date. The Ministry would begin developing these while the Bill progresses through Parliament. It then would have around two years after the date of royal assent to consult and finalise them.

The key points to note from this process are:

- a. a lot of work remains to be done – the Bill sets out the legislative framework for the new regulatory scheme, but the detail of how this scheme will work in practice (ie, the regulations, rules and notices) still needs to be developed
- b. this consultation document does not offer your last chance to provide input into how the new scheme would work. Further consultation opportunities will follow during the select committee process and when the regulations, rules and notices are being developed.

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Executive summary

Why the Therapeutic Products Bill has been developed

Therapeutic products are a diverse group of products that everyone is likely to need at some time during their life. This Bill is about making sure that these products are as safe as possible and that they work. The Therapeutic Products Bill would repeal and replace the outdated Medicines Act 1981 to provide modern, comprehensive and cost-effective regulation of therapeutic products in New Zealand.

The Medicines Act 1981 is becoming ever less fit for purpose. It is dated, inflexible and hard to use, and has significant gaps in coverage (eg, it provides no pre-market controls on medical devices). It is also prescriptive and prevents regulatory efficiencies; and makes it difficult for some cell- and tissue-based products to come to market.

Attempts at legislative change in this area date back to the late 1980s and early 1990s when reform was first proposed. For much of this long history, efforts were focused on establishing a joint regulatory scheme and agency (Australia New Zealand Therapeutic Products Agency, ANZTPA) with Australia. In late 2014, when that initiative ceased, work on the Therapeutic Products Bill began.

The new regulatory scheme is being developed with the aim of meeting the current and future needs of the health and disability sector, while being mindful of modern approaches to the design of regulatory schemes and the size of the New Zealand market and its regulatory capacity.

In this context, the objectives for the regulatory scheme are that it:

- a. meets expectations of risk management and assurance of acceptable safety
- b. results in efficient and cost-effective regulation
- c. is flexible, durable, up to date and easy to use
- d. ensures high-quality, robust and accountable decision-making
- e. is able to sustain capable regulatory capacity
- f. supports New Zealand's trade and economic objectives
- g. is trusted and respected
- h. supports consumer access to, and individual responsibility for, care.

Achieving these objectives involves putting in place:

- a. regulatory requirements that are consistent with international approaches and effectively administered
- b. a regulator that can exercise regulatory powers effectively, is accountable, and can engage internationally and recognise work done by trusted overseas regulators
- c. an enabling legislative framework that can be readily maintained and updated.

One of the issues with the Medicines Act 1981 is the difficulty of keeping it up to date. Consistent with the recommendations of the Productivity Commission,¹ the Bill reflects a shift to a principles-based legislative framework. Therefore, much of the detail that is currently in the Medicines Act 1981 would be included in subordinate legislative instruments (regulations or rules), or in notices that are made by the regulator. The Bill includes a clear purpose statement and principles to guide the regulator (and any other person exercising powers in the new scheme) when developing rules and notices or administering the regulatory scheme.

What will the new regulatory scheme look like

The scheme would cover all therapeutic products used in public and private health care in New Zealand across the lifespan of the product. The Bill defines four types of therapeutic products:

- a. medicines (which include most cell and tissue therapies, vaccines and biological medicines)
- b. active ingredients of medicines (called active medicinal ingredients or AMIs in the Bill)
- c. medical devices (including in-vitro tests and software)
- d. type-4 products. This is a placeholder category intended to capture any future innovative therapeutic products that do not fit under the definitions of medicine or medical device.

The Government intends to exclude natural health products (including rongoā Māori and dietary supplements) from regulation under this new legislation.

The regulatory scheme to be established by the Bill is based around two broad components:

- a. **Product approval requirements:** Products would generally need to be approved before they can be imported or supplied and approval holders would need to comply with requirements around monitoring for post-market safety. There would be an ability to make exceptions or exempt particular classes of products from needing an approval.
- b. **Controlled activity requirements:** These vary across product types and include conducting a clinical trial, manufacturing, wholesale supply, prescribing, and pharmacy activities. It would be unlawful to perform a controlled activity without an appropriate authorisation. Authorisation can be given through licences, provisions of the legislation (in the Bill or regulations) or permits.

¹ New Zealand Productivity Commission. 2014. *Regulatory Institutions and Practices: A review of regulatory practice in New Zealand and the Government's Statement of Regulatory Stewardship*. Wellington: New Zealand Productivity Commission.

The Bill would also enable obligations to be placed on people who carry out a controlled activity; or who, in the course of business, import, supply, administer or use, or have possession of any therapeutic products.

Advertising would only be allowed for approved products. It must be truthful and not misleading.

The Bill would also prohibit particular activities, such as tampering with, or misrepresenting, a therapeutic product.

Under the Medicines Act 1981, the Minister of Health and Director-General of Health hold regulatory accountability and associated regulatory powers. Under this new scheme, the regulator would hold such accountability and powers, independent of the Minister of Health.

The form of the independent regulator (ie, whether it is a Crown entity, a departmental agency or part of the Ministry of Health) will be decided in 2019. As a placeholder, the draft Bill currently provides for the Chief Executive of the Ministry of Health (ie, the Director-General of Health) to administer the scheme.

The regulator would be able to make a number of regulatory orders, where relevant people are required to take particular actions. Examples include recall orders, advertising remediation orders, and medicines access limitation orders (currently known as restriction notices, and used to manage drug-seeking behaviour).

The regulator would continue to be able to vary or revoke product approvals and licences (and permits) or suspend licences (and permits).

The regulator would have a comprehensive set of enforcement options that are more appropriate than those in the Medicines Act 1981. In addition to prosecutions, the regulator would be able to issue infringement notices for minor instances of non-compliance and accept enforceable undertakings (which offer an alternative to prosecution, allowing the regulator to work with people to improve their compliance without prosecuting them). Under the Medicines Act 1981, the maximum penalty for most offences is inappropriately low (\$500), with higher penalties available for only a few specified offences (the highest is up to \$100,000 for a body corporate). Under the new scheme, the maximum penalties for criminal offences would be much higher.

To enable more flexibility in how the regulator implements the scheme, the Bill would not specify operational aspects such as committee structures. However, the regulator would have the ability to establish expert advisory committees.

The Bill provides a two-tier merits review mechanism for decisions about product approvals, licences and permits. Decisions would initially be reviewed by a specially convened review panel. Following that process, a person who was still aggrieved could appeal to the District Court.

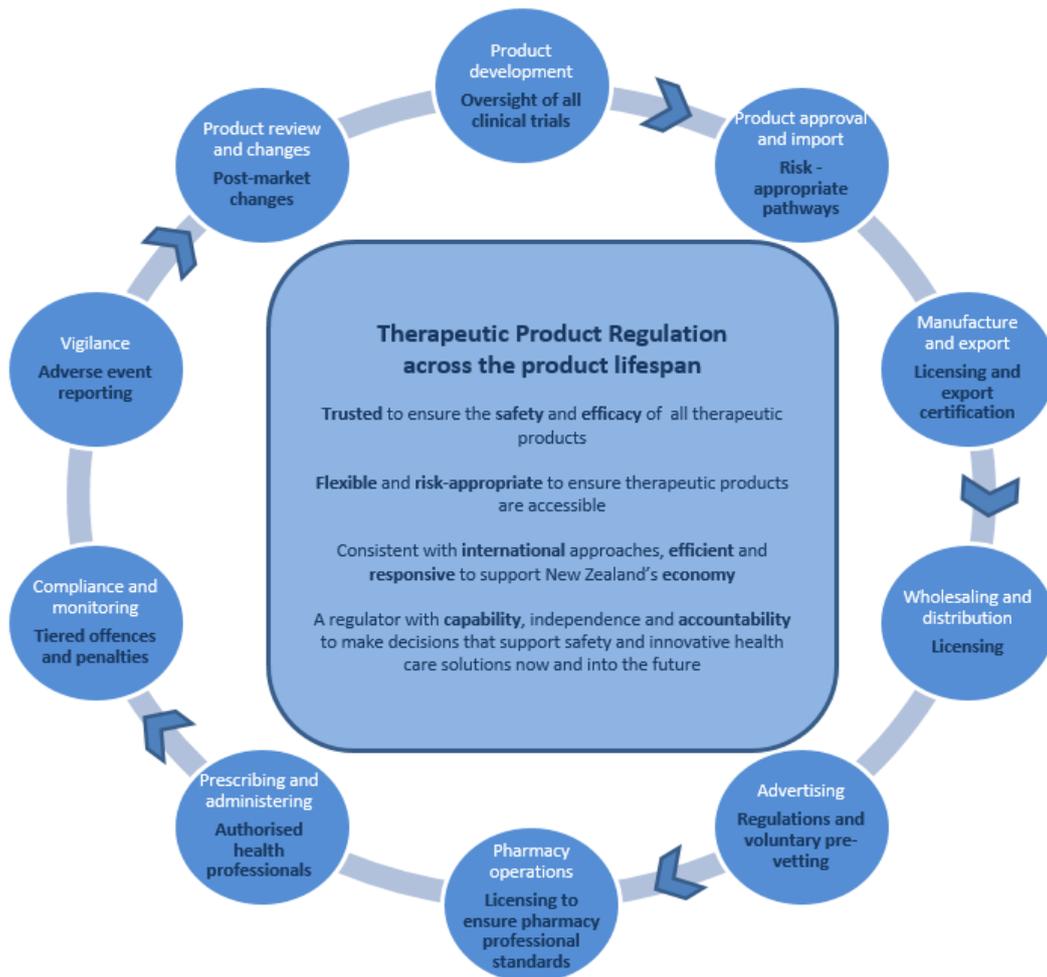
To ensure a smooth transition for those affected by the regulatory scheme, the Bill sets out transition measures covering those moving from regulation under the Medicines Act 1981 to regulation under the new scheme, as well as for those being regulated for the first time.

Chapter A: Key features of the new regulatory scheme

A1 Rationale for new legislation

1. Everyone is likely to need a therapeutic product at some time. All developed countries recognise that assuring the safety of therapeutic products is fundamental to the delivery of high-quality public and private health and disability support services as therapeutic products have both benefits and risks, including risks of serious harm.
2. The Government wishes 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. Consistent with the international approach to regulating such products, it intends to provide this protection through pre- and post-market controls that regulate their manufacture, import, promotion, supply and administration or use.
3. To achieve this purpose, it proposes to replace the current Medicines Act 1981 and its associated regulations with a new comprehensive and cost-effective regulatory scheme, consisting of the Therapeutic Products Bill and its associated subordinate instruments.
4. The Medicines Act 1981 is dated, inflexible and prescriptive, and has failed to keep pace with changing international regulatory practice and emerging technologies. It also contains much of the detail about the regulatory requirements; this approach contrasts with modern legislative practice, which enables regulatory schemes to be readily maintained and updated by using legislative instruments to capture operational requirements.
5. The weaknesses of the current legislation have been under discussion for many years. From the late 1980s, efforts first focused on establishing a joint regulatory scheme and agency (Australia New Zealand Therapeutic Products Agency, ANZTPA) with Australia. In late 2014, when these efforts ended, a decision was made to work on a comprehensive therapeutic products regulatory scheme to replace the Medicines Act 1981 and its regulations.
6. To address current weaknesses, changes in three key areas are proposed so that the new scheme improves on the current one.
 - a. Use a principles-based legislative framework.
 - b. Cover a broader range of products.
 - c. Provide the regulator with a set of tailored and responsive regulatory tools.

7. The objectives for the regulatory scheme are that it:
 - a. meets expectations of risk management and assurance of acceptable safety, quality and efficacy or performance of therapeutic products
 - b. results in efficient and cost-effective regulation
 - c. is flexible, durable, up to date and easy to use
 - d. ensures high-quality, robust and accountable decision-making
 - e. is able to sustain capable regulatory capacity
 - f. supports New Zealand's trade and economic objectives
 - g. is trusted and respected
 - h. supports consumer access to, and individual responsibility for, care.
8. Achieving these objectives involves putting in place:
 - a. regulatory requirements that are consistent with international approaches and effectively administered
 - b. a regulator that can exercise regulatory powers effectively, is accountable, and can engage internationally and recognise work done by trusted overseas regulators
 - c. an enabling legislative framework that can be readily maintained and updated.
9. Diagram A shows how the regulatory controls would be applied across the lifecycle of a product. Note that not all controls are applied to all product types.

Diagram A: Regulatory controls across a product's lifecycle

A2 A principles-based legislative framework

10. The Bill would shift to a principles-based legislative framework. In practice, this means that the resulting Act would contain less operational detail, while regulations and regulator-made instruments would contain more.
11. The Bill would enable regulations to be made and authorise the regulator to make rules and regulator's notices on matters such as technical requirements and processes. The draft Bill sets out the parameters that guide the development of these other instruments and requirements for how they are made.
12. Diagram B illustrates the placement of provisions across the four tiers of the legislation.

Diagram B: Four tiers of legislation

Instrument	Type of instrument	What they will contain
Therapeutic Products Act	 Legislative instrument. Follows the parliamentary process.	Primary legislation sets out the purpose of the Act, provides a set of principles to set the parameters of the regulatory regime and, importantly, sets boundaries for the scope and development of the subordinate instruments (regulations, rules and notices), contains the primary elements of the regulatory scheme (including the offences), provides enforcement powers, and sets out accountability arrangements.
Regulations	 Legislative instrument made by the Governor-General, by Order in Council. Is subject to review and disallowance by the Regulations Review Committee.	Regulations would contain further detail on matters not appropriately dealt with in regulator-made instruments (eg, fee setting), and key elements of the regulatory scheme (eg, standards setting) that would remain relatively stable and that are significant to the design of the regulatory requirements.
Rules	 Legislative instrument made by the regulator. Is subject to review and disallowance by the Regulations Review Committee.	Rules would contain the detail of the regulatory requirements. They would be used to specify technical and detailed matters such as: qualifications and competency requirements, and minor changes to products.
Regulator's notices	 Non-legislative instrument made by the regulator. Is not subject to disallowance or review by the Regulations Review Committee.	Regulator's notices would only be used for administrative detail. The regulator would only be able to make notices if it was necessary or desirable to promote the purposes of the Act and was consistent with the principles in the Act.

13. Changes to regulations, rules and notices would not need to go through the full parliamentary process. As a result, it would be easier to make changes to the scheme when issues arise, the need for improvements is identified, or in order to keep in line with international best practice.
14. Regulations and rules would still be subjected to external scrutiny, as they could be reviewed by the Regulations Review Committee and could be 'disallowed' by Parliament if made inappropriately. Consultation is required on regulations and rules.
15. In essence, the Bill sets out the matters that regulations, rules or regulator's notices can cover and the matters that would need to be considered when any of those instruments is being developed.

A3 Broader product coverage

16. New Zealand is currently out of step with most other developed countries because the following three important groups of therapeutic products are largely unregulated here:
 - a. cell and tissue products
 - b. medical devices
 - c. radioactive medicines.
17. These significant gaps in product coverage reflect the age of the current legislation. The new scheme is designed to ensure that all therapeutic products are regulated across their lifespan and that, as far as possible, the benefits of a product outweigh its risks.
18. To apply regulatory controls that are consistent with international approaches, the Bill divides therapeutic products into four types. This enables the regulatory tool box to be deployed differentially across the product types where that is appropriate. The four types of product are: medicines (which include most cell and tissue therapies and radioactive medicines); medical devices; active medicinal ingredients; and type-4 products (future, and as yet unknown, therapeutic products).
19. The Government is considering options for regulating natural health products and therefore intends to exclude them as far as is possible from the Therapeutic Products Bill. We will work with the parliamentary drafters to develop and include the exclusion provisions before the Bill is introduced to Parliament. In the interim, section 16(3) has been included in the draft Bill as a placeholder provision.

Medicines

20. Radiopharmaceuticals and most cell and tissue products would be regulated under the umbrella term of 'medicines', as well as the pharmaceutical products currently regulated as medicines under the Medicines Act 1981. The regulatory requirements for different kinds of medicines would be tailored to accommodate their different characteristics and risk profiles. For more detail on how the new scheme would regulate medicines, see Chapter C1.
21. We are aware of concern about using the term 'therapeutic product' for donated human tissue. The draft Bill uses this term as a practical measure to enable the scheme to apply appropriate regulatory controls across a range of cell and tissue activities and therapies, which run from processing and using minimally manipulated cells and tissues to creating and using highly manipulated or engineered products. For more detail on how the new scheme would regulate cell and tissue products, see Chapter C2.

Medical devices

22. The term 'medical device' covers a wide range of products used in primary and secondary health care as well as in the home. The product range spans a broad risk spectrum from low-risk products such as tongue depressors and bandages to higher-risk products, including diagnostic and surgical equipment, implantable products such as orthopaedic joints, heart valves and surgical mesh, and diagnostic equipment such as X ray machines and computed tomography scanners. It also includes in-vitro diagnostic tests such as pregnancy tests and tests for serious conditions such as HIV or hepatitis C, as well as software used for a therapeutic purpose.
23. Medical devices are currently not subject to any pre-market regulatory scrutiny to assess safety and performance and post-market controls are minimal. Under the new scheme, the intention is to apply the full range of pre- and post-market controls in accordance with the risk-based model developed initially by the Global Harmonisation Taskforce (GHTF) and continued and maintained by the International Medical Device Regulators Forum (IMDRF).
24. This would be a major change for the sector. We intend to ensure that appropriate risk-based requirements (based on the international classification system developed by the GHTF) are developed and that any costs can be justified from a safety perspective.
25. For more detail on how the scheme would regulate medical devices, see Chapter C3.

Active medicinal ingredients

26. Active ingredients of medicines (known internationally as active pharmaceutical ingredients) are defined as a separate type of therapeutic product so that a smaller set of regulatory controls can be applied to them. Controls would be applied to ensure they are manufactured to an appropriate standard and are not supplied outside the regulated supply chain.

Type-4 products

27. Type 4 is a 'reserve' category to future-proof the scheme for therapeutic products that, in the future, may not fit under the medicine or medical device definitions. We consider it prudent to do this given the rapid pace of innovation and technology development in health-related fields. While new and innovative products currently on the market can be dealt with appropriately under the medicine or medical device frameworks, this may not always be possible. The Bill therefore creates this framework of controls so that, if and when such products are identified, it would be possible to develop the appropriate controls and place this detail in regulations, rules and notices (as appropriate). This would allow the new type of products to be appropriately regulated until the Act could be reviewed and, if necessary, amended to accommodate them.

A4 Tailored and responsive regulatory tools

28. Medsafe, the business unit of the Ministry of Health that administers the Medicines Act 1981 (ie, the current regulator), has a limited range of responses available when breaches or issues occur and many of these have protracted timelines. For example, product approvals and licences can be amended and revoked and where a pharmacy is operating without a licence a fine of up to \$40,000 can be imposed on conviction. Penalty levels are generally low compared with those in modern legislation and for many offences the standard penalty available (following a successful conviction) is \$500. The highest penalty available is \$100,000 for a body corporate convicted of an offence such as selling or advertising a medicine that does not have an approval (referred to as 'a consent'). In some situations, Medsafe is able to seize and destroy stock.
29. Under the new scheme, a wider range of tools would be available to encourage compliance and deal with serious offending, which would enable more appropriate and timely responses when non-compliance occurs. The draft Bill includes:
 - a. a tiered set of criminal offences – with penalties based on the level of intent
 - b. infringement fines – for immediate responses to lower-level breaches
 - c. enforceable undertakings – for use when a person who has been non-compliant agrees (ie, undertakes) to address the issue and take active steps to reduce the risk of it happening in the future. In return, the regulator would not prosecute for the breach unless the undertaking was breached.
30. The regulator would also have a range of regulatory orders that it could make if a product or activity presents an unacceptable risk of harm.

A5 Regulator form

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. The Government intends to consider whether it would be a Crown entity, a departmental agency, or part of the Ministry of Health in 2019. As a placeholder, the draft Bill currently provides for the scheme to be administered by the Chief Executive of the

Ministry of Health (ie, the Director-General of Health). Regardless of the form, the regulator would have a legislative mandate and accountability for its role.

33. The Bill enables the regulator to charge fees to cover any costs not covered by government funding. The split between the costs recovered from industry and those met by the government has not yet been decided. However, it is expected that a large proportion of the costs is likely to be recovered through industry fees or charges. This would be discussed further and consulted on during the development of the regulations that would set out the cost-recovery details.

Question A1

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

- 1 Support
- 2 Partially support
- 3 Neutral
- 4 Partially don't support
- 5 Don't support

Chapter B:

Content of the draft Bill

34. **Drafting style:** The Bill has been drafted using the modern approach to legal drafting. This impacts not only what is included in the Bill (and what is correspondingly included in regulations or regulator-made instruments), but also how it is worded and where it is placed within the Bill. This means those aspects of the current scheme that have been retained may be worded in a different way, spread across more than one part of the Bill, or included in regulations or regulator-made instruments (when previously they were in the Act itself).
35. **Policy settings:** The new scheme is designed to meet the needs of the health and disability support sector now and into the future, to give effect to the Government's expectations for regulatory schemes and be mindful of the global settings for therapeutic products. This approach is consistent with the Productivity Commission's 2014 report *Regulatory Institutions and Practices*.²
36. The international arena has had a considerable influence on the design of this new scheme and it is important that New Zealand is responsive to these settings. Therapeutic products are generally global commodities and regulation in developed countries is guided by international approaches for assuring the safety, quality and efficacy or performance of products. Developed countries also have formal and informal obligations in respect of global safety concerns (eg, counterfeit products).
37. Internationally, regulators are looking for ways to respond to regulatory challenges. These include capacity constraints driven by the regulatory challenges that innovative products present, increasingly complex supply chains (eg, a product may have components from many sources or supply may be many steps removed from manufacture), and the desire for continued efficiencies.
38. Key policies that would form the basis of the new therapeutic products regulatory scheme were agreed by respective governments in December 2015, March 2016 and December 2018. The draft Bill has been developed based on these decisions.

² New Zealand Productivity Commission. 2014. *Regulatory Institutions and Practices: A review of regulatory practice in New Zealand and the Government's Statement of Regulatory Stewardship*. Wellington: New Zealand Productivity Commission.

B1 Overview of the draft Bill

39. The draft Bill comprises nine parts and four schedules. Diagram C provides an overview of the content of these parts and schedules.

Diagram C: Overview of the content of the draft Therapeutic Products Bill

<p style="text-align: center;">Part 1: Preliminary</p> <p>Purpose Principles Outline of scheme (as a guide only)</p>	<p style="text-align: center;">Part 2: Interpretation (definitions)</p> <p>General Product-related Activity-related Miscellaneous</p>	<p style="text-align: center;">Part 3: Dealing with therapeutic products</p> <p>Product approval requirements and associated offences Controlled activities and supply-chain activities and associated offences Authorisations Other offences</p>
<p style="text-align: center;">Part 4: Product approval</p> <p>Approval of products Approval-exempt products Obligations of sponsors Data protection for medicines</p>	<p style="text-align: center;">Part 5: Licences and permits</p> <p>Licences Permits Provisions applying to licences and permits Obligations of licensees and responsible persons</p>	<p style="text-align: center;">Part 6: Regulator</p> <p>Powers and functions Investigative powers Offences relating to regulator Review of regulator's decisions Administrative matters</p>
<p style="text-align: center;">Part 7: Enforcement</p> <p>Enforceable undertakings Injunctions Offences Attribution of liability and defences Evidentiary matters Infringement offences</p>	<p style="text-align: center;">Part 8: Administrative matters</p> <p>Cost recovery Regulations, rules, notices and exemptions Review of Act Relationship with other Acts</p>	<p style="text-align: center;">Part 9: Repeals and amendments to other enactments</p> <p>Repeals and revocations Amendments to other Acts</p>
<p>Schedule 1: Transitional, savings and related provisions</p> <p>Schedule 2: Reviewable decisions</p> <p>Schedule 3: Regulations, rules and regulator's notices</p> <p>Schedule 4: Amendments to other enactments</p>		

B2 Tips to help with understanding the draft Bill

40. Read the 'Outline of Regulatory Scheme' section of the draft Bill (ss 7–13) and check Diagram C above to gain a 'helicopter view' of the scheme and a sense of how provisions relating to a particular topic are spread across the draft Bill.
41. Where the term 'person' is used, it means either a body corporate or an individual.
42. A singular term is used to cover both singular and plural; for example, 'person' means 'person or persons'.
43. Part 2 of the draft Bill contains a comprehensive set of defined terms that are used later in the draft Bill. Bear these definitions in mind as you read the rest of the draft Bill. If a term is not defined in the draft Bill, it has its normal, everyday meaning.
44. The provisions in a Bill are technically considered to be 'clauses' until the Bill is passed and becomes an 'Act'. At that point the 'clauses' become 'sections'. For the sake of consistency with the terminology in the draft Bill and readability, we have referred to the 'clauses' in the draft Bill as 'sections' within this document. These are often shown in brackets for example (ss 3 and 4) means sections 3 and 4 in the draft Bill.

B3 Part 1 of the Bill: Preliminary provisions

Purpose and principles (ss 3 and 4)

45. These sections in the draft Bill state the purpose and principles that are the central elements of the scheme and a guide to actions and decisions under it.

Question B1

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

Outline of the regulatory scheme (ss 7–13)

46. These sections provide a high-level outline of the scheme and explain that the scheme would have two broad components:
 - a. product approval requirements
 - b. controlled activity restrictions.
47. The outline is intended as a helpful guide, but its sections do not affect the meaning of any provisions in the Bill.

B4 Part 2 of the Bill: Interpretation

48. Part 2 of the draft Bill defines terms that have a special meaning when they are used in the draft Bill and not an ordinary or dictionary meaning.

Definitions and meanings – points of interest or difference (ss 14–50)

49. Listed below are key or new concepts in the draft Bill, to draw attention to their meaning. They are listed in the order in which the definitions appear in the draft Bill rather than being alphabetical.
 - a. **health practitioner prescriber** (s 14): Under the new scheme, a health practitioner's authority to prescribe would be established in, and bounded by, the person's scope of practice. In contrast, in the current approach the Medicines Act 1981 and regulations list the professions that can prescribe (and any parameters relating to their prescribing authority). However, the new scheme would require the Minister of Health's approval before a profession's responsible authority under the Health Practitioners Competence Assurance Act 2003 could include the authority to prescribe in a scope of practice. For further detail of the rationale for, and implications of, this change see Chapter C8.
 - b. **regulatory entity** (s 14): This lists the bodies or office holders that the regulator is able to share information with and receive information from under section 209. The list includes some entities with roles that are not strictly 'regulatory' in nature.
 - c. **therapeutic purpose** (s 15): This is in line with international definitions.
 - 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.

- e. **medicine** (s 18): This is in line with international definitions. Based on their mode of action, most cell and tissue products are a type of medicine rather than a completely separate category of therapeutic product. Under the new scheme, a risk-based set of controls is proposed that is in line with international approaches. For a full discussion of the regulation of cells and tissues, see Chapter C2.

In recent years, so-called hybrid products have become more common. Hybrid products have some features of both a medicine and a medical device (eg, a coronary stent that has a heparin coating). For each hybrid product, it is necessary to determine the nature of the principal intended mode of action in order to decide whether the product is a medicine or a device. As products become more complex, it can be difficult to make this judgement. For this reason, the regulator would be able to declare that a particular therapeutic product or class of therapeutic products is a medicine (or alternatively that it is a medical device) via a notice. Once this type categorisation has been determined, the product would follow the regulatory pathway that is appropriate for the product type, but importantly the technical requirements placed on that hybrid product would reflect its hybrid nature.

- f. **categories of medicine** (s 19): The Bill specifies four categories of medicines that, for future-proofing reasons, are called categories 1, 2, 3 and 4. The regulations would specify the categorisation criteria for each category, which must result in every medicine being in one of the four categories. It is intended that the regulations would carry forward the current categorisation criteria (although these could change in the future), namely: prescription medicines (category 1); pharmacist medicines (category 2); pharmacy medicines (category 3); and general-sale medicines (category 4). Part 3 of the Bill sets out the supply and use controls relating to medicines in those categories as well as authorisations for health practitioner prescribers and others.
- g. **active medicinal ingredient (AMI)** (s 20): These are defined separately from medicine so that a more limited set of controls can be applied to them.
- h. **medical device** (s 21): This definition is based on the international approach where something is considered to be a medical device if it is a therapeutic product that, because of its mode of action, does not meet the definition of medicine. See Chapter C3 for more information about how the global model for device regulation would be applied under the new scheme.
- i. **supply-restricted devices and use-restricted devices** (s 22): Medical devices would not be subject to access restrictions applied through a categorisation system such as the one used for medicines. However, the scheme would enable supply restrictions and/or use restrictions to be placed on a device or class of devices where safety concerns arise from the setting in which they are being used. In such cases, it would be possible to declare them to be a 'supply-restricted' or 'use-restricted' device in regulations. Regulations would then specify the circumstances in which

- they can be supplied or used on a patient (eg, by requiring them to only be used by a health practitioner).
- j. **type-4 product** (s 23): This is a 'reserve' term in order to future-proof against products we don't know about yet. This concept would allow the regulator to declare something to be a type-4 product if it was used for a therapeutic purpose, but had a mode of action that did not fit well within the medicine and medical device definitions.
- k. **approved product, approval-exempt product, unapproved product** (s 24): In general, an:
- i. **approved product** has been reviewed by the regulator and authorised for supply in New Zealand
 - ii. **approval-exempt product**, due to its nature or risk profile, has been declared to be approval exempt because the Regulator considers that an approval is not required
 - iii. **unapproved product** is not approval-exempt or prohibited. It is therefore a product that either has not been the subject of an application for approval or, if an application for approval has been lodged, that application is still pending or the regulator has declined to approve the product. Note that, if a product that appeared from its packaging and labelling to be the same as an approved product was imported without the consent of the New Zealand sponsor, that product would be considered to be an unapproved product. This is because products with the same brand often have different formulations in different markets and are produced at different manufacturing facilities.
- l. **prohibited product** (s 25): This is a product that, due to serious safety concerns, has been declared by regulations to be prohibited. It would be an offence to import, manufacture, supply, prescribe, use or be in possession of the product unless authorised to do so (s 171).
- m. **administer a medicine** and **prepare a medicine for administration** (s 26): These definitions include a new concept of 'prepare for administration' to ensure that when health practitioners (eg, nurses) are reconstituting a medicine, or mixing it with another medicine, for the purpose of administration, that activity is not considered compounding.
- n. **compound a medicine** (s 28): This defines a specific type of manufacturing activity. It is defined because it is used in Part 3 of the draft Bill, which authorises a pharmacist (or other person authorised by Part 3 of the draft Bill) to compound a medicine without needing a licence to manufacture (ss 58 and 60). The amount they would be able to compound is limited to either no more than a patient needs or maximum quantities set in rules.
- o. **dispense a medicine** (s 29): This defines a specific manufacturing activity. It is defined because it is used in Part 3 of the draft Bill, which authorises a pharmacist (or other person authorised by Part 3 of the draft Bill) to dispense without needing a licence to manufacture (ss 57 and 60).

- p. **responsible manufacturer** (s 31): This is the person who is primarily responsible for the manufacture of the product. This section sets out relevant considerations when determining who the responsible manufacturer is for a medicine or an AMI and a different set of considerations for a medical device or type-4 product.
- q. **manufacture a medicine** (s 32): This clarifies that compounding and dispensing are part of manufacture and that preparing a medicine for administration is not part of manufacturing as long as it is done appropriately.
- r. **manufacture a medical device** and **remanufacture** (s34): These definitions make it clear that assembling or calibrating a device before use in accordance with the responsible manufacturer's instructions is not part of manufacture. The definition of 'remanufacture' is intended to cover refurbishment, reprocessing and rebuilding activities that produce a device significantly different from the original, or that are carried out on devices originally intended for a single use only. The definition also clarifies that activities such as normal repairs and maintenance are not remanufacture.
- s. **pharmacy business** and **pharmacy activity** (s 36): These definitions are designed to deliver more flexibility than the current approach to pharmacy licences under the Medicines Act 1981. The two main ways it achieves this are by:
- i. allowing for different types of distribution and supply arrangements, which may not involve a bricks and mortar pharmacy (eg, mobile services)
 - ii. not requiring a pharmacy business to be capable of conducting all pharmacy activities.

Therefore each licence would only require the applicant to have the equipment, facilities and systems that are relevant for the pharmacy activities they seek approval to perform. The draft Bill defines a business as a pharmacy business if it conducts core activities (compounding, dispensing or supplying category 1 or 2 medicines). It also defines the term 'pharmacy activities' as including, in addition to the above, supplying category 3 medicines (by non-wholesale) and supplying medicines and medical devices by wholesale in the circumstances permitted by regulations. The reason for separating the supply of category 3 medicines from the core pharmacy activities (which require a pharmacy licence) is to allow the current concept of 'retail licences' for remote settings to continue. This type of licence would allow a store that is not a pharmacy (and therefore has no pharmacist present) to supply category 3 (pharmacy) medicines. Such licences would continue to be allowed on an exceptions basis, where access is an issue due to the lack of a pharmacy in the area.

- t. **prescription, complying prescription** and **prescribe** (s 38): The wording is intended to better allow for the shift to electronic prescriptions.

- u. **special clinical needs supply authority** and **complying special clinical needs supply authority** (s 39): The authority is a document issued by an authorised health practitioner following a formal assessment that a patient has a special clinical need for a product that has not been approved for supply in New Zealand. Issuing a special clinical needs supply authority is a controlled activity.
- v. **standing order** and **complying standing order** (s 40): The draft Bill would continue to enable the supply and administration of category 1, 2 and 3 medicines to a patient, and the supply and administration of category 1 (prescription) medicines without a prescription, under a standing order. Issuing a standing order is a controlled activity. The person who is authorised to do something under the standing order is taken to be the agent of the person who issued the order.
- w. **supply** (s 42): The meaning is intentionally broad so that the requirement for a product approval captures all situations where a therapeutic product is supplied, including when it is sent overseas. The two types of supply (supply by wholesale and supply that is not wholesale) are also defined (s 43) to enable different controls to apply to them.
- x. **supply chain activity** and **person in the supply chain** (s 44): Again these definitions are intentionally broad, so that controls and obligations can be applied (via regulations) when needed to anyone who is carrying out a controlled activity, or has a business that involves handling or storing therapeutic products but does not involve the activities specified as controlled activities in the draft Bill.
- y. **fit and proper person** (s 47): The 'fit and proper person' test is one of the criteria that a person must meet to be a product sponsor, to hold a licence or to be a responsible person under a licence. It would be up to the regulator to determine whether the person is a fit and proper person, considering the matters set out in this section. For companies, it is important to note that under subsection (2), these criteria also apply to senior managers.
- z. **senior manager** (s 48): This section defines senior manager to include not just directors, but also people who are in a position to exert influence either formally (such as chief executives) or informally. This is a concept commonly used in modern commercial legislation. The concept of senior manager is relevant when considering a licence application and the suitability of a senior manager. Likewise, if concerns about the suitability of a senior manager arose after a licence had been issued (perhaps because the person received a criminal conviction), that could be a ground for suspending or cancelling the licence.

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)

50. The product approval requirements in these sections are a key control mechanism in the regulatory scheme. They do not, however, apply to active medicinal ingredients because their safety is assessed during the approval process for the medicine they are used in.
51. This subpart specifies that it would not be lawful to import or supply (whether within New Zealand or by exporting it) a medicine, medical device or type-4 product, unless that product was approved or approval-exempt or the person importing or supplying it was authorised to do so.
52. It would also not be lawful for a person who is not the product's sponsor (ie, the person to whom the approval was granted) to import an approved product without the written consent of the product's sponsor, or an authorisation given by a licence, permit or provision in the regulations. This would eliminate the ability to parallel import, except in authorised circumstances. The ability to grant an authorisation has been provided to ensure there is flexibility to deal with exceptional circumstances such as the death or insolvency of a sponsor, or a sponsor who is unwilling to supply an important product.
53. The process for obtaining a product approval and requirements and obligations relating to product sponsors are covered in Part 4 of the Bill and in Chapter C1 of this document.

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)

54. Subpart 2 specifies which activities are controlled activities and that it would be an offence to perform these activities without some form of authorisation. The authorisation can be in the legislation (ie, the Bill or regulations), or be given by a licence or permit (s 53).

55. The controlled activities are:
- a. manufacturing a therapeutic product
 - b. wholesale supply of a therapeutic product (other than a category 4 medicine and an AMI that is not a category 1 AMI)
 - c. non-wholesale supply of a category 1 medicine, a category 2 or 3 medicine in the course of business, a supply-restricted device contrary to supply restrictions, a type-4 product
 - d. prescribing a medicine
 - e. issuing a special clinical needs supply authority for a therapeutic product
 - f. administering a category 1 medicine to a person or animal
 - g. possessing a category 1 medicine or a category 1 AMI
 - h. taking a medicine or a category 1 AMI overseas in the course of business
 - i. issuing a standing order in relation to a medicine
 - j. using a use-restricted device on a person contrary to use restrictions
 - k. using a type-4 product on a person or animal in the course of business
 - l. conducting a clinical trial of a therapeutic product
 - m. carrying on a pharmacy business.
56. The draft Bill does not stipulate if an activity should be authorised via the legislation, a licence or a permit. Generally, if an authorisation needs to apply to a class of persons or to all persons in a specific circumstance, the Bill or regulations would be used. If there is a need to authorise a particular person on an ongoing basis, a licence would be more appropriate. A permit would be used for short-term or exceptional circumstances. The intention is that the types of authorisations used currently for particular activities would generally continue. For instance:
- a. manufacturing, wholesale supply, non-wholesale supply and carrying on a pharmacy business would continue to be authorised via a licence. In future, clinical trials would also be authorised via a licence
 - 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.
57. Some medical devices could be declared (via regulations) to be supply-restricted or use-restricted. Regulations would then specify the supply and/or use restrictions. Supplying or using them contrary to those restrictions would be a controlled activity that would be unlawful without an authorisation. The regulations that impose the supply or use restrictions might also include authorisations (eg, authorising health practitioners to supply or use the device on certain conditions).

58. If there are any type-4 products (s 53), using them on a person or animal in the course of business would be a controlled activity. It is likely the regulations would authorise their use by health practitioners in appropriate circumstances.
59. If a person exports a category 1, 2 or 3 medicine or a category 1 AMI by supplying it to someone outside New Zealand, they would be covered by the controlled activities of wholesale supply or non-wholesale supply. 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. This makes it clear that an authorisation would still be required. The type of authorisation would depend on the circumstance, but in general would be via a regulation or permit. For example, regulations could be developed enabling New Zealand armed forces to take medicines with them for supply while deployed overseas (and setting suitable requirements). A permit could be used to authorise aid workers for a charitable organisation to take and supply medicines while working overseas.
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.
61. Section 55 sets the requirement for a person in the supply chain to comply with requirements (which would be specified in regulations) relating to:
- a. how a person carries on a controlled activity
 - b. product or consumer information for therapeutic products
 - c. packaging and labelling for therapeutic products
 - d. storage, handling, security, transport or disposal of therapeutic products
 - e. tracing and recall of therapeutic products
 - f. record-keeping, auditing and giving of information to the regulator
 - g. ongoing monitoring, by the issuer, of conduct authorised by a standing order or a special clinical needs supply authority.
62. Requirements could be applied to anyone involved in the supply chain of therapeutic products, not just to people who carry out controlled activities. For instance, although supply of category 4 (general-sale) medicines is not a controlled activity (meaning it does not require a licence), it would be possible to set requirements that ensure medicines are stored appropriately (eg, away from products such as garden chemicals that may cross-contaminate them, or out of the reach of children).

Question B4

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

Subpart 3: Authorisations (ss 56–80)

63. Subpart 3 would provide authorisations that apply generally to all members of each profession (subject to their scope of practice). If a particular practitioner wanted to be able to do something that was beyond what is authorised by subpart 3, they could apply for a licence or permit to do so. Further authorisations would be provided in the regulations for more specialised, small-scale or frequently changing situations (eg, nurses supplying medicines in prisons).

Pharmacists and qualified pharmacy workers (ss 57–60)

64. Sections 57–60 provide the authority for pharmacists and qualified pharmacy workers to perform controlled activities that occur within the dispensary, including compounding and dispensing, without needing a licence to authorise manufacturing. They also specify the requirements that would need to be complied with when performing the activities.
65. The authority to perform such activities does not obviate the need to comply with other requirements such as those relating to pharmacy business licences, special clinical needs supply authorities, compliant prescriptions and regulations under section 55.
66. Section 60 provides the authority for qualified pharmacy workers and sets the level of supervision required for pharmacy activities that require an authorisation (ie, controlled activities). For supply of category 3 (pharmacy) medicines, general supervision of a pharmacist is required, while all other activities require direct supervision of a pharmacist (unless rules allow a lower level of supervision). The level of qualification required for a pharmacy worker to perform a particular activity would be specified in rules (see s 37). The intention is for the rules to reflect the status quo.
67. If a supervising pharmacist's authority to carry out the activity is subject to any limitations, the pharmacy worker would be subject to the same limitations. The draft Bill is explicit that the determination of the appropriateness of a category 2 (pharmacist) medicine is to be made by the pharmacist, not by a pharmacy worker.

68. Section 59 would allow pharmacists to supply by wholesale, without a licence, if regulations authorised this and the pharmacist complied with the specified requirements for such supply. We intend to develop regulations to allow pharmacists to supply to other health practitioners, in the types of situations that currently occur under practitioner supply orders. We are also considering allowing a pharmacist to supply a medicine to a nearby pharmacy that is out of stock of the medicine requested by a patient.

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).

Health practitioners and health practitioner’s staff (ss 61–65)

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. A ‘health practitioner prescriber’ is a health practitioner whose scope of practice includes prescribing (as defined in s 14). The Health Practitioners Competence Assurance Act 2003 (HPCA Act) would be amended to specify that scopes of practice may include the authority to prescribe, subject to the approval of the Minister of Health (see ss 276–285). Chapter C8 contains further information on the proposed amendment to the HPCA Act and the proposed approach for establishing a new or changed authority to prescribe.
70. As in the current scheme, not all health practitioner prescribers would automatically be authorised to issue a standing order (eg, midwives cannot do this currently). A health practitioner prescriber would only be able to issue a standing order if their scope of practice explicitly included this authority. The person issuing a standing order is deemed to be in a principal / agent relationship with a person authorised by the order (see s 41(5)). Consequently, the attribution of liability and defence provisions (see ss 239–241) apply to both parties.
71. Section 61(2) would also authorise a health practitioner (including those who are not a prescriber) to supply category 3 (pharmacy) medicines to their patients if the medicine is relevant to a health service that is part of the practitioner’s scope of practice. The medicines they could supply would therefore be limited to those that are appropriate for the treatment of a condition covered by the scope of practice of the practitioner. For example, a podiatrist would only be able to supply pharmacy medicines for the treatment of conditions affecting the feet and lower limbs. Currently health practitioners are able to administer these types of medicines, but not supply them to patients for follow-up care. We consider

that if a health practitioner has the competencies required to administer these medicines, then they also have the competencies required to safely supply them.

72. Section 62 would provide the same authorisations for unapproved medicines, but would include the additional requirement for a complying special clinical needs supply authority (SCNSA). Note, that a product approval only approves the product for the purposes specified in the approval (s 99(2)). This means that whenever a medicine is prescribed for off-label use it is an unapproved medicine and would require a SCNSA.
73. The reason for requiring a SCNSA to authorise the supply of an unapproved product is to ensure that the issuing practitioner actively considers whether the patient has a special clinical need that an approved product cannot adequately meet. Therefore, they need to be satisfied that the decision to use an unapproved product is clinically appropriate. The regulations detailing requirements for SCNSAs could specify matters such as the:
 - a. form and manner in which they are issued (s 39(2))
 - b. need for periodic review and monitoring (s 55(1)(g)).
74. The provisions relating to the issue of a SCNSA are set out in section 64. Health practitioners would be authorised to issue SCNSAs for medical devices and health practitioner prescribers would be authorised to issue them for medicines. However, both authorisations would be subject to regulations that specify the circumstances in which particular classes of practitioners can issue them (s 64).
75. Our intention is to use regulations to specify graduated requirements for unapproved medicines, based on the level of regulatory oversight of the product. In particular, we propose that there would be two main types of authorisation covering:
 - a. **the off-label use of medicines that have been approved in New Zealand** – our intention is to authorise all health practitioner prescribers to issue a SCNSA for off-label use (as long as the medicine is covered by their scope of practice) and have minimal requirements for what that SCNSA would need to involve (potentially a tick box)
 - b. **medicines that do not have a product approval in New Zealand** – our intention is to continue to limit the ability to issue a SCNSA for these products to medical practitioners. This is in line with the current approach under the Medicines Act 1981. The policy intent is to ensure that unapproved medicines are only used when a patient has a special clinical need that an approved medicine cannot meet. However, once a SCNSA has been issued, any health practitioner prescriber would be able to prescribe that unapproved medicine for that patient (as long as it is within their scope of practice) (s 62).
76. Section 63 means that regulations could be developed to authorise health practitioner prescribers to supply small amounts of medicine to each other (eg, to assist a neighbouring practice that is out of stock) and for health practitioners to supply medical devices to each other, if that was considered appropriate.

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

Question B7

Please provide any comments on the authorisations for health practitioners (ss 61–64).

Question B8

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

Veterinarians and veterinary staff (ss 66–70)

78. Sections 66–70 would provide the authority for veterinarians and veterinary staff to use human therapeutic products as part of their practice. While the Bill is primarily concerned with human health, it still needs to control the supply of therapeutic products used on animals to mitigate risks of diversion into the illicit supply chain. These provisions largely reflect the position under the Medicines Act 1981 but have been aligned with those for health practitioners for consistency; however, how they would be implemented would be up to the Veterinary Council of New Zealand. See Chapter C9 for further discussion.

Question B9

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

Personal imports (ss 76–77)

79. When someone brings a medicine into the country from overseas, its safety is considered to be unknown because it has not been reviewed and approved by the New Zealand regulator. While many countries have well-developed schemes for safety, many others do not, and products that have been counterfeited or adulterated are circulated widely.

80. Section 76 would allow travellers to bring medicine(s) with them when they come into New Zealand (eg, as a tourist or a returning New Zealand resident). However, there would be quantity restrictions to stop people bringing in more than they need for personal use. If the medicine was lawfully prescribed by an authorised prescriber in New Zealand, or by an overseas health professional, they could bring in the amount prescribed. In any other case, the limit would continue to be three months' supply and no more than 15 months' supply in a year.
81. Section 76 would continue to allow consumers to import category 2, 3 or 4 (non-prescription) medicines by post. However, it would not allow consumers to order category 1 (prescription) medicines from an overseas supplier. This is because of the level of counterfeit or substandard products in many overseas markets. Such products pose significant safety risks that consumers are unable to detect.
82. A category 1 (prescription) medicine could be obtained from overseas for a patient if a medical practitioner is satisfied that the patient has a special clinical need that cannot be met by using a medicine available in New Zealand (s 64). The issuer of the special clinical needs supply authority (s 64(2)), a pharmacist (s 58(5)), or a wholesaler (whose licence allows them to do so) could then import the medicine for the patient.
83. Section 77 would allow a person or carer to bring in medical devices for their own use (ie, by bringing the devices with them or ordering online). However, if there are concerns around the risks associated with particular devices, it would be possible to prohibit the personal import of those devices (via regulations).

Question B10

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

Other authorisations (ss 71–75 and 78–80)

84. Section 71 provides the authority for someone working under a standing order to perform the controlled activities authorised by the standing order (eg, to supply and administer a prescription medicine).
85. The requirements for standing orders would be set via regulations. In particular, the:
- a. circumstances, form, content and issuing requirements for a standing order would be specified in regulations made under section 40
 - b. effect of a standing order (eg, if the issuer ceases to be authorised to issue it) would be specified in regulations made under section 41
 - c. requirements for ongoing monitoring would be set by regulations made under section 55.

86. We are aware of a range of concerns about the current use of, and requirements for, standing orders. We intend to address these, where appropriate, when developing these regulations and will engage with relevant stakeholders to help inform this process.
87. Section 72 authorises people to supply or administer a category 1, 2 or 3 medicine to the intended patient, as long as the medicine has been lawfully supplied to them. This covers common supply situations (see s 42(5) for the definition of supply), such as a pharmacist supplying a medicine to a parent when the patient is a child, or to a spouse, and supply and administration within institutions such as hospitals and prisons.
88. As possessing a category 1 (prescription) medicine and category 1 AMI is an offence, sections 73 and 74 set out the situations in which possession would not be an offence. Examples would be if the medicine was lawfully supplied to a patient, or the person is authorised by regulations, or has a licence or permit for supplying category 1 medicine. Regulations could be used to authorise generic situations.
89. Section 75 would allow someone to manufacture a custom-made device without a licence, as long as they met the requirements specified in regulations (which would include who is able to do this). For example, this could be used to allow the manufacture of custom-made artificial limbs and dental crowns by skilled technicians.
90. Section 78 would deal with situations where a product ceases to be approved without the product being a risk to anyone. Examples might be if an approval lapsed because the sponsor failed to comply with a condition on the approval and the regulator was satisfied there was no safety risk with the product, or on the death of a sponsor. The provisions would enable 'stock in trade' that is already in the supply chain to be used in the event an approved product becomes an unapproved product as long as the regulator had issued a 'use of current stock' notice for the product.
91. Section 79 would enable regulations to be made that would authorise people to carry out a controlled activity or import or supply an unapproved product in specific circumstances. This is intended to allow for more tailored authorisations for specific circumstances, such as:
 - a. importing or manufacturing samples of products that are not intended for supply but for uses such as demonstration or display, research and development, or submission to the regulator
 - b. importing a product ahead of a decision on a pending application for approval
 - c. visiting sports groups, military groups or heads of state delegations importing medicines and supplying and administering them to members of those groups
 - d. a health practitioner arriving from overseas with an air ambulance patient importing medicines, and subsequently administering them to that patient
 - e. importing therapeutic products that are part of the first aid stock to be used on board visiting aircraft and vessels.

92. We also intend that this regulation-making power would be used to authorise specified types of health practitioners to carry out specified controlled activities in relation to a named medicine. The authorisation may be subject to conditions specified in the regulation. Currently this is often done using the classification entry in the First Schedule to the Medicines Regulations 1984 to create an exception scenario for a medicine.
93. For example, the current entry for trimethoprim states:
- trimethoprim is a prescription medicine except in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16–65 years for the treatment of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the New Zealand College of Pharmacists’ training in the treatment of urinary tract infections.
94. The current approach is not ideal because it creates uncertainty about the classification at certain points in the supply chain. In future, we envisage trimethoprim would be a category 1 (prescription) medicine, but the regulations would authorise a pharmacist with the specified training to supply it without a prescription in the circumstances set out in the regulations.
95. In some situations, the ability to obtain particular medicines from vending machines may help facilitate better access. To ensure these are only used in circumstances where the regulator considers it is safe and appropriate, the draft Bill requires an explicit authorisation (generally on a licence) for supply involving a vending machine.

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)

96. **Prohibited products** (s 81): The Bill defines a prohibited product as one that has been specified in regulations to be prohibited (s 25). To make such a regulation, the Minister must be satisfied that the product poses a significant risk of death or serious harm that cannot be adequately managed by the exercise of the regulator’s powers under the Act. Note that these powers include allowing the regulator to issue a temporary product prohibition order (for a term of one year unless renewed) (s 170), which could prohibit specific activities for a particular product and would deliver a similar effect to actions currently taken under sections 36, 37 and 38 of the Medicines Act 1981. It would be possible for a permit to enable someone to perform particular activities with a prohibited product in specific circumstances (eg, testing or research).

97. **Advertising** (ss 82–83): The advertising provisions reflect the current core requirements under the Medicines Act 1981 where unapproved products cannot be advertised and advertisements must not contain misleading information. Under the new scheme, it would also be possible for the regulator to issue an advertising remediation order (s 166). The provisions would enable further requirements to be specified in the regulations. These requirements would be likely to focus on specifying minimum content requirements to support the safe use of therapeutic products.
98. The Bill would continue to permit direct-to-consumer advertising of prescription medicines (DTCA). Currently, New Zealand and the United States of America are the only developed countries that allow DTCA in a form in which a product can be identified. DTCA is a contentious issue: views on the practice are split and the evidence base on its impacts is mixed. The Government therefore anticipates there will be considerable consultation feedback on the issue and is interested in exploring whether increased regulation is warranted. See Chapter C10 for further comment on the regulation of advertising.
99. **Tampering** (ss 84–87): Adulteration of a medicine is already an offence under the Medicines Act 1981. This offence has been retained and widened to cover other ways in which a product could be interfered with that might adversely affect its quality, safety, efficacy or performance (eg, changing the expiry date on packaging). Section 87 imposes a duty on everyone in the supply chain to report even a suspicion of tampering, or that someone is proposing to tamper with a product. However, failure to do so would only be an offence if the person knows that a product has in fact been tampered with and wilfully fails to notify the regulator.
100. **Misrepresenting a therapeutic product** (s 88): Misleading branding is already an offence under the Medicines Act 1981. However, this section would cover a broader range of misrepresentation behaviours in relation to a product or its regulatory status.
101. **Holding out to have an approval or authorisation when you do not** (s 89): This would make it an offence for someone to represent that they or another person can legally do something within the therapeutic products scheme when they cannot. For example, they might pretend to have a manufacturing licence, or to be the sponsor of a particular product. Some of this behaviour is also (and will continue to be) captured under the Health Practitioners Competence Assurance Act 2003 (eg, representing yourself as a medical practitioner when you are not).
102. **Agreeing or offering to carry out a supply chain activity unlawfully** (s 90): If such activity occurs, then it would be covered by the relevant offences specified elsewhere in the Bill (eg, supplying an unapproved product). This offence, however, covers the initial action of agreeing or offering to perform the activity, regardless of whether it occurs. For example, someone might accept money to supply a product that they are not legally authorised to supply and never intend to supply.

103. **Obtaining a therapeutic product when supply is unlawful** (s 91): This section would make it an offence for a person to obtain a therapeutic product from another person who is not authorised to supply it, if the first person knows or ought to have known that the supplier was not authorised to supply it. Note that, because of section 72 of the Crimes Act 1961, a person who attempts to obtain a therapeutic product in those circumstances but fails (eg, because the supplier refuses to supply) may still be committing an offence.
104. **Misleading information in records** (s 92): This offence would cover the falsifying, or altering, of any records required under the scheme (eg, certificates of analysis, manufacturing records). Note that section 197 establishes a related offence of providing misleading information to the regulator. See sections 55(1)(f), 118(1)(f) and 158(1)(b) for the regulation-making powers under which record-keeping requirements would be imposed.
105. **Health practitioner prescriber must not hold interest in a pharmacy business** (s 93): This restriction has been carried over from the Medicines Act 1981, due to a concern about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions. Drafting this provision, however, has raised some questions regarding the practicality of the restriction, its one-sided nature (as pharmacists can hold an interest in a general practice, for example) and the potential impact on pharmacists who become qualified as a pharmacist prescriber. See Chapter C6 for more detail and a question seeking feedback on this particular offence.

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)

106. Section 51 would establish the requirement for a product approval to import or supply a therapeutic product. Part 4 of the draft Bill specifies the scope of the product approval, and lays the foundations for the application process for obtaining a product approval, the criteria for product approval and the criteria for a person to be a sponsor of an approved product. Note that Part 6 (subpart 5) of the draft Bill deals with the administrative detail about all applications, including those for product approval.

107. In broad terms, the applicant would need to satisfy the regulator that:
 - a. the quality, safety and efficacy or performance of the product are satisfactorily established (s 95(a))
 - b. the likely benefits of the product outweigh its likely risks (s 95(b))
 - c. the applicant meets the criteria for being a sponsor (s 97)
 - d. the product will meet the product standards (s 96).
108. Other criteria could also be specified in rules (s 95(c)). It is intended that these rules would set out the requirements for different kinds of products. We know the sector is very interested in these details and will consult with stakeholders as they are being developed.
109. When considering an application, the regulator would be able to rely on reports or assessment made by recognised authorities (s 207). This would enable regulatory efficiencies, while also ensuring that New Zealand makes its own decisions about products on its market.
110. For further information about the approval of products, see Chapter C. Approvals for the medicines (excluding cells and tissues) sector are covered in C1, for the cell and tissue sector in C2 and for the medical device sector in C3.
111. Products manufactured in New Zealand that are only intended for supply in overseas markets would still require a product approval. We envisage a simplified pathway for this approval (which would be conditional on the product being supplied only for export and not in New Zealand) that would enable local requirements of the importing country such as product labelling to be met.
112. In the current regulatory scheme, it is not always clear who is responsible for a therapeutic product that is on the market. For example, current legislation refers to manufacturers, importers, proprietors and sponsors, with various obligations placed on these people. The draft Bill sets up a single responsible person (called a sponsor), specifies criteria for being a sponsor of an approved product (s 97) and specifies a set of obligations that sponsors must meet (ss 116–118). The sponsor would be the primary point of contact for any issues arising with an individual product.
113. For an approved product, the sponsor is the person to whom the approval was granted. The draft Bill allows the Crown to be a sponsor to allow for extraordinary situations where there is no willing or suitable private sector sponsor (s 97(a)(iii)).
114. One of the criteria for being a sponsor is that the person has a contractual relationship with the responsible manufacturer (s 97(c)). This is intended to reinforce the sponsor's obligations regarding the integrity of the product and its regulatory approval, and also to ensure the relationship between sponsor and manufacturer facilitates investigations related to manufacturing issues. We are very aware of the critical importance of manufacturers keeping sponsors informed about planned changes to products and inventory and quality issues.
115. The new scheme deals with changes to medicines in a different way from section 24 of the current Act. This is covered in more detail in Chapter C1.

116. Product approvals would generally not have an expiry date, but it would be possible to specify an expiry date on the approval or in regulations (s 103) if it was considered necessary.
117. It would be possible to place conditions on an approval (eg, a requirement to provide more clinical data by a specified date) and to add or amend conditions after approval (ss 105–107).
118. The grounds and process for, and effect of, cancellation of an approval are set out in sections 108–112. Non-payment of fees would be a ground for cancellation.
119. Details of all approved products, declined applications, and applications where a decision is pending would be contained on a publicly available product register maintained by the regulator (s 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)

120. The regulator would be able to issue a notice to declare products or classes of products to be approval-exempt if satisfied that this was necessary or desirable to promote the purposes of the Act (s 114). This type of exemption would be used considering the nature of the product and whether the risks associated with it were adequately managed through other controls such as a manufacturing licence.
121. Further consultation would occur as the notice was being developed. However, we envisage the following classes of product would be included:
 - a. whole blood collected by the New Zealand Blood Service
 - b. many blood components manufactured by the New Zealand Blood Service from whole blood, and apheresis donations using simple processing steps
 - c. minimally manipulated tissue that is stored in licensed tissue facilities
 - d. custom-made devices manufactured by, or for, an individual clinician for the sole use of a particular patient.

122. Approval-exempt products would still have a sponsor. The notice specifying that a product was approval-exempt would also specify who the sponsor was for that product (s 115). Generally this would be likely to be the person importing the product into, or manufacturing it in, New Zealand.

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)

123. Subpart 3 sets out obligations for sponsors of both approved and approval-exempt products. Under the new scheme, sponsors of an approved product would have an explicit obligation to ensure the product complies with its approval and with product standards. This obligation applies not just when the product is manufactured or imported, but also while the product is in the supply chain.
124. More detailed obligations would be set out in regulations. These would include obligations for post-market safety monitoring and reporting.

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)

125. The provisions in this subpart would provide the same protection as the relevant provisions in the Medicines Act 1981. New Zealand is required by the Trade-Related Aspects of Intellectual Property Rights agreement (known as TRIPS) to provide such protection for confidential information supporting a regulatory approval of a new medicine.

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

126. This part sets out the criteria and processes for obtaining a licence or permit.
127. To provide flexibility for the future, the Bill would enable any controlled activity to be authorised by a licence, permit or provision of the legislation. The draft Bill does not stipulate if an activity should be authorised via the legislation, a licence or a permit. Generally, if an authorisation needs to apply to a class of persons or to all persons in a specific circumstance, the Bill or regulations would be used. If there is a need to authorise a particular person on an ongoing basis, a licence would be more appropriate. A permit would be used for short-term or exceptional circumstances.
128. The intention is that the types of authorisations used currently for particular activities would generally continue. For instance, manufacturing, wholesale supply, non-wholesale supply of a category 3 medicine, and carrying on a pharmacy business would continue to be authorised via a licence; and, in future, clinical trials would also be authorised via a licence.

Subpart 1: Licences (ss 123–130)

129. The Bill does not name or specify different types of licences in the way the Medicines Act 1981 does. Any given licence would be able to authorise a number of controlled activities. For example, the same licence would (as now) authorise both the manufacturing and wholesaling of a product by the manufacturer. A licence would be able to authorise a pharmacy business and any depots used by the pharmacy as collection points for consumers to pick up their medicines. It would be up to the regulator to decide how best to implement the approach to licensing and it would be accountable for doing so effectively and efficiently.
130. For most medical devices, a licence would not be required for non-wholesale supply (ie, supply to the end user) or use on a patient. However, if a product was declared to be supply- or use-restricted, then some form of authority could be required, which may be via a licence. Similarly, if in the future a product is declared to be a type-4 product, then the supply and use of that product could be authorised by a licence.

131. The Bill would also enable other activities that would otherwise be unlawful to be authorised via a licence (s 123(2)). For example, a licence for a clinical trial could also authorise the supply of an unapproved medicine for the purpose of that trial. The one activity a licence could not authorise is one that involves a prohibited product, as these can only be authorised by a permit (s 81).
132. A licence could also authorise a person other than the licensee to conduct an activity (s 123(3)). For example, if company B was sterilising a product for medical device company A (which was the responsible manufacturer of that product), it may be appropriate for company B to be authorised to perform that activity under company A's licence.
133. Each licence would clearly specify the persons and activities it is authorising, the locations where the activities may occur and any conditions (s 124). A licence could specify different places for different activities. For example, a licence could authorise a clinical trial and the import of unapproved products for that trial. Alternatively, a pharmacy licence could authorise compounding, dispensing and supply from the licensee's main premises and dispensing and supply at an aged care facility. It would be up to the regulator to determine how to most effectively and efficiently implement this arrangement.
134. A licence would authorise workers of the licensee to conduct the activities authorised by the licence (s 125). For example, it would authorise workers in a manufacturing company to manufacture medicines. However, a licence to carry out a pharmacy business would not authorise anyone to carry out a pharmacy activity (ie, to compound or dispense a medicine or supply a category 1, 2 or 3 medicine) unless they are a pharmacist or a qualified pharmacy worker and comply with sections 57–60, or are otherwise authorised to do so (s 126).
135. The concept of having responsible persons named on a licence exists under the Medicines Act 1981 and would continue under the new scheme. Sections 128–130 would establish criteria for granting a licence and for the licensee and responsible persons. Of note, the licensee and responsible persons named on the licence must pass the 'fit and proper person' requirements, and have sufficient knowledge of the obligations, products and activities covered by the licence to be able to comply with the legislation. The new scheme would include competency requirements for people in the responsible person roles (s 130(e)). They would also have statutory obligations.
136. The Medicines Act 1981 requires a pharmacy to be majority owned and effectively controlled by a pharmacist. The Government is seeking feedback on options to retain and improve the majority pharmacist ownership requirement, or to replace the pharmacist ownership requirement with other licensing requirements. See Chapter C6 for more detail and questions.

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)

137. This subpart sets out the content and effect of permits. Permits are intended to be used for shorter-term and/or urgent situations. For example, a permit might be used to authorise:
- a. a pharmacy to be set up in temporary accommodation
 - b. the import and supply of an unapproved medicine or medical device in an emergency.
138. The criteria for granting a permit (s 135) differ from the criteria for granting a licence because permits are intended to provide flexible short-term solutions to particular issues.
139. As with a licence, a permit could authorise someone to perform a controlled activity or anything else that would otherwise be unlawful under the legislation (s 131).

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)

140. Licences and permits would be able to cover a number of activities and sites. For example, a licence could authorise a pharmacy to compound at its main premises and supply via home or marae visits within a particular region. However, section 136 would empower the regulator to split up a licence or permit application where the activities would be more appropriately regulated via two or more licences or permits.
141. Licences would no longer be limited to one year. The regulator would be able to issue a licence, based on an appraisal of safety concerns, up to a maximum of three years (s 137). The duration of a permit is up to two years.

142. The Bill does not provide a separate process for renewing licences and permits; it would simply be a matter of applying for another one. However, we envisage a simplified administrative procedure for 'renewals'.
143. Licences and permits would be subject to any conditions:
- a. specified in rules – for example, standard licence conditions that apply to a particular controlled activity irrespective of who the licensee is
 - b. imposed by the regulator – this would allow for more tailored conditions to be imposed either when the licence is granted or during the life of the licence.
144. Like the Medicines Act 1981, the Bill allows the regulator to vary a licence or permit (s 140). For example, a variation could result from a safety concern (eg, removing an authority to do a particular activity) or be at the request of the licensee (eg, if they request authority to perform an activity not currently authorised).
145. If a person was non-compliant with their licence, they would be considered to be conducting a controlled activity without approval and therefore committing an offence (s 53).
146. The regulator would continue to be able to suspend or cancel a licence or permit. The grounds and procedures for doing so are set out in sections 141–149.
147. While a licence or permit cannot generally be transferred (s 150), the Bill does allow for automatic transfer to occur in the case of death, bankruptcy or insolvency of the licensee or permit holder. Section 151 specifies to whom the licence or permit is transferred under those scenarios. Because a licence or permit is not generally transferable, if a licensee or permit holder wishes to sell the business to which the licence or permit relates, the purchaser of the business must obtain their own licence or permit before they take over the business.
148. A register of licences and permits will be publicly available (s 152).

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)

149. The Bill includes specific obligations on licensees to mitigate the risk of commercial incentives overriding safety considerations. In particular, it would be an offence to:
- not provide a responsible person with the authority and resources to perform their role (s 153)
 - encourage a health practitioner to act unprofessionally (s 155).
150. Another requirement would be for responsible persons named on a licence to report non-compliance to the regulator if they have raised it with the licensee and the licensee has not addressed that issue (s 156). Related to this provision, the Bill includes an offence around any retaliation against a responsible person for fulfilling their obligations under the legislation, particularly the requirement to report ongoing non-compliance to the regulator (s 157). This is intended to mitigate some of the employment tension that would occur in this type of situation. While it is not possible to remove this type of tension entirely, these provisions are intended to make the expectations on responsible persons and licensees explicit.
151. It would also be possible to set specific obligations for responsible persons via regulations (s 158). While most of the obligations relating to licensed activities would reside with the licensees, there could be particular activities that, for safety and quality reasons, should be performed by the responsible person.
152. The requirement for a pharmacist to be present for a pharmacy to perform pharmacy activities would continue (s 159). Note that pharmacy activity covers the compounding, dispensing or supply of category 1, 2, and 3 medicines by non-wholesale supply. If a licensee wanted to open their pharmacy premises without a pharmacist present in order to only supply category 4 (general-sale) medicines or other products, then the licensee would need to provide the regulator with assurance of how they would ensure that their category 1–3 medicines were secure and safe from diversion and that no pharmacy activities were able to occur (eg, by securing the dispensary and closing off all access to category 1–3 medicines).

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)

153. This subpart covers the regulator’s powers and functions. It includes provisions placing obligations on the regulator that are not covered elsewhere.
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. Product sponsors would have explicit obligations in relation to post-market monitoring, reporting and risk management for their products. In addition, section 160 requires the regulator to have a system to continuously monitor the safety of approved, approval-exempt and lawfully supplied unapproved products and to do so in accordance with requirements to be set in the regulations.
155. The regulator would be able to issue privileged public safety notices if needed to address a particular safety concern with a product, advertisement or a sponsor or person in the supply chain (s 161).
156. Sections 162–182 deal with regulatory orders. The regulator would have the power to issue a number of regulatory orders and there would be a corresponding offence for non-compliance with those orders. The grounds for issuing these orders depend on the existence of a risk of harm (which is defined in s 14). The regulator would be able to issue the following regulatory orders.
- a. **Recall orders:** As in the current Act, the regulator would be able to issue recall orders (s 162). The regulator’s first course of action would be to work with the sponsor and relevant persons in the supply chain to oversee a voluntary product recall. However, if necessary, the regulator would be able to issue a mandatory order. If the sponsor or person in the supply chain did not comply with this order, they could be prosecuted (s 163).
 - b. **Premises restriction orders:** The regulator would have a new power to issue a premises restriction order (ss 164 and 165). If a serious concern arises about the use of premises specified in a licence or permit, the concern could be addressed through the licensing mechanism. The premises restriction order is intended to be used for other situations that could not be addressed this way and where products were being handled or stored in unsanitary or unsuitable premises. Examples might be the storage of category 4 (general-sale) medicines in a building that was not watertight or was contaminated with a dangerous chemical; and the inappropriate storage of category 3 medicines in unlicensed premises.

- c. **Advertising remediation orders:** As well as prosecuting a non-compliant advertiser, the regulator would be able to issue an order directing the advertiser, or person involved in the distribution of an advertisement, to stop or correct the advertisement (ss 166 and 167). This would place an additional obligation on the advertiser or persons involved to actively stop ongoing non-compliance by pulling the advertising material and could involve issuing a retraction or correction.
- d. **Directions order:** This is quite a broad power, which is why it has a high threshold and could only be used if there was a significant risk of death or serious harm (ss 168 and 169). Where the serious risk threshold is met, the regulator would be able to direct anyone involved with that product to do, or not to do, something in relation to that product, as long as the direction is no broader than is reasonably necessary to address the risk.
- e. **Product prohibition orders:** The regulator would be able to prohibit a number of activities across the supply chain in relation to a product, including: importing, manufacturing, supplying, prescribing and administering (in the case of a medicine), use and possession. This power would be reserved for situations where there were serious safety concerns (s 170). For medicines, this aligns with the current power of the Minister of Health under section 37 of the Medicines Act 1981. For medical devices, this would be an enhanced power. Under section 38 of the Medicines Act 1981, the Director-General of Health is able to request information from an importer or manufacturer of a medical device to satisfy them of the safety of that device. Until that information has been provided, it is an offence to sell that product. However, under the current Act, once the information is provided, the Director-General does not have a clear power to prohibit future supply of the product, aside from requiring further information. A product prohibition order would be limited to one year. However, if the safety issue continues, the regulator would be able to issue another order. If the risks associated with the product are permanent, the product could be declared a prohibited product via regulations (see ss 25 and 81).
- f. **Medicines access limitation orders:** A medicines access limitation order would be equivalent to a supply restriction notice issued under section 49 of the Medicines Act 1981 (ss 172–176). The regulator could issue this type of order if it believed on reasonable grounds that someone was addicted to a category 1 or 2 medicine, or had obtained more than is reasonably necessary for their use. The provisions are aimed at helping to manage addictions and avoiding diversion of product into the illicit supply chain. The regulator would also be able to issue a statement about an oversupplied person (defined in s 172). This power would be used to limit the inappropriate supply of medicines to the person and assist in their treatment for addiction. It also protects the regulator from a charge of defamation if they notify particular people (s 175). For example, the regulator might notify all prescribers of the existence of a medicines access limitation order for a particular individual or might notify pharmacies of a particular individual's attempt to seek medicines using false prescriptions or particular aliases. Where this information has been provided, those that receive it are required to keep it confidential, but can discuss it with other people that are able to receive the information (eg, another prescriber) (s 176).

157. Sections 177 to 182 set the content and process requirements for regulatory orders, including the requirements around when the regulator can vary or revoke an order.
158. The intention of section 179 is to ensure that where someone has misrepresented something as a therapeutic product, the regulator would be able to make an order, even though the product does not meet the definition of a therapeutic product.
159. The person required to comply with a regulatory order or the product's sponsor is able to apply to the regulator to vary or revoke the order (ss 181–182). The requirements for such applications to the regulator are set out in sections 211–217. The detailed requirements would be set in rules. For instance, it is intended that there would be a limit on how frequently someone subject to a medicines access limitation order can apply for it to be revoked to mitigate the risk of someone continually applying. However, it is not intended that such a limit would apply to health practitioners applying to have the order amended or revoked for clinical reasons.

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)

160. As it does now, the regulator would undertake a range of activities to monitor the level of compliance with the scheme. These activities would be likely to include audits of licensed premises, an active border surveillance programme to detect importations of unapproved products, and a routine and complaints-based product testing programme to check products for compliance with required standards.
161. The Search and Surveillance Act 2012 provides the standard set of investigative powers used in New Zealand. Therefore, provisions in the Bill relating to investigative powers contain cross-references to powers under the Search and Surveillance Act 2012 (eg, s 191). The Bill would also amend that Act to include a reference to the Therapeutic Products Act (see s 287).
162. Consequently, the majority of investigative powers that an enforcement officer would use under the new scheme are covered in Part 4 of the Search and Surveillance Act 2012. This section of the Bill would establish the powers of entry that then link into the investigative powers under the Search and Surveillance Act 2012. This subpart of the Bill also includes some additional powers that are not included in the Search and Surveillance Act 2012, but that would be necessary for the operation of this regulatory scheme (such as the testing power in s 186). It also modifies the operation of some of the powers from the Search and

Surveillance Act 2012³ to tailor them to the needs of the therapeutic products scheme (eg, the destruction of seized things in s 193).

163. The investigative powers would be largely consistent with the current powers.
164. The definition of 'investigative purposes' covers both investigations with a focus on obtaining evidential material for a prosecution, and also routine monitoring of compliance with the legislation and regulatory requirements (s 183).
165. The draft Bill does not provide a formal process for the regulator to appoint enforcement officers. Instead, enforcement powers are conferred on the regulator, who would be able to delegate those powers to suitably qualified or trained people (s 184).
166. The regulator would be able to require information as part of its compliance and safety monitoring of products (s 185). This would include the ability to require a sponsor to obtain relevant information; for example, requiring them to perform additional tests and provide the results.
167. The regulator would be able to use a notice to designate recognised laboratories and the analysts in charge of those laboratories (s 187). Regulations would be developed to authorise any activities involved in the collection of samples to ensure they are not considered unlawful supply.
168. As in the current scheme, the Bill would allow the regulator to enter and inspect most premises without a warrant in order to monitor compliance or because there were concerns (s 189). However, this power could not be used in a home or marae, or in a treatment room while a patient is in the room, without the consent of the relevant person or a warrant (ss 190–191).
169. The Search and Surveillance Act 2012 sets out the powers exercisable by officers during a search. The one gap, which section 192 of the Bill would address, is the ability to require something to be held in an unaltered state for a reasonable period. This may be used where it is not practical to seize a large piece of equipment or stock at the time of the search. As a result, the regulator could require that the equipment or stock remain at the premises untouched, while the investigation is conducted.
170. While the Search and Surveillance Act 2012 allows for the destruction of items seized during a search, the criteria do not fully align with the circumstances where the regulator may want to destroy something to address a safety risk or avoid it being used for an unlawful activity. Section 193 would allow the regulator to destroy seized items if the regulator believes there is a risk that the safety, quality, efficacy or performance of those items may be unacceptable, or that they are likely to be used for an unlawful activity. It would also allow seized imported goods to be destroyed if the regulator had given the importer a requirement under section 194 to remove the goods from New Zealand and the importer had not complied with that requirement. Section 195 would allow the regulator to recover any costs incurred in the seizure, storage or destruction of items.

³ To review the powers provided under the Search and Surveillance Act 2012, go to: www.legislation.govt.nz/act/public/2012/0024/latest/DLM2136536.html

171. Section 194 would enable the regulator to require seized stock of imported product to be returned to the country of origin. This provides an alternative option to destroying stock that could be provided legally in the country of origin (but not New Zealand), or where there would be environmental impacts from destroying the stock in New Zealand.
172. The Customs and Excise Act 2018 enables customs officers to intercept therapeutic products being brought into New Zealand and provide them to the regulator. Section 196 requires customs officers to provide the regulator with information requested for investigative purposes.

Question B25

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

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

173. This subpart would make it an offence to provide misleading information to the regulator, not to comply with an investigative requirement, or to obstruct the regulator.

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)

174. Most of the regulator's decisions in relation to product approvals, licences and permits would be reviewable through a merits review process, with the decision ultimately able to be appealed to the District Court. The review process differs from that in the Medicines Act 1981 because it would not involve using an independent standing committee with set membership.

175. The new approach has been developed after considering the number and type of appeals under the current legislation and the broader scope of the new scheme. It has also followed further consultation with the Ministry of Justice and review of its *Tribunal Guidelines*.⁴
176. The merits review would be conducted by a panel of at least three people appointed by the regulator who have not previously been involved in the decision (s 201). The regulator would act independently in appointing a panel but would be accountable for its decisions to appoint particular people. The Bill would require the regulator to appoint people with suitable knowledge and expertise for the issue at hand, with no conflict of interest, and at least one person who is a lawyer with at least 7 years' experience. The panel would change depending on the matter being reviewed. For example, expertise in pharmacy matters would be needed for a pharmacy licensing decision whereas the expertise needed for a medicine approval matter is likely to be in pharmacology or a practise of medicine related to the type of medicine. Similarly, the expertise required for a medical device matter would depend on the type of device and could range over fields such as biomedical engineering, plastics technology and electrical engineering. This approach has been taken to provide flexibility to respond to the wider range of products and activities being regulated.
177. The panel would not re-make decisions made by the regulator, but would either confirm the original decision or refer the matter back with recommendations for consideration of a new decision (ss 202–203). Decisions of the regulator and the panel could be appealed to the District Court (s 204). These decisions would also be subject to judicial review by a judge of the High Court. A judicial review is a challenge to the way in which a decision has been made (ie, the process), rather than considering the rights and wrongs of the conclusion reached.

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)

178. Section 205 is a flag to indicate that the regulator, as the Chief Executive of the Ministry of Health, has powers, responsibilities, duties and powers derived from the State Sector Act 1988.
179. Section 206 covers what the regulator must do before exercising a power if the Bill specifies the person affected must be given an opportunity to comment.

⁴ Ministry of Justice. 2017. *Tribunal Guidelines: Choosing the right decision-making body. Equipping tribunals to operate effectively*. Wellington: Ministry of Justice.

180. Section 207 is an important provision as it would allow the regulator to rely on recognised authorities. This is intended to assist the efficiency of this regulatory scheme and ensure the regulator is able to draw on work done by overseas regulators or bodies accredited by them and to seek and rely on expert advice.
181. This provision would allow the regulator to base its decisions on reports, assessments, decisions or information provided by other recognised authorities. This does not mean the regulator is bound by the decision of the other authority, as it is required to make its own decisions based on the relevant criteria and context of this regulatory scheme.
182. The regulation of therapeutic products overlaps with a number of other regulatory systems, including the regulation of health practitioners under the Health Practitioners Competence Assurance Act 2003. An information sharing section has been included in the Bill to ensure that, when the regulator holds information that is relevant to the role of another regulatory entity (in New Zealand or overseas), the information can be provided to that other entity and vice versa (s 209).
183. If the information includes personal information, it should not be shared unless the regulator is confident it will be treated confidentially.
184. The regulator would also be able to act on requests from an overseas regulator, but only if doing so would not affect its other functions and appropriate privacy protections are in place (s 210).
185. Sections 211–217 cover the procedural requirements for applications to the regulator. The detailed requirements for particular types of applications would be specified in rules (s 211); however, application fees would be specified in regulations.
186. Section 219 covers what the regulator must do if a document or information is required to be publicly available.
187. Section 221 deals with export certification for approved and approval-exempt products and for unapproved products manufactured in New Zealand.

Question B28

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

B9 Part 7 of the Bill: Enforcement

188. The Bill includes flexible modern offences and penalties, aligned with recent similar legislation (such as the Food Act 2014 and the Health and Safety at Work Act 2015). The proposed enforcement tools would allow the regulator a wide range of enforcement options, meaning enforcement action could be commensurate with the severity of misconduct, and the regulator's approach could be flexible according to circumstances.
189. The hierarchy of enforcement tools includes:
- a. tiered criminal offences (subparts 3–5)
 - b. enforceable undertakings (subpart 1)
 - c. infringement notices (subpart 6).
190. These enforcement tools are in addition to the ability to: add or vary conditions on a product approval, licence or permit; suspend or cancel a licence or permit; or cancel a product approval.
191. We are also considering whether civil pecuniary penalties should be a regulatory option. They are used in some markets to deter non-compliance for commercial gain. As they are a reasonably new concept, we are working with relevant government agencies to see if they are appropriate for this scheme.

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

192. Where an alleged contravention of the Act has occurred, the regulator would be able to accept an enforceable undertaking, in lieu of more severe enforcement action (ss 223–231).
193. This is not intended to impact the quality improvement focus of audits. The regulator would continue to work in a constructive manner to encourage and support sponsors, licensees and others in the supply chain to improve compliance. When this is not successful, an enforceable undertaking could then provide an intermediate step to escalate the issue, instead of proceeding to a criminal prosecution.
194. For example, if a licence holder failed a particular aspect of an audit, the regulator would be likely to first provide guidance on the non-compliance and allow an opportunity to address the issue. If the issue represented a serious safety concern and was not addressed, then the regulator could signal that it was intending to prosecute. At this point, the licensee could offer to give an enforceable undertaking that would address the issue and reduce the risk of reoccurrence. Giving such an undertaking is not an admission of guilt. If the regulator accepted the undertaking, then it could not prosecute for the alleged contravention while the undertaking was in force and if it was completed. However, if the licensee did not complete the undertaking as agreed, the

regulator could prosecute them for the original alleged contravention and for contravening the enforceable undertaking.

195. Enforceable undertakings are intended to promote a quality improvement focus. They are not a way to avoid prosecution if the person knew what they were doing was unlawful and did so maliciously or to achieve some benefit (s 223(4)).
196. Where someone has breached the Act and it is likely they would continue to engage in that conduct, the regulator could apply to a court for an injunction banning the person from performing that activity in the future (s 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)

197. Every offence provision in the Bill specifies a band and tier that applies to the offence. Different penalties apply to each band and tier (s 233).
198. Penalties are broken into two bands. Band A would apply to offences that have a real potential to cause harm. Band B would apply to offences that might be described as regulatory, procedural, or administrative offences (ie, they impact the regulator's ability to perform its regulatory function, which indirectly creates a risk of harm).
199. Within these two bands would be three tiers of penalties, based on the level of culpability. Most offences have three tiers, but some have only one or two. Depending on the nature of the conduct, the degree of culpability may be based on whether the person was wilful or reckless, or whether they had knowledge of, or were reckless as to the existence of, relevant facts. Most, but not all, offences include a strict liability tier, which is where the conduct has simply occurred regardless of whether there was any intent or knowledge. This reflects the fact that anyone operating within the therapeutic products supply chain is obligated to find out what the requirements are and comply with them.
200. For some offences, some level of knowledge of a circumstance is built into the wording of the offence itself. This is to ensure that a person only commits the offence if they have that level of knowledge. If they do have that knowledge, then the question arises as to whether they committed the offence wilfully. Examples are: section 87 – notifying the regulator of suspicion of tampering; and section 171 – compliance with a product prohibition order.

201. While most offences under this scheme would be strict liability offences (meaning the prosecution only needs to prove that a person committed the offence, not that they intended to), a number of defences provide protection for someone being prosecuted inappropriately (ss 243–246).
202. Section 238 would require the court registrar to notify the relevant regulator of any relevant decisions. In particular, if the court makes an order to cancel or suspend a licence or permit or to cancel a product approval, it would need to inform the therapeutic products regulator. If a health practitioner (or veterinarian) was convicted of an offence against the Act, the court would need to notify their responsible authority (or the Veterinary Council of New Zealand).
203. Sections 239–242 set out the circumstances when someone’s conduct can be attributed to another person. These involve attributing conduct of senior managers, workers and agents to employers or principals, and of corporate bodies to their senior managers. This kind of attribution regime is now common in legislation regulating commercial activities (eg, the Financial Markets Conduct Act 2013).
204. Sections 243–246 set out the defences that apply in relation to most of the offences against the Act. Many of the offences in the Bill could only be committed by a sponsor, someone in the supply chain or someone who is otherwise knowingly involved in the therapeutic products business. The defence of taking reasonable steps to ensure the offence did not occur is provided for the benefit of those people (s 243). However, as some offences can be committed by anyone and may catch people unaware, and as they do include strict liability tiers, a wide reasonable excuse defence is provided for the benefit of those people (s 244). Other defences include reliance on information from another person where it is reasonable to rely on that information (s 245) and compliance with a specified standard (s 246).
205. If court proceedings are occurring under the new scheme, section 247 allows the contents of a container to be presumed to conform to any description of the contents on the label of the container unless the contrary is proven. Section 248 allows a certificate of analysis from an analyst to be proof of the matters set out in it unless the contrary is proved. These both continue current arrangements that exist under the Medicines Act 1981, although the terminology is different.

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)

206. Less serious conduct would be declared an infringement offence in regulations. For this conduct, the regulator would be able to issue an infringement notice (the equivalent of a speeding ticket by police). This would provide a useful tool to:
- a. promote compliance with administrative requirements that would not justify criminal proceedings, but are important for the efficient and effective administration and oversight of the scheme – for example, record-keeping requirements
 - b. deter conduct of relatively low seriousness that would not justify criminal proceedings – for example, some small-scale advertising breaches.
207. The infringement fee is the amount someone must pay if they receive an infringement notice. The level for the different conduct would be set in regulations, but must be within the maximum set by the Bill (5 percent of the bottom-tier criminal fine for that offence).
208. An infringement fine is the amount someone might be ordered to pay if the matter was taken to court, at the request of either the regulator (if the person fails to pay the infringement fee) or the person who received the notice (if they dispute it). The maximum amount for an infringement fine could be no more than the bottom-tier (ie, A3 or B3) criminal fine (s 250).

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)

209. The Bill would enable the regulator to charge fees to cover any costs not covered by government funding (s 256). The split between the costs recovered from industry and those met by the government has not yet been decided. However, it is expected that a significant proportion of the costs would be recovered through industry fees or charges as is the case now. The fees and charges would be set in regulations following consultation with the sector (s 257). The methods and levels of cost recovery would be reviewed at least every three years.
210. This subpart covers the types of secondary legislation and instruments available under the scheme (regulations, rules, regulator’s notices and exemptions). It includes the interplay between them, their scope and the requirements for consultation during their development. Schedule 3 to the Bill summarises the matters that each type could be made for.

- 211. Regulations would be made by the Governor-General, by Order in Council.
- 212. Rules and regulator’s notices would be made by the regulator. The regulator would also be able to exempt a person, act or thing from any provision of the Act.
- 213. The reason for setting the detail of the scheme in these instruments is to enable regulatory requirements to be updated more quickly than is possible if the Act needed to be updated. Therapeutic products and the settings in which they are used are evolving quickly, so it is important that regulatory requirements can be amended to keep pace with these changes. The suite of instruments under the scheme is intended to provide greater responsiveness to change and the flexibility to provide tailored authorisations and requirements.
- 214. While these instruments do not go through the full parliamentary process, the following safeguards ensure they would be used appropriately.

Regulation	Regulations and rules would be subject to external scrutiny, as they could be reviewed by the Regulations Review Committee and could be ‘disallowed’ by Parliament if made inappropriately.
Rule	
Regulator’s notice	The regulator must not issue a notice or make an exemption unless satisfied that doing so is necessary or desirable in order to promote the purposes of the Act; and the extent of the exemption or notice is no broader than is reasonably necessary to address matters that gave rise to it.
Exemption	

- 215. The Minister would be required to review the Act at five-yearly intervals following its commencement (s 268).
- 216. Subpart 4 explains the relationship between the Bill and other Acts with which it has an interface because a therapeutic product may also be covered by another regulatory scheme.

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)

217. This section repeals the Medicines Act 1981 and revokes the regulations made under it.

Subpart 2: 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:
- a. be explicit that a scope of practice can include an authority to prescribe and issue a standing order
 - b. enable requirements for the form and content of the prescribing aspects of a scope of practice to be set in regulations under the HPCA Act. This is intended to ensure a reasonable level of consistency in the way this authority is set up for different practitioner groups. These regulations would be developed (and consulted on) when regulations under the Therapeutic Products Act were being developed
 - c. require the Minister of Health's approval before a scope of practice could include a new or amended authority to prescribe (in addition to the standard consultation requirements specified for any change of scope). Note that the Minister could delegate this approval for more technical amendments; for example, if a scope of practice for a particular practitioner group included a list of medicines, the Minister could delegate the power to the regulator to approve a change to that list
 - d. allow the Minister of Health to direct a responsible authority to amend or revoke the prescribing provisions in a scope of practice. This would provide the Minister with a way to respond if a practitioner group had been granted a prescribing authority and was not adequately managing the risk associated with this authority
 - e. include transition provisions so that the responsible authorities for health professions that currently have an authority to prescribe under the Medicines Act 1981 could update the relevant scope of practice to reflect this authority, without having to comply with the consultation requirements specified in the HPCA Act. This reflects the fact that the

update would not be a change in the scope of practice itself, but a change relating to how the scope is expressed.

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)

219. Part 4 of the Search and Surveillance Act 2012 establishes the standard search, surveillance and inspection powers for monitoring compliance with New Zealand laws. This amendment would reference the Therapeutic Products Act so that the regulator would have those powers.
220. This amendment would empower a customs officer to seize product being brought into the country if they considered it was non-compliant with the Therapeutic Products Act. For instance, if a suspected prescription medicine was imported for personal use or a shipment of unapproved medicines was brought in for supply, the customs officer would then provide the seized items to the therapeutic products regulator to investigate and respond to.
221. Amendments would be required to other legislation as well. Further work is under way to review the Acts and regulations that have interfaces with the Medicines Act 1981 and its associated regulations and to determine the amendments required.
222. In particular, the Misuse of Drugs Act 1975 has several linkages with medicines regulation as some controlled drugs are used therapeutically. Further work is required to determine the linkages that would need to be updated, and to consider whether any other minor changes could be made to improve the alignment between the two regulatory schemes.
223. Schedule 4 lists the Acts and regulations we have identified as containing references to or interfaces with the Medicines Act 1981 or its associated regulations.

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 Schedule 1: Transitional, savings and related provisions

224. This schedule sets out how products and processes would be dealt with during the transition to full implementation of the new Act. Section 1 of this schedule provides a useful overview of the general approach for transitioning to the new scheme.
225. A description of how the transitional arrangements would apply to the various sectors is provided as relevant in Chapter C. Questions seeking feedback from each sector on the proposed transitional arrangements are contained under the individual sector headings.

B13 Schedule 2: Reviewable decisions

226. This schedule lists the decisions that would be reviewable and who may apply for a review.

Question B35

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

B14 Schedule 3: Regulations, rules and regulator's notices

227. This lists the matters that could be specified in regulations, rules or regulator's notices. This is a useful summary of the places in the Bill where it states further details or requirements can be specified in a subordinate instrument and in which type of instrument.

Question B36

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

B15 Schedule 4: Amendments to other enactments

228. This lists the Acts and regulations that have been identified as containing an interface with the Medicines Act 1981 or its associated regulations.

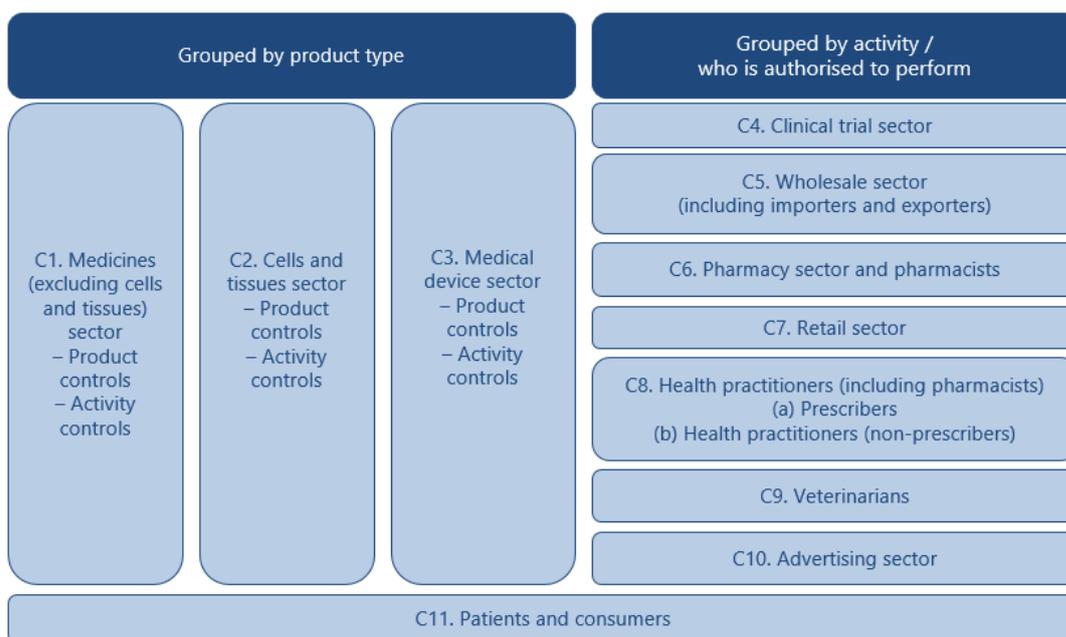
Question B37

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

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

229. This chapter is designed to allow people within particular sectors to see which aspects of the draft Bill would be most relevant to them and what those aspects would mean for them. Diagram D provides a key to the topics this chapter covers.
230. We have grouped material in a way that enables people to find the information most relevant to them, while trying to avoid repetition where possible. For some authorisations (particularly product approvals), the way the controls would be applied differ for the different product types. Therefore, we have grouped the sectors according to product type and then covered the relevant products and activities. For activities further along the supply chain, we have grouped the sectors by activity (ie, the relevant step in the supply chain) and then signalled if any controls differ based on product type. An additional topic highlights aspects of the draft Bill that are likely to be of special interest from a consumer perspective.
231. To avoid repetition, this chapter refers back to relevant questions in Chapter B. It provides additional questions focused on a particular policy issue where we are seeking feedback, as well as questions on specific issues that are only relevant for particular sectors. Each question is numbered once, so if the same question is asked in two topics within this chapter, the question number is repeated. For example, question C6 appears in the topics for both the medicines and the wholesale sectors. For this reason, the questions in this chapter do not follow a strictly sequential order.

Diagram D: Key to the topics in Chapter C



C1 Medicines (excluding cells and tissues) sector

Product-based controls

232. Under the new scheme, a product approval would generally be required to import or supply a medicine (s 51). In contrast, under the Medicines Act 1981 consent is required only before distribution, not before importation.
233. In addition, under the new scheme a person must not import an approved product unless they are the product's sponsor (ie, the approval holder), have the written permission of the sponsor or are authorised by a licence, permit or a provision in the legislation to import without the sponsor's consent (s 52). The policy intent behind this provision is to prohibit 'parallel importation' except in special circumstances; such as when a sponsor is not willing to supply a needed product. This approach is consistent with the policy position under the Medicines Act 1981.
234. For an approved product, the sponsor is defined in the draft Bill (s 14) as meaning the person to whom the approval was granted or a person to whom the sponsorship was transferred under the process set out in section 102.

235. The only situations where a product approval would not be required under the new scheme would be if the product was approval-exempt or if another form of authorisation had been given by a licence, permit or provision of the Act. The policy decision to place a control at the point of importation has been taken to enable earlier interventions to keep poor-quality or unsafe products out of the New Zealand supply chain and to facilitate enforcement.
236. Regulator's notices would be used to declare a medicine or class of medicine to be an approval-exempt product. We envisage these would be used for products with characteristics that mean their safety, efficacy and quality could more appropriately be regulated through a different regulatory control. For example, we envisage that whole blood collected and provided by the New Zealand Blood Service, as well as many blood components manufactured by the service from whole blood, and apheresis⁵ donations using simple processing steps, would be declared to be approval-exempt. The controls on, and oversight of, these approval-exempt products would mainly occur through auditing and licensing of the manufacturing activities of the New Zealand Blood Service.
237. The sponsor for an approval-exempt product would be specified in the notice that declared the product to be approval-exempt (s 115).
238. Regulations would be used to authorise the importation and supply of unapproved medicines in particular generic circumstances. For example, we envisage regulations authorising importation of medicines:
- a. for use by visiting sports teams, military groups and heads of state
 - b. on visiting aircraft and vessels
 - c. by a health care practitioner who is accompanying a patient coming into New Zealand
 - d. by international emergency response teams assisting New Zealand in a civil defence emergency
 - e. by a sponsor who has applied, and is waiting for, a product approval
 - f. for examination or testing purposes (other than a clinical trial as authorisation for trial medicines will be given through the clinical trial licence).
239. The regulations would include appropriate controls around matters such as use and record-keeping in relation to these products. There are also likely to be other scenarios that should be catered for in regulations, which would be considered when the regulations are developed and during the consultation process on the draft regulations. The authorisation in the regulations would apply to everyone who came within the criteria set out in the regulations.

⁵ An apheresis system uses an automated cell-separating machine to remove donor blood, separate and collect the platelets or plasma (depending on the type of donation) and return the rest of the blood to the donor.

240. Licences would be used to authorise the importation and supply of unapproved products on a case-by-case basis for purposes such as:
- a. use in a clinical trial
 - b. supply by a wholesaler in response to a request for supply that is supported by a special clinical needs supply authority
 - c. enabling a New Zealand manufacturer to undertake a step in manufacture such as packaging and labelling.
241. The Bill requires a special clinical needs supply authority for the import and supply of an unapproved product for an identified patient. This additional step is intended to ensure a health practitioner actively considers whether the patient has a special clinical need that an approved product cannot adequately meet. Once the SCNSA has been issued, the issuer of the SCNSA, a pharmacist, or wholesaler whose licence allows them to import unapproved medicines would need to import it on the patient's behalf. Note, that a product approval only approves the product for the purposes specified in the approval (s 99(2)). This means that whenever a medicine is prescribed for off-label use it is an unapproved medicine and would require a SCNSA.
242. The provisions relating to the issue of SCNSAs are set out in section 64. Our intention is to use regulations to set up two main types of authorisation covering:
- a. **the off-label use of medicines that have been approved in New Zealand** – our intention is to authorise all health practitioner prescribers to issue a SCNSA for off-label use (as long as the medicine is covered by their scope of practice) and have minimal requirements for what that SCNSA would need to involve
 - b. **medicines that do not have a product approval in New Zealand** – our intention is to continue to limit the ability to issue a SCNSA for these products to medical practitioners. This is in line with the current approach under the Medicines Act 1981. The policy intent is to ensure that unapproved medicines are only used when a patient has a special clinical need that an approved medicine cannot meet.
243. While the special clinical needs supply authority remains in force, repeat prescriptions could be issued by another medical practitioner or another health practitioner who has prescribing authority. Therefore, while the special clinical needs supply authority would need to be reviewed periodically, it would not have to be renewed every time a new prescription is needed.
244. We envisage permits would be used only to authorise the importation and supply of unapproved products in exceptional circumstances. For example, a permit might be issued to deal with a public health emergency or to rapidly access an essential medicine if no approved product was available.

Obtaining a product approval

245. To obtain a product approval, a person (an individual who is ordinarily resident in New Zealand or a body corporate incorporated in New Zealand) who meets the criteria for being a sponsor of an approved product would need to apply to the regulator. Those criteria (set out in s 97 of the draft Bill) are principally designed to ensure:
- a. 'legal reach' is sufficient to hold approval holders to account
 - b. approval holders have a contractual relationship with the manufacturer (if they are not themselves the manufacturer) that enables them to access information necessary to keep the regulatory file up to date
 - c. approval holders have the knowledge and capacity to be able to comply with their regulatory and safety-related obligations as a sponsor
 - d. the person's compliance and criminal history does not make them unsuitable as a sponsor (ie, they are a fit and proper person).
246. Under the Medicines Act 1981, while applicants must be in New Zealand, the absence of other suitability requirements for approval holders has led to situations where the approval holder lacks product and regulatory knowledge or the means to access it rapidly. This has led in turn to uncertainty and delays when the regulator is conducting post-market surveillance and compliance activities.
247. The rules would set out detailed technical and process requirements for applications for product approval. As in the current scheme, the requirements for the technical data to be submitted would be tailored to suit different types of medicines such as new chemical entities, generics, biosimilars and non-prescription medicines and would be based on international (and therefore current) norms for such products. The policy intent is to continue the interface with the hazardous substances and new organisms (HSNO) legislation to allow:
- a. the therapeutic products regulator to give a HSNO approval for qualifying medicines with 'low-risk' new organisms
 - b. a parallel process involving both the HSNO and therapeutic products regulator for medicines with higher-risk new organisms.
248. This aspect of the interface with the HSNO scheme has not yet been drafted.
249. The new scheme would give the same level of data protection as the Medicines Act 1981 provides for confidential supporting information submitted with applications for approval of innovative new medicines (ss 120–122).
250. Where we do envisage change is that the new scheme would give the regulator greater flexibility to establish a number of approval pathways. These could be tailored to suit, for example, products with a long approval history in one or more recognised overseas jurisdictions or products at the leading edge of innovation that were designed to address an unmet clinical need. Under this approach, the data requirements, time to regulatory approval and fee structure could be tailored to suit different circumstances. We envisage this flexibility would also be likely to encourage sponsors of many unapproved medicines

currently supplied under section 29 of the Medicines Act 1981 to seek approval for those products.

251. When evaluating an application for product approval, the regulator must consider the criteria for product approval, whether the product (if approved) would comply with any specified product standards and whether the proposed sponsor meets the criteria for being a sponsor (s 97). The criteria for product approval (s 95) involve a consideration of whether the quality, safety and efficacy of the medicine (for the purpose for which it is to be used) have been satisfactorily established, and whether the likely benefits of the product outweigh the likely risks associated with it, in addition to any other criteria that are specified in rules.
252. The new scheme would allow the regulator to rely on work done by other recognised authorities (eg, reports, assessments or decisions) or information received from a recognised authority (s 207). The regulator would specify the authorities it recognised in a notice. In the case of medicines, we expect those authorities would be the national regulatory bodies we have confidence in because they have a sound track record of administering a strong and effective regulatory system based on international norms and they regulate for a population demographic that is broadly representative of the New Zealand population. The regulator would also be able to seek expert advice from an expert or an expert committee on any matter, but would not be required to do so.
253. After the evaluation process (including any interaction with the applicant to seek more information about issues identified in that process) has been completed, the regulator must either approve the product (with or without conditions) or refuse to grant approval. Conditions may be tailored for a particular product or may be ones set out in rules that would apply across a specified kind of product.
254. While approvals would normally be granted without an expiry date, an expiry date could be imposed if deemed appropriate. The requirements for the content of an approval have been expressed in a generic way in section 98 because they apply to medicines of different kinds, medical devices and type-4 products. Regulations would be used to set out requirements that need to be tailored to different types of products or groupings within those types.
255. The new scheme would no longer require issuing a Gazette notice as the indicator of approval as the regulator would be required to maintain a publicly accessible register of therapeutic products, including both those that have been approved and those that have been refused approval. The register would be required to include the information referred to in section 98, but may also contain additional information that the regulator deems appropriate and not commercially sensitive. For example, it could contain prescribing information or consumer medicine information for approved products.
256. Under the new scheme, sponsors of approved and approval-exempt products must comply with a set of obligations (ss 116–118). If they do not, they would be committing an offence. Specifically the sponsor is obliged to:

- a. comply, in the case of approved products, with the approval (eg, with any conditions on the approval)
 - b. ensure that an approved product complies with the approval
 - c. ensure that any person who is required by the product approval to do or not do something complies with that requirement
 - d. ensure that the product (whether approved or approval-exempt) complies with any specified product standards, or requirements in the regulations relating to matters such as product or consumer information, labelling and record-keeping (s 118).
257. For an approved product, non-compliance with these obligations may also give rise to grounds to cancel the approval. These grounds may apply either directly (product not complying with product standards – s 108(d)) or indirectly as a result of the sponsor’s non-compliance affecting their ‘fit and proper person’ status, and thus whether they meet the criteria for being a sponsor (s 108(e)).
258. If someone was authorised to import an approved product without the sponsor’s consent, then the sponsor obligations would not apply (s 119).

To comment, refer to questions B3, B13, B14, B15 and B16.

Changes to approved products

259. A different approach is proposed under the new scheme for dealing with changes to approved medicines. Changes would be categorised as either major or minor. Rules would be used to specify the changes in each category. Minor changes are ones that may be implemented without needing the regulator’s approval, but some minor changes would require notification to the regulator. The rules would be used to specify the minor changes that require notification, as well as detail such as timeframes within which notification must occur. We envisage changes to contact details would need to be notified promptly, whereas other minor changes may occur through a consolidated six-monthly or annual update. Currently under the Medicines Act 1981, several changes are handled as ‘self-assessable’ changes. We envisage that, under the new scheme, the set of notifiable changes would be aligned with the European and Australian models where appropriate.
260. Under the new scheme, ‘major’ changes would be changes to the product, or to any matter or information relating to the product, that may have a significant impact on the quality, safety or efficacy of the product. Rules would specify exactly what that set of changes would be (ss 100 and 101). In contrast to the Medicines Act 1981, under the new scheme a major change to an approved product would be a different product requiring a new approval (s 100) before it is released onto the market.

261. This approach would not increase the regulatory burden or lengthen the timeline associated with gaining an approval for a major change. The application process and data set to be submitted for a new approval required to make a major change to an approved product would be tailored to the nature of the change. In addition, the regulator would be able to evaluate only the data relevant to the change(s) (which could be grouped) and to rely on its previous assessment of the unchanged aspects of the product. The fee for applying for this type of approval would be proportional to the work required to assess the change.
262. Once the application was approved, a new approval document would be issued. The approval relating to the unchanged product would remain in place unless the sponsor asked for it to be cancelled (or there was a subsequent need to revoke it for safety or non-compliance reasons).
263. The new approach has been designed to increase clarity about approved products. Under the Medicines Act 1981 process, it is often unclear whether a change such as a change to formulation or manufacturing method sits alongside or replaces previous 'versions' of the product. Under the new scheme, a product approval would cover the product as described in the approval at the time the approval was granted and any subsequent minor changes (s 99).
264. The Bill does not specify timeframes for processing changes to medicines. However, the regulator would be expected to set performance targets and to report against them.

Question C1

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

Merits review of decisions

265. Schedule 2 to the draft Bill sets out the decisions that are reviewable and who may apply for a review. Applicants include those who are aggrieved by a decision to not approve a product or to cancel an approval. The merits review would be conducted by a panel of at least three people appointed by the regulator who have not previously been involved in the decision (s 201). The regulator would act independently in appointing a panel but would be accountable for its decisions to appoint particular people. The Bill would require the regulator to appoint people with suitable knowledge and expertise for the issue at hand, with no conflict of interest, and at least one person who is a lawyer with at least 7 years' experience. The panel would change depending on the matter being reviewed. For example, expertise in pharmacy matters would be needed for a pharmacy licensing decision whereas the expertise needed for a medicine approval matter is likely to be in pharmacology or a practise of medicine related to the type of medicine. Similarly, the expertise required for a medical device matter would depend on the type of device and could range over fields such as biomedical engineering, plastics technology and electrical engineering. This approach has been taken to provide flexibility to respond to the wider range of products and activities being regulated.

266. Sections 202 and 203 set out the requirements for the review procedure and the review decision. The panel must either confirm the original decision, or set aside the original decision and refer the matter back to the regulator. If the matter is referred back, the regulator must reconsider the application in accordance with any recommendations made by the review panel and make a fresh decision. An applicant for review may appeal to the District Court if the review panel confirms the decision of the regulator or if the regulator makes a new decision (following a referral from the review panel) that the applicant continues to be aggrieved with.

To comment, refer to questions B27 and B35.

Categorisation (classification) of medicines

267. As new medicines come through the approval process, the regulator would assign a classification to them as a category 1 (prescription), category 2 (pharmacist), category 3 (pharmacy) or category 4 (general-sale) medicine. The regulations would provide criteria for the categorisation of medicines and would be able to allow the regulator to categorise medicines through a regulator's notice.
268. The new scheme would enable wider access to specified medicines in particular categories. Currently, the classification schedule has been used as the tool for doing this, with entries such as 'prescription medicine except when supplied by ...' enabling pharmacists to prescribe and/or supply medicines such as trimethoprim, or other health workers to access medicines such as fluoride preparations. Under the new scheme, regulations would instead be used to provide an authorisation. We envisage being able to then list the class of health practitioner who has the authorisation to perform specified activities (such as prescribe and/or supply) with named products or classes of products, including any requirements such as the maximum amount to be supplied. This new approach would remove the current legal ambiguity about the point in the supply chain when the classification of the medicine changes.
269. The new scheme would continue to have a mechanism to enable the regulator to 'switch' an active ingredient in a medicine from one category to another and therefore change the category of medicines with that ingredient. The regulations would be used to set out details of how this would operate. The regulator would be able to seek advice from an expert committee in relation to switching decisions.

Question C2

Please provide any comments on the approach for medicines categorisation (classification).

Transition for existing products and applications

270. The transition proposals for existing products and applications and any appeals before the Medicines Review Committee are set out in Schedule 1 to the draft Bill. The policy intent is to allow existing approvals to continue and allow the new regulator to deal with pending matters as efficiently as possible.

Question C3

Please provide any comments on the transition arrangements for existing medicine product approvals.

Post-market controls

Cancellation of approvals

271. Under the new scheme, product approvals could be cancelled but not suspended. The purpose of this provision is to avoid legal uncertainty about the status of stock that is already in the supply chain before a suspension occurs. If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to supply and use existing stock (s 78).
272. The sponsor could apply to the regulator seeking cancellation of an approval. This might occur, for example, if there was no longer commercial interest in supplying a product, or because a new approval for the product had been granted to authorise one or more major changes.
273. The regulator would have the power to cancel an approval if satisfied that there were grounds to do so (ss 108–109), but must first give the sponsor an opportunity to comment and comply with any procedural requirements in regulations (s 110). The draft Bill sets out the meaning of 'opportunity to comment' (s 206). The cancellation grounds would include non-payment of any applicable fees. Note, however, that the regulator is not required to cancel the approval even if there are grounds to do so. For example, the facts giving rise to the grounds to cancel might also constitute an offence, in which case the regulator might decide that it is more appropriate to prosecute, particularly if it is an essential product and product safety is not an issue.

To comment, refer to question B14.

Pharmacovigilance

274. Under the new scheme, sponsors would have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. These pharmacovigilance requirements would be set out in regulations. It is intended that they would be aligned with international norms. For example, we would expect sponsors to follow guidance in International Conference on Harmonisation documents when establishing their monitoring and reporting systems, reporting adverse events and providing periodic benefit risk evaluation reports and risk management plans.
275. Currently in New Zealand, such obligations are recommended but not underpinned by legislation.
276. For the first time in New Zealand, the new scheme would also place an obligation on the regulator to ensure it has a system in place to monitor the safety of products that are being lawfully supplied (s 160). Regulations would specify details about the monitoring system and the information that must be publicly available. This requirement is included in the legislation to highlight the importance of post-market safety, risk management and communication in a modern regulatory scheme.
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.

Question C4

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

Activity-based controls

Clinical trials

278. Pharmaceutical companies and independent researchers are actively involved in clinical trials of medicines in New Zealand. Under the new regulatory scheme, all clinical trials of therapeutic products would require an authorisation. It is intended this authorisation would generally be a licence. See Chapter C4 for details of the clinical trial proposals.

Manufacturing

279. Under the new scheme, manufacturing a therapeutic product is a controlled activity requiring an authorisation (s 53). Under the Medicines Act 1981, those manufacturing medicines and their active ingredients require a licence. The same approach is intended to be the main method of authorisation under the new scheme. While a permit could be used to authorise manufacture, this would be used only in exceptional circumstances.
280. The term 'manufacture a medicine' (defined in s 32 of the draft Bill) covers all aspects of producing the product and bringing the product to its final state, including testing, sterilising, releasing for supply, packaging and labelling. It is intended that the licence would specify the scope of the activities it authorises. Those wishing to only pack or label would be able to seek a licence that authorises only those activities, whereas the licence for manufacturers who perform all aspects of the manufacturing process would have a broader coverage. The audit process and licensing fees would be calibrated to reflect the complexity and scale of the manufacturing operation and compliance history. The draft Bill uses the term 'responsible manufacturer' (s 31) to mean the person who is primarily responsible for the manufacture of the product. This is the person who (if not themselves the manufacturer) the sponsor must have a contractual relationship with (s 97).
281. Because the definition of 'manufacture' is (intentionally) broad, the compounding and dispensing activities undertaken by pharmacists and other health sector workers come within its scope. This is explicitly acknowledged in the definitions of those activities in sections 28 and 29 of the draft Bill. For this reason, Part 3 provides the necessary authorisations for pharmacists, qualified pharmacy workers, health practitioner prescribers and veterinarians to undertake one or both of those activities without the need for a licence.
282. The administrative detail around licensing would be set out in a combination of regulations and rules. Whereas the term for a licence to manufacture under the Medicines Act 1981 is one year, a term of up to three years is proposed for licences under the new scheme. The criteria for granting licences (of any kind) and for licensees and responsible persons to be named on a licence are set out in sections 128–130 of the draft Bill. They include requirements for the licensee and responsible person(s) to be a fit and proper person (as defined in s 47).
283. It is intended that manufacturers will need to comply with good manufacturing practice requirements and that these, as is the case now, would be based on the Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice. These requirements would be specified in regulations under section 55.
284. Note that the suitability of overseas manufacturers would continue to be assessed during the product approval process. Sponsors would be expected to supply ongoing evidence that approved manufacturing sites continued to meet good manufacturing practice requirements.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

Question C5

Please provide any comments on the manufacturing-related definitions.

Wholesale supply

285. Pharmaceutical companies use a number of different arrangements, including the use of third parties, to move their product into and along the wholesale supply chain in New Zealand. Currently anyone who supplies prescription, pharmacist or pharmacy medicines by wholesale supply requires a licence under the Medicines Act 1981. Under the new scheme, this level of control would continue because the wholesale supply of category 1, 2 and 3 medicines is a controlled activity requiring an authorisation. A licence would continue to be the main method for authorising this activity. Wholesale supply is defined in section 43.
286. The administrative detail around licensing would be set out in a combination of regulations and rules. Whereas the term for a licence to wholesale under the Medicines Act 1981 is one year, a term of up to three years is proposed for licences under the new scheme. The criteria for granting licences (of any kind) and for licensees and responsible persons to be named on a licence are set out in sections 128–130 of the draft Bill. They include requirements for the licensee (that take into account any senior managers of that licensee) and responsible person(s) to be a fit and proper person (as defined in s 47).
287. A licence that authorises supply by wholesale would also specify the scope of the wholesaling activity that is allowed. For example, this would include the types of medicines and whether the licensee is authorised to supply an unapproved medicine in response to a request supported by a special clinical needs supply authority.
288. Under the new scheme, a licence to supply by wholesale would also be the mechanism used to authorise the activities of the mobile salespeople referred to in the Medicines Act 1981 as hawkers. This sales force is employed by some pharmaceutical companies to work within a defined territory to promote and supply products to prescribers and pharmacies. Currently a separate licence to hawk is required to authorise the individuals undertaking the activity. Over the course of the licensing year, it is not uncommon for multiple changes to be needed to the licence because of changes to the workforce, products or territory. This has an administrative cost for the company and the regulator.

289. Under the new scheme, a licence to supply by wholesale would specify whether the company was authorised to use a mobile sales force. If so, the licensee would need to comply with requirements in the regulations relating to the oversight of its mobile sales staff, their transport and storage arrangements for stock, and the creation and maintenance of records covering the 'hawking' activity. A review of compliance with those requirements would form part of the routine audits performed by the regulator.
290. It is envisaged that the new regulator would enable licensees to have secure online access to its database to enable them to maintain an up-to-date record of their own mobile staff and their territories and products. This would remove the need for the licence itself to be amended as these details changed, but would allow the regulator to have up-to-date information for compliance checks.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

Question C6

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

Transition arrangements for activity-based controls

291. Under the transition arrangements set out in Schedule 1 to the draft Bill, those with current licences issued under the Medicines Act 1981 before the commencement of the new scheme could continue to operate on those licences until their expiry date.

C2 Cell and tissue sector

292. Currently in New Zealand, the Human Tissue Act 2008 provides protections around the collection or use of human tissue. These are largely aimed at ensuring any such collection or use occurs with proper recognition of, and respect for, the donor and their immediate family, cultural, ethical and spiritual values and the public good associated with this activity. A further aim of the Human Tissue Act 2008 is to ensure collection and use do not endanger the health and safety of the public, and generally do not involve trading.

293. The Human Tissue Act 2008 does not, however, provide controls to manage the risks associated with the processing and use of human tissue for a therapeutic purpose, including the risk of infection or transmission of disease and the failure of transplanted material that has not been processed appropriately. Other developed countries have controls to manage these risks and the new scheme is intended to close these regulatory gaps.
294. Both the Human Tissue Act 2008 and the Therapeutic Products Act would apply to medicines and medical devices that are, or contain, human tissue. However, an amendment would be made to the Human Tissue Act 2008 to allow for the appropriate supply, in a commercial market, of engineered cell- and tissue-based products. The trade of human organs and inappropriate collection and use of human tissue will continue to be prohibited.
295. Cells and tissues are used in a wide range of health care settings, which include:
- a. transplantation of whole organs or tissues shortly after their removal
 - b. use of reproductive cells in fertility treatment
 - c. use of parts of organs (such as corneas and heart valves) that have been processed and banked previously
 - d. use of highly manipulated cell and tissue material (such as CAR-T cell medicines).
296. Cells and tissues are also used in many medical devices, usually when the material has been rendered non-viable.
297. Under the new scheme, we are proposing to regulate the cell and tissue sector using the European approach, which distinguishes between cells and tissues that are minimally manipulated and those that are engineered. **Engineered cells and tissues** are those that are subject to substantial manipulation, or that perform a function in the recipient that is different from their function in the donor.
298. In the European system, engineered cell and tissue products are a type of advanced therapy medicinal product⁶ and subject to product approval and post-market monitoring requirements. In contrast, cells and tissues that have not been engineered are regulated through controls on the activities occurring in the places where the cells and tissues are handled.
299. Adopting the European approach under the new scheme would mean:
- a. **Licensing tissue establishments** – that is, a tissue bank or a unit of a hospital or other body or place where activities of processing, preservation, storage or distribution of tissues and cells are undertaken – to undertake these activities. Such activities would be considered a controlled activity (manufacturing) requiring an authorisation. The cell and tissue material being handled would not require a product approval (unless it was engineered) because it would be declared to be approval-exempt.

⁶ In Europe, an advanced therapy medicinal product means: a gene therapy medicinal product, a somatic cell therapy medicinal product, or a tissue-engineered product. Each of these subtypes is defined in European Directive 2001/83/EC.

b. **Requiring engineered cells and tissues to have a product approval.**

Authorisation could also be given through a permit. New Zealand manufacturers of engineered products would also require a licence.

300. In some situations, the therapeutic products scheme would not apply at all. For example, if an organ was removed from a donor and transplanted into a recipient without further processing, the organ would not be considered to be a therapeutic product because it had not been changed from its naturally occurring state (s 16). For the same reason, tissues and cells used as an autologous graft where the retrieval and use occurred within the same surgical procedure would not be regulated under the scheme.
301. Under the scheme, regulations could be used to declare something to not be a therapeutic product (s 16(4)). We envisage this would be helpful in situations where there is ambiguity about whether something falls under the definition of therapeutic product and such a declaration would be consistent with the purposes and principles of the Act. We are aware there may be other use settings that should be subject to an exemption or not fall under the new scheme. This level of detail would be set out in regulations developed in consultation with the sector.
302. The European Union uses the same approach for regulating these activities and products and has developed comprehensive guidance on the technical requirements related to both activity licensing and product approval. For the licensing of tissue establishments, it includes traceability requirements (from donor to recipient), quality and safety standards for the activities being undertaken and the reporting of adverse events and adverse reactions. We envisage drawing heavily on this material as the regulations, rules and notices are developed in consultation with the sector.
303. Under the new scheme, products derived from human or animal cells and tissues would be regulated as a therapeutic product, with some exceptions. Most would be regulated as medicines because of their mode of action and because they comprise, contain or are derived from cells or tissues (see s 18).
304. Products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, would be regulated as a medical device under the new scheme (see s 21).
305. The following discussion details how the product-based and activity-based controls would be tailored to suit the cell and tissue sector.
306. We are aware of concern about using the term 'therapeutic product' for cells and tissues. The draft Bill uses this term as a practical measure to enable the scheme to apply appropriate regulatory controls across a range of cell and tissue activities and therapies, which run from processing and use of minimally manipulated cells and tissues to the creation and use of highly manipulated or engineered products. This classification is in no way intended to undermine the importance and recognition of the donor when gifting an organ or other cell and tissue material.

Product-based controls

307. Cell and tissue material that was substantially manipulated or used for a different function in the recipient would be regulated as a therapeutic product requiring approval as a medicine. This is the approach used in Europe where such products are termed 'tissue-engineered products'.
308. Cell and tissue material that is considered not to have been substantially manipulated or engineered would be declared approval-exempt by regulator's notice (s 114). Persons importing or supplying such material would not be required to obtain a product approval, but the sponsors for such products (who are likely to be the importers or manufacturers) would be subject to the set of obligations applicable to sponsors of approval-exempt products (see ss 116–118).
309. We envisage adopting the European Union definition to specify those manipulations that are **not considered** substantial. The European Union currently defines them as cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilisation, irradiation, cell separation, concentration or purification, filtering, lyophilisation, freezing, cryopreservation and vitrification.
310. A tissue-engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.
311. Consistent with the approach internationally, products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, would not be regulated as a tissue-engineered product. These would instead be regulated as medical devices.
312. Under the new scheme, generally a product approval would be required in order to lawfully import or supply a medicine or medical device (s 51). In addition, a person must not import an approved product unless they are the product's sponsor (ie, the approval holder), have the written permission of the sponsor or are authorised by a licence, permit or a provision in the legislation to import without the sponsor's consent (s 52).
313. The term sponsor is defined in the draft Bill (s 14) to mean, in relation to an approved product, the person to whom the approval was granted or a person to whom the sponsorship was transferred under the process set out in section 102. For an approval-exempt product, the person who is the sponsor must be specified in the notice that the regulator issues to declare the product, or class of products, approval-exempt (s 115).

314. The only situations where an approval would not be required under the new scheme would be if the product is approval-exempt or if another form of authorisation had been given by a licence, permit or provision of the Act. If an unapproved product is needed for a particular patient, the Bill enables the import and supply of the product to be authorised by a special clinical needs supply authority (SCNSA) (refer C1 medicines (excluding cells and tissues) sector / product-based controls for more detail on SCNSAs).
315. Regulator's notices would be used to declare a medicine or type of medicine to be an approval-exempt product. This mechanism is intended to be used for products whose characteristics mean their safety, efficacy and quality can be more appropriately regulated through a different regulatory control, for example a licence to manufacture. This is the approach intended for human cells and tissues that are not engineered products because they have been minimally manipulated.
316. Regulations would be used to authorise the importation and supply of unapproved medicines in particular generic circumstances. For example, we envisage regulations authorising importation of medicines:
- a. by a health care practitioner who is accompanying a patient coming into New Zealand
 - b. by a sponsor who has applied, and is waiting for, a product approval
 - c. for examination or testing purposes (other than a clinical trial as authorisation for trial medicines will be given through the clinical trial licence).
317. The regulations would include appropriate controls around matters such as use and record-keeping in relation to these products. There are also likely to be other scenarios that should be catered for in regulations. These will be considered when the regulations are developed and during the consultation process on the draft regulations. The authorisation in the regulations would apply to everyone who came within the criteria set out in the regulations.
318. Licences would be used to authorise the importation and supply of unapproved products on a case-by-case basis for purposes such as:
- a. use in a clinical trial
 - b. supply by a wholesaler in response to a request for supply that is supported by a special clinical needs supply authority
 - c. enabling a New Zealand manufacturer to undertake a step in manufacture such as packaging and labelling.
319. We envisage permits being used only to authorise the importation and supply of products in exceptional circumstances. For example, a permit might be issued to deal with a public health emergency or to rapidly access an essential medicine if no approved product was available.

To comment on the requirement for product approval and ability to exempt products, refer to question B3.

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?

Obtaining a product approval

320. To obtain a product approval, a person (individual who is ordinarily resident in New Zealand or body corporate incorporated in New Zealand) who meets the criteria for being a sponsor of an approved product must apply to the regulator. Those criteria are set out in section 97 of the draft Bill.
321. Rules would detail the technical and process requirements for applications for product approval. The requirements for the technical data to be submitted would be tailored to suit tissue-engineered products – for example, CAR-T cell therapies – and would be based on international norms for such products.
322. The new scheme would allow the regulator the flexibility to establish a number of approval pathways. These could be tailored to suit, for example, products with one or more approvals granted by a recognised overseas jurisdiction or products at the leading edge of innovation that are designed to address an unmet clinical need. Under this approach, the data requirements, time to regulatory approval and fee structure could be tailored to suit different circumstances.
323. When evaluating an application for product approval, the regulator must consider the criteria for product approval, whether the product (if approved) would comply with any specified product standards and whether the proposed sponsor meets the criteria for a sponsor (s 97). The criteria for approval (set out in s 95) involve a consideration of whether the quality, safety and efficacy of the medicine (for the purpose for which it is to be used) have been satisfactorily established, whether the likely benefits of the product outweigh the likely risks associated with it, and any other criteria that are specified in rules.
324. The new scheme allows the regulator to rely on work done by other recognised authorities (eg, reports, assessments or decisions) or information received from a recognised authority (s 207). The regulator would specify the authorities it recognised in a notice. The regulator is also able to seek expert advice from an expert or an expert committee but is not required to do so.
325. After the evaluation process (including any interaction with the applicant to seek more information about issues identified in that process) has been completed, the regulator must either approve the product (with or without conditions) or refuse to grant approval. Conditions may be tailored for a particular product or be ones that are set out in rules that could apply across a specified kind of product.

326. Approvals may be granted with or without an expiry date. The requirements for the content of an approval are set out in section 98. They have been expressed in a generic way because they apply to medicines of different kinds, medical devices and type-4 products. Regulations would be used to set out requirements that need to be tailored to suit tissue-engineered products.
327. The regulator would be required to maintain a publicly accessible register of therapeutic products.
328. Under the new scheme, sponsors of approved and approval-exempt products must comply with obligations set out in sections 116–118. If they do not, they would be committing an offence. For an approved product, non-compliance with these obligations may also give rise to grounds to cancel the approval, either directly (product not complying with product standards – s 108(d)) or indirectly because the sponsor’s non-compliance affects their ‘fit and proper person’ status and thus whether they meet the criteria for being a sponsor (s108(e)). Sponsor obligations do not, however, apply to the sponsor of an approved or approval-exempt product that is imported without the sponsor’s consent (s 119).

To comment, refer to questions B13, B14, B15 and B16.

Changes to approved products

329. Under the new scheme, changes to approved medicines would be categorised as either major or minor. Rules would be used to specify the changes in each category. Minor changes are ones that may be implemented without needing the regulator’s approval. Some minor changes would need to be notified to the regulator and these would be specified in rules. We envisage that, under the new scheme, the set of notifiable changes would be aligned if possible with the European and Australian models.
330. Major changes are changes to the product, or any matter or information relating to the product that may have a significant impact on its quality, safety or efficacy. Major changes would be specified in rules and result in the need for a new product approval before the changed product is released onto the market.
331. This approach would not increase the regulatory burden or lengthen the timeline associated with gaining an approval for a major change. The application process and data set to be submitted for a new approval required in order to make a major change to an approved product would be tailored to the nature of the change. The regulator would be able to evaluate only the data relevant to the change(s) (which could be grouped) and to rely on its previous assessment of the unchanged aspects of the product. The fee for applying for this type of approval would be proportional to the work required to assess the change.
332. Once the application was approved, a new approval document would be issued. The approval relating to the unchanged product would remain in place unless the sponsor asked for it to be cancelled (or there was subsequently a need to revoke it for safety or non-compliance reasons).

333. The draft Bill does not specify timeframes for processing changes to medicines. However, the regulator would be expected to set performance targets and to report against them.

Question C1

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

Merits review of decisions

334. Schedule 2 to the draft Bill sets out the decisions that are reviewable and who may apply for a review. The merits review would be conducted by a panel of at least three people appointed by the regulator who have not previously been involved in the decision (s 201). The regulator would act independently in appointing a panel but would be accountable for its decisions to appoint particular people. The Bill would require the regulator to appoint people with suitable knowledge and expertise for the issue at hand, with no conflict of interest, and at least one person who is a lawyer with at least 7 years' experience. The panel would change depending on the matter being reviewed. For example, expertise in pharmacy matters would be needed for a pharmacy licensing decision whereas the expertise needed for a medicine approval matter is likely to be in pharmacology or a practise of medicine related to the type of medicine. Similarly, the expertise required for a medical device matter would depend on the type of device and could range over fields such as biomedical engineering, plastics technology and electrical engineering. This approach has been taken to provide flexibility to respond to the wider range of products and activities being regulated.
335. Sections 201 and 202 set out the requirements for the review procedure and the review decision. The panel must either confirm the original decision, or set aside the original decision and refer the matter back to the regulator. If the matter is referred back, the regulator must reconsider the application in accordance with any recommendations made by the review panel and make a fresh decision. An applicant for review may appeal to the District Court against a decision of the review panel, or a new decision that the regulator made following a referral from the review panel.

To comment, refer to questions B27 and B35.

Categorisation and supply of cell and tissue products

336. Medicines need to be categorised into one of the four available categories (s 19). We envisage tissue-engineered products being classified as category 1 (prescription) medicines but would expect other products to be placed in category 4 (general sales) as access to them would be adequately controlled

through treatment providers. Those supplying category 1 products by wholesale would require a licence whereas no authorisation would be required for supplying category 4 products.

Interface with other legislation

337. There would be interfaces between the Therapeutic Products Act, the Human Tissue Act 2008, the Human Assisted Reproductive Technology Act 2004 (HART) and the Hazardous Substances and New Organisms Act 1996. Before the Therapeutic Products Bill is introduced to Parliament, further work will be needed to clarify those interfaces and this work will be informed by the feedback on the draft Bill. In relation to the HSNO interface, the policy intent is that HSNO controls on new organisms (which includes human cell lines) would continue to apply. Likewise, the Human Assisted Reproductive Technology Act 2004 would apply alongside the Therapeutic Products Act.

Question C8

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

Post-market controls

Cancellation of approvals

338. Under the new scheme, product approvals could be cancelled but not suspended. The purpose of this provision is to avoid legal uncertainty about the status of stock that is already in the supply chain before a suspension occurs.
339. The sponsor could apply to the regulator seeking cancellation of an approval. This might occur, for example, if there was no longer commercial interest in supplying a product, or because a new approval for the product had been granted to authorise one or more major changes to it.
340. The regulator would have the power to cancel an approval if satisfied that there were grounds to do so (ss 108–109) but must first give the sponsor an opportunity to comment and comply with any procedural requirements in regulations (s 110). The meaning of ‘opportunity to comment’ is set out in the draft Bill (s 206). The cancellation grounds would include non-payment of any applicable fees. Note, however, that the regulator is not required to cancel the approval even if there are grounds to do so. For example, the facts giving rise to the grounds to cancel might also constitute an offence, in which case the regulator might decide that it is more appropriate to prosecute, particularly if it is an essential product and product safety is not at issue.

To comment, refer to question B14.

Pharmacovigilance

341. Under the new scheme, sponsors would have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. These pharmacovigilance requirements would be set out in regulations. It is intended that they would be aligned with international norms. For example, we would expect sponsors to follow the guidance in the International Conference on Harmonisation document E2R *Pharmacovigilance Planning* when establishing their monitoring and reporting systems and companion Conference documents when reporting adverse events and providing Periodic Benefit Risk Evaluation Reports (PBERs) and Risk Management Plans.
342. Currently in New Zealand, such obligations are recommended but not underpinned by legislation.
343. For the first time in New Zealand, the new scheme would also place an obligation on the regulator to ensure it has a system in place to monitor the safety of products that are being lawfully supplied (s 160). Regulations would specify details about the monitoring system and the information that must be publicly available. This requirement is included in the legislation to highlight the importance of post-market safety, risk management and communication in a modern regulatory scheme.
344. 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 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.

Question C4

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

Transition for product approval controls

345. Schedule 1 to the draft Bill includes proposed transition arrangements for products that were being lawfully supplied before the commencement of the new scheme. Note that the commencement date is expected to be around two years after the Bill receives royal assent. The policy intent is as follows.

- a. Cell and tissue products that are not engineered would be declared to be approval-exempt in a regulator's notice that would come into force on commencement of the scheme and therefore could continue to be supplied without an approval. Temporary licences would be automatically issued to provide transition cover for the controlled activities performed by tissue establishments in relation to these products. (See s 34 of Schedule 1 for more detail.)
- b. An approval would be required before new engineered products could be imported or supplied unless they had been granted ministerial consent under the Medicines Act 1981. In such a case, that approval would continue, and be subject to new requirements under the scheme (eg, the requirement for the sponsor to have a contractual relationship with the responsible manufacturer).
- c. During a transition period, importation and supply of products that are not therapeutic products before commencement, but that would be therapeutic products requiring an approval after commencement, could continue while applications for their approval were being considered. (See s 34 of Schedule 1 for more detail.)

Question C9

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

Activity-based controls

Clinical trials

346. Conducting a clinical trial using cells or tissues of human or animal origin would be a controlled activity requiring an authorisation. This would ordinarily be provided by a licence. Xenotransplantation is currently regulated under the Medicines Act 1981 as a specified biotechnical procedure but there is no pathway to approve products used in xenotransplantation. This would change under the new scheme, allowing the possibility, should clinical trial results support the safety and efficacy of the products, that they could be approved.
347. See Chapter C4 for further details of the regulation of clinical trials.

Manufacturing and wholesale supply

348. Under the new scheme, manufacturing a therapeutic product is a controlled activity requiring an authorisation and so is supplying a category 1, 2 or 3 medicine by wholesale (s 53). A licence would be the main method of authorising these activities.

349. Tissue establishments that are performing activities captured through the definition of ‘manufacture a medicine’, such as processing, testing, preservation, storage or distribution of tissues and cells (s 32), would require an authorisation, which would ordinarily be a licence. The licence would specify the scope of the manufacturing activities being authorised and would also authorise the wholesale supply of the products being manufactured. The audit process and licensing fees would be calibrated to reflect the complexity and scale of the manufacturing operation.
350. The administrative detail around licensing would be set out in regulations and rules. A term of up to three years is proposed for licences under the new scheme. The criteria for granting licences (of any kind) and for licensees and responsible persons to be named on a licence are set out in sections 128–130 of the draft Bill. They include requirements for the licensee (that take into account any senior managers of that licensee) and responsible person(s) to be a fit and proper person (as defined in s 47).
351. It is intended that tissue establishments that are manufacturing would need to comply with good manufacturing practice requirements. It is further intended that these requirements would be specified in regulations under section 55 and would be consistent with international norms.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

Question C5

Please provide any comments on the manufacturing-related definitions.

Transition arrangements for activity-based controls

352. We are aware that the new scheme would bring significant change for the cell and tissue sector. Under the transition arrangements set out in Schedule 1 to the draft Bill, persons, such as tissue establishments, that are operating prior to the commencement of the new scheme would be considered to have an automatic temporary licence to enable them to continue to operate. That licence would cover their manufacturing activities and the continued supply of products. Within 12 months of commencement, they would need to apply for a licence under the new scheme for ongoing authorisation of their manufacturing and wholesaling activities. Once they had applied, they could continue to operate under their temporary licence until a decision was made on the new licence application.

Question C10

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

C3 Medical device sector

353. The new scheme would bring significant change to the medical device sector, which is currently regulated only through outdated and piecemeal post-market controls in the Medicines Act 1981. The new scheme would include a full suite of pre- and post-market controls across the lifecycle of devices used in New Zealand. The intention is to adopt the regulatory model initially developed by the Global Harmonisation Taskforce (GHTF) and further developed by its successor the International Medical Device Regulators Forum (IMDRF).
354. Under this model, medical devices are assigned to a risk class using agreed classification rules, and manufacturers are required to ensure the devices they produce meet requirements for safety and performance. These are referred to as Essential Principles. How they are required to demonstrate conformity with those Essential Principles is dependent on the risk classification for the device. Under the model, there are also ongoing requirements in relation to risk assessment and management and post-market monitoring. A further and more recent aspect of the model is a requirement for devices to have a globally harmonised unique device identifier (UDI). This is expected to increase patient safety and help optimise patient care by facilitating the:
- traceability of medical devices, especially for field safety corrective actions
 - adequate identification of medical devices through distribution and use
 - identification of medical devices in adverse events
 - reduction of medical errors
 - documentation and longitudinal capture of data on medical devices in clinical registers.
355. The definition of medical device in the draft Bill draws on the definition of therapeutic purpose in section 15 and then specifies when a therapeutic product is a medical device (s 21). When these sections are read together, the definition is consistent with the definition in the GHTF/IMDRF model and would therefore capture the same set of products that are regulated globally as medical devices.
356. A number of products that have similar features and risks to a medical device would not be captured under this scheme as they are not intended for a therapeutic purpose. Examples include planar contact lenses, facial or other dermal fillers, and equipment used for cosmetic purposes that emits high-intensity electromagnetic radiation.

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

357. The following paragraphs explain how the new scheme would implement the global model for product-based controls.
358. Rules made by the regulator would be used to specify the core elements of the global model and would do so through a product standard that specified:
- two broad categories for medical devices: in-vitro diagnostic medical devices (IVDs) and medical devices that are not IVDs
 - the set of Essential Principles that IVDs must meet and the set that devices that are not IVDs must meet. The two sets of principles would be those used in the global model
 - risk classifications for medical devices and the rules for determining which risk class a device belongs in. We intend these to be aligned with the global model
 - conformity assessment procedures for medical devices. These would also be consistent with the global model.
359. Section 96 of the draft Bill provides the authority for product standards to cover such matters. Section 265 would enable rules to specify matters individually or by class and to make different provisions for different cases (eg, type of device or risk class) on any differential basis. Risk classes for devices have not been specified in the draft Bill in order to enable this important aspect of device regulation to be updated readily if the global model is modified in the future.
360. Under the new scheme, generally a product approval is required to import or supply a medical device (s 51). In addition, a person must not import an approved medical device unless they are the product's sponsor (ie, the approval holder), have the written permission of the sponsor or are authorised by a licence, permit or a provision in the legislation to import without the sponsor's consent (s 52). The policy intent behind this provision is to prohibit 'parallel importation' unless there are special circumstances such as a sponsor who is not willing to supply a needed product.
361. The only situations where an approval would not be required under the new scheme would be if the product is approval-exempt or if another form of authorisation has been given by a licence, permit or provision of the Act. If an unapproved medical device is needed for a particular patient, the Bill enables a health practitioner to issue a special clinical needs supply authority to authorise the import and supply of that device for that patient (s 64).

362. Regulator's notices would be used to declare a medical device or type of medical device to be an approval-exempt product and further consultation would happen as the notice was being developed. We envisage them being used, for example, for custom-made devices that were made by, or at the request of, a health practitioner and to a technical specification issued by the practitioner, in order to meet the needs of an individual patient of that practitioner.
363. The term 'sponsor' is defined in the draft Bill (s 14) to mean, in relation to an approved product, the person to whom the approval was granted or a person to whom the sponsorship was transferred under the process set out in section 102. For an approval-exempt product, the regulator must specify who the sponsor is in the notice that declares a product to be an approval-exempt product or class of products (s 115). In determining who is to be the sponsor, the draft Bill requires the regulator to consider the desirability that the person named would meet the criteria for being the sponsor of an approved product (s 97) but the regulator is not bound by those criteria.
364. Regulations would be used to authorise the importation and supply of unapproved medical devices in particular generic circumstances. For example, we envisage regulations authorising importation of devices:
- a. by a health care practitioner who is accompanying a patient coming into New Zealand
 - b. by a sponsor who has applied, and is waiting for, a product approval
 - c. for examination or testing purposes (other than a clinical trial as authorisation for trial devices would be given through the clinical trial licence).
365. The regulations would include appropriate controls around matters such as use and record-keeping in relation to these products. There are also likely to be other scenarios that should be catered for in regulations and this would be considered when the regulations are developed and during the consultation process on the draft regulations. The authorisation in the regulations would apply to everyone who came within the criteria set out in the regulations.
366. Licences would be used to authorise the importation and supply of unapproved products on a case-by-case basis for purposes such as:
- a. use in a clinical trial
 - b. supply by a wholesaler in response to a request for supply that is supported by a special clinical needs supply authority
 - c. enabling a New Zealand manufacturer to undertake a step in manufacture such as packaging and labelling.
367. We envisage permits being used only to authorise the importation and supply of unapproved products in exceptional circumstances. For example, a permit might be issued to deal with a public health emergency or to rapidly access an essential product if no approved product was available.

Question C12

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

To comment on the requirement for product approval and ability to exempt products, refer to question B3.

Obtaining a medical device approval

368. To obtain a product approval, a person (individual who is ordinarily resident in New Zealand or body corporate incorporated in New Zealand) who meets the criteria for being a sponsor of an approved product must apply to the regulator. Those criteria (set out in s 97 of the draft Bill) are principally designed to ensure:
- 'legal reach' is sufficient to hold approval holders to account
 - approval holders have a contractual relationship with the responsible manufacturer (if they are not themselves the manufacturer) that enables them to access information necessary to maintain the currency of the regulatory file and meet sponsor obligations
 - approval holders have the knowledge and capacity to be able to comply with their regulatory and safety-related obligations as a sponsor
 - they are a fit and proper person.
369. Rules would detail the technical and process requirements for applications for product approval.
370. When evaluating an application for approval of a device, the regulator must consider the criteria for product approval, whether the device (if approved) would comply with specified product standards (eg, Essential Principles) and whether the proposed sponsor meets the criteria for being a sponsor (s 97).
371. The criteria for approval (set out in s 95) involve a consideration of whether the quality, safety and performance of the medical device (for the purpose for which it is to be used) have been satisfactorily established, whether the likely benefits of the product outweigh the likely risks associated with it, and any other criteria that are specified in rules.
372. We intend to specify product approval criteria in the rules to link the matters specified in the product standards with the evidence that must be submitted to show that the manufacturer has produced a device that meets those standards. The rules would also specify the approval arrangements for medical devices that come under the Mutual Recognition Arrangement between New Zealand and Europe, the circumstances when a 'family' of devices could be grouped together under one application and other aspects of device regulation such as requirements for unique product identifiers.

373. The new scheme would allow the regulator to rely on work done by other recognised authorities (eg, reports, assessments or decisions) or information such as conformity assessment certificates issued by a recognised authority (s 207). The regulator would specify the authorities it recognised in a notice, which would be available at the time of commencement and updated as necessary. For medical devices, we expect the authorities would be a mix of third-party conformity assessment bodies, such as those designated under the European Union system, and national regulatory bodies we have confidence in. It is not intended that the new regulator would offer conformity assessment services to medical device manufacturers.
374. New Zealand manufacturers would be able to seek conformity assessment services from third-party bodies and would be expected to select a recognised authority named on the list. Conformity assessment for devices in the lowest-risk class could be performed by the manufacturer of the device.
375. A core component of the scrutiny of applications for a product approval would be checking that: the device has been assigned to the correct risk class; an appropriate conformity assessment procedure was conducted by a recognised authority; and certification of compliance is within its expiry date and contains the required information. After the evaluation process has been completed, the regulator must either approve the product (with or without conditions) or refuse to grant approval. Conditions may be tailored for a particular product or be ones that are set out in rules that could apply across a specified kind of product.
376. There would be a requirement for evidence of periodic recertification of conformity assessment to be submitted to the regulator. This could be either done as a condition of approval or specified in regulations as a generic requirement. The onus would be on the sponsor to obtain the information from the manufacturer and submit it to the regulator.
377. Approvals may be granted with or without an expiry date. The requirements for the content of an approval are set out in section 98. They have been expressed in a generic way in this section because they apply to medicines of different kinds, medical devices and type-4 products. Regulations would be used to set out requirements that need to be tailored to different types of products or groupings within those types.
378. The regulator would be required to maintain a publicly accessible register of medical devices, including those that have been approved and those that the regulator has refused to approve. The register would be required to include at least the set of information referred to as the content of the approval in section 98, but may contain any additional information the regulator considers appropriate.
379. Under the new scheme, sponsors of approved and approval-exempt products must comply with a set of obligations that are set out in sections 116–118. If they did not, they would be committing an offence. The obligations are designed to ensure the sponsor:
- a. complies, in relation to approved products, with the approval (eg, with any conditions on the approval)

- b. ensures that an approved product complies with the approval
 - c. ensures that any person who is required by the product approval to do or not do something complies with that requirement
 - d. ensures that the product (whether approved or approval-exempt) complies with any specified product standards, or requirements in the regulations relating to matters such as product or consumer information, labelling and record-keeping.
380. For an approved product, non-compliance with these obligations may also give rise to grounds to cancel the approval, either directly (product not complying with product standards – s 108(d)) or indirectly because the sponsor’s non-compliance affects their ‘fit and proper person’ status and thus whether they meet the criteria for being a sponsor (s 108(e)).
381. Sponsors of medical devices who are not themselves the manufacturer would need to play an important and active intermediary role between the manufacturer and the regulator. Because of their sponsor obligations, they – rather than an offshore manufacturer – would be the person held to account for any breaches of the approval conditions or failure of the product to comply with its approval or product standards.
382. Sponsor obligations would not, however, apply to the sponsor of an approved product that is imported without the sponsor’s consent (s 119).

To comment, refer to questions B3, B13, B14, B15 and B16.

Changes to approved products

383. Under the new scheme, changes would be categorised as either major or minor. Rules would specify the changes in each category. Minor changes are ones that may be implemented without needing the regulator’s approval. Some minor changes would, however, need to be notified to the regulator and the Rules would specify such detail, including timeframes for notification. We envisage this might mostly occur, for example, through a consolidated six-monthly or annual update, while changes to important contact details would need to be notified immediately.
384. Major changes are changes to the product, or any matter or information relating to the product, which may have a significant impact on its quality, safety or performance. Rules would specify exactly what that set of changes would be (ss 100 and 101). We envisage changes such as the risk classification of a device, the manufacturer’s intended purpose for the device and changes to the name of the manufacturer or the device would be examples of major changes. Under the new scheme, if a major change is made to an approved product, the changed product is a different product requiring a new approval (s 100) before the changed product is supplied.

385. The application process and data set to be submitted for a new approval required to make a major change to an approved product would be tailored to the nature of the change. The regulator would be able to evaluate data relating only to the change(s) (which could be grouped under one application) and to rely on its previous assessment of the unchanged aspects of the product. The fee for applying for this type of approval would be proportional to the work required to assess the changed component.
386. Once the application was approved, a new approval document would be issued at the end of the process. The approval relating to the unchanged product would remain in place unless the sponsor asked for it to be cancelled (or there was subsequently a need to revoke it for safety or non-compliance reasons).
387. This way of dealing with major changes is intended to provide greater clarity about approved products. Under the new scheme, a product approval approves the product as described in the approval and any subsequent minor changes (s 99).

Question C1

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

Merits review of decisions

388. Schedule 2 to the Bill sets out the decisions that are reviewable and who may apply for a review, including applicants who are aggrieved by a decision to not approve a product or to cancel an approval. The merits review would be conducted by a panel of at least three people appointed by the regulator who have not previously been involved in the decision (s 201). The regulator would act independently in appointing a panel but would be accountable for its decisions to appoint particular people. The Bill would require the regulator to appoint people with suitable knowledge and expertise for the issue at hand, with no conflict of interest, and at least one person who is a lawyer with at least 7 years' experience. The panel would change depending on the matter being reviewed. For example, expertise in pharmacy matters would be needed for a pharmacy licensing decision whereas the expertise needed for a medicine approval matter is likely to be in pharmacology or a practise of medicine related to the type of medicine. Similarly, the expertise required for a medical device matter would depend on the type of device and could range over fields such as biomedical engineering, plastics technology and electrical engineering. This approach has been taken to provide flexibility to respond to the wider range of products and activities being regulated.
389. Sections 202 and 203 set out the requirements for the review procedure and the review decision. The panel must either confirm the original decision, or set aside the original decision and refer the matter back to the regulator. If the matter is referred back, the regulator must reconsider the application in accordance with any recommendations made by the review panel and make a fresh decision. An applicant for review may appeal to the District Court against a decision of the

review panel, or against a new decision that the regulator made after a referral from the review panel.

To comment, refer to questions B27 and B35.

Supply-restricted and use-restricted devices

390. The new scheme would not use a categorisation mechanism to regulate access to devices as is done with medicines to, for example, specify products that are only available on prescription or from a pharmacy.
391. We envisage, however, that there may be some devices that should have either access or supply restrictions applied to them for safety reasons. For this reason, the Bill would allow regulations to be made to declare a specified device or class of device to have a specified restriction on use or supply (or both) (s 22). Regulations would specify the restrictions, and non-compliance with those would be an offence. We envisage this regulation-making power would be used if concerns arose about the misuse of products or about adverse events linked to the use of a device by untrained service providers.

Question C13

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

Post-market controls

Cancellation of approvals

392. Under the new scheme, product approvals may be cancelled but not suspended. The purpose of this provision is to avoid legal uncertainty for those in the supply chain. If an approval is cancelled for reasons that do not relate to safety concerns, the regulator would be able to issue a 'use of current stock' notice that would allow people in the supply chain (but not the sponsor) to use existing stock (s 78).
393. The sponsor could apply to the regulator seeking cancellation of an approval. This might occur, for example, if there was no longer commercial interest in supplying a product, or because a new approval for the product had been granted to authorise one or more major changes to it.
394. The regulator would have the power to cancel an approval if satisfied that there were grounds to do so (ss 108–109) but must first give the sponsor an opportunity to comment and comply with any procedural requirements in regulations (s 110). The meaning of opportunity to comment is set out in the

draft Bill (s 206). Note, however, that the regulator is not required to cancel the approval even if there are grounds to do so. For example, the facts giving rise to the grounds to cancel might also constitute an offence, in which case the regulator might decide that it is more appropriate to prosecute, particularly if it is an essential product and product safety is not at issue.

To comment, refer to question B14.

Product vigilance

395. Under the new scheme, sponsors would have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. These requirements would be set out in regulations. It is intended that they would be aligned with international norms. Currently in New Zealand, such obligations are recommended but not underpinned by the legislation.
396. For the first time also in New Zealand, the new scheme would place an obligation on the regulator to ensure it has a system in place to monitor the safety of products that are being lawfully supplied (s 160). Regulations would specify details about the monitoring system and the information that must be publicly available. This requirement is included in the legislation to highlight the importance of post-market safety, risk management and communication in a modern regulatory scheme.
397. Medsafe currently runs and oversees important post-market monitoring initiatives for medical devices, such as a reporting scheme for adverse events and quality issues and an early warning scheme. These initiatives would be continued, and potentially enhanced, under the new scheme.
398. The regulator would also be able to seek expert advice from a subject matter expert or from an expert committee (but would not be required to do so).

Question C4

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

Transition for product approval controls

399. The proposed transition arrangements are set out in Schedule 1 to the draft Bill. The policy intent is to allow a person who is lawfully importing or supplying a device or carrying out a controlled activity before the commencement of the new scheme to continue to do so for a six-month transition period. This would be achieved by automatically creating a licence that would authorise those activities for six months. If the person wished to continue to import or supply, then within that six-month period they would need to apply for a product approval. The

product approval application would trigger the creation of a temporary licence that authorises the applicant to continue to import and supply the device until the regulator has made a decision on the product approval application.

400. Wholesalers who are obtaining medical devices from a New Zealand supplier would need to apply for a licence within six months of commencement to seek authorisation for ongoing supply by wholesale.

Question C14

Please provide any comments on the transition arrangements for product approval controls for medical devices.

Activity-based controls

Clinical trials

401. For the first time in New Zealand, under the new scheme all clinical trials of a medical device would require regulatory approval. The meaning of 'clinical trial' in the context of medical devices is set out in section 27 of the draft Bill. See Chapter C4 for details of the clinical trial proposals.

Manufacturing

402. Under the new scheme, manufacturing a therapeutic product is a controlled activity requiring an authorisation (s 53). We intend the authorisation would ordinarily be a licence; however, we consider that because the Bill enables the use of regulations or licences, this would provide the flexibility to deal with new and emerging technologies such as 3D printers, which are new forms of manufacture. Permits would only be used for exceptional circumstances.
403. The terms 'manufacture a medical device' and 'remanufacture' are defined in section 34 of the draft Bill. This section indicates manufacture covers all aspects of producing the product and bringing the product to its final state, including testing, sterilising, releasing for supply, packaging or labelling the product. However, it makes clear also that assembling or calibrating a device before use in accordance with the responsible manufacturer's instructions is not part of manufacture. The definition of remanufacture is intended to cover refurbishment, reprocessing and rebuilding activities that produce a device significantly different from the original, or activities that are carried out on devices originally intended for a single use only. The definition also clarifies that activities such as normal repairs and maintenance are not remanufacture.
404. The draft Bill includes the concept of a responsible manufacturer. The term, as defined in section 31, is intended to mean the person who is primarily responsible for the manufacture of the product (even if they did not personally undertake the

manufacture). This is a helpful concept in the context of the regulation of medical devices and a good fit with the global model. If the sponsor is not the responsible manufacturer, they would need to have a contractual relationship with the responsible manufacturer to gain a product approval.

405. The administrative detail around licensing would be set out in regulations and rules. A term of up to three years is proposed for licences under the new scheme. The criteria for granting licences (of any kind) and for licensees and responsible persons to be named on a licence are set out in sections 128–130 of the draft Bill. They include requirements for the licensee (including taking into account any senior managers of that licensee) and responsible person(s) to be a fit and proper person (as defined in s 47).
406. The licensing scheme for device manufacturers is intended to simply capture establishment details for manufacturers such as name, site address(es) and information about their product range but would not involve conformity assessment of the products being manufactured. Where a responsible manufacturer was using other manufacturers to perform steps of manufacture, the other manufacturers would not need to obtain their own licence but could be named and authorised through the licence issued to the responsible manufacturer.
407. A licence to manufacture would also authorise the supply by wholesale of those devices.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

Question C5

Please provide any comments on the manufacturing-related definitions.

Wholesale supply

408. Under the new scheme, the supply of medical devices by wholesale is a controlled activity requiring an authorisation. It is intended to use a licence as the means of authorising this activity for those supplying medical devices other than those in the lowest-risk category. We propose to use regulations to authorise the supply by wholesale of medical devices in the lowest-risk class rather than requiring individual businesses to apply for a licence. The use of permits to authorise supply would be reserved for dealing with exceptional circumstances.
409. The administrative detail around licensing for supply by wholesale would be set out in regulations and rules.

410. A licence that authorises supply by wholesale would also specify the scope of the wholesaling activity that is allowed (eg, the types of devices). This includes whether the licensee is authorised to supply an unapproved device in response to a request supported by a special clinical needs supply authority.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

Transition arrangements for activity-based controls

411. The proposed transition arrangements are set out in Schedule 1 to the draft Bill. The policy intent is to allow a person who is lawfully carrying out a controlled activity before the commencement of the new scheme to continue to do so for a six-month transition period. This would be achieved by automatically creating a licence that would authorise those activities for six months.
412. If, within the six-month period after commencement, a valid application for a licence for a controlled activity (such as manufacturing or supplying by wholesale) is made, a temporary licence is created that would authorise the applicant to carry out the activities in the licence application until the regulator has made a decision on the application.

Question C15

Please provide any comments on the transition arrangements for regulating activities involving medical devices.

C4 Clinical trial sector

413. Under the new scheme, conducting a clinical trial of a therapeutic product would be a controlled activity requiring an authorisation (s 53). It is intended that the approval would take the form of a licence that could authorise the supply of the product(s) being trialled to the specified clinical trial site(s) as well as the trial itself.
414. This means that for the first time in New Zealand, medical device and cell and tissue researchers will work within a regulated trial environment, in contrast to the current scheme, which requires only an ethics approval. For pharmaceutical researchers, it would mean that all clinical trials of a medicine would require approval whereas the current legislation requires approval only for trials of unapproved medicines. This approach aligns with Organisation for Economic Co-operation and Development advice on the governance of clinical trials for medicinal products.

415. The new scheme would take a risk-based approach to licensing so that greater scrutiny would be given to applications to trial novel products being used for the first time in humans and high-risk products, than applications for trials researching new uses for approved products or comparing approved products. The licensing system would follow international norms for good clinical research practice.
416. The criteria for granting licences of any kind are set out in section 128 of the draft Bill. They include requirements for the licensee to be a fit and proper person (as defined in s 47). For a licence that authorises the conduct of a clinical trial, an additional requirement is that an ethics approval must be in force for the trial unless an ethics approval body certifies that ethics approval is not required. The term 'ethics approval entity' is defined in Part 2 of the draft Bill. This is the first time the requirement for an ethics approval has been written into New Zealand law, although it is established practice.
417. It would be possible for the ethics approval process and the regulatory process to run in parallel (and we would expect this to be the usual practice). However, it would not be lawful to grant a licence to conduct a clinical trial without an ethics approval being in place (unless that is not required under the ethics system).
418. A combination of regulations and rules would be used to set out the detail of the licensing scheme for trials, including the obligations of those named as a responsible person on a licence. It is envisaged these would include a requirement for registration of specified trial information in a publicly accessible registry that could be entered via the search portal on the World Health Organization's International Clinical Trials Registry Platform.
419. In addition, for regulatory purposes, the regulator would be required to maintain a publicly accessible register of licences. This system would therefore provide a comprehensive record of all clinical trials conducted in New Zealand.
420. It is intended that online tools would be used to expedite the submission of applications and their consideration, because shortening the time to decision is important if New Zealand is to remain an attractive setting for conducting clinical research. The regulator would be expected to set performance targets for deciding applications that were linked to the risk profile of the trial and report on achievement against them.
421. The regulator would be able to grant or refuse an application for a clinical trial licence without first seeking advice from the Health Research Council, as is currently required for approvals under the Medicines Act 1981. This is consistent with the principle of independent decision-making. The regulator instead would have the flexibility to seek expert advice on a trial application from an individual or committee, or to determine the application using its own in-house resources.
422. The regulator would also have the power to monitor trials and audit clinical trial sites.
423. Schedule 1 sets out proposed transition arrangements for clinical trials that are under way before the commencement of the new scheme.
424. Under the proposed arrangements, trials that have been approved by the Director-General of Health under section 30 of the Medicines Act 1981 would

automatically be covered by a temporary licence, which would stay in force for at least 12 months. Before then, if the trial needed to continue beyond the 12-month point, the person who made the section 30 application would need to apply for a licence under the new scheme. Once that application was lodged, the temporary licence would continue until a decision was made on the application for a new licence.

425. A similar temporary licence scenario is proposed for trials that did not require approval before commencement (eg, trials of medical devices or trials using approved medicines). The principal investigator for the trial would need to apply for a licence under the new scheme within six months of commencement.

To comment on the proposed licensing requirements, refer to questions B18, B19, B21 and B22.

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)

426. Under the new scheme, supply by wholesale of category 1, 2 and 3 medicines, medical devices and category 1 active medicinal ingredients (AMIs)⁷ would be a controlled activity requiring an authorisation (s 53). This would apply irrespective of whether the supply was within New Zealand or for export.
427. We intend to use regulations to authorise supply by wholesale of devices in the lowest-risk class. This would mean that a licence was not required. The activity would still be subject to standard requirements set via regulations under section 55, which, for example would set minimum standards in relation to storage and record-keeping.
428. If you are also wholesaling a controlled drug, then a 'licence to deal' would still be required under the Misuse of Drugs Act 1975.

⁷ Those active ingredients that, when present in a medicine, make that medicine a prescription medicine.

429. Under the new scheme, if you wholesale a product (medicine or medical device) that you obtain from a company in New Zealand, the person who imported it, or commissioned its manufacture in New Zealand, would be responsible for obtaining the product approval. The obligations associated with that approval would also sit with that person.
430. The impact of the new scheme on those who wholesale medicines manufactured in New Zealand is expected to be minor for the following reasons.
- a. A licence would continue to be needed for the supply by wholesale of prescription, pharmacist, and pharmacy (category 1, 2 and 3) medicines but not for general-sale (category 4) medicines. Wholesalers that also supply prescription-type AMIs would be authorised to do so on the same licence.
 - b. Under the transition arrangements, wholesalers who hold licences issued under the Medicines Act 1981 would be able to continue to operate under those licences until their expiry date. A new licence issued under the new scheme would then be needed (see Schedule 1 of the draft Bill).
431. The impact for those who supply medical devices they obtain from a company that manufactured them in New Zealand would be more significant because an authorisation would in future be required to supply medical devices by wholesale. For most devices, this would mean wholesalers would need to obtain a licence. However, we intend to authorise the supply of the lowest-risk class of device through regulations. This would mean that the regulations (rather than a licence) would provide the authority for anyone supplying devices in the lowest risk class.
432. If, however, you were importing a medicine or medical device for wholesale supply in New Zealand, then the requirements would depend on the status of the product. Diagram E explains these requirements.

Diagram E: Import requirements for medicines or medical devices for wholesale supply in New Zealand

Status of product	Requirement for import
Already approved for supply in New Zealand	You would only be able to import an approved product if you had the written consent of the sponsor (ie, the person who holds the approval) (s 52).
Approval-exempt	Some classes of product would be declared approval-exempt by regulator’s notice (s 114). This would occur if the regulator, having considered the nature of the product and its risk profile, decided the risks of the product could be addressed without requiring a product approval. The regulator’s notice that declares a product or class of product to be approval-exempt must also specify who the sponsor for that product is. A person would be able to import an approval-exempt product without the sponsor’s consent. In many cases, the person importing the product is likely to be declared to be the sponsor.

Status of product	Requirement for import
Unapproved product – imported because you wish to supply a product for which there is a special clinical needs supply authority (SCNSA)	<p>The supply of a product not approved in New Zealand could be authorised when a patient has a clinical need for it and no appropriate approved product is available. In these situations, it is intended that regulations would authorise a medical practitioner to issue a SCNSA. This would then enable the issuer of the SCNSA, a pharmacy, or wholesaler to import that product on that patient’s behalf (noting that for a prescription medicine, a prescription would also be required).</p> <p>As a wholesaler, you would only be able to import an unapproved product if your licence specifically authorised this (s 51(1)(b)). In most cases, the import would be requested by a pharmacist or health practitioner prescriber because a doctor had issued a SCNSA. For some medicines, however, it may be necessary for the wholesaler to maintain a small stockpile of the product so it is available for immediate release once a SCNSA has been issued. If so, the licence would authorise such stockpiling. This approach might be used, for example, for medicines that must be available urgently.</p>
Unapproved product that you wish to import and supply as the sponsor of an approved product	You would first need to obtain a product approval. See Part 4 of the draft Bill and Chapter C1 or C3 for more information.

433. A list of approved products and approval-exempt products would be publicly available on the regulator’s website (ss 113 and 219).

To comment on product approval controls and requirements, refer to questions B3, B13, B14, B15 and B16.

Licence to wholesale

434. Part 5 of the draft Bill sets out the criteria and requirements for licences. The draft Bill would allow more flexibility about what a licence can authorise than the current scheme provides (s 123). For wholesale licences, the main application of this change would be that a wholesale licence may also authorise the supply of unapproved products, subject to appropriate licence conditions. As in the current scheme, a licence would authorise workers of the licensee to conduct the activities authorised by the licence (s 125).
435. The criteria for obtaining a licence would change. In particular, the licensee and responsible persons named on the licence would need to:
- a. pass the ‘fit and proper person’ requirements (ss 128–130) – the regulator can take into account relevant information such as the criminal history of a senior manager (as defined in s 48) of the licensee when assessing the licensee

- b. have sufficient knowledge of the obligations, products, and activities covered by the licence to be able to comply with the legislation (s 128).
436. Licences would no longer be limited to one year, but may be issued for up to three years (s 137).
437. General requirements that apply to all wholesalers may be specified in regulations (s 55). As in the current scheme, the regulator would be able to include tailored conditions on the licence and add, remove or vary those over the life of the licence.
438. It would also be possible to suspend or cancel licences (ss 141–149).
439. Licences would continue to have responsible person(s) listed on them. Under the new scheme, it would also be possible to set:
- a. specific obligations on the responsible persons (s 158)
 - b. qualifications, training or competency requirements if these are required for the person to be able to adequately meet their obligations (s 130).
440. These obligations would relate to the quality assurance and control activities required for the safe wholesale supply of the therapeutic product(s) covered by that licence. The licensee would be required to ensure the responsible person has adequate authority and resources to meet their obligations (s 153).
441. The responsible person listed on the licence would also have an obligation to report any non-compliance, if they have raised it with the licensee and the licensee has not adequately resolved the issue within a reasonable timeframe (ss 156–157).

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

442. The draft Bill is testing a proposal to curtail the personal importation of prescription medicines via the post and courier. In situations where a patient had a clinical need for an unapproved prescription medicine, they would need to follow the regulated supply channel for unapproved medicines (ie, they would require a special clinical needs supply authority (SCNSA) and a prescription). This would then enable the issuer of the SCNSA, a pharmacy or wholesaler to import that product on that patient's behalf. Although, in some situations it may be appropriate to authorise someone to personally import prescription medicines via a permit.
443. The intention of this proposal is to reduce the amount of substandard or falsified prescription medicines being brought into New Zealand as personal imports. In practice, pharmacies and wholesalers are best placed to source these medicines from a reputable supplier. Therefore, for this approach to work, pharmacies and/or wholesalers would need to be willing to source the medicines on the patient's behalf.

Question C18

What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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

444. Under the Medicines Act 1981, people such as medical representatives who 'hawk' medicines for promotional purposes – for example, by providing professional samples to doctors – require a licence to hawk medicines. The new scheme would no longer have a separate licence for 'hawkers'. Instead hawking would be authorised by a licence to wholesale. See Chapter C1 for more information on the new proposals for authorising hawkers.

Question C6

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

Transition

445. The proposed transition arrangements are set out in Schedule 1 to the draft Bill.
446. Wholesalers with a licence for the wholesale supply of medicines that was in force at the time the scheme commenced would be able to continue to operate under that licence (subject to new requirements under the scheme) until it expired. Pending applications would also be processed by the new regulator as if they had been made under the new Act.
447. Different arrangements would apply in relation to transition for those handling medical devices because product approval and licensing requirements would be new for this sector. The policy intent is to allow a person who is lawfully importing or supplying a medical device or carrying out a controlled activity with a device before commencement to continue to do so for a six-month transition period. This would be achieved by automatically creating a licence that would authorise those activities for six months.
448. If, within that period, a valid application for product approval is made, a temporary licence would be created that authorises the applicant to continue to import and supply the device until the regulator has made a decision on the application. Anyone else wishing to continue to conduct a controlled activity (eg, supply by wholesale) for a device would need to apply for a licence within six

months of commencement. On the date of application, a temporary extended licence would be generated that would stay in force until the licence application was determined.

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

449. Pharmacist and pharmacy practice and, as a result, patient safety and access are influenced by the levers and controls described below.
- a. **Current regulation of pharmacy activities:** Pharmacies are licensed to operate under the Medicines Act 1981 and pharmacy businesses would continue to be licensed and audited under the Therapeutic Products Act.
 - b. **Professional regulation of pharmacy activities:** Pharmacists are regulated by the Pharmacy Council, under the Health Practitioners Competence Assurance Act 2003. The Pharmacy Council is responsible for ensuring that pharmacists, whether working in a pharmacy, a hospital or another setting, are competent and fit to practise. The Pharmacy Council sets competency standards and issues a range of professional requirements and guidance to pharmacists. These include the Code of Ethics 2018, which expresses the responsibilities and professional values that are fundamental to the pharmacy profession. Therefore, both the pharmacy licensing regulator and Pharmacy Council have core roles in ensuring that pharmacist services being provided under a pharmacy licence are of a suitable quality. The two regulators have a constructive working relationship and are currently looking to identify opportunities for more collaboration and sharing of relevant information. The draft Bill includes information-sharing provisions to support this and to facilitate timely responses to safety issues.
 - c. **Funding of medicines:** The Pharmaceutical Management Agency (PHARMAC) is responsible for determining which medicines (and increasingly medical devices) should be publicly funded and negotiates pricing. As part of this process, PHARMAC sets the requirements for receiving funding. This can impact the pack sizes available, period of supply, and whether a prescription authorised by a particular health professional (eg, a nurse practitioner) is eligible for public funding.

- d. **Commissioning and funding of pharmacy services:** A licence to carry out a pharmacy business is a prerequisite for a service contract, but does not entitle the licensee to a contract, as contracting decisions are the responsibility of the district health boards (DHBs). Local commissioning by DHBs is a key enabler to ensure services are available to meet the needs of the local community and address inequities. DHBs are actively considering how they can ensure the pharmacy networks within their regions are delivering equitable access to a range of high-quality pharmacy and pharmacist services. To achieve this, DHBs have signalled a shift to a more deliberate approach to the commissioning of pharmacist services, including the ongoing development of support packages for rural and/or vulnerable services. DHBs are also shifting from a 'one size fits all' approach to a tiered commissioning model. This would provide national contracts for the supply of medicines and standardised services, while allowing DHBs greater flexibility to commission services locally, based on their specific population needs. The increased flexibility for pharmacy licences proposed as part of the new therapeutic products regulatory scheme (described below) is in line with, and would support, the shift to more tailored commissioning of pharmacy services.
- e. **Relevant strategies and action plans:** The Pharmacy Action Plan 2016 to 2020⁸ and Implementing Medicines New Zealand 2015 to 2020⁹ both provide guidance for the evolution and implementation of high-quality clinical pharmacist services.
450. It is the combination of all these different mechanisms, as well as the pharmacy licensing requirements, which ensure New Zealanders receive safe and high-quality pharmacist and pharmacy services. Therefore, it is important to consider any changes to the way pharmacies would be regulated under the Therapeutic Products Bill within the context of these other mechanisms and how these are changing.

Future regulation of pharmacy business activities

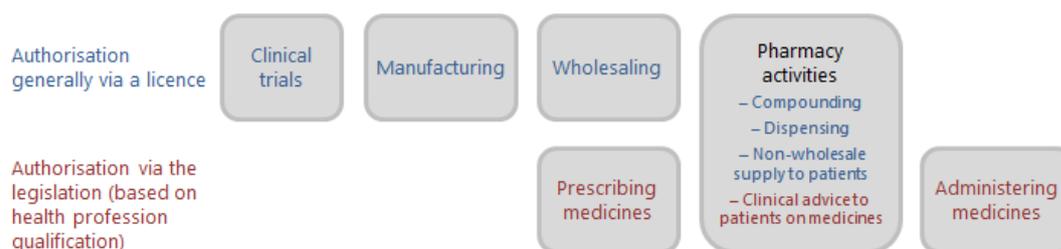
451. Pharmacists do not require a pharmacy licence to provide clinical advice. They are registered with the Pharmacy Council for this purpose. The draft Bill regulates supply chain activities involved in the provision of medicines to consumers; that is, compounding, dispensing, non-wholesale supply of medicine to patients, storage and record-keeping.
452. The draft Bill would enable controlled activities, including pharmacy business activities, to be authorised through: provision(s) in the legislation (which includes the Act and regulations); a licence; or a permit. In practice, the main type of authorisation used for particular activities would be the same as under the Medicines Act 1981. In particular, pharmacy activities would continue to require both:

⁸ Ministry of Health. 2016. *Pharmacy Action Plan 2016 to 2020*. Wellington: Ministry of Health.

⁹ Ministry of Health. 2015. *Implementing Medicines New Zealand 2015 to 2020*. Wellington: Ministry of Health.

- a. a licence
 - b. professional qualifications (ie, these activities can only be performed by a pharmacist or by appropriately qualified and trained staff under the supervision of a pharmacist).
453. Pharmacy activities are the one area of the supply chain where both these types of authorisations are required (see Diagram F). This arrangement reflects the fact that these activities may include aspects of manufacturing (ie, compounding and dispensing), as well as clinical judgements regarding the appropriateness of particular medicines for patients.

Diagram F: Licence- and qualification-based requirements



Licence to carry out a pharmacy business

454. Under the new scheme, a licence would continue to be required to carry out a pharmacy business that involves one or more of the following activities: compounding; dispensing; or supplying prescription or pharmacy medicines (category 1 and 2) to consumers (s 36).
455. The supply of pharmacy medicines (category 3) is a pharmacy activity, but is not included in the core definition of a pharmacy business in the draft Bill to enable ‘retail-only licences’ to continue. This type of licence allows a store to supply pharmacy medicines without meeting the standard pharmacy requirements (ie, requiring a pharmacist to be present). These would continue to be issued on an exceptions basis in areas that are not served by a local pharmacy.
456. In this document, and in the draft Bill, the term ‘pharmacy licence’ is used as short-hand for a ‘licence to carry out a pharmacy business’.
457. Under the new scheme, two key changes are being proposed, or considered, in relation to pharmacy licensing requirements.
- a. **Proposed:** To enable different distribution and supply arrangements.
 - b. **Under consideration:** To identify the best approach to ensuring pharmacy activities are under the control of a pharmacist.

Proposed: To enable different distribution and supply arrangements

458. The new therapeutic products regulatory scheme is designed to allow flexibility in the way pharmacist activities involving medicines are regulated in order to accommodate new approaches to providing pharmacy services into the future.
459. Barriers to innovation under the Medicines Act 1981 include expectations that:
- a. all regulated activities are performed inside fixed premises (ie, a bricks and mortar pharmacy)
 - b. a pharmacy must have the equipment and resources to perform all pharmacy activities (ie, compounding, dispensing and non-wholesale supply).
460. Under the proposed new approach, an applicant for a pharmacy licence would specify the types of services they wish to provide under that licence, the place(s) where the services will be delivered and how the services will be provided (eg, as an internet operation, a mobile pharmacy covering a stated geographic area, fixed premises or a combination of these).
461. The regulator would then assess whether the services the applicant wants to provide, and how they intend to provide them, would meet the required standards. For example, it would assess whether the medicines would be appropriately and securely stored.
462. If approved, the licence would include conditions specific to the type of services being provided and the way they will be provided.
463. The new approach would enable service innovation such as:
- a. licensing pharmacists to provide pharmacist services involving therapeutic products outside a pharmacy – for example, a pharmacist might visit rest homes and supply particular medicines, provide marae-based services or provide pharmacist services at events such as Field Days
 - b. enabling mobile pharmacies in the form of a vehicle set up to provide pharmacist services, including the supply of particular medicines.

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.

Under consideration: Identifying the best approach to ensuring pharmacy activities are under the control of a pharmacist

464. Community pharmacies and pharmacists provide publicly funded health services. Community pharmacies also operate in complex, commercial settings. The challenge for the regulatory scheme is to ensure the integrity of the supply chain and the delivery of safe pharmacy practice. It also needs to do so in ways that support other parts of the health system (eg, integrated care with general practice teams and providing services closer to home).
465. The need for professional control of pharmacy activities by a pharmacist is clear. When a pharmacist controls pharmacy systems and practice, they are not only required to ensure pharmacy activities comply with the Medicines Act 1981 (or in the future the Therapeutic Products Act), but are also bound by the Health Practitioners Competence Assurance Act 2003 to uphold professional standards and ethics.
466. Under the Medicines Act 1981, a pharmacy licence can only be granted to a company if a pharmacist has more than 50 percent of share capital and is in effective control of the company. The Act also restricts individuals who are not pharmacists holding a pharmacy licence or holding a majority interest in a pharmacy. Further, it prohibits a company from operating more than five pharmacies or an individual from operating or holding the majority interest in more than five pharmacies.
467. However, in practice the current approach is not working as originally intended. The ownership requirements are not well defined and have allowed a wide range of business arrangements to develop. While some business arrangements may have been entered into for genuine commercial reasons, some appear to have been set up for the purpose of avoiding the intention of the ownership rules. For example, in some business arrangements:
 - a. a pharmacist has the majority of shares, but the type of shares they hold are worth much less than the type of shares held by other investors and/or do not return any dividends
 - b. the company with the minority shareholding has loaned the pharmacist the capital for their shares.
468. While the Medicines Act 1981 limits a pharmacist to holding the majority interest in up to five pharmacies, this has been interpreted as allowing two or more pharmacists to jointly hold the majority interest in an unlimited number of pharmacies.

469. These types of business arrangements call into question whether the ownership control is in fact being implemented as intended and in turn whether the pharmacist listed as the majority owner on the licence is always in effective control of the pharmacy in question.
470. Modern good practice for the drafting of legislation requires clear definitions. It would be difficult to justify the continuation of provisions where there are already serious concerns about their effectiveness. It would, therefore, not be appropriate to carry the current ownership provisions over to the new Bill.
471. The Government is considering two options to ensure pharmacy activities remain under the control of a pharmacist.
- a. Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit)
 - b. Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.
472. The draft Bill does not currently contain either option. We are seeking feedback on the two options and will update the Bill to include the preferred option following consultation and decisions by the Government. There will be an opportunity to comment on the detail of the option contained within the Bill when the Bill is next consulted on as part of the Select Committee process.

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

473. The Government has heard views from parts of the sector that they consider an ownership requirement is necessary to protect consumers from the risk that commercial interests might override professional judgement in community pharmacies. It also recognises the importance of supporting local health services, led by health practitioners with connections to the communities they serve.
474. As a result, the Government is considering retaining pharmacist ownership requirements within the set of criteria for gaining a licence to operate a pharmacy business. The ownership requirements would be framed to achieve the policy intent of the current requirement, but set out in the Bill to avoid the ambiguities in the current legislation in order to achieve the policy intent more effectively.
475. The policy intent of this option is that a pharmacist(s) has financial, governance and operational control of the pharmacy business. These policy objectives would be given effect in the Bill through two key requirements.
- a. Majority pharmacist ownership: A pharmacist(s) receives the majority of profit and has the majority of governance rights. Therefore, at the highest organisational level, there is a pharmacist(s) ensuring that the commercial interests are appropriately balanced against the professional, ethical and legal obligations associated with the pharmacy activities.
 - b. Effective control: A pharmacist(s) is responsible for how the pharmacy operates. That is, they have management and operational control over the pharmacy's systems and practices.

476. The Medicines Act 1981 also prohibits a company from operating more than five pharmacies or an individual from operating or holding the majority interest in more than five pharmacies. This is intended to ensure that the pharmacist has an appropriate level of professional oversight over all the pharmacies they are responsible for. The five-pharmacy limit would be retained, but could be achieved in a number of ways (discussed under 'Implementation considerations' below).
477. To implement this option, the draft Bill would include pharmacy business ownership requirements. These requirements would be informed by modern commercial legislation (eg, the Financial Markets Conduct Act 2013) and tax legislation, which have comprehensive provisions dealing with ownership and control of businesses in various contexts.
478. The pharmacy business ownership requirements would apply regardless of the legal structure or legal entities involved. However, pharmacies owned and operated by a hospital would continue to be exempt from this requirement, as they are not subject to the same commercial incentives. We would need to consider whether it is appropriate to also continue to exempt pharmacies owned by friendly societies.
479. To ensure the requirements would be implemented as intended, the Bill would also include:
- a. appropriate investigative powers to ensure the requirements are being genuinely implemented
 - b. an offence, with penalties, for any conduct intended to undermine the requirements.

Implementation considerations

480. The pharmacy sector has evolved markedly since the current ownership controls were introduced in 2004. There is considerably more commercial investment in the sector and both the pharmacist workforce and primary health care systems are evolving. In addition, the new regulatory scheme is intended to enable innovative service delivery models to develop. Therefore, while the policy intent of this option is clear, we need to consider carefully how ownership requirements would be applied in practice and the impact they would have.
481. The definition of 'pharmacy business' and 'pharmacy activities' in the draft Bill are focused on the controlled activities it covers (compounding, dispensing, and supply of medicines, excluding general-sale medicines, as defined in s 36). An ownership requirement (for a pharmacist to have majority profit and governance rights) linked to this definition would apply only to those controlled activities. Alternatively, the requirement could be applied more broadly to cover other activities happening at the premises. However, not all pharmacy activities are delivered from a traditional 'pharmacy shop'. Linking the requirement to a 'pharmacy shop' concept may constrain the ability of the scheme to enable different types of delivery models. Further, it may not be appropriate for the ownership requirements to affect all activities carried out at the premises when many of them may be unrelated to medicines (eg, the sale of cosmetics). As such,

we are interested to hear views on what types of pharmacy activities a pharmacist ownership requirement should apply to and why.

482. The Medicines Act 1981 requires the same pharmacist(s) to have both majority ownership and effective control. However, the policy intent could also be potentially achieved by allowing a pharmacist(s) to have majority ownership and to employ another pharmacist to manage the business. This would still result in a pharmacist being responsible for balancing commercial pressures and professional obligations at both the governance and operational levels. We invite feedback on whether this approach would be effective or whether there is a rationale for requiring the same pharmacist(s) to have both levels of control.
483. The five-pharmacy limit is intended to ensure the pharmacist responsible has an adequate level of oversight for each pharmacy. Pharmacies differ in scale and can be geographically dispersed. We are seeking feedback on whether the requirement should be retained as a specific limit (ie, five pharmacies) or whether the same outcome could be achieved by a licence requirement that the pharmacist has appropriate oversight of the pharmacy. The regulator would then determine whether the requirement had been met based on the number, scale and location of the other pharmacies that the pharmacist was responsible for. If the five-pharmacy limit was retained, a related question is how it should be applied when pharmacists jointly share responsibility for the pharmacy.
484. Currently six pharmacies are owned by friendly societies. These pharmacies were exempted from the ownership requirement when the regulation of pharmacies was included as part of the Medicines Act 1981 in 2004. Friendly societies are not corporate bodies and are registered under the Friendly Societies and Credit Unions Act 1982. They are funded by voluntary subscriptions of members or donations to provide for the relief or maintenance of members and their families during sickness, in old age or in widowhood. If the pharmacist ownership requirement is retained in the new scheme, we would need to consider whether it is appropriate for friendly societies to continue to be exempt from this requirement indefinitely or whether this exemption should be removed after a suitable transition period.

Potential benefits and risks

485. A number of stakeholders have expressed concerns about the potential negative impact of increased commercial interest in, and influence over, pharmacies. These concerns include that it may lead to:
 - a. inadequate staffing levels
 - b. a reduced range of medicines supplied and therefore reduced consumer choice
 - c. a focus on profit rather than patient outcomes.
486. Retaining and improving the pharmacist ownership requirement would ensure that a pharmacist is in both operational and financial control of the pharmacy. As such, any commercial motivations should be tempered by their professional and ethical obligations.

487. A potential risk associated with this approach is that it limits the potential for commercial investment and competition, which could reduce opportunities for greater economies of scale and investment in technology and subsequent innovation.
488. Another risk is that business, loan or fee-based arrangements could be used to circumvent the ownership requirements. The requirements in the Bill would be set up to mitigate this risk as much as possible.

Potential impacts

489. We anticipate that clarifying the policy intent of the current ownership requirement is likely to result in some pharmacies needing to change their business arrangements to continue to be eligible for a licence. We do not have full information on current business arrangements and would welcome information on the potential impact of this option on current pharmacy businesses. Based on the information available from the recent audit pilot, we estimate that approximately 80 percent of pharmacies have some form of investment. As this includes structures where the minority shareholders are family trusts and family members, the proportion of structures that could be affected (ie, those that have corporate investment) is estimated at between 50 and 80 percent.
490. If this option was implemented, a transition period would be needed to give any pharmacies that did not meet the new requirements adequate time to either change their business arrangements or change ownership.
491. This option would have compliance costs for the sector, as the regulator would be required to ensure that any licence applications comply with, and continue to comply with, these requirements. We consider the most cost-effective approach would be for the regulator to have staff with the legal and accounting skills required to review pharmacy ownership structures. They could adopt a two-tiered approach, where the ownership structures of all new pharmacy licence applicants would be reviewed and then a sample of existing pharmacy businesses would be reviewed during the renewal process or if there were concerns. The operational detail would be developed once the detail of the policy is settled.

Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy

492. An alternative approach is that, rather than setting controls via ownership requirements, a new requirement could be established for pharmacy licence applicants to nominate a 'supervisory pharmacist'. The 'supervisory pharmacist' would be responsible for the quality management systems that impact pharmacy and pharmacist practice and the safe provision of therapeutic products. In addition, a pharmacist would be required to be in charge of the day-to-day operations of the pharmacy. Depending on the size of the organisation, one pharmacist may perform both functions or the functions could be split.

493. The policy intent of this option is that a pharmacist is responsible for the design of pharmacy systems and practice and their implementation.
494. In the draft Bill, all licensees are required to nominate 'responsible persons'. Under this option, there would be an additional licensing requirement that the responsible person(s) for a pharmacy licence must be a pharmacist(s)
495. For all types of licences, specific obligations for the responsible persons would be set in regulations, and the number of responsible persons required (eg, if the obligations need to be split) and any competency or qualification requirements would be set in rules. Therefore, to implement this option, the detail of what the pharmacist(s) named as the responsible person(s) would be responsible for, and any additional competencies required, would be specified in these instruments.
496. The licence holder would be required to ensure the pharmacist(s) had sufficient authority, mandate and resources to enable them to perform their function (with penalties attached if they did not) (as would be the case with responsible persons on all licences – s153).
497. While this option has similarities with overseas approaches (eg, in the United Kingdom), it is not identical and has been developed based on the lessons learnt from overseas experiences.

Implementation considerations

498. One of the concerns with this option is that the pharmacist in the 'supervisory pharmacist' role would not feel able to report or address any safety issues, due to concerns that doing so would impact their employment. This concern could be addressed by:
- a. requiring the licensee to ensure the pharmacists named as a responsible persons have the authority and resources to fulfil their obligations (s 153)
 - b. requiring the pharmacists named as responsible persons to report any non-compliance not appropriately addressed by the licensee (s 156)
 - c. making it an offence for a licensee to take any retaliatory action against each pharmacist named as a responsible person (s 157)
 - d. requiring the 'supervisory pharmacist' to have a certain level of experience, which would be set in rules, but could include a particular number of years of experience and/or training in quality management systems
 - e. setting the clear expectation that ultimate accountability for the licence remains with the licensee.
499. Note that some of these requirements are already included in the draft Bill as they apply to all licences and are relevant regardless of which of these two options is included in the regulatory scheme.
500. We are interested in feedback on whether these requirements would ensure the pharmacist in the 'supervisory pharmacist' role would be able to effectively perform this function.

Potential benefits and risks

501. The intention of this option would be to ensure a pharmacist has control over the aspects of the pharmacy considered to influence the safety and quality of the supply of medicines.
502. It would enable the regulator to direct efforts towards ensuring pharmacies have transparent, evidence-based systems that support patient safety.
503. This option could allow for greater investment in pharmacies, which could improve efficiencies through improved technology, automation or innovation.
504. Overseas research on the potential impact of removing the ownership restriction is limited. Countries where the regulation of pharmacy has changed were previously more highly regulated than New Zealand has been with its partly corporatised model that has evolved. Other countries also use different levers and controls. Moreover, PHARMAC model may result in market behaviour that differs from that in other countries. This difference makes international comparisons difficult.
505. While noting the above caveat, an Organisation for Economic Co-operation and Development study that followed liberalisation in some European countries found:
 - a. a general increase in the accessibility of medicines, partly related to the establishment of new pharmacies
 - b. relatively rapid development of pharmacy chains
 - c. the tendency for new pharmacies to be established in urban areas, while in rural areas that had an existing pharmacy few or no pharmacies opened but no decreases were observed either
 - d. an overall increase in opening hours
 - e. some distortion of competition occurring when some market players (eg, wholesalers) gained market dominance and aligned the pharmacy product range to those they supplied, which limited the availability of less frequently requested medicines.
506. Depending on how the market develops, these findings suggest this approach may increase accessibility for consumers. The findings also suggest there could be a risk that increased vertical integration with wholesalers reduces the range of medicines provided. This issue would be mitigated to some degree by the requirements for fulfilling prescriptions contained in pharmacy contracts. The anti-competitive controls of the Commerce Act 1986 would also apply.

Potential impacts

507. This option would not have a major immediate impact, as the removal of the ownership requirement would not impact any current pharmacy owner's eligibility for a licence.

508. The market is likely to change due to an increasing number of other players entering it over time and potentially quite quickly. It is difficult to predict what impact this change would have, particularly given that the pharmacy sector and pharmacist services are markedly evolving in a number of ways. As outlined above, having other players entering the market is likely to bring both benefits and risks.
509. The compliance costs of this option would be lower than Option 1, as the regulator would not be required to review detailed business documents.
510. If specific qualification or training requirements were required for the 'supervisory pharmacist', this could add costs for the pharmacists performing those functions. Any such requirements could be incorporated into their continuing professional development plan and there would be a transition period for pharmacists currently performing these functions.

Question C22

Which option do you support?

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

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

511. The Bill establishes the standard licensing criteria and requirements that apply to all types of licences, including pharmacies. These are largely the same as under the Medicines Act 1981. The main licensing differences are listed below.
512. **A single licence could authorise a range of controlled activities, the supply of unapproved products and/or use of a number of premises, when appropriate** (s 123): For example, a licence could authorise a clinical trial and the importation of unapproved products for that trial, or a pharmacy licence could authorise compounding, dispensing and supply from the licensee's main premise and dispensing and supply at an aged care facility. The regulator would have the ability to split licence applications if it considered separate licences would enable the activities or premises to be more appropriately regulated (s 136). For example, the regulator may consider that a one-year licence was appropriate for one activity and three-year licence for another activity.
513. **Requirements and obligations for licensees and responsible persons are clearer**: These provisions would include a 'fit and proper person' test (ss 128–130 and 153–158).
514. **The regulator would also be able to take into account the suitability of a senior manager** (ie, someone who has significant influence over the licensee; see s 48) when considering whether to approve a licence: This provision will enable the regulator to respond if it became aware that someone 'back stage', who is actively influencing a pharmacy business, has a criminal background or had a previous pharmacy licence cancelled due to serious compliance issues (ss 127–129 and s 141).
515. **A licence can be issued for up to three years** (s 137).
516. **The responsible persons would have an obligation to report any non-compliance**: Reporting is only required in circumstances where they have raised the issue with the licensee and the licensee has not addressed the issue (s 156). No offence is attached to this provision; however, non-compliance would impact that person's suitability to perform the relevant responsible person function in the future through the 'fit and proper person' test. Section 157 creates an offence for taking retaliatory action against a responsible person.
517. **It would be an offence for a licensee or manager to induce a health professional to act unprofessionally** (s 155).

518. The Bill specifies that an authorisation to supply medicine does not authorise that supply by a vending machine unless this is expressly stated (s 80). This means that vending machines can only be used when the regulator is satisfied that this will occur safely.

To comment on proposed licensing requirements, refer to questions B18, B19, B21, B22 and B23.

519. The Bill also includes specific requirements for pharmacy licences. Consistent with the current requirement, pharmacy activities can only be performed when a pharmacist is present at the place (or vehicle) (s 159). The new scheme continues to have this requirement to ensure that:
- a. pharmacy workers performing these activities have access to the clinical and professional advice of a pharmacist
 - b. a pharmacist has adequate oversight to identify and respond if any activities are not being performed to the required clinical or ethical standards.
520. Given the different opportunities new technologies offer for engaging with people, we have wondered whether this requirement would be too rigid and whether the same outcomes could be achieved in other ways. For example, in a hub and spoke model, a pharmacy worker could Skype with a pharmacist based at the 'hub' to confirm the clinical appropriateness of a pharmacist or pharmacy medicine (category 2 or 3) before its sale at a 'spoke' premise authorised under the licence.

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?

521. The Medicines Act 1981 contains a provision restricting a prescriber from holding any interest in pharmacies, unless granted an exception by the regulator. This reflects concerns about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions.
522. The wording of this restriction under the Medicines Act 1981 is quite broad as it covers any 'interest'. As such, there are concerns that this restriction has had a negative impact on the development of integrated health services (eg, those involving shared systems, staff or working space). This restriction would be

continued under the new regulatory scheme, but the provision would clarify that this is intended to cover interests that affect the ownership, management or control of the pharmacy business (s 93). As such, it would not apply to shared systems and other arrangements.

523. The regulator would continue to be able to issue exemptions to this restriction. If the regulator was confident the associated risks could be managed, it could authorise a prescriber to hold an interest in the pharmacy on a licence, and include any relevant licence conditions to manage this risk.
524. Drafting this provision, however, has raised some questions regarding the practicality of the restriction. For example, a prescriber could hold shares in a company as part of their investment portfolio and that company could then hold shares in a pharmacy. In this scenario, neither the pharmacy licence holder (who would be required to declare whether any prescribers had a financial interest in the pharmacy) nor the prescriber would be aware of this connection. This restriction also only applies one way, as no restrictions apply to pharmacy owners holding an interest in general practices.
525. Another question is whether this restriction might have a negative impact on the evolution of the pharmacist profession. For instance, it might impact the uptake of pharmacists becoming qualified as pharmacist prescribers, or the development of other scopes of practice that include prescribing authorities in particular circumstances (eg, a scope of practice similar to registered nurses prescribing in community health).
526. We are therefore interested in stakeholder views on whether this restriction is still required.

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?

527. Under the new scheme, it would be possible to apply for a permit to authorise controlled activities or the supply of unapproved products (see Part 5, subpart 2). Permits have similar requirements and obligations to licences, but are intended to be used for shorter-term, special situations. For example, a permit might be issued to authorise a pharmacy to operate in a container following an earthquake or to authorise supply of an unapproved product when there is a shortage of the equivalent approved product. This provision would provide greater flexibility to ensure continued access to therapeutic products during civil emergencies.

Question C38

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

Depots

- 528. Depots will continue to be allowed as a storage and pick-up point for dispensed medicines in situations where no one in the area has a pharmacy licence.
- 529. Authorisation to operate a depot would need to be part of a pharmacy licence, meaning a standard pharmacy (which meets all the criteria) could have an associated depot as part of its licence. Requiring this link to a standard pharmacy would ensure that the depot has access to clinical advice if needed. For example, it might require advice if the stock arrives damaged and the depot staff need to check whether the stock is still safe to supply, or if a patient had a question when they were picking up their medicine. It would also ensure that if the medicine was not collected, staff knew where to return it to.

Retail-only licences

- 530. Retail-only licences would continue to allow the supply of category 3 medicines in particular circumstances. These are not considered to be a licence to carry out a pharmacy business as such, as the licensee is not required to meet all the criteria (in particular, the requirement to have a pharmacist present).
- 531. As in the current scheme, these licences will only be issued on an exceptions basis, where there is an access issue in the area. The regulator would issue guidelines on when this type of licence would be appropriate (currently the requirement is that there is no licensed pharmacy within 10 kilometres). When this type of licence is issued, it would continue to contain appropriate limitations (eg, on the medicines the licensee can supply) and other requirements.
- 532. The need for retail-only licences and depots could decline, due to the new scheme allowing increased flexibility in how pharmacy activities can be provided.

Question C39

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

Unapproved medicines

533. The draft Bill is testing a proposal to curtail the personal importation of prescription medicines via the post and courier. In situations where a patient had a clinical need for an unapproved prescription medicine, they would need to follow the regulated supply channel for unapproved medicines (ie, they would require a special clinical needs supply authority (SCNSA) and a prescription). This would then enable the issuer of the SCNSA, a pharmacy or wholesaler to import that product on that patient's behalf. Although, in some situations it may be appropriate to authorise someone to personally import prescription medicines via a permit.
534. The intention of this proposal is to reduce the amount of substandard or falsified prescription medicines being brought into New Zealand as personal imports. In practice, pharmacies and wholesalers are best placed to source these medicines from a reputable supplier. Therefore, for this approach to work, pharmacies and/or wholesalers would need to be willing to source the medicines on the patient's behalf.

Question C18

What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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

535. Here we cover the authorisations specific to pharmacists and pharmacy workers. The Bill also contains authorisations for health practitioners that would apply to pharmacists as well. These include authorisations for health practitioner prescribers that would apply to pharmacist prescribers. These authorisations are covered in Chapter C8.
536. Pharmacy activities involving medicines require both a pharmacy licence and relevant qualifications. Sections 57–60 provide the authorisations for pharmacists and pharmacy workers to compound, dispense and non-wholesale supply medicines to patients. These provisions are consistent with what is permitted under the Medicines Act 1981.
537. Even if sections 57–60 authorises a pharmacist or pharmacy workers to perform particular activities, they must still comply with all the other requirements of the Act (see s 56). This includes complying with the regulations made under section 55.

538. The non-wholesale supply of a prescription medicine (category 1) will continue to require a prescription. The definition of prescription is designed to allow for increased electronic prescribing in the future (s 38). The detailed requirements for prescriptions would be set out in regulations (s 38(6)). There will be consultation with the sector when these regulations are being developed.
539. Note that the provision focused on activities involving approved products (s 57) does not include compounding, as when a pharmacist compounds a medicine this medicine is by definition unapproved. The authorisation for pharmacists to compound medicines is therefore covered in the provision focused on activities involving unapproved products (s 58).
540. In a similar manner, section 57 does not include authorisation for the supply of an approved general-sale (category 4) medicine, as this is not a controlled activity (meaning anyone can do it). However, section 58 provides the authorisation to supply a category 4 unapproved medicine (when the criteria are met) as otherwise the supply of an unapproved product would be an offence.
541. Rules would set the qualifications required for a pharmacy worker to do particular pharmacy activities and the level of supervision required (s 37).
542. Pharmacists and pharmacy workers would continue to be authorised to compound medicines on request for a particular patient (s 28). The maximum quantity that can be compounded under a pharmacy licence would be specified in rules. If a pharmacy wishes to compound more than that, it would need to seek an authority to manufacture on its licence (and meet the related requirements).

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?

543. The Bill enables regulations to be made that would authorise a pharmacist to wholesale supply, without a licence to wholesale, in specific circumstances (s 59). We consider there are situations when it would be appropriate and safe for a pharmacist to wholesale. For example, regulations could allow pharmacists to wholesale to other health practitioners in a similar manner to current practice under practitioner supply orders. We also think it may be appropriate to allow a pharmacist to provide medicine to a nearby pharmacist if a patient requests a particular medicine that their pharmacy does not have in stock. The detail would be worked through when the regulations are drafted, but the requirements in

the United Kingdom may provide a useful model.¹⁰ Any such regulations would set clear boundaries on when it was appropriate for this wholesale supply to occur. The regulations would also authorise the pharmacist to repack and label the medicines for individual patient supply (basically dispensing without the patient name) where appropriate.

Question C41

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

C7 Retail sector

544. The planned approach to the retail sale of medicines is consistent with the current approach. In particular:
- only approved medicines could be imported and supplied (unless a specific authorisation authorised the supply of an unapproved medicine) and only the approval holder (known as the sponsor) or a person who has the written consent of the sponsor could lawfully import that medicine. Chapter C1 sets out the approval process for medicines
 - medicines would continue to be classified. A retailer of general-sale medicines (referred to as category 4 in the new scheme) would not require a licence (consistent with the current scheme)
 - requirements for matters such as the appropriate storage, display and supply of general-sale medicines would be set in regulations. Consultation on the detail of the requirements would happen as the regulations are developed. We envisage they are likely to cover matters such as ensuring medicines are stored out of the reach of children and away from chemicals that could cause cross-contamination and not supplying products after their expiry date.
545. Medical devices would also be covered by the Bill. Medical devices would not be subject to the same classification system as medicines (eg, prescription medicines). A licence would generally not be required to sell devices by retail (as the non-wholesale supply of medical devices is not listed as a controlled activity – s 53). However, some devices could be declared ‘use-restricted’ or ‘supply restricted’ if there were safety concerns linked to how a device was being supplied or used. For these devices, the regulations would specify the circumstances in which they could be legally supplied or used. Retailers of all

¹⁰ Medicines and Healthcare Products Regulatory Agency. Guidance for pharmacists on the repeal of Section 10(7) of the Medicines Act 1968. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/423246/Guidance_for_pharmacist_on_repealed_exemption.pdf (accessed 17 November 2018).

devices would also need to comply with any applicable regulations under section 55 relating to matters such as storage.

546. A key difference for retailers who import devices or commission their manufacture is that retailers would need to apply for, and obtain, a product approval in order to continue to import and supply. The requirements for obtaining an approval for a device are covered in Chapter C3. They include a requirement for the approval holder to have a contractual relationship with the responsible manufacturer of the product.
547. Retailers who source their products from a New Zealand manufacturer or wholesaler should expect the importer or manufacturer to obtain a product approval and take responsibility for its quality, safety and performance.
548. Retailers would also be subject to the advertising and misrepresentation provisions in the Bill.

Question C42

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

C8 Health practitioners (including pharmacists)

549. The Bill regulates therapeutic products in two main ways: by requiring product approvals to supply and import therapeutic products (s 51); and by requiring authorisation for activities that are specified to be controlled activities (s 53). These provisions apply to everyone, including health practitioners. The Bill would provide health practitioners with the authorisations required for the activities they currently perform under the Medicines Act 1981.

Prescribers

Authority to prescribe

550. Medicines would continue to be classified into the categories of prescription, pharmacist, pharmacy and general-sale – referred to in the draft Bill as categories 1, 2, 3 and 4 (s 19). The supply and administration of a prescription medicine would continue to require a prescription (as it is a controlled activity; see s 53). The definition of ‘prescription’ is intended to allow for possible changes and growth in electronic prescribing in the future. The detailed requirements for prescriptions (eg, content, period of supply) would be set via regulations (s 38). Further requirements in relation to the controlled activity of

prescribing could also be set via regulation (s 55(3)). The draft Bill includes a transition provision so that a prescription issued under the Medicines Act 1981 would continue to be valid for a period of time to be specified in regulations (Schedule 1, s 31).

551. The approach to authorising which practitioner groups may prescribe would change. While closely connected with the safety of products, prescribing is an aspect of clinical practice. Therefore, rather than listing the practitioner groups in the Act or regulations, the draft Bill defines a 'health practitioner prescriber' as a health practitioner whose scope of practice includes prescribing (s 14). This is intended to clarify that a practitioner's prescribing authority is set and bounded by their scope of practice.
552. The proposed approach would also simplify the process for seeking a new, or a change in, prescribing authority while still ensuring appropriate controls. The first stages would remain the same. To gain the Minister of Health's approval, the relevant responsible authority under the Health Practitioners Competence Assurance Act 2003 would need to consult with its sector and other potentially affected responsible authorities and organisations. It would then develop a case outlining the benefits and risks of the proposition for review by the Ministry of Health and approval by the Minister of Health. Under the new approach, the process would stop there, ending the need to go through the regulation-making process.
553. To implement this change, the draft Bill includes amendments to the HPCA Act to make it explicit that a scope of practice can include prescribing (refer Part 9, subpart 2). It also includes an additional requirement to the process for changing a scope of practice, which would only apply when that change is to include a new or changed authority to prescribe. In these instances, the responsible authority would need to seek the Minister of Health's approval before the updated scope could be published.
554. The relevant scope of practice would need to include any additional training requirements or restrictions on the circumstances or medicines that may be prescribed.
555. We are aware of concerns around the practicality of some of the current medicines lists. Where a practitioner group is currently authorised to prescribe only from a particular list of medicines, this restriction would continue. However, the relevant responsible authority could consider revising the way it lists these medicines in the future, for example by specifying them in a class grouping. Under the new scheme, making these changes would be a simpler process.
556. The amendment to the HPCA Act includes a regulation-making power, so that it would be possible to set requirements relating to the form and content of prescribing provisions within a scope of practice. This would allow regulations to be developed, if considered necessary, to ensure consistency in the way responsible authorities set out the prescribing aspects of a scope of practice.

557. The new scheme would no longer have categories of prescribers (such as authorised, designated and delegated prescribers). Where a prescribing authority includes particular restrictions or requirements (as often occurs for 'designated' prescriber), this would be reflected in the scope of practice. To date, no practitioner group has sought a 'delegated' prescribing authority. This concept would still be possible under the new scheme, as a practitioner group could seek to include prescribing as part of its scope of practice together with a requirement that it only occur under the direct supervision of a prescriber.
558. In practice, this change does not reflect a change for the practitioner groups who currently have the authority to prescribe. All practitioners who prescribe now are bounded by their scope of practice. Once a practitioner group has the authority to prescribe, it has always been the role of responsible authorities to ensure their members have the appropriate competencies to safely prescribe and to respond when there are concerns about a prescriber's practice. What is required is that the practitioner groups that currently have a prescribing authority update their scopes of practice to explicitly include this within three months of the new scheme's commencement (Part 9, subpart 2). Any restrictions or requirements would need to be included in the scope of practice. The amendment to the HPCA Act includes a transition provision to allow responsible authorities to make these changes to their scope of practice without undertaking the consultation usually required for a change in scope (Part 2 of the proposed amendment to the HPCA Act, provided in Part 9 of the Bill). This transition provision applies only to current prescribing authorities. If a responsible authority wished to make any changes to its prescribing authority, concurrent with the Therapeutic Products Bill coming into force, it would need to go through the appropriate process (ie, consult and seek the Minister of Health's approval).

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?

Authority to issue standing orders

559. The Bill would continue to enable the supply and administration of category 1, 2 and 3 medicines to a patient, and the supply and administration of category 1 (prescription) medicines without a prescription, under a standing order. As in the current scheme, standing orders could not authorise the supply or administration of an unapproved medicine without a prescription. Supply of an unapproved medicine requires the explicit authorisation of a medical practitioner for a specific patient based on clinical need, whereas a standing order relates to supply and administration to a patient who is unknown when the standing order is issued.
560. We are aware of a range of concerns about the current use of, and requirements for, standing orders. Under the new scheme, we consider the need to use standing orders is likely to decrease because more options would be available for authorising this type of supply, where appropriate (eg, via regulations or permits). However, it is likely that the need for standing orders will continue in some situations and, if used appropriately, they can help improve access to medicines when a prescriber is not immediately available.
561. Issuing a standing order would be a controlled activity (s 53). Health practitioner prescribers would be authorised to issue a standing order if their scope of practice explicitly specifies this (s 61(6)). This reflects the current situation where not all health practitioner prescribers are authorised to issue a standing order (eg, midwives).
562. As in the current scheme, a standing order could only be issued to a person engaged in the delivery of health services (s 61(6)). The Bill clarifies the legal liabilities associated with issuing, and operating under, a standing order by specifying that the person who is authorised to do something under a standing order is taken to be the agent of the person who issued the order (s 41(5)). Consequently the attribution of liability and defence provisions apply (ss 239–241).
563. The requirements for standing orders will be reviewed when the relevant regulations are made (ss 40(2), 41(4) and 55). At that stage, we would consider how we can ensure they are used safely and also that the requirements are practical in various settings.
564. There would be a 12-month transition period for standing orders issued under the Medicines Act 1981. These would need to be replaced within 12 months of commencement of the new scheme (Schedule 1, s 33). This time period was set as it is currently a requirement for standing orders to be reviewed every 12 months.

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.)

Authority to issue a special clinical needs supply authority

565. The draft Bill contains a modified process for accessing unapproved therapeutic products. This approach aims to address difficulties with section 29 of the Medicines Act 1981 and draws on the approach used in the United Kingdom. Specifically, an unapproved medicine has an additional requirement for a special clinical needs supply authority (SCNSA). Similar to section 29 of the Medicines Act 1981, this would allow an unapproved medicine to be prescribed for a particular patient.
566. Note, that a product approval only approves the product for the purposes specified in the approval (s 99(2)). This means that whenever a medicine is prescribed for an off-label use it is an unapproved medicine and would require a SCNSA.
567. The reason for requiring a SCNSA to authorise the supply of an unapproved product is to ensure that the issuing practitioner actively considers whether the patient has a special clinical need that an approved product cannot adequately meet. Therefore, they need to be satisfied that the decision to use an unapproved product is clinically appropriate. The regulations detailing requirements for SCNSAs could specify matters such as the:
- a. need for periodic review and monitoring (s 55(1)(g))
 - b. form and manner in which they are issued (s 39(2)).
568. The provisions relating to the issue of a SCNSA are set out in section 64. Health practitioners would be authorised to issue SCNSAs for medical devices and health practitioner prescribers would be authorised to issue them for medicines. However, both authorisations would be subject to regulations that specify the circumstances in which particular classes of practitioners could issue them.
569. Our intention is to develop graduated requirements for unapproved medicines based on the level of regulatory oversight of the product (s 64(3)). In particular, we propose that there would be two main types of authorisation covering:
- a. **the off-label use of medicines that have been approved in New Zealand** – our intention is to authorise all health practitioner prescribers to issue a SCNSA for off-label use (as long as the medicine is covered by their scope of practice) and have minimal requirements for what that SCNSA would need to involve (potentially a tick box)
 - b. **medicines that do not have a product approval in New Zealand** – our intention is to continue to limit the ability to issue a SCNSA for these products to medical practitioners. This is in line with the current approach under the Medicines Act 1981. We realise this approach diverges slightly from the trend of widening access to medicines via other practitioner groups; however, we are wanting to minimise the use of products that have not been approved in New Zealand (due to the lack of oversight of what they contain and whether they are what they claim to be) while still allowing reasonable access to them when they are clinically appropriate and no suitable approved option is available. This approach is also intended to increase awareness of the additional accountability that a medical practitioner takes on when prescribing this type of unapproved

medicine. In these circumstances, there is no regulatory oversight of the quality and safety of the product. Therefore the medical practitioner becomes responsible for weighing up the expected quality and safety aspects of the unapproved medicine when they make a decision on whether to issue the SCNSA. However, once a SCNSA has been issued, any health practitioner prescriber would be able to prescribe that medicine for that patient (as long as it is within their scope of practice) (s 62).

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:

- only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product
- 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?

570. The other change in relation to unapproved medicines involves the personal importation of medicines by consumers via the post and courier. Under the new scheme, a consumer would continue to be able to import non-prescription medicines via post and courier, but not prescription medicines (s 76). To gain access to an unapproved prescription medicine, a person would first need to consult a medical practitioner to seek a special clinical needs supply authority (SCNSA). If the doctor agreed to issue a special clinical needs supply authority, other health practitioner prescribers would be able to prescribe that medicine for that patient. The consumer could not then import it themselves, but would need to obtain the medicine either directly from their prescriber or from a pharmacy. The pharmacy or issuer of the SCNSA could import the medicine themselves or obtain the medicine from a licensed wholesaler that was authorised to import and supply unapproved medicines. The rationale for this approach is that those in the regulated supply chain have more knowledge of where they can safely source this product from. The increase in international online suppliers has increased the risks associated with substandard and counterfeit products being brought into New Zealand.
571. In considering this issue, we have tried to balance people's personal freedoms (by allowing non-prescription medicines to be personally imported) with the management of the risk presented by unknown products (which is more serious in the case of prescription medicines). There would still be an avenue for the importation of unapproved prescription medicines (as described above).

572. Another possibility is to use permits to authorise the personal importation of prescription medicines via the post and courier in situations where it is in the best interest of the consumer and in line with the purpose of the Therapeutic Products Bill. This may be a suitable approach for visitors to New Zealand who require additional medicine or for buying groups that have identified a suitable and safe supplier.
573. People would continue to be allowed to bring lawfully prescribed prescription and non-prescription medicines with them when they come into New Zealand. The quantity imported should not exceed three months' supply or the amount prescribed (as some countries allow a longer period of supply) (s 76).

Question C18

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

To comment on other aspects of personal import allowances, refer to question B10.

Other authorisations

574. The Bill would continue to authorise a health practitioner prescriber to dispense, administer and supply medicine to their patients or to another patient at the request of their prescriber (s 61).
575. The Bill would allow a health practitioner prescriber to supply by wholesale medicine to another health practitioner prescriber if regulations setting out the circumstances and requirements for this (eg, record-keeping and storage) were in place (s 63).
576. As the wholesale supply of medical devices would be regulated under the new scheme, the draft Bill enables regulations to be made that would authorise health practitioners to supply medical devices to other health practitioners, without being required to have a wholesale licence (s 62).

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 C49

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)

577. Health practitioners would continue to be able to:
- supply category 1, 2 and 3 medicines to a patient for whom they have been prescribed
 - administer category 2 and 3 medicines
 - administer a category 1 medicine, in accordance with the directions of the health practitioner prescriber that prescribed the medicine for that patient (s 72)
 - supply and administer category 1 medicines without a prescription under a standing order (s 71)
 - supply category 2 or 3 medicines under a standing order (s 71).

Note that an authorisation is not required to administer a category 2, 3 or 4 medicine as these are not controlled activities.

578. The Bill would also allow health practitioners (including those who are not a prescriber) and their staff to supply category 3 (pharmacy) medicines to the patients of that practice (ss 61(2) and 65). This is essentially broadening the access to pharmacy medicines by allowing the supply of these medicines by a registered health practitioner and staff under the supervision of that practitioner.
579. The medicines they could supply would be limited to those that are appropriate for the treatment of a condition covered by the health practitioner's scope of practice. For example, a podiatrist would only be able to supply pharmacy medicines for the treatment of conditions affecting the feet and lower limbs. Currently health practitioners are able to administer these types of medicines, but not supply them to patients for follow-up care. We consider that if a health practitioner has the competencies required to diagnose and administer these medicines, then they also have the competencies required to safely supply them.
580. Health practitioners would be authorised to issue a special clinical needs supply authority to authorise the import and supply of unapproved medical devices. This authority would be subject to any regulations that specify the circumstances in which particular classes of practitioners could issue them (s 64).

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?

To comment on other aspects of the authorisations for health practitioners and their staff, refer to questions B7 and B8.

Advertising

581. Under the new scheme, it would continue to be an offence to advertise an unapproved product or include any false or misleading information in an advertisement. A wider range of enforcement tools would be available where breaches occur, including much higher criminal penalties, infringement fines and advertising remediation orders. The improved set of enforcement tools is intended to improve compliance and allow the regulator to respond more effectively when breaches occur.
582. Under the draft Bill, direct-to-consumer advertising (DTCA) of therapeutic products would continue to be allowed. Currently New Zealand and the United States of America are the only countries in the developed world to allow DTCA of named (ie, branded) prescription medicines (DTCA of non-prescription medicines is permitted in virtually all countries). DTCA of prescription medicines is a contentious issue: views on it are split and the evidence base on its impacts is mixed. Those who oppose DTCA are concerned that the commercially driven intent of this advertising results in advertisements that do not provide balanced information and encourage consumers to pressure prescribers for specific products, which may not be clinically required or the best option for them. The counter-argument is that DTCA may have some benefits in terms of increasing consumers' awareness of treatments and medical conditions and prompt them to discuss treatment options with their health practitioner.
583. In this context, it is useful to note that the new regulatory scheme will require greater availability of consumer medicine information.
584. Several studies have found evidence that consumer and prescriber behaviour alters in response to advertising of therapeutic products. Prompted by such advertising, people are more likely to go to practitioners to discuss and request advertised medicines, with prescriptions for those medicines increasing. However, evidence is unclear as to whether this results in a positive outcome

(due to more people accessing therapeutic products and services that they need) or a negative outcome (due to people being given medicines they do not need).

585. The Government has heard concern from health practitioners about DTCA. In light of that concern, it is interested in exploring whether increased regulation is warranted.

Question C52

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

Question C53

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

C9 Veterinarians

586. The draft Bill is focused on therapeutic products intended for use in, on, or in relation to humans. As such, it does not cover products used solely for animals.¹¹ However, some therapeutic products that are primarily designed for human use may also be used for the treatment of animals (especially companion animals) in particular circumstances.
587. A therapeutic product could be considered to be no longer a therapeutic product once it enters the animal supply chain. However, the therapeutic products regulator still needs some level of oversight to manage the risk of diversion back into the human supply chain. Therefore, rather than declare these products to be not therapeutic products at the stage where they enter the animal supply chain, the intention, as is the case under the current scheme, is to continue to cover them under the therapeutic products scheme.
588. The Bill, therefore, needs to provide authorisation for veterinarians to access and use these products and for prescriptions for products intended for animal use to be dispensed in a pharmacy. The Bill would continue to provide veterinarians with the same authorisations as they hold under the Medicines Act 1981 (s 66). That is, they would continue to be able to:
- a. supply all categories of medicines (noting supply of category 4 medicine does not require an authority)
 - b. prescribe and administer prescription (category 1) medicines
 - c. dispense medicines.

¹¹ Animal medicines are regulated separately under the Agricultural Compounds and Veterinary Medicines Act 1997. This act is administered by the Ministry for Primary Industries.

589. If a medicine or medical device is not approved for supply in New Zealand, then a 'special clinical needs supply authority' would be required before the activities listed above can be performed (s 67). A veterinarian would be authorised to issue this authority for an animal under their care (s 69). They would then be able to import the medicine for the care of that animal or the product could be obtained from a wholesaler with a licence that authorised the import and supply of unapproved medicines.
590. As in the current scheme, veterinarians would not be able to issue a standing order. However, the Bill would authorise veterinary staff to perform any of the activities a veterinarian is authorised to carry out if they were under the direct supervision of a veterinarian, or their general supervision for category 3 (pharmacy) medicines (s 70). Veterinary staff are not, however, able to issue a special clinical needs supply authority for an unapproved product.
591. As the new scheme is focused on human health, the clinical appropriateness of a medicine for an animal is not within its scope. Therefore, we did consider whether the requirements for a prescription and special clinical needs supply authority should apply to veterinarians. In the draft Bill the high-level requirements that apply to health practitioner prescribers would also apply to veterinarians, as they should go through the same thinking processes when prescribing and supplying an unapproved product. However, the more detailed requirements (set by regulations) for a prescription and special clinical needs supply authority may be different. These would be developed taking into account current veterinary practices and what is required to ensure the integrity of the supply chain for therapeutic products.
592. The Bill would enable regulations to be made that would authorise a veterinarian to wholesale supply to another veterinarian without needing a wholesale licence (s 68). This means that if no regulations are made, they would not be able to do this. However, if there are situations where it would be appropriate for veterinarians to be able to supply therapeutic products to another veterinarian, regulations could be developed that would set out the situations when it is allowed and set any requirements needed to ensure it occurred safely.

Question C54

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

C10 Advertising sector

593. In the Bill, it would continue to be an offence to:
- a. advertise an unapproved product (noting that approval-exempt products can be advertised because the regulator has declared they do not require an approval so they do not qualify as unapproved products)
 - b. include information that is inconsistent with the product's approval, false or misleading in an advertisement (s 83 and definition of 'misleading' in s 14).
594. This approach is in line with the approach under the Medicines Act 1981.
595. Advertisements must contain the name of the person promoting the product, so that the regulator is able to respond if there are concerns. More detailed advertisement or distribution requirements could be set via regulations (s 83(3)). We would consult with the sector when these regulations are being developed.
596. The main change in relation to advertising would be the penalties available in response to breaches. The penalty following conviction would be higher: up to \$1,000,000 for a company or \$200,000 for an individual, depending on how intentional the breach was. Part 7, subpart 3 sets out the penalties for criminal offences and the attribution of liability and defences that can be applied in criminal proceedings.
597. It would also be possible to declare some lower-level advertising breaches an infringement offence (via regulations). This means the regulator could issue the advertiser with an infringement fine (similar to a speeding ticket). Part 7, subpart 6 sets out the infringement offence aspects of the scheme.
598. The regulator would also have a new power to issue advertising remediation orders. This means that where a breach has occurred, the regulator would be able to direct the advertiser, or a person involved in the distribution of the advertisement, to take actions such as retrieve the advertisement, remove it from a website or distribute a retraction (s 166).
599. The draft Bill would continue to allow direct-to-consumer advertising of prescription medicines (DTCA) and regulate the content (through the requirements mentioned above). Currently New Zealand and the United States of America are the only developed countries that allow DTCA of named (ie, branded) prescription medicines in a form that allows a product to be identified.
600. DTCA of prescription medicines is a contentious issue: views are split and the evidence base on its impacts is mixed. Those who oppose DTCA are concerned that the commercially driven intent of this advertising results in advertisements that do not provide balanced information and encourage consumers to pressure prescribers for specific products, which may not be clinically required or the best option for them. The counter-argument is that DTCA may have some benefits in terms of increasing consumers' awareness of drug treatments and medical conditions and prompt them to discuss treatment options with their health practitioner.

601. Several studies have found evidence that consumer and prescriber behaviour alters in response to advertising of therapeutic products. Prompted by such advertising, people are more likely to go to practitioners to discuss and request advertised medicines and prescriptions for those medicines increase. However, evidence is unclear as to whether this results in a positive outcome (due to more people accessing therapeutic products and services that they need) or a negative outcome (due to people being given medicines they don't need).
602. The Government has heard concerns about DTCA. In light of that concern, it is interested in exploring whether increased regulation is warranted.

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

603. Therapeutic products include medicines and medical devices. These products are used by New Zealanders throughout their lives. They are important for everyone including disabled people and those with long-term health conditions who will rely on these products on a day-to-day basis and for those with acute episodes of ill health or impairment. It is important that they meet safety standards and work effectively.
604. The Therapeutic Products Bill is intended to modernise the regulation of medicines and medical devices and bring this more in line with international approaches and modern expectations. It would also address gaps in the Medicines Act 1981 by introducing regulation for cell and tissue products and radioactive medicines and increasing the regulation of medical devices.
605. The detail of the scheme would be set out in regulations, rules and notices, so that it could readily be kept up to date.
606. The approach for medicines is largely consistent with the current approach. Medicines would generally need to be approved by the regulator before they could be supplied or imported into New Zealand. Medicines would continue to be classified as prescription, pharmacist, pharmacy and general-sale medicines (referred to as categories 1–4 in the draft Bill).

607. The regulation of medical devices would increase. Under the new scheme, medical devices would, for the first time in New Zealand, generally require a product approval to be imported or supplied. This means there would be more oversight of the safety and performance of these products before they enter the New Zealand market. Medical devices would not be classified for supply in the same way that medicines are (eg, there is no prescription category). However, if safety concerns arose from the way they were supplied or used, it would be possible for a medical device to be declared 'supply-restricted' or 'use-restricted' and requirements to ensure safe use and supply could be set in regulations.
608. The purpose of the Bill is to ensure that medicines and medical devices are of acceptable safety, quality and efficacy or performance (meaning they do what they are intended to do) and that their likely benefits outweigh likely risks. To do this, the Bill would regulate the way the products are manufactured, imported, promoted and supplied in New Zealand.
609. Please note, decisions about which therapeutic products are funded by the public health system are a separate matter and dealt with by PHARMAC. That will not be changed by this Bill.
610. In setting the controls and requirements, there is often a trade-off between safety risks and access. For example, placing tighter controls on who can supply a medicine often makes it more costly or difficult for consumers to access those products. In developing the draft Bill, we have tried to look for appropriate ways to improve access. Therefore, we would welcome feedback from consumers and patients on whether we have this balance right – or whether particular restrictions should be tighter to improve safety or lower to increase access.
611. Below we have identified some areas where the Bill proposes changes from either a safety or an access perspective. However, please feel free to provide feedback on other aspects of the Bill where you think we have or have not achieved the right balance.

Unapproved medicines

612. For medicines not approved in New Zealand, the New Zealand regulator has not reviewed any clinical data on whether these products are safe and work as intended. It also has no controls for their safe manufacture or knowledge of whether they are being manufactured safely.
613. Medicines approved in New Zealand are also considered to be 'unapproved' if they are being prescribed for a purpose not covered by the approval (meaning the regulator has not reviewed any clinical evidence that they work for that purpose).
614. The intention under the Therapeutic Products Bill is to try to minimise the use of unapproved medicines in New Zealand. The Bill would allow for different approval pathways, which should make it simpler for some medicines or medical devices to get an approval. For instance, the regulator would be able to rely on assessment conducted by overseas regulators, where appropriate.

615. Even with these changes, occasions will still arise when someone requires an unapproved medicine. Therefore, the Bill would continue to allow unapproved medicines to be prescribed for patients. However, in allowing this we want to make sure that prescribers are giving appropriate consideration as to whether this is the best option for the patient. Given the risks associated with an unapproved product, these should only be prescribed because a suitable approved medicine is not available in New Zealand, or because there are no approved medicines for the condition being treated.
616. Under the Medicines Act 1981, unapproved medicines may only be supplied at the request of a doctor who wishes to treat a patient under their care. Under the draft Bill, a 'special clinical needs supply authority' is required in addition to a standard prescription. The intention of requiring this additional authority is to ensure the prescriber actively considers whether there is a suitable approved product that could meet the clinical needs of their patient before deciding to prescribe an unapproved medicine.
617. The ability to issue a special clinical needs supply authority for a medicine not approved in New Zealand would continue to be restricted to doctors (this will be specified in the regulations supporting the Bill). While a number of other professions can now prescribe, we want tighter controls on the supply of this type of unapproved product due to the risks associated with them. However, once a special clinical needs supply authority has been issued for a particular medicine for a particular patient, any prescriber (as long as their prescribing authority covers that medicine) would be able to prescribe the ongoing supply of that medicine. For example, if a patient usually receives their prescriptions from a nurse practitioner, they would need to see a doctor initially to get a special clinical needs supply authority. Once they have that authority, they would be able to get their ongoing prescriptions from the nurse practitioner. Allowing prescribers other than doctors to prescribe medicines not approved in New Zealand, once a special clinical needs authority is in place, is new. The intent of this approach is to balance the intention of minimising the use of this type of unapproved product with the intention of allowing reasonable access to them when they are clinically appropriate and no suitable approved option is available.
618. As mentioned above, whenever a medicine is prescribed for off-label use (ie, it is used for a purpose other than what it was approved for) it is an unapproved medicine. Currently all prescribers are able to prescribe for off-label use (as long as the medicine is covered by their scope of practice). Therefore, our intention is to authorise all health practitioner prescribers to issue a SCNSA for off-label use of a medicine and have minimal requirements for what that SCNSA would need to involve.

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:

- only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product
- 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

619. Currently anyone can bring medicines into New Zealand with them or receive medicines (other than controlled drugs) from overseas by mail or courier. When ordering prescription medicines, the person is expected to have a prescription to ensure they would be lawfully in possession of the product when it arrived. When Customs intercept prescription medicines at the border, they ask the person who ordered them to provide a letter of authority from their prescriber before they release the medicines.
620. The personal importation of medicines for your own personal use, or use by a person who is in your care, is an area where the trade-off between access and safety is particularly apparent. On the one hand, allowing personal imports means people are able to access products or brands not available in New Zealand. On the other hand, because these products have not been reviewed by the New Zealand regulator, there is a significant risk that they may be substandard or counterfeit.
621. Therefore, the following approach under the new scheme is proposed.
- Continue to allow people to bring medicines (prescription and non-prescription) with them when they come into New Zealand:** For non-prescription medicines, a person could bring in three months' supply. For prescription medicines, they could bring in as much as they could legally receive in the country they obtained the medicines in. This is because some countries allow a longer period of supply under a prescription.
 - Continue to allow people to import (eg, buy online or receive from a family member who is overseas) non-prescription medicines:** The risks associated with these products are lower; therefore, it seems appropriate to allow people to buy the products online if they wish to do so. When they do, they are taking on the risk of whether the product would be safe and effective. However, there would still be limits on the quantity that could be imported.

- c. **No longer allow people to personally import (eg, buy online) prescription medicines:** Medicines are classified as prescription when they have a higher risk associated with them and their use. In addition, they are generally prescribed to meet a significant clinical need. With the increase of online suppliers, there is an increased risk of people self-prescribing prescription medicines that are not clinically appropriate and may actually harm health. Also, if someone has received a prescription and they purchase a prescription medicine that does not work, then their illness or condition would continue untreated, potentially having negative health impacts. A further concern in relation to imported product is the very significant international trade in counterfeit and substandard medicines.

622. When someone does require a prescription medicine that is not available in New Zealand, they would need to see a medical practitioner (ie, a doctor), as they do under the current scheme. The doctor would then assess whether there is a clinical need and whether there is a suitable medicine available in New Zealand. The main difference from the current scheme is that, once the doctor has prescribed the unapproved medicine, the consumer could not import it themselves. Instead, they would need to obtain the medicine either directly from the issuer of the special clinical needs supply authority or from a pharmacy. The issuer of the SCNSA or pharmacy could import it themselves or could get it from a licensed wholesaler who was authorised to import and supply unapproved medicines. The rationale is that those in the regulated supply chain have more knowledge of where they can safely source this product from.
623. Under the new scheme, it would also be possible to use permits to authorise the personal importation of prescription medicines via the post and courier in situations where it is in the best interest of the consumer and in line with the purpose of the Therapeutic Products Bill. This may be a suitable approach for visitors to New Zealand who require additional medicine (particularly if it is not funded in New Zealand) or for buying groups that have identified a suitable and safe supplier.

Question C18

What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription 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

624. Pharmacies are the main place that people access their medicines. Under the new scheme, pharmacy businesses would continue to be required to have a licence. It is worth noting that a pharmacist does not need a licence under the Medicines Act 1981 or this Bill to provide clinical advice and that their clinical competencies are regulated through their registration under the Health Practitioners Competence Assurance Act 2003. What this draft Bill would regulate is pharmacist activities that involve medicines. For example, a pharmacist can work in a primary care setting providing advice on medicines management without a pharmacy licence. However, they are not able to supply any medicine as part of that advice without an appropriate authorisation (eg, they are a pharmacist prescriber).
625. The licensing approach for pharmacy businesses in the draft Bill is designed to enable greater flexibility in the way pharmacy activities are provided. The current expectation is that all pharmacy activities are performed inside fixed premises (ie, a bricks and mortar pharmacy). Under the new approach, it would be possible for a pharmacy licence to authorise different distribution and supply models. For instance, a licence might allow a pharmacy business to:
- a. provide pharmacy services involving medicines outside a pharmacy shop – for example, enabling a pharmacist to visit rest homes and supply particular medicines, provide marae-based services or provide pharmacist services at events such as Field days
 - b. provide mobile pharmacies in the form of a vehicle that was set up to provide pharmacy services, including the supply of particular medicines.

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?

626. Pharmacies provide public health services in a complex, commercial setting. To be eligible for a pharmacy licence, the Medicines Act 1981 requires a pharmacist to have more than 50 percent of share capital and to be in effective control of the pharmacy. It also prohibits operating or holding the majority interest in more than five pharmacies.

627. The intention behind this requirement is to ensure a pharmacist is in control of the pharmacy, as they are not only bound by the requirements of the Medicines Act 1981, but also have professional and ethical requirements under the Health Practitioners Competence Assurance Act 2003.
628. The need for professional control of pharmacy activities by a pharmacist is clear. As part of the development of the new regulatory system, two options are currently under consideration to achieve that.
629. **Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit):** Under this option, majority ownership and control by a pharmacist would continue to be required. The intention of this option is to mitigate potential risks of negative commercial influence on pharmacy practice. On the other hand, this option reduces the potential for commercial investment and competition. In the Medicines Act 1981, the current ownership requirement is not well defined and has allowed a range of business models to develop where it is not clear whether the pharmacist 'owner' actually has control. If retained, the requirements would more clearly establish the ownership requirement so that it is implemented as originally intended.
630. **Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy:** Under this option, anyone would be able to own a pharmacy, but to gain a licence they would need to employ a pharmacist who has control over the quality systems and any other aspects of the business that impact pharmacy practice. This option would allow for greater corporate investment in pharmacies, which could improve efficiencies, through improved technology, automation or innovation. On the other hand, concerns have been expressed about the risk of increased commercial influence over pharmacies.
631. This is a very quick overview of the two options. If you are interested in more information on the two options under consideration, please refer to Chapter C6 (in particular, pages 100–109).

Question C22

Which option do you support?

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

632. Pages 107–109 include further detailed questions in relation to the options being considered, which we would welcome a consumer perspective on.

Access to pharmacy medicines

633. Currently pharmacy medicines can only be provided from a licensed pharmacy business or from licensed retail premises in areas remote from a pharmacy (or from a prescriber). The Bill would widen access to pharmacy (category 3) medicines by allowing other health practitioners (who are not prescribers), and their staff, to supply pharmacy medicines to patients of that practice. The medicines they could supply would be limited to those that are appropriate for the treatment of a condition covered by their scope of practice. For example, a podiatrist would only be able to supply pharmacy medicines for the treatment of conditions affecting the feet and lower limbs. Currently health practitioners are able to administer these types of medicines, but not supply them to patients for follow-up care. We consider that if a health practitioner has the competencies required to diagnose and administer these medicines, then they also have the competencies required to safely supply them.

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

634. Under the new scheme, it would continue to be an offence to advertise an unapproved product or include any false or misleading information in an advertisement. A wider range of enforcement tools would be available where breaches occurred, including much higher criminal penalties, infringement fines and advertising remediation orders. The expanded set of enforcement tools is intended to improve compliance and allow the regulator to respond more effectively when breaches occur.
635. Under the draft Bill, direct-to-consumer advertising (DTCA) of therapeutic products would continue to be allowed. Currently New Zealand and the United States of America are alone in the developed world in allowing DTCA of prescription medicines (DTCA of non-prescription medicines is permitted). DTCA of prescription medicines is a contentious issue: views are split and the evidence base on its impacts is mixed. Those who oppose DTCA are concerned that the commercially driven intent of this advertising results in advertisements that do not provide balanced information and encourage consumers to pressure prescribers for specific products, which may not be clinically required or the best option for them. The counter-argument is that DTCA may have some benefits in terms of increasing consumers' awareness of drug treatments and medical conditions and prompt them to discuss treatment options with their health practitioner.
636. Several studies have found evidence that consumer and prescriber behaviour alters in response to advertising of therapeutic products. Prompted by such advertising, people are more likely to go to practitioners to discuss and request advertised medicines, and prescriptions for those medicines increase. However, evidence is unclear as to whether this results in a positive outcome (due to more people accessing therapeutic products and services that they need) or a negative outcome (due to people being given medicines they do not need).
637. The Government has heard concern from health practitioners about DTCA. In light of that concern, it is interested in exploring whether increased regulation is warranted.

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

638. It is important that medicines and medical devices come with understandable information to support people to use them safely and understand the risks associated with particular products. Internationally there is a shift to requiring more consumer information to be provided with medicines and medical devices.
639. The Bill would enable packaging and labelling requirements as well as requirements for product information for health professionals and consumers to be set in regulations. Setting the requirements in regulations, rather than the Bill, means it would be a simpler process to update them in future, as required.
640. We realise the information provided with medicines and medical devices is extremely important from a consumer perspective. We are also aware that some consumers have particular challenges in reading and understanding the information provided with therapeutic products. We will consult with consumer groups, including disability sector groups, when the regulations are being developed.
641. One point to keep in mind for future discussion is that while we want to ensure consumers have the best information possible, we also need to align with international requirements, as most companies produce for multiple markets. If the requirements for New Zealand are set substantially higher than, or differently from, those in other like countries, that can impact a company's willingness to bring a product to our market.

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

642. This regulatory scheme only covers products that have a therapeutic purpose. A number of products that have similar features and risks to a medical device would not be captured under this scheme as they are not intended for a therapeutic purpose. Examples include planar contact lenses, facial or other dermal fillers, or equipment used for cosmetic purposes that emits high-intensity electromagnetic radiation.

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

643. Post-market monitoring will be strengthened under the new scheme. Product sponsors would have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. Currently in New Zealand, such obligations are recommended, but not underpinned by the legislation. The detail of these requirements would be set out in regulations and consultation will occur when they are being developed.
644. For the first time also in New Zealand, the new scheme would place an obligation on the regulator to ensure it has a system in place to monitor the safety of products that are being lawfully supplied (s 160). Regulations would specify details about the monitoring system and the information that must be publicly available. This requirement is included in the legislation to highlight the importance of post-market safety, risk management and communication in a modern regulatory scheme.

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

- A1 Do you support the general design of the new regulatory scheme for therapeutic products?
- 1 Support
 - 2 Partially support
 - 3 Neutral
 - 4 Partially don't support
 - 5 Don't support.

Chapter B

Part 1: Preliminary provisions

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

Part 2: Interpretation

- B2 Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).

Part 3: Dealing with therapeutic products

- B3 Please provide any comments on the product approval controls (ss 51 and 52).
- B4 Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).
- B5 Please provide any comments on the authorisations for pharmacists (ss 57–59).
- B6 Please provide any comments on the authorisations for pharmacy workers (s 60).
- B7 Please provide any comments on the authorisations for health practitioners (ss 61–64).

- B8 Please provide any comments on the authorisations for health practitioners' staff (s 65).
- B9 Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).
- B10 Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).
- B11 Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.
- B12 Please provide any comments on the offences created in sections 81–94.

Part 4: Product approval

- B13 Please provide any comments on the sections covering product approval requirements (ss 94–104).
- B14 Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).
- B15 Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).
- B16 Please provide any comments on the sections covering sponsor obligations (ss 116–119).
- B17 Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).

Part 5: Licences and permits

- B18 Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).
- B19 Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).
- B20 Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).
- 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).
- B22 Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).

- B23 Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).

Part 6: Regulator

- 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).
- B25 Please provide any comments on the regulator's investigative powers (ss 183–196).
- B26 Please provide any comments on the offences relating to the regulator (ss 197–199).
- B27 Please provide any comments on the review of regulator's decisions (ss 200–204).
- B28 Please provide any comments on the administrative matters relating to the regulator (ss 205–222).

Part 7: Enforcement

- B29 Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).
- B30 Please provide any comments on the sections covering penalties, court orders, liability, defences and evidentiary matters for criminal offences (ss 233–248).
- B31 Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).

Part 8: Administrative matters

- 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).
- B33 Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).
- 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: Schedule 1: Transitional, savings and related provisions

See under individual sector subheadings in Chapter C for sector-specific questions.

B13: Schedule 2: Reviewable decisions

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

B14: Schedule 3: Regulations, rules and regulator's notices

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

B15: Schedule 4: Amendments to other enactments

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

- C1 Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).
- C2 Please provide any comments on the approach for medicines categorisation (classification).
- C3 Please provide any comments on the transition arrangements for existing medicine product approvals.
- C4 Please provide any comments on the approach to post-market controls.
- C5 Please provide any comments on the manufacturing-related definitions.
- C6 Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.
- 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?

- C8 Please provide any comments on any interface issues between the draft Bill and other legislation covering cells and tissues.
- C9 Please provide any comments on the transition arrangements for product approval controls for cell and tissue products.
- C10 Please provide any comments on the transition arrangements for regulated activities involving cell and tissue products.
- 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?
- C12 Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?
- C13 Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.
- C14 Please provide any comments on the transition arrangements for product approval controls for medical devices.
- C15 Please provide any comments on the transition arrangements for regulating activities involving medical devices.
- C16 Please provide any comments on the change in approach to regulating clinical trials.
- C17 Please provide any comments on the transitional arrangements for clinical trials.
- C18 What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?
- C19 What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?
- C20 Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?
- C21 Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.
- C22 Which option do you support?
- Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit).
 - Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.
- C23 Why do you support that option?

- C24 What do you consider are the benefits and/or risks that could result from Option 1?
- C25 Are there ways in which Option 1 could be improved?
- C26 What activities do you consider a pharmacist ownership requirement should cover?
- 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?
- 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)?
- C29 If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?
- C30 Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?
- C31 What transition time do you consider would be required if Option 1 was implemented?
- C32 Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?
- C33 What do you consider are the benefits and/or risks that could result from Option 2?
- C34 Are there ways in which Option 2 could be improved?
- C35 Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?
- 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 (s159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?
- C37 Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 93)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?
- C38 Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?
- C39 Please provide any comments on the intended approach to depots and/or retail-only licences.

- 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?
- C41 Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?
- C42 Do you consider the new scheme will have any significant impacts on retailers?
- C43 Do you have any comments on the arrangement for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?
- 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?
- 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.)
- C46 What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?
- C47 What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that:
- only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product
 - 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?
- C48 In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?
- C49 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?
- 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?
- C51 Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to the patients of the practice? What are the benefits and/or risks of allowing this?
- C52 Please provide any comments on the advertising requirements and enforcement tools.
- C53 Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?

- C54 What do you think about the approach for veterinarians and veterinary staff?
- C55 Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?
- C56 Please provide any other comments from a patient, consumer, or disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.