

## **Regulatory Impact Statement**

Therapeutic Products Regulation – Replacement of the Medicines Act 1981 and the Medicines Regulations 1984 with a new legislative scheme for therapeutic products  
– Analysis of specific issues and options.

## **Agency Disclosure Statement**

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health.

There are limitations on the extent to which the impacts of the options explored in this RIS can be assessed specifically or quantitatively. This is due to:

- The high-level changes being sought in the legislation and placement of details into regulation or lower level instruments, whose precise impact it is not possible to measure.
- The development and implementation of the new regime being staged over several years.
- The specific regulatory approach in new areas still to be developed by the regulator.

Previous Cabinet decisions have directed analysis towards consideration of a more enabling regulatory environment and lean principles-based primary legislation (SOC-15-MIN-0050 and SOC-15-MIN-0049 refer). Cabinet has agreed strategic policy and key elements for the regulatory regime. This RIS is focussed on:

1. Clinical trials
2. Cell and tissue therapeutic product regulation
3. Prescribing and dispensing
4. Pharmacy licensing
5. Import and export
6. Offences and penalties framework
7. Regulator form
8. Interface with the Hazardous Substances and New Organisms Act.

The options analysis in this RIS considers a range of options, from more to less regulated, against the regime's objectives agreed by Cabinet (SOC-15-MIN-0050 and SOC-15-MIN-0049 refer). The options considered are not exhaustive, and focus on those sought to achieve the largest benefits against our objectives. Not all the regime's objectives are used to assess all options considered, only those considered most relevant.

The analysis of the options in this RIS is informed by long-standing appreciation of the key problems that need to be addressed, and design of regulations around

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meeting health objectives; accepted international practice; current public sector standards for legislative and regulatory design; and a measured timetable for decisions, development and implementation.

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## Introduction

1. In November 2015 a RIS for the new Therapeutic Products Bill was prepared for two parallel Cabinet Papers; Paper 1 – Context and Overview; and Paper 2 – Proposals for a Therapeutic Products Bill. Those papers covered the high level setting for the new Therapeutic Products regime to replace the Medicines Act 1981 and the Medicines Regulations 1984. This RIS analyses the options for a specific set of issues.
2. The major focus of the medicines legislation (both the Medicines Act and its Regulations) is on medicines. It seeks to ensure that they are safe and that access to them is appropriately controlled and managed. It does this through establishing: an approval process (to enable the medicine to be marketed); a classification process (to determine how access may be gained); a licensing system for various medicine-related activities (eg, manufacturing, supplying, dispensing); and addresses a range of exemptions, restrictions (eg, pharmacy ownership), detailed procedures and processes, and enforcement. The Act also covers medical devices to a very limited extent, and a range of other administrative issues.
3. The problems with the medicines legislation relate to issues of clarity, coverage, flexibility, and cost.
  - 3.1. The legislation is dated and inflexible.
  - 3.2. There are significant gaps in coverage.
  - 3.3. The Act places many core regulatory powers with the Minister of Health (eg, approval of new medicines) which are exercised under delegation.
4. The new Therapeutics Products regime seeks to address these problems through a new legislative design that meets the needs of the health sector now and into the foreseeable future, international regulatory and market settings (and New Zealand's small market), and the Government's expectations for regulatory regimes. Cabinet agreed that the objectives will be best met by (SOC-15-MIN-0050 and SOC-15-MIN-0049 refer):
  - 4.1. an enabling legislative framework
  - 4.2. regulatory requirements that reflect international norms, standards and frameworks
  - 4.3. a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable, and able to engage internationally.
5. And specifically meet objectives that it;
  - 5.1. [Safe] - meet expectations of risk management and assurance of safety
  - 5.2. [Efficient] - result in efficient and cost effective regulation
  - 5.3. [Flexible] – be flexible, durable, up-to-date, and easy to use
  - 5.4. [Quality decisions] - ensure high-quality, robust and accountable decision-making
  - 5.5. [Capacity] - foster sustainable regulatory capacity
- 5.6. [Economy] - support New Zealand trade and economic objectives

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- 5.7. [Trust] - be trusted and respected
- 5.8. [Access] - support consumer access and individual responsibility for care.
6. This RIS provides analysis of options and recommendations on the following issues:
  - 6.1. Clinical trials
  - 6.2. Cell and tissue therapeutic product regulation
  - 6.3. Prescribing and dispensing
  - 6.4. Pharmacy licensing
  - 6.5. Import and export
  - 6.6. Offences and penalties framework
  - 6.7. Regulator form
  - 6.8. Interface with the Hazardous Substances and New Organisms Act.
7. In assessing these issues the following processes were followed:
  - 7.1. Identifying the outcomes sought, and designing arrangements to achieve them.
  - 7.2. Testing various regulatory options against the objectives agreed by Cabinet.
  - 7.3. Consideration of the preferred option against the status quo
  - 7.4. Consultation of options with stakeholders.

# 1. Clinical trial arrangements

## What are we regulating and why?

8. Clinical trials are research studies designed to assess the safety, efficacy and effectiveness of therapeutic products. Clinical trials play a critical role in the development and evaluation of new therapeutic products, new uses of existing products, and contribute to improved patient safety and public health. The information gathered may be used to support further development of the product, as supporting evidence for an application seeking marketing authorisation for the product, to increase an understanding of the product's safety, or to provide evidence of benefit (particularly where two standard treatments are commonly used). Clinical trial information may also be used to develop treatment guidelines.
9. Clinical trials offer a number of key social and economic benefits to New Zealand<sup>1</sup>:
  - 9.1. A strong culture of health research helps to attract and retain high quality innovative clinicians, academics, and scientists.
  - 9.2. Commercial health research brings investment in research and development and employment opportunities.
  - 9.3. New Zealand generated intellectual property has the potential to add significant value to the economy.
  - 9.4. Clinical trials have been shown to improve the overall standards of health in countries where they are carried out.
  - 9.5. Healthcare professionals are able to gain early experience and expertise in the selection and use of new therapeutic interventions.
  - 9.6. Relevant and timely access to evidence from clinical trials can support healthcare professionals and policy makers to implement public health interventions.
  - 9.7. Trials also benefit other patients from data gleaned and lessons learnt from clinical trials. Patients, as study participants, gain new knowledge about therapeutic benefits through the informed consent process in a trial, and are often willing to participate as an aid to improving healthcare for future generations.
10. The health research sector could be a source of significant economic benefit to New Zealand. Estimates indicate that clinical trials currently generate between New Zealand \$30-100 million per year for New Zealand.<sup>2</sup> By comparison the Australian clinical trial industry is worth AU\$450 million per year.<sup>3</sup>
11. New Zealand has many features that make it an attractive place to conduct clinical trials. These include patients who have not been exposed to new or innovative medicines previously, diverse patient groups, ethnic sub-population groups, and an English-speaking health sector with a robust ethics system, a highly trained and regulated workforce of clinicians, and a trusted academic research infrastructure.

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<sup>1</sup> Health Committee (2010) Inquiry into improving New Zealand's environment to support innovation through clinical trials, June 2010.

<sup>2</sup> More accurate estimates for New Zealand are not currently available as the necessary information is not currently reliably collected. *Inquiry into improving New Zealand's environment to support innovation through clinical trials* Report of the Health Committee June 2011

<sup>3</sup> Australian Clinical Trials Action Group *Clinically Competitive: Boosting the Business of Clinical Trials in Australia* (2011)

12. The development of new domestic therapeutic regulation is an opportunity to review and update processes to maximise efficiency whilst maintaining robust protection of patient safety, in order to realise New Zealand's potential as a clinical trial destination and to support knowledge based innovation.

## **Status Quo**

### *Regulatory approval*

13. Clinical trials in New Zealand require approval from the regulator (regulatory approval for the purposes of this paper) and an ethics committee. These are separate but parallel processes. In general, all clinical trials require ethics committee approval whereas regulatory approval currently only applies to trials using certain types of medicines.
14. The Medicines Act requires that an approval from the Director General of Health (Director-General), based on recommendations from the Health Research Council (HRC), be obtained before a new medicine can be used in a clinical trial<sup>4</sup>. The HRC maintains two non-statutory standing committees for this purpose: the Standing Committee on Therapeutic Trials (SCOTT) which reviews applications for pharmaceutical type products, and the Gene Technology Advisory Committee (GTAC) which considers applications for trials involving gene and biotechnology therapies. Most applications go to SCOTT.
15. The application and approval process is administered by Medsafe. Approval is issued by Medsafe under delegation from the Director-General and must be granted or refused within 45 working days of receipt of an application (or five working days for an abbreviated approval).<sup>5</sup>
16. Currently clinical trials of medical devices and some cell and tissue therapeutic products do not require approval. However, Medsafe asks to be informed of any trials of medical devices.<sup>6</sup>
17. Approval is not required if the trialled products have already been approved for distribution in New Zealand. This includes trials using approved medicines for a new indication, new population groups, or new dosage or form of administration.

### *Ethics Approval*

18. Processes for ethical approval sit outside the Medicines Act under the NZ Public Health and Disability Act 2000 (NZPHD Act) and are outside the scope of this review.
19. An ethics committee considers the ethical standards, which are set out in the National Ethics Advisory Committee (NEAC) guidelines and the procedural requirements contained in the Standard Operating Procedures for the Health and Disability Ethics Committees (HDECs). They must make a decision within 35 calendar days for full reviews or 15 calendar days for expedited reviews.

## **Problem Definition**

20. The current legislation relating to clinical trials is outdated and inadequate for modern practice. A number of therapeutic products are not covered, and there is therefore no

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<sup>4</sup> See Section 30 of the Medicines Act.

<sup>5</sup> The following text describing the New Zealand arrangements has been derived from the [Guideline on the Regulation of Therapeutic Products in New Zealand. Part 11: Good Clinical Research Practice and Obtaining Approval for Clinical Trials](#) published on the Medsafe website.

<sup>6</sup> Medsafe *Current Guidelines on the Regulation of Therapeutic Products in New Zealand: Part 11: Good Clinical Research Practice and obtaining approval for clinical trials*. Edition 1.3 November 2012.



way to ensure the safety of trials involving them. This includes medicines that are approved but are being tested outside approved indications. There is also currently no requirement to obtain approval to conduct a trial to test the efficacy of medical devices or a number of cell and tissue therapies and no controls for these trials beyond the requirements of the Health and Disability Commissioner Code of Rights. Further, the regulator currently has no statutory powers to audit or monitor clinical trials and no enforcement powers to suspend or revoke trials, meaning that there is no way of checking that studies are carried out in accordance with the approved protocol.

## **Options and impact analysis**

### *Issue 1 – Expanding the oversight of clinical trials*

21. A framework which provides sufficient regulatory oversight of clinical trials of all therapeutic products (including medicines, medical devices, cell and tissue therapies and hybrids thereof) is needed in order to:
  - Ensure that the design of the study is robust and scientifically valid and is conducted efficiently, so that it leads to reliable, scientifically sound results.
  - Ensure that products used in trials meet specified requirements for use and are safe and fit-for-purpose. Requirements may pertain to conditions on the use of the products, principles to be followed in the use of the products, the monitoring of use, the results of use and the circumstances in which use of the products must cease.
22. Having consistent policy settings and processes for all trials is important for an internationally credible regulator and regime. It could enhance New Zealand's competitiveness as a trial destination. There is a reasonable public expectation that all trials should have scientific oversight and that all therapeutic products, devices and tissue therapies – not just new medicines – are subject to a system of regulatory controls to ensure the safety of participants in trials.

### *Issue 2: Increasing the powers of the regulator*

23. It is important to ensure that the regulator has sufficient powers and monitoring capabilities to enable it to instigate actions to protect the safety of study participants, gather further information and compel reports and take action.
24. Currently section 30(8) of the Medicines Act specifies that the Director General of Health may revoke an approval of a clinical trial, but no powers are specified which enable the regulator to carry out basic safety monitoring of clinical trials such as:
  - inspecting the premises of clinical trial sites
  - auditing clinical trials
  - setting and changing conditions of approval, including requiring further information
  - implementing safeguards and protocols for safety breaches
  - requiring reporting of adverse events
  - suspending or revoking approvals.
25. These new powers will ensure that emerging risks with trials can be identified as early as possible and that, if those risks cannot be managed through changes to

processes, the regulator can act quickly to stop them. With improved access to information and the ability to seek more if required, the regulator will be in a better position to make informed decisions on safety issues.

26. The regulator will need to be resourced to carry out new monitoring and enforcement procedures. Cabinet has agreed that the Therapeutic Products Bill will include the ability for both cost recovery and Crown funding. Work is yet to be done on the method of funding individual activities. A degree of cost recovery is likely based on current practice and government policy. Some resource implications can be managed through implementation design, for example how audits are conducted, how they are scheduled or whether they are conducted at random. As is the case for all regulatory regimes, the regulations must be proportionate to the risks involved and cost effective.

### **Consultation**

27. Thorough research and internal consultation has taken place on these proposals, including with the secretariat to the ethics committees. There is general support for them. PHARMAC made the point that approval of clinical trials should require a long term commitment to participants and asked to be involved in developing the detailed requirements. The Cabinet paper reflects these points. ACC asked about what meets the definition of a 'clinical trial'. The Cabinet paper now makes it clear that this needs to be clarified in the new regime, particularly the distinction between trials and innovative clinical practices.
28. Officials will consult with external stakeholders such as the HRC and its committees, the HDECs and the research community prior to the release of the exposure draft of the Therapeutic Products Bill.

### **Conclusions and recommendations**

29. It is recommended that the new regulatory regime cover all trials of all therapeutic products, that there are sufficient powers for the regulator to assess and manage risks, and the technical requirements to be met will follow international norms and be risk appropriate, set in either regulations or third tier instruments.

### *General comments*

30. The combination of these two proposals will enhance the quality of the regulatory approval process for clinical trials. It will bring these processes into line with international norms. This should not represent a barrier to future trials, as the expectations are consistent with other jurisdictions. If better quality trials are conducted in New Zealand, this may also make the health sector a more attractive proposition for clinical staff.
31. There is also scope to further improve the process for applicants by streamlining regulatory and ethical applications and approvals. This is most likely to occur at an operational level, outside of regulatory instruments, but the development of new legislation provides a foundation to build and improve on. These changes should help to reduce the administrative burden on the relevant regulatory bodies, and should also help New Zealand maintain and improve its reputation as an attractive place to conduct trials.

## 2. Regulatory approach to cell and tissue therapeutic products

### What are we regulating and why?

32. This section of the document uses the terms 'product', 'pre-market', and 'post-market' as is the case across the rest of this document and the regulatory regime. In doing so it is important to acknowledge these terms are not used by donation and transplant services to describe the tissues and organs that they work with or their clinical practice. They are used here for clarity and consistency with the rest of this paper and the wider regulatory regime.
33. Cell and tissue therapeutic products are derived from the living cells and tissues of humans or animals. Products range from organs for transplantation through to innovative and substantially-manipulated cellular therapies. While boundaries are not clean, these products fall into the four general groups:
  - 33.1. **Minimally-manipulated tissue for immediate transplantation** such as kidney, heart, and skin transplants
  - 33.2. **Minimally-manipulated tissue that is stored** such as bone and corneas that are banked for later transplantation
  - 33.3. **Tissue that is more than minimally-manipulated** such as mesenchymal stem cells to repair cartilage, and bone marrow derived cells modified to perform neural repair.
  - 33.4. **Blood and blood products such as** whole blood, plasma, and Factor VIII.
34. Like other therapeutic products, cell and tissue therapeutic products make important contributions to patient care. Minimally manipulated tissue for immediate transplant (kidneys and hearts) and blood transplants are well established internationally. Cell therapeutic products are expanding treatment options for cancer patients, transplant patients with unresolved infections, orthopaedic patients and others.
35. There is also considerable innovation in these products – particularly in those products that are more than minimally manipulated. For example, the US Food and Drug Administration has recently approved corneas and testicles that have been grown in the laboratory for transplantation, current xenotransplantation trials show promise in respect of the treatment of Parkinson's disease and research is underway into stem-cell based therapies to treat age-related macular degeneration, a leading cause of blindness in the elderly.

### Status Quo and problem definition

36. Currently, New Zealand does not specifically regulate cell and tissue therapeutic products. Some, innovative cellular products at the clinical trial stage and various blood products, are currently regulated as medicines. The rest are unregulated.
37. The cell and tissue therapeutic product sector is a mix of non-profit entities (universities and health services) and commercial companies. Although volumes are generally low, a wide range of cell and tissue products are on the market.
38. Lack of comprehensive regulation creates a number of problems.
  - It creates a risk of adverse patient outcomes from the use of unregulated products that are contaminated or have a high rate of product failure.

- It can create a barrier to innovation as organisations either defer developing new products and processes due to concern about compliance with future regulation (many have long lead-in times)
  - There is a lack of clarity for the sector as to what standards are appropriate. Organisations currently look to a range of international standards for guidance and are unclear which they should follow and consequently may be over or under scrutinising their performance, and are investing considerable energy in separately working through complex regulatory issues.
  - It is a barrier to service delivery due to the Human Tissue Act 2008 requirement for an exemption from the Minister of Health to trade in human tissue. An application for a Ministerial exemption would require some form of assessment of the product to verify it met agreed standards for safety and quality. The lack of comprehensive regulation means that for many products the regulator has neither agreed standards nor capability to assess. In recent years this has impacted on the supply of imported bone, tendons, skin grafts, demineralised bone matrix, and musculoskeletal tissue.
  - Some cell and tissue products are used for cosmetic purposes and it may be appropriate for these to be regulated as therapeutic products (eg, injectable dermal fillers).
39. Internationally the norm is now to regulate these products and in November 2015 Cabinet agreed that New Zealand would do likewise under the therapeutic products regulatory regime. Regulation will provide benefits in terms of:
- patient safety and access
  - regulation that is tailored to these products and that is risk-appropriate
  - supporting sector innovation and investment
  - facilitating import and export of these products
  - providing better information about activity in this sector.

### **Options and impact analysis**

40. The regulatory regime is being designed to put risk-proportionate controls in place across the lifespan of products. For cell and tissue therapeutic products it is generally true that the less manipulation a product has been subject to and the closer it is to being used to perform the same function in the recipient as in the donor (homologous use), the lower risk it is. For example banked bone or corneas for transplant are lower risk than highly manipulated stem cells for cartilage repair.
41. Cell and tissue therapeutic products also have many characteristics in common that guide the types of regulatory controls that are needed. Commonalities stem from the biological origin of the material. This means that regulatory controls must, for example, take into account that:
- products should be screened for infectious diseases
  - there will be an inherent diversity in products made from cells and tissues (the uniformity that is expected of pharmaceutical manufacture is not possible)
  - in order to be efficacious, products cannot be terminally sterilised.

42. A key difference however is how the products are needed and used in clinical practice. There are long-waiting lists for minimally-manipulated tissue for immediate transplantation especially donated organs from deceased persons. This is particularly so for kidneys where 442 people are on the active waiting list for a transplant and there were 53 deceased donors in 2015.
43. In this context, the reality is that there is wide variation in what is considered to be an acceptable quality safety profile for these tissues. For example, organs with suboptimal physiological function or the potential for infectious disease transmission may still be used as this is in the recipient's best interests given their critical health status. These are difficult clinical decisions taken with recipients fully informed of the issues. Decisions about the use of these tissues also need to be taken within hours and these time constraints impact on, for example, the amount of testing for infectious disease transmission risk that can be done (some tests take several days to yield reliable results for example, tests for malaria and Chagas disease).
44. The new regulatory regime will apply the international norm of pre-market product approval and activities licensing, and post-market monitoring; with requirements at each of these points commensurate with the risk a product presents. The key issue with respect to cell and tissue therapeutic products is the extent to which pre-market controls should apply to all of these products. The options are:
  - 44.1. Apply all pre-market controls to all cell and tissue therapeutic products
  - 44.2. Tier the application of pre-market controls for cell and tissue therapeutic products
45. These options and their impacts are described below and summarised in the table.

*Apply all pre-market controls to all cell and tissue therapeutic products*

46. Under this option all cell and tissue therapeutic products would require an approval before they could be used and related activities (such as manufacture, storage & distribution) would require a licence. The requirements for pre-market approval would vary depending on the assessed level of risk.
47. Given the potential risks of these products and the benefits that regulation can bring there is a prima facie case for pre-market controls applying to all cell and tissue therapeutic products. That said, the reality of the clinical need for minimally-manipulated tissue, the nature of these products, and the clinical practice settings in which they are used mean that these requirements may not assist with managing risks or result in benefits.
48. As noted, **minimally-manipulated tissue for immediate transplantation** has a potentially wide variation in what is considered to be acceptable quality of physiological functioning and in the potential for disease transmission. Suboptimal organs may be used because transplant recipients are critically ill and because it simply isn't possible to do comprehensive testing in the time available. From a regulatory perspective this variation in quality and process makes setting minimum standards for safety, quality, and efficacy very challenging. It is also difficult to see how an approval could realistically be issued for these time-critical and highly individual products. The Ministry considers that minimally-manipulated tissue for immediate transplantation should not be subject to pre-market approval requirements.
49. Cabinet has agreed that the regulatory regime will contain mechanisms for unapproved products to be available in individual clinical circumstances. This will be done by an ex-ante permission being granted by the regulator on an individual

product basis. The Ministry has considered whether minimally-manipulated tissue for immediate transplantation should be subject to minimal regulatory oversight through this mechanism. It concludes that, while it would be possible to apply for a permission on a product-by-product basis for minimally-manipulated tissue for immediate transplantation this is likely to create a significant administrative burden for organisations and unacceptable time delays for transplant recipients. In addition, as noted above, it would be very difficult for the regulator to judge, even to the light-touch standard needed for a permission to be granted, the safety, quality or efficacy of these products. The Ministry considers that minimally-manipulated tissue for immediate transplantation should not be subject to the requirement that the use of unapproved therapeutic products is subject to a permission being granted by the regulator.

50. The other limb of pre-market controls is activities licensing. Cabinet has agreed that the new regulatory regime will continue the standard international approach of licensing activities related to the production and distribution of therapeutic products (eg, manufacture, wholesaling, distribution etc.). Licensing aims to control product quality and the integrity of the supply chain. In respect of minimally-manipulated tissue for immediate transplantation the relevant activities would be the processes within the clinical setting for donor testing, organ testing, recipient testing, labelling, and transport.
51. The Ministry has considered whether standards for these processes should be made mandatory for minimally-manipulated tissue for immediate transplantation through requiring an activity licence. As is the case for approvals, the Ministry's view is that these activities are more effectively overseen as a matter of clinical practice than from the perspective of a therapeutic products regulatory regime.
52. For **minimally-manipulated tissue that is stored** the considerations are similar but not identical:
  - 52.1. Approval or permission – as is the case for minimally-manipulated tissue for immediate transplantation, minimally-manipulated tissue that is stored is highly individual and the need for it, while not as acute, is also highly individual. Setting minimum standards for individual products is unlikely to be easily done and is unlikely to add safety benefits
  - 52.2. Activities licensing - minimally-manipulated tissue that is stored is different from minimally-manipulated tissue for immediate transplantation in terms of the timeframe within which it is used: by definition it is transported and stored. These activities can have a material impact on the quality and safety of the tissues and the Ministry considers that it is both appropriate and possible for these activities to require a licence.
53. For **tissue that is more than minimally-manipulated and blood and blood products** both approvals and activities licences are appropriate to manage risks. The majority of these products are currently subject to some of these controls as they are considered to be medicines under the current regulatory regime.
54. For these products, pre-market approvals and licences would apply. This would include meeting Good Manufacturing Practice (GMP) and regular audits. Regulatory requirements would be calibrated to the risk a product poses and both the regulator and the person marketing the product would have post-market monitoring responsibilities.

*(Preferred) Tiered application of pre-market controls for cell and tissue therapeutic products*

55. Under this option the different types of cell and tissue therapeutic products would be subject to different pre-market requirements:
- 55.1. **Minimally-manipulated tissue for immediate transplantation** – no pre-market controls under the regulatory regime. Decisions over the safety, quality and efficacy of a product and the clinical needs of a recipient would remain within the clinical setting and subject to controls such as those outlined in the Health and Disability Commissioner’s Code of Rights and clinical practice standards (which include matters such as keeping accurate records).
- 55.2. **Minimally-manipulated tissue that is stored** no pre-market requirement for product approval (or permission to use an unapproved product). Activity licences would be required for matters such as processing, storing, and transporting tissue.
- 55.3. **Tissue that is more than minimally-manipulated and blood and blood products** – pre-market approvals and activities licensing to apply.
56. This option is designed to maximise the benefit that a regulatory regime for therapeutic products can add to the safety, quality and efficacy of products in use and to sector innovation. And to recognise that a subset of these products are high individual and used within closely controlled clinical settings.

**Table 1. How should cell and tissue therapies be regulated?**

Question	Option 1 (Status quo)	Option 2 (All pre-market approval for all)	Option 3 (Mixed model) [Preferred]
<b>How should cell and tissue therapies be regulated?</b>	Most moderate to highly manipulated products regulated as medicines (ie, clinical trials of cellular therapies and blood). No regulation of minimally manipulated products.	Require pre-market approval of all cell and tissue therapeutic products	Mix of: pre-market approval for more than minimally manipulated products; a requirement for a licence to handle minimally manipulated products that are stored; and no pre-market requirement for services handling minimally manipulated products for immediate transplant (preferred option)
<b>Strategic objectives</b>			
<b>Safety</b>	Benefit only to consumers of moderate to highly manipulated products	Provides clarity of safe pathways	Provides clarity, but use of products without pre-market approval will carry increased risks (which must be balanced against the benefit of access)
<b>Access</b>	Provides no means of approval for access to minimally manipulated therapeutic products	Provides pathway for access to most products, but would limit access to those that may be sub-optimal.	Provides a pathway for all variations of cell and tissue product for a variety of uses.
<b>Flexible</b>	Can be a barrier to innovation as no clear regulatory pathway. Organisations likely to use a mix of international and self-generated quality measures with no external review. Products may not meet int’l markets requirements.	Does not recognise the variation in safety and functioning of donated tissue. Would very likely mean a reduction in tissues and organs available for transplant.	Can be adapted depending on the situation.
<b>Impacts</b>	Currently organisations working with minimally manipulated products voluntarily adhere to international best practice and are not subject to independent audit for these products. These organisations would require a longer transition timeframe to regulation under the regime. Preferred option recognises the range of products within the cell and tissue framework and that minimally manipulated tissue is not a ‘conventional’ therapeutic product.		

*Post-market controls*

57. The different types of cell and tissue therapeutic products would be subject to different post-market controls:

- 57.1. **Minimally-manipulated tissue for immediate transplantation** – potentially reporting requirements and responsibility on the regulator for data analysis and information provision.
- 57.2. **Minimally-manipulated tissue that is stored** – requirement for audit against minimum standard(s) for processing, storing and transporting tissue.
- 57.3. **Tissue that is more than minimally-manipulated and blood and blood products** – regular GMP audits.

#### *Future-proofing*

- 58. The Ministry has considered whether the differences between minimally-manipulated tissues for immediate transplant and other cell and tissue therapies are such that they should be excluded from the scope of the regulatory regime entirely. On balance it concludes that this is not desirable for the following reasons:
  - 58.1. There is considerable innovation in the cell and tissue area generally (see para 34).
  - 58.2. Boundaries can be difficult to draw, for example while the term 'minimally manipulated tissue' is widely used, there is not an internationally agreed definition of minimally manipulated. Inclusion within the regime removes the need to develop a definition that sets a boundary between tissues for immediate use and those that are stored. In addition, inclusion within the regime allows more timely response to innovation where regulatory oversight may be beneficial.
  - 58.3. Safety issues may emerge in response to new infectious diseases or changing processes/products. The sector itself is looking to improve standards and the regulator could be a useful mechanism to embed quality improvement initiatives.

#### *Mechanisms and processes*

- 59. The transplantation sector is relatively comfortable with the inclusion of minimally-manipulated tissue for immediate transplantation within the scope of the regime, provided that there are process requirements governing how any decisions to put regulatory requirements in place are made. The need for clear process requirements is necessary for the whole of the cell and tissue sector, particularly the small non-profit organisations.

#### *Xenotransplantation*

- 60. Xenotransplantation is the practice of using live animal cells in human therapy. Specific provisions regulating xenotransplantation clinical trials are contained in the Medicines Act and ensure a high level of scrutiny of trials and ministerial approval of applications. New Zealand is at the forefront of this innovative technology with approvals issued for three pig cell therapy clinical trials for type 1 diabetes and Parkinson's Disease.
- 61. Although not yet an issue, as xenotransplantation products have not yet developed beyond clinical trials in New Zealand, there is a gap in the Medicines Act in respect of xenotransplantation products that may emerge from trials to be marketed. It is proposed that xenotransplantation be included in the therapeutic products regulatory scheme to ensure complete coverage of these products. The impact of inclusion on the sector is expected to be minimal. The one organisation active in this space is



currently meeting clinical trial regulatory requirements as a medicine and obtaining ministerial approval for its activities.

## **Consultation**

62. The Ministry has held an initial workshop and discussions with key stakeholders in the research and transplant communities, including the New Zealand Blood Service, Organ Donation New Zealand and the Malaghan Institute of Medical Research.
63. Stakeholders recognise the gaps in current regulation, seek regulation specifically designed for their products, want the regulator to have a 'consultative' approach, to align with international regulatory requirements and to develop capacity and capability, particularly in areas of cellular therapies and xenotransplantation where New Zealand is at the forefront of innovation.
64. Stakeholders are relatively comfortable with the proposal that minimally-manipulated tissue for immediate transplant is included in the regulatory scheme with the proviso that there are controls over how any decisions to apply regulatory controls in the future would be made.
65. Stakeholders note that for minimally-manipulated tissue that is stored, inclusion within the therapeutic products regulatory regime is likely to generate compliance costs that they may struggle to meet. The organisations working with these products (such as the New Zealand National Eye Bank and New Zealand Blood Service's bone and tissue bank) are small, not-for-profit, or both. Similar issues were faced in Australia when regulation of tissue banks was introduced there in 2011 and time-limited government funding was provided to smooth the transition for this sector. Further advice will be prepared on options for mitigating potential negative impacts on the sector and the availability of products for patient care.
66. Engagement with stakeholders will be ongoing as the exposure draft and regulatory regime are developed.

## **Recommendations and conclusions**

67. It is recommended that:
  - 67.1. All cell and tissue therapeutic products should be captured by the regulatory regime
  - 67.2. A tiered approach should be taken to pre-market requirements
  - 67.3. Post-market controls calibrated to the risk of a product may be appropriate for all products
  - 67.4. The regime contain mechanisms that ensure that there are process requirements governing how decisions to put regulatory requirements are place are made.
  - 67.5. Sector engagement continue as the details of the regime are designed in 2016.
  - 67.6. Further advice be developed, as requirements are clearer, on the financial impact of regulation and how adverse impacts can be mitigated.

### 3. Prescribing and dispensing

#### What are we regulating and why?

68. Therapeutic products carry benefits and risks that require specialist expertise to assess the most effective and safe use for a patient. Only certain health practitioners are permitted to prescribe and dispense therapeutic products because they have the qualifications, training and competence to do so.

#### Status Quo

69. The current Medicines Act 1981 and Medicines Regulations establish three categories of prescriber.

**Table 2: A brief overview of prescriber categories**

Category of prescriber	Health practitioners	Description
<b>Authorised</b>	Named in primary legislation, includes medical practitioners, dentists, nurse practitioners, midwives, optometrists	<ul style="list-style-type: none"> <li>• Prescribe independently</li> <li>• Prescribe medicines within scope of practice</li> </ul>
<b>Designated</b>	Established by regulations, includes Diabetes nurse prescribers, pharmacist prescribers, dietitians	<ul style="list-style-type: none"> <li>• Prescribe independently</li> <li>• Prescribe medicines within scope of practice from a gazetted list of permissible medicines</li> </ul>
<b>Delegated</b>	Future groups as approved by Minister of Health. Currently there are none.	<ul style="list-style-type: none"> <li>• Prescribe under the authorisation of an authorised prescriber who is not a designated prescriber</li> <li>• Prescribe in accordance with a delegated prescribing order (which must specify the medicines, the circumstances in which, and the people to whom, they may prescribe)</li> </ul>

70. The act of dispensing is broadly defined in the Act. Regulations establish who may dispense prescription medicines.
71. Health practitioners are regulated under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act). The principal purpose of the HPCA Act is to protect the health and safety of the public. The HPCA Act contains the necessary provisions concerning the roles and functions of Responsible Authorities, scopes of practice, qualifications, competence and fitness for registration or regulated health professionals to ensure that practitioners are competent and fit to practise their professions for the duration of their professional lives.
72. The Minister of Health retains some important powers under the HPCA Act – to designate health professions for regulation, to establish new Responsible Authorities, to audit Responsible Authorities, to appoint or remove authority members, to determine mechanisms to facilitate resolution of disputes over scopes of practice and to gazette restricted activities that can be performed only by regulated health practitioners.

#### Problem definition

##### *Regulation of prescribing*

73. The main issues raised to date with the current regulatory arrangements for authorised and designated prescribers (issue 1) are:

- Authorised prescribers are named by practitioner grouping in the primary statute. This has caused significant delays to improved service delivery because of the need to amend the primary statute when there are advances in the use of the workforce.
- A list of medicines may not be an effective regulatory tool for defining a scope of practice as it relates to prescribing for some practitioners. For example, the list of medicines for pharmacist prescribers is over 1500 in number. Additionally, it is well recognised that by the time a list of permissible medicines has been approved and published by Gazette notice it is often out of date.
- Designated prescribers are defined as authorised prescribers in the primary statute, but work within particular scope of practice conditions regarding their prescribing. In principle, all prescribers work within particular scope-of-practice conditions. Translating this approach into a refreshed regulatory arrangement affords no clarity.

### *Standing Orders*

74. A Standing Order is a written instruction issued by a medical practitioner, dentist, registered midwife, nurse practitioner, optometrist, or veterinarian. It authorises a specified person or class of people (such as paramedics) who do not have prescribing rights to administer and/or supply specified medicines (including some controlled drugs). The intent is that Standing Orders are used to improve patients' timely access to medicines; for example, by authorising a paramedic to administer certain medicines in an emergency.
75. A Standing Order does not allow a person to generate a prescription and provide it to a patient to take to a pharmacy to be dispensed. Medicines and controlled drugs must be administered and/or supplied on-site.
76. No changes are proposed. The preference is for the detail of Standing Orders to be maintained in a subordinate instrument and the parameters and obligations of use (notably the audit and accountability requirements) be applied in a standardised manner throughout the health sector. Issues with the use of Standing Orders will be considered in the consultation and development of the regulatory detail of Standing Orders.

### *Dispensing*

77. Dispensing entails the preparation of a therapeutic product (typically a medicine) for sale to the public and is subject to a framework of accountability measures to protect the community, ie, the packaging, labelling, recording, and delivery of that medicine.
78. Dispensing also encompasses a number of other functions, including checking the authenticity of the prescription and prescriber, the appropriateness of the medicine for an individual patient as well as the assembly of the product. In common usage dispensing usually refers to the activity of pharmacists and dispensing doctors.
79. Under the current arrangements regulations establish who may dispense a prescription medicine (an authorised prescriber, veterinarian, or pharmacist), as well as who may dispense prescription medicines under the direct personal supervision of a pharmacist (pharmacy graduates, pharmacy technicians, dispensary technicians and students).
80. No changes are proposed to the status quo mechanisms for dispensing and this will be directly translated into the new regulatory regime with any necessary updates.

## Options and impact analysis

### Issue 1: Regulation of prescribing

81. It is proposed that the following principles should govern who is authorised to prescribe prescription therapeutic products:
- 81.1. a practitioner who is authorised to prescribe must be a registered health practitioner under the meaning of the HPCA Act, and
  - 81.2. a practitioner must only prescribe therapeutic products within their scope of practice and competence (under Section 11 of the HPCA Act scopes of practice must be gazetted by Responsible Authorities), and
  - 81.3. Responsible Authorities have the statutory accountability for establishing scopes of practice, the qualifications necessary for registration within that scope, and for the ongoing competence and activities of their registered health practitioners.

**Table 3: How should prescribing be regulated?**

Question	Option 1 (Status quo)	Option 2	Option 3 [Preferred]	Option 4
<b>How should prescribing be regulated?</b>	<p>Authorised (including designated) prescribers may only prescribe prescription therapeutic product, in accordance with conditions (if any) stated in their scope of practice.</p> <p>Authorised prescribers (who are not designated prescribers) are named by practitioner grouping in the <b>primary statute</b>.</p> <p>Designated prescribers are established by regulations and may only prescribe prescription therapeutic products from a <b>gazetted</b> list of permissible therapeutic products.</p>	<p>Authorised prescribers are not named by practitioner title in primary statute and prescriptive detail is used in subordinate legislative instruments.</p>	<p>Detail identifying the authority to prescribe will be included in relevant scopes of practice detail as gazetted by Responsible Authorities under the HPCA Act.</p> <p>Note that the existing parameters for the current prescribing groups can be directly translated into this regulatory option. The process for establishing a need for new groups of prescribers will remain unchanged.</p> <p>The current requirement for some prescribing groups to prescribe within particular conditions (such as prescribing under supervision or as part of a team environment and from a list of permissible medicines) will be included in scope-of-practice detail to authorise prescribing.</p> <p>There will be a single category of authorised prescriber (unless a practitioner is prescribing on a delegated basis under the parameters of a delegated prescribing order).</p>	<p>Section 9 of the HPCA Act allows for specified activities to be restricted to competent and registered health practitioners, in order to protect members of the public from the risk of serious or permanent harm. Prescribing to be listed as a restricted activity.</p>
<b>Strategic objectives</b>				
<b>Safety</b>	<p>Provides a level of clarity in terms of prescribing authority including any conditions on such prescribing.</p>	<p>Provides a level of clarity in terms of prescribing authority including any conditions on such prescribing.</p>	<p>Ensures regulatory role clarity between the therapeutic products regulator and Responsible Authorities. This option recognises the jurisdiction of Responsible Authorities for the practise of their regulated professions.</p> <p>Guidance will be provided to ensure a level of stringency in how the prescribing parameters of the scopes of practice are drafted.</p>	<p>Ensures regulatory role clarity between the therapeutic products regulator and Responsible Authorities.</p>

<b>Efficient</b>	<p>In principle all prescribers must work within their scopes of practice. Therefore, translating a distinction between the authorised and designated prescribers into a refreshed regulatory arrangement is unwarranted.</p> <p>A list of permissible medicines is not an effective regulatory tool for defining scope of practice.</p>	<p>Use of detail in subordinate instruments enables updates to occur in a timely way.</p> <p>This option requires duplicating the relevant scope of practice, qualifications and ongoing competence requirements (as relates to regulating prescribing) from the HPCA Act.</p> <p>Permits a greater degree of flexibility by placing prescriptive details in subordinate instruments.</p>	<p>The prescribing authority and any conditions/parameters on prescribing can be updated readily.</p> <p>Avoids the need to duplicate the relevant scope of practice, qualifications and ongoing competence requirements (as relates to regulating prescribing) from the HPCA Act.</p>	<p>This option offers no particular benefit over the preferred option. The HPCA Act already prohibits practitioners from acting outside their scope of practice.</p>
<b>Capacity</b>	<p>Increased resource demands placed on officials to make changes.</p>	<p>Increased resource demands placed on officials to make changes.</p>	<p>Better use of the capacity of Responsible Authorities.</p> <p>There would be modest compliance costs to Responsible Authorities to amend scopes of practice for prescribing. Guidance would be provided.</p>	<p>Better use of the capacity of Responsible Authorities.</p>
<b>Impacts</b>	<p>Two amendments would be needed to the HPCA Act to support the preferred option:</p> <ul style="list-style-type: none"> <li>i) A provision will be introduced for the Minister to approve the prescribing parameters for inclusion in a scope of practice.</li> <li>ii) An exception will be added to Section 11(2) as pertains to prescribing parameters.</li> </ul> <p>The list of permissible medicines for relevant prescribing groups will still be approved by the Director-General of Health (or delegate) and will be made publicly available by the relevant Responsible Authority. Reference to the list of permissible medicines will be included in the relevant scope of practice detail.</p> <p>In principle all prescribers must prescribe within their scope of practice. Therefore, translating a distinction between authorised and designated prescribers into a new regulatory arrangement appears to offer no additional clarity as to prescribing rights and parameters. There will be a single category of authorised prescribing, unless the practitioner is prescribing on a delegated basis under the parameters of a delegated prescribing order.</p>			

### *Issue 2: Delegated prescribing*

82. The delegated prescriber was introduced as a new prescribing category under the Medicines Amendment Act. This category enables registered health professionals to prescribe within limited parameters to be set out in a written instruction (a delegated prescribing order) under the sanction of an authorised prescriber. The delegated prescribing order would set specific conditions and restrictions on prescribing (such as only certain medicines for certain patients) for an individual delegated prescriber. The competence, training and qualifications required of delegated prescribers would be established in consultation with the relevant Responsible Authority.
83. This prescribing category was envisaged to allow more timely access to medicines for patients (especially important in community and rural settings and in meeting the growing demands of chronic disease), make better use of the skills of prescribers, and provide flexibility to allow for innovative models of care (under approved supervisory arrangements).
84. To date there has been no uptake of delegated prescribing, although some practitioner groups have indicated an interest in this type of prescribing. The following issues have been raised by the sector with regards to the current arrangements:
- delegated prescribing is perceived to hinder the legitimate progress of certain practitioner groups to prescribe on an independent basis
  - Standing Orders have been widely adapted over time and in many settings and therefore may have reduced the need for delegated prescribing

- establishing the training requirements for delegated prescribing and a lack of access to appropriate supervision to support delegated prescribing have acted as barriers to its uptake
- Responsible Authorities remain concerned about the issue of vicarious liability.

**Table 5: How should delegated prescribing be regulated (if at all)?**

Question	Option 1 Status Quo	Option 2 [Preferred]	Option 3
<b>How should delegated prescribing be regulated (if at all)?</b>	Primary legislation will enable a subordinate instrument to: <ul style="list-style-type: none"> <li>• establish the competence, training and qualifications required of delegated prescribers</li> <li>• set out the parameters and requirements of a written delegated prescribing order</li> <li>• enable the Director-General of Health to approve the prescription therapeutic products that may be prescribed under delegated prescribing orders.</li> </ul>	As for authorised prescribing, delegated prescribing requires the relevant Responsible Authority to establish the competence, training and qualifications required of delegated prescribers.  Details included in the relevant scopes of practice would establish both who could authorise a delegated prescribing order and who could prescribe on a delegated basis.  Primary legislation will enable a subordinate instrument to set out the parameters and requirements of a written delegated prescribing order.	Remove the ability to prescribe on a delegated basis.
<b>Strategic objectives</b>			
<b>Safety</b>	Ensures a standardised framework for delegated prescribing. The obligations of use and accountability requirements would be consistent and more broadly understood in the sector.	Ensures a standardised framework for delegated prescribing. The obligations of use and accountability requirements would be consistent and more broadly understood in the sector.	
<b>Efficient</b>	Ensures a standardised framework for delegated prescribing.	Ensures a standardised framework for delegated prescribing.	Would remove flexibility.
<b>Capacity</b>	Use of detail in a subordinate instrument will enable updates to be made in a timely way.	Use of detail in a subordinate instrument will enable updates to be made in a timely way.	Some of regulated health professions have clearly stated they wish to retain the option of delegated prescribing ability in a new regulatory arrangement to allow for innovative models of care in the future.
<b>Impacts</b>	Aligns with the preferred regulatory option discussed in the table above, whereby detail identifying who is authorised to prescribe is included in relevant scopes of practice detail as gazetted by Responsible Authorities under the HPCA Act. Note, a provision will be included in the HPCA Act for the Minister to approve the prescribing parameters for inclusion in a scope of practice.		

## Consultation

85. The Ministry of Health has consulted the following in relation to the changes proposed to prescribing and dispensing. These groups are:

- Responsible Authorities - Nursing Council, Medical Council, Pharmacy Council, Physiotherapy Board, Midwifery Council, Dental Council, Dietitians Board, Optometrists & Dispensing Opticians Board, Podiatrists Board, New Zealand Chiropractic Board, Occupational Therapy Board of New Zealand, Osteopathic Council of New Zealand, Medical Sciences Council of New Zealand, Veterinary Council.
- Representative bodies and providers - New Zealand Nursing Organisation, National Nursing Organisation, Nurse Executives of New Zealand, New Zealand Medical Association, GP New Zealand, Association of Salaried Medical

Specialists, Pharmaceutical Society of New Zealand, New Zealand Association of Optometrists, New Zealand Dental Association, Ambulance New Zealand, Directors of Nursing, Directors of Allied Health, Hospice New Zealand, Pharmacy Steering Group, Dietitians New Zealand, Family Planning New Zealand, Plunket, Bupa Care Services, Pharmacy Guild, New Zealand Society of Anaesthetists.

- Colleges - New Zealand College of Midwives, College of Nurses Aotearoa, Royal Australian and New Zealand College of Ophthalmologists, Council of Medical Colleges, Australian and New Zealand College of Anaesthetists, Royal Australian and New Zealand College of Psychiatrists, The Royal New Zealand College of General Practitioners, New Zealand College of Public Health Medicine.
  - Government - HQSC, HDC.
86. The majority of stakeholders and Responsible Authorities supported the option of using the scope of practice detail to identify those that are authorised to prescribe. The Medical Council has decided to await the draft Bill before providing a position.
87. Responsible Authorities noted some concerns about the need for stringency in how scopes of practice are drafted, a risk that some Responsible Authorities may seek to advance their own profession, and the need for greater transparency in the consultation process. These concerns will be addressed in how the changes are implemented, in particular, guidance will be provided to the sector to support the drafting of scopes of practice. The issue relating to Responsible Authorities advancing their own profession is mitigated by the Minister of Health approving prescribing parameters, as decisions will be taken in light of service need, the overall strategic direction of the sector and the best possible use of the workforce.

## Conclusions and recommendations

### *Issue 1: Regulation of prescribing*

88. The preferred option is to include the detail of who is authorised to prescribe prescription therapeutic products (including any conditions for certain prescriber groups, such as prescribing under supervision and from an approved list of permissible medicines) into the detail included in the scopes of practice published by Responsible Authorities under requirements in the HPCA Act.
89. Importantly, this option recognises the regulatory role and jurisdiction of Responsible Authorities over the professions.
90. The prescribing authority and any conditions/parameters on prescribing can be updated without waiting for primary legislation to be amended or new regulations drafted. Alongside this, the HPCA Act already contains substantial provisions to provide checks and balances for oversight of scopes of practice and the activity of regulated health practitioners.
91. Guidance will be provided to ensure a level of consistency and stringency in how the prescribing parameters for inclusion in a scope of practice are drafted (and any conditions on prescribing).
92. For registered health practitioners for whom prescribing is not a component of their scope of practice, no change is proposed and the process for establishing a new group of prescribers to meet a service need would not need to change.
93. It is expected that the lists of permissible medicines (for relevant prescribing groups) will still be approved by the Director-General of Health (and made publicly available

by the Responsible Authorities). The associated scope of practice will note this list where relevant. This approach affords some flexibility in the future, should permissible lists no longer be required.

*Issue 2: Delegated prescribing*

94. The consultation with Responsible Authorities and key representative groups revealed mixed views as to the purpose and value of delegated prescribing. The Nursing Council and Midwifery Council do not support the use of delegated prescribing for their practitioners, but recognise that other practitioner groups may find it an appropriate model of care. The majority of stakeholders supported retaining the option of delegated prescribing in a new regulatory regime.
95. The preferred option is to identify in the scope of practice detail (as relevant) those who can authorise delegated prescribing orders and those who can act under delegation (including the training and competence requirements). The detail of a delegated prescribing order is to be maintained in a subordinate instrument to ensure a standardised framework for delegated prescribing.



## 4. Pharmacy Licensing and Control

### What are we regulating and why?

96. Access to, and effective use of, therapeutic products is critical for the delivery of the Government's health objectives. To ensure the safe distribution and supply of therapeutic products, the supply chain is licensed with conditions set by the regulator.
97. This section specifically considers the supply of therapeutic products to consumers through licensing of pharmacies, but notes here that the regulator's ability to manage risks also extends to business to business distributions e.g. wholesalers.
98. With regard to access to therapeutic products, it is important to note that decisions to fund pharmacies and pharmacy services rest with District Health Boards. This division of licensing and funding roles is crucial to ensuring a safe and efficient public health system.

### Status Quo

99. New Zealand has more than 3500 practising pharmacists and over 980 community pharmacies. Around 75 percent of pharmacists work in community pharmacy, dispensing over 50 million prescriptions each year and providing advice on medicines and the management of minor ailments, from a network of distributed and highly accessible community pharmacies.
100. Pharmacy licences are issued by the Ministry of Health's Medicines Control Unit to applicants who meet the criteria for licensing approval which includes:
  - A pharmacy must be majority-owned and operated by a pharmacist with few exceptions (eg, a hospital pharmacy).
  - A pharmacist may own a majority stake in not more than five pharmacies (there is no limit on the number of minority stakes).
  - Prescribers are prohibited from holding an interest in a pharmacy (authorised prescribers, delegated prescribers).

### Problem definition

101. While the current regime functions without significantly compromising primary goals of patient safety and access, the repeal of the Medicines Act 1981 allows consideration of the most efficient way of achieving our objectives.
102. The most significant issues relate to:
  - 102.1. Limitations on the regulator's ability to:
    - determine the duration of licences (currently limited to 12 months), and
    - issue licences for pharmacies that are not fixed to physical premises, and to allow pharmacy practice to occur in other than licensed pharmacy premises

These limitations are an unnecessary regulatory burden for Regulators and licensees, and reduce the incentives to improve, innovate health services.
  - 102.2. Restrictions on who can be licence-owners:
    - adds unnecessary compliance costs for applicants and the regulator, and

- reduces competition.

These restrictions reduce investment in pharmacy, and restrict innovative ownership models (e.g. community trusts).

102.3. Restrictions on prescriber interests in pharmacy (with exceptions granted by the regulator) is an unintended barrier to the integration of health services (between medical practitioners, pharmacists and other health professionals) to develop better patient centred care.

## Options and Analysis

103. The options analysis address the problems identified:

- Licensing generally.** Creating a more enabling licensing environment where the regulator can set appropriate conditions to manage the risks associated with different distribution and supply models and licence durations for therapeutic products.
- Ownership restrictions.** Removing the pharmacy ownership restrictions, and replacing it with appropriate licensing conditions, or requirements, for example, that a pharmacist be engaged with the responsibility for ensuring the implementation of appropriate pharmacy standards.
- Integrated services.** Clarifying how prescribers and pharmacies provide better integrate services to consumers, without creating a situation where prescribers are seen to benefit financially from their prescribing decisions.

### Issue a: Licensing generally

104. An initial issue to consider is whether licensing is the most appropriate means of managing the risks associated with supply of therapeutic products to consumers, or whether other mechanisms may achieve the same goals.

**Table 7: Should pharmacies be licensed, or is another mechanism for the supply of therapeutic products to consumers appropriate?**

Pharmacy licensing				
Question	Option 1 (Most regulated)	Option 2 [Preferred]	Option 3	Option 4 (Least regulated)
Should pharmacies be licensed, or is another mechanism for the supply of therapeutic products to consumers appropriate?	Yes – We should have a licensing regime in the primary legislation with a regulator responsible for issuing licences. All terms for obtaining a licence should be in primary legislation.	Yes – We should have a licensing regime in the primary legislation with a regulator responsible for issuing licences. The regulator must consider specific terms for granting a licence but should have flexibility in doing so.	Partly - We should have a soft approach to approving pharmacies using notification systems whereby applicants provide evidence that they meet a minimum standard set within a code or guideline.	No – We should not have a licensing regime for pharmacies. As an alternative, pharmacists can sell and dispense medicines so long as they comply with dispensing and storage requirements for those medicines. Professional bodies may provide additional guidance on sale and dispensing.
Strategic objectives				
<b>Safety</b>	Allows for the setting of terms for storage, practice and service.	Allows for the setting of terms for storage, practice and service.	Reduced government oversight, increased risk for people.	Potentially riskier – less accountability to government.
<b>Access</b>	Ensures safe access, public confidence.	Ensures safe access, public confidence.	Increased ease of regime may increase access.	May lead to greater access options.
<b>Efficiency</b>	Higher regulatory compliance costs, inflexible.	More flexible, easier to change in future if required	May lead to reduced time and costs for pharmacies and regulator.	May lead to new market innovations and efficiencies.
Current regulation				

Status Quo (mix option 1 and 2)
The Medicines Act creates framework for licensing of pharmacies. The majority of the licensing requirements are set in the primary legislation for pharmacy licences (ss17, Part 3 Licences, S51, 52, 55A, 55B, 42, 55C, 55E, 55F, 42C) and regulations providing further requirements on applications (e.g. Regs s45, 45A, 46, Form 7 Schedule 2).

105. The regulator's role in licensing pharmacies is to manage the risks associated with the supply of therapeutic products to the public. It does this most effectively through the ability to require pharmacies to be licensed, set conditions on licences and require information. In addition, the regulator is required to make an assessment of the applicant as a fit-and-proper person or, if a corporate, of good repute to hold a licence. These arrangements have proven sound and should continue.
106. The preferred approach is to remove some general restrictions in the current Act which include, for example, tying licenses to fixed physical premises, and licences being provided for only 12 months. Further, the regulator should be able to clearly tie pharmacy standards to conditions in a licence, currently there are some challenges doing this.
107. The benefits of not necessarily tying licences to fixed physical premises include enabling applicants to develop new service models. The regulator will require evidence of capability and systems to manage risks related to new supply models. This will provide flexibility for pharmacy services to be provided at other than licensed fixed pharmacy premises, for example a rest home or the patient's home, or through a mobile service.

*Issue b: Ownership Restrictions*

108. Pharmacy licence ownership restrictions are an anomaly in New Zealand's licensing system. Licences do not normally seek to restrict business owners, but rather regulate the risk of an activity via conditions. Conditions on a licence rather than ownership restrictions better manages risks and avoids a restricted market.
109. We can better understand why the restricted ownership model exists by looking at the historical context and assessing its current merit. Ownership restrictions date back to 1954, when they were more restrictive still (pharmacies were required to be 75% owned by pharmacists, and no pharmacist was permitted to own more than one pharmacy). By 2004 the Medicines Act 1981 (the Act) update permitted a pharmacist to be the majority shareholder for up to five licensed pharmacies. (All pharmacies still have to be majority owned by pharmacists, ie, 51%).
110. The changes reflect a shift from the old business model, where the pharmacist owner was the day-to-day pharmacist in control of the pharmacies, to the new model where the pharmacist-owner could determine the extent of their engagement in the business. However, the Act requires the pharmacist majority shareholder in a company to have "effective control" over the pharmacies that the company owns. Effective control is not defined in the Act.
111. Today, a majority pharmacist licence-owner is not expected to be in their pharmacy day-to-day, and the Act does not require them to be, a fact reflected by allowing a majority pharmacist to be the owner of up to five pharmacies. Pharmacist licence-owners may have as little or as much involvement with to day-to-day operations as they like as long as they can demonstrate effective control of the pharmacy. Performance is measured against licence requirements, not ownership.
112. The value of pharmacist owners is arguably to ensure non-pharmacist business investors understand practical pharmacy issues, and pharmacists' professional obligations and standards of practice. However, this objective could be achieved

through the engagement of a pharmacist to ensure the implementation of appropriate pharmacy standards and to protect professional obligations.

113. Further, a licence condition such as the one proposed is unlikely to create any cost or change for existing pharmacy models as they currently all have a pharmacist-owner is capable of undertaking these roles or already undertakes them.
114. The table below briefly sets out the options against summarised assessment criteria. The main distinction between the central options (2 & 3) is whether the new pharmacist role is always a requirement, or is a consideration for the regulator in managing the risks.

**Table 8: What license restrictions or conditions are required?**

<b>Ownership</b>				
No changes to: <ul style="list-style-type: none"> <li>The regulator has the ability to make an assessment of the applicant as a fit-and-proper person or, if a corporate, of good repute to hold a licence.</li> <li>Licences require naming of a Responsible Person(s) for day-to-day oversight of the pharmacy.</li> <li>The condition of every licence to operate a pharmacy that the holder of the licence must not request or require any pharmacist who is employed or engaged in duties at a pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice.</li> </ul>				
	<b>Option 1 (Most regulated – Status Quo)</b>	<b>Option 2 [Preferred]</b>	<b>Option 3</b>	<b>Option 4 (Least regulated)</b>
<b>What license restrictions or conditions are required?</b>	The licensing regime requires majority pharmacist ownership and limits the number of pharmacies a majority pharmacist may have to five.	Ownership restrictions are removed.  A licence applicant is required to name and engage a pharmacist with responsibility for advising on the implementation of pharmacy standards, professional standards and licence conditions.	Ownership restrictions are removed.  A licence applicant <u>may be</u> required to name and engage a pharmacist with responsibility for advising on the implementation of pharmacy standards professional standards and licence conditions.	Ownership restrictions are removed.  No new role required.
<b>Strategic objectives</b>				
<b>Safety</b>	The majority pharmacist ownership licensing restrictions do not provide any additional safe guards for the public in the provision of services. Owners do not have any special safety obligations other than requirements placed on them by licence conditions and the owners' professional obligations as a pharmacist.	Ensures a means of managing risks through licence conditions, using a pharmacist that is knowledgeable and sufficiently capable to advise on the implementation of pharmacy standards, professional standards and licence conditions. This option provides a better line of sight for the regulator to pharmacy service issues and safety, as well as a single point across commonly owned pharmacies to ensure efficient provision of information and reporting on change.	Ensures a means of managing risks through licence conditions, using a pharmacist that is knowledgeable and sufficiently capable to advise on the implementation of pharmacy standards, professional standards and licence conditions. This provides a better line of sight for the regulator to pharmacy service issues, and safety, as well as single point across commonly owned pharmacies to ensure efficient point of contact for providing information and reporting on change.	There may be safety risks from owners not being adequately informed of pharmacy standards professional standards and licence conditions. Employed pharmacists may have to take on more responsibility and find it challenging relating back to non-pharmacists without the intermediary role propose in option 2. Lack of clarity around roles and responsibilities may translate to risks to the public.
<b>Access</b>	Access is determined by funding choices of DHBs	Access is determined by funding choices of DHBs  New investment and ownership models may create innovative ways of delivering pharmacy services that increase access and availability to the public.	Access is determined by funding choices of DHBs  New investment and ownership models may create innovative ways of delivering pharmacy services that increase access and availability to the public.	Access is determined by funding choices of DHBs  Depending on the capabilities and resources of industry the market could freely open new pharmacy delivery models, but perhaps at the risk of safety.

<b>Efficiency</b>	There are challenges for applicants to meet ownership restrictions and the regulator to monitor them, with no benefits for either parties or the public.	Reduces time and complexity for businesses and the regulator to comply with current ownership restriction rules.  Allows various ownership models to develop to suit different service delivery needs e.g. corporate, sole, or community trusts.  Facilitates development of new innovations from different business sectors.	May provide more flexibility – particularly where it may be deemed that the role is not necessary.  Reduces time and complexity for businesses and the regulator to comply with current ownership restriction rules.  Allows various ownership models to develop to suit different service delivery needs e.g. corporate, sole, or community trusts.  Facilitates development of new innovations from different business sectors.	Allows various ownership models to develop to suit different service delivery needs whether corporate, sole, or community trusts.  Facilitates development of new innovations from different business sectors.
<b>Impacts Comment</b>	The preferred approach provides a balance of flexibility and oversight and aligns with the objectives of the Act. Current pharmacy operations are expected to be minimally affected by the change.			
<b>Current regulation</b>				
	Status Quo			
The Medicines Act creates framework for licensing of pharmacies. The majority of the licensing requirements are set in the primary legislation for pharmacy licences (ss17, Part 3 Licences, 551, 52, 55A, 55B, 42, 55C, 55E, 55F, 42C) and regulations providing further requirements on applications (e.g. Regs 45, 45A, 46, Form 7 Schedule 2).				

*Issue c: Integrated services*

115. Prescribers (including pharmacist prescribers and all other authorised prescribers) are prohibited from having any financial interest in any pharmacies unless approved to do so by the regulator. The prohibition is designed to limit the ability of a prescriber to profit from their prescribing practice, and thus avoid a conflict of interest and losing the trust of patients.
116. Currently the definition of ‘interest in a pharmacy’ is particularly wide, and appears to be a barrier to developing better-integrated health services between prescribers and pharmacists. The preferred option below suggests a more focussed prohibition on prescribers profiting from prescribing actions via interests in pharmacies, while enabling better integration of health services.

**Table 9: How should the prescriber / pharmacy relationship be managed to enable integrated health services, and prohibit prescribers benefiting from prescribing behaviour?**

Integrated services / prescriber interests				
	Option 1 (Most regulated)	Option 2 [Preferred]	Option 3	Option 4
<b>How should the prescriber / pharmacy relationship be managed to enable integrated health services, and prohibit prescribers benefiting from prescribing behaviour?</b>	Prohibit prescribers taking any interest in pharmacies unless approved to do so by the regulator.	Prohibit profiting directly or indirectly through prescribing decisions via an interest in pharmacies. The regulator is not able to exempt anyone from this prohibition. However, the regulator may determine whether or not there is a direct or indirect financial benefit that may flow to the prescriber from prescribing decisions based on proposed arrangements integrating services with pharmacies.	No general or specific prohibition against prescriber interests in pharmacies, but disclosure required by applicants of prescriber interest. The regulator may impose conditions to manage risks, e.g. additional disclosure, monitoring and information requirements.	No prohibition – require prescribers to disclose interest to regulator, responsible authorities and patients, allow industry to develop guidelines.
Strategic objectives				
<b>Safety</b>	Provides public confidence that the prescriber is not financially benefiting when prescribing by directing patients to specific pharmacies in which they may have an interest.  Removes incentives on prescribers to over prescribe on the basis of supporting their commercial interest.	Provides public confidence that the prescriber is not financially benefiting when prescribing.  Avoids the potential temptation of prescribing for benefit through directing patients to specific pharmacies.  There may be some perceived conflict of interest from shared services integration.	Prescribers will not be above suspicion and there may be a perceived loss of trust in prescribers who can potentially benefit from prescribing activity.  However, conditions imposed by regulator should manage perceived risks and preserve consumer choice.  Professional and ethical duties already imposed.	Prescribers will not be above suspicion and there may be a loss of trust in prescribers who can potentially benefit from prescribing activity.  However, professional and ethical duties already imposed. Patients allowed to take prescriptions to the pharmacy of their choice.
<b>Access</b>	No change.	May facilitate closer integration and more convenient access in some circumstances.	May facilitate closer integration and more convenient access in some circumstances.	May facilitate closer integration and more convenient access in some circumstances.
<b>Efficiency</b>	May inhibit development of integrated health services.  May be a lack of clarity around what considerations are relevant for a prescriber to be granted an exception and approval to invest in a pharmacy.	Allows for integrated health services depending on Regulators ability to assess whether there may be a benefit flowing to the prescriber. Assessments may take more time for the regulator.  The development of guidelines over time may streamline the efficiency for how prescribers and pharmacies may work closely together.  Although the prohibition is in place it will be difficult to monitor and enforce in instances where prescribers use companies or trusts to mask their interest.	Facilitates integrated health services.  Reduces burden on regulator to monitor the prohibition.	Facilitates integrated health services.  Reduces burden on regulator to monitor the prohibition.
<b>Comments</b>	The recommended option maintains the prohibition to avoid prescribers benefiting from their prescribing actions, but does not preclude building other integrated connections with pharmacists. Note that there is currently a prohibition on a person who is licensed to operate a pharmacy from giving, offering or agreeing to give any authorised or delegated prescriber any money as a commission on prescriptions (s 76A). This or a similar requirement should remain.			
Current regulation				
	Status Quo			
The Medicines Act 1981, s42C <b>Restriction on authorised prescribers and delegated prescribers holding interest in pharmacies</b>				

## Consultation

117. The Ministry of Health has discussed the objectives and pharmacy licensing options with the Pharmacy Guild, the Pharmaceutical Society, the Pharmacy Council, Green Cross Health, Countdown Retail, Retail New Zealand, PHARMAC, New Zealand Medical Association as well as Government agencies, the Ministry for Business Innovation and Employment (MBIE), and the Treasury.
118. MBIE and the Treasury support proposals to remove ownership restrictions and enable the regulator to manage risks through the setting of appropriate licence conditions.
119. Pharmacy sector stakeholders were focused on ensuring that the quality of service provision remains high and that corporate motivations do not disrupt professional pharmacy practice. This feedback has been taken into account in the proposal of the requirement to appoint a Supervisory Pharmacist. Countdown Retail and Retail New Zealand were supportive of changes to the ownership restrictions which they felt added complexity to arrangements. Countdown Retail provided information on the mechanisms that they have put in place to ensure quality of service provision, including a pharmacy business manager to oversee pharmacy practice. All stakeholders agreed that it was important that a registered pharmacist was involved in oversight of any pharmacist business.
120. We have indicated that the Ministry will continue an open dialogue with stakeholders to ensure all concerns relating to the agreed objectives are addressed.

## **Conclusions and recommendations**

### *Issue a: Licensing generally*

121. A more flexible licensing environment will facilitate greater innovation and access objectives while still managing risks through the licensing framework, including conditions in licences.
122. The recommended approach is to enable the regulator to set appropriate conditions to manage the risks associated with different distribution and supply models for therapeutic products and different models of pharmacy practice. This includes, for example, not tying licences to fixed physical premises, providing a licence for up to 3 years where there is evidence that quality systems and standards warrant it, and setting minimum pharmacy standards to be met under a licence.

### *Issue b: Ownership Restrictions*

123. The current ownership restrictions do not further the safety objectives of the Bill. Safety objectives can be managed through the licensing framework, including conditions in a licence set by the regulator.
124. The recommended approach is to remove the pharmacy ownership restrictions, and replace it with an appropriate licensing condition, or requirement, to nominate a pharmacist with the responsibility for ensuring the implementation of appropriate pharmacy standards.

### *Issue c: Integrated services*

125. Balancing the financial incentives for prescribers while enabling a better integrated patient centred service is challenging.
126. The recommended approach is to prohibit prescribers receiving benefit from prescribing decisions through investment in pharmacies. The regulator will still be enabled to grant exceptions, and guidelines may be developed for integration of services that do not infringe the prohibition.



## 5. Import and export (including parallel importation)

### What are we regulating and why?

127. Therapeutic products are global commodities that are freely traded around the world. We want to ensure that the therapeutic products regime has export and import controls that appropriately balance the scale of the risks to patient safety and New Zealand's reputation with the need to support New Zealand's trade and economic objectives.

### Status Quo

#### *Medicines*

128. Exported medicines currently fall into the following categories:
- a. Medicines manufactured entirely in New Zealand following Good Manufacturing Practice (GMP).
    - If they were manufactured for the domestic market, they would require regulatory product approval from Medsafe.
    - If they are made for export, adjustments may be made to the substance, dosage and treatment indications and claims to meet third party jurisdiction preferences.
  - b. Medicines or active pharmaceutical ingredients (APIs) imported and altered in New Zealand (eg, recombined or relabelled) for export only.
    - There are no domestic controls beyond GMP.
  - c. Medicines imported in their final dose forms for the purpose of export only.
    - This may be part of legitimate trading operations (eg, many of our medicines transit Australia or are transacted through Australia but would not be saleable there).
    - Alternatively, the exporter could be using New Zealand's safety reputation in third party markets without any formal supporting evidence of compliance with New Zealand safety standards.
129. With the exception of medicines that are controlled drugs (see below), the import and export of medicines from New Zealand is currently subject to minimal specific regulation or process requirements.
130. For imports, existing controls are generally only apply to the manufacturing and supply chain within New Zealand, when something is done after import has happened to hold as stock, such as sale. This also applies to offences for enforcement purposes. For a prescription medicine, a reasonable excuse is required for possession on import (see section 43 of the Medicines Act).
131. The importer must, however, be able to produce details of the specifications for testing the quality of any medicine that they have imported for distribution in New Zealand and a certificate of the results of testing in respect of every batch of that medicine (see section 42 of the Medicines Act). They also have a duty to report "untoward effects" of the medicine both in New Zealand and in other jurisdictions (see section 41).

*Medical devices*

132. As there is only a very rudimentary regulatory regime for devices, there are no import or export regulatory requirements but there is a one-off notification requirement (see the Medicines (Database of Medical Devices) Regulations 2003). The regulations define a sponsor as a person who exports, imports or who arranges for exportation or importation of medical devices from or into New Zealand. It is a mandatory requirement for importers, exporters and local manufacturers to notify their medical devices to the Web Assisted Notification of Devices (WAND) database. The notification records the details of the device (even if it is intended only for export), but not every export consignment. Notification is free and there are no on-going fees.
133. Medical devices may be exported claiming or implying either New Zealand safety approval or third party certification, but with no New Zealand verification of this at the point of export.

*Controlled Drugs and Precursor Substances*

134. Consignments of controlled drugs, other than those prescribed and carried for personal use, require import and export licences. These licences are issued by Medicines Control pursuant to section 8 of the Misuse of Drugs Act 1975 and Regulations 3 and 7 of the Misuse of Drugs Regulations 1977. The Regulators of the country importing from or exporting to New Zealand are also required to issue reciprocal import or export licences. Every detail of the shipments is recorded.
135. Precursor substances that are not also controlled drugs are subject to a Pre-export Notification (PEN) scheme administered by the National Drug Intelligence Bureau in New Zealand.
136. 'Letters of No Objection' are issued by an importing country if a substance is not a controlled drug in that country but is a controlled drug in the exporting country.

*Export Certification*

137. The exporter of a therapeutic product may choose to seek a certificate from Medsafe that confirms that their product meets the requirements to be placed on the New Zealand market.
138. Medsafe issues export certification for medicines under the World Health Organization's (WHO) Certification scheme on the quality of pharmaceutical products moving in international commerce.
139. For medical devices, Medsafe issues export certification when this is requested by local manufacturers. Since 2010 this has been in the form of a regulatory Statement to Foreign Governments (RSFG).

*Parallel importing*

140. For therapeutic products, parallel importation would effectively mean the importation and marketing of products by a supplier that does not hold a regulatory approval for those products. Even if they appear to be the same as an approved product, the quality and safety of these products could not be assured and it would be impossible to hold the approval holder to account for them. Parallel importing of medicines is effectively prohibited now as a result of requiring regulatory approvals.
141. Section 32A of the Medicines Act does, however, provide a mechanism whereby the Crown can import and use any medicine, whether approved or not.

## **Problem definition**

142. The risks for New Zealand in having limited controls at the border are essentially:
- low-quality or counterfeit products entering our supply chain
  - being seen as not meeting our international commitments
  - reputational – for New Zealand manufactured products and more broadly for New Zealand Inc.
143. Medsafe is concerned that some companies/wholesalers may be acting as 'middlemen' in transacting (importing then exporting) unapproved and possibly low quality products. Sometimes the transactions occur in New Zealand, but no physical stock may actually come into the country, so it is very difficult to detect. These 'middlemen' would most likely be supplying them through New Zealand to nations with less financial ability to pay, for instance the Pacific Islands. These products might make their way into the New Zealand supply chain. There are many control points for the supply of publicly funded medicines, so these risks are most acute for the private market and the supply of other therapeutic products such as medical devices. There is no evidence of this to date, but Australia and other developed countries have had these problems and a large proportion of the products in Africa are counterfeit. Therapeutic products may also be imported and altered in New Zealand, sometimes simply being relabelled or repackaged, and then exported either claiming or implying New Zealand regulatory approval.
144. If New Zealand comes to be seen as a source or transit point for low-quality or counterfeit products, this may affect the reputation of New Zealand manufactured therapeutic products. Other jurisdictions and consumers may perceive a link between food, therapeutic products and New Zealand's image. The reputational risk may therefore have flow on implications for the wider New Zealand Inc. brand. There is already evidence that suppliers based overseas are trading off this brand by using '.co.nz' domain names when they have little or no connection with New Zealand.
145. In light of the emerging and potential risk scenarios, there is also a question as to whether New Zealand's current practice of minimal requirements for the import and export of medicines and devices adequately meets our responsibility under international arrangements. These arrangements seek to protect public health and safety, including preventing the manufacture and sale of substandard and counterfeit medicines. Some of these commitments relate to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1999). The Certification Scheme is not mandatory and the guidelines are just that, but New Zealand may not be seen to acting in the spirit of these commitments. New Zealand's approach to import and export controls is out of step with other developed jurisdictions.

## **Options and impact analysis**

### *Issue 1 – Import Controls*

146. Imported therapeutic products are generally intended for supply to the New Zealand market. If those products are counterfeit, adulterated or do not meet regulatory requirements, they could pose a direct safety risk to New Zealand consumers.
147. The current arrangements do not seem to adequately manage this risk as prosecutions can only be made once an actual sale has occurred or an intention to sell has been established. It also means that information about who is importing

therapeutic products, in what quantities and where that product is going is not collected and collated at the border.

148. The benefits need to be balanced against the costs, particularly to industry. The compliance costs should be limited, as the system can effectively be automated and only requires some additional data entry. There should be no justification for industry passing on substantial costs to consumers or the health system. It will be a significant change for the medical devices and cell and tissue industries, but may be welcomed by compliant and trusted suppliers as it will protect the integrity of the market.
149. We also want to retain the current ability for individuals to bring in small quantities of therapeutic products for personal use, so long as they have met regulatory requirements (currently that they have a prescription, when it is required).

**Table 10: What are the appropriate controls for imports?**

Question	Option 1 Status Quo (Low)	Option 2 Licencing (Medium) [Preferred]	Option 3 Licencing (High) – Full Inspection
<b>What are the appropriate controls for imports?</b>	Controls and offences effectively start at the point of supply.	Import is a licenced activity, but the process is effectively automated	Reciprocal import and export licences are required at both ends as well as full records of all shipments (similar to what happens for controlled drugs).
<b>Strategic objectives</b>			
<b>Safety</b>	Does not address the safety risks as products can freely enter the country.	Goes some way to addressing the safety risks. Information gathered could also help with traceability for recalls.	Would more fully address the safety risks. Even more detailed information would be available to the regulator.
<b>Efficient</b>	Does not affect efficiency as little is done.	As the process is mostly automated, it should be efficient.	Efficiency could be improved with IT (eg, data entry) but there would be significant transaction costs.
<b>Flexible</b>	There are almost no requirements.	The details of procedures would be in lower instruments and it should be easy to change them. It should only involve more data entry for suppliers.	Some of the details might have to be legislation as they are for controlled drugs.
<b>Capacity</b>	No regulator resources expended at the moment.	Will involve some resource for the regulator to issue licences.	Would require significant Customs and regulator resource.
<b>Economy</b>	Low quality/illegal products could be competing unfairly with domestic producers and compliant suppliers.	Should reduce some of this effect. Unlikely to be seen as a 'barrier' to the market.	The costs incurred might deter some importers from bringing products into New Zealand.
<b>Trust</b>	New Zealand may not be meeting international obligations in relation to the trade of counterfeit products.	This will go some way to meeting these obligations, which are not mandatory anyway.	Could be seen as being more than what is required.
<b>Access</b>	Consumers may have greater access to unsafe products.	Should not adversely affect access.	Access to consumers might be reduced if these controls were perceived as a barrier to market entry.
<b>Impacts Comment</b>	Given that the publicly-funded supply chain for medicines already has a number of control points, the risks to the majority of the supply chain are not that high. This seems like the appropriate level of control.		

*Issue 2 – Export Controls*

150. New Zealand's approach to export controls is out of step with other developed jurisdictions. The proposed requirement to notify all NHP exports is also more rigorous than the current requirements that apply to the export of medicines. Even export-only devices have to be notified. It is hard to argue that this anomaly in the status quo should be retained given the higher risk profiles of some medicines and their more stringent management requirements.
151. The options for export controls of medicines and devices are:
- *A notification-only system* – this could have requirements similar to the current notifications for devices, which include the details of the sponsor and manufacturer, a description of the product and its classification and intended purpose.
  - *A notification combined with certification* – this would add some indication of GMP or certification from the overseas regulator that the product meets the standards in the importing country.
  - *An export-only approval* – the exporter would be required to submit an application, including certifications that the product was safe for the purposes for which it was intended to be used, was stable over time and met the regulatory requirements in the destination country. This is done in Australia and was envisaged for ANZTPA.

**Table 11: What are the appropriate controls for exports?**

Question	Option 1 Status Quo - Notification (Low)	Option 2 Notification & evidence (Medium) [Preferred]	Option 3 Export-only approvals (High)
<b>What are the appropriate controls for exports?</b>	Only notifications are required (and not for medicines)	Notification accompanied by evidence that the product meets the requirements of the receiving country.	The regulator would issue a form of approval for all exported products.
<b>Strategic objectives</b>			
<b>Safety</b>	Does not address the safety risks at all, but would provide some information at the border.	Gives some assurance that the product meets some minimal standards.	Would more fully address the safety risks as an assessment would be made by the regulator.
<b>Efficient</b>	Notifications are currently made to the WAND database for devices.	Exporters should be able to lodge all material electronically.	Approvals could be done efficiently (eg, electronic lodgement), but there would be much more for all parties to do.
<b>Flexible</b>	In legislation now.	The detailed requirements could be done in lower level instruments and updated as necessary.	As it is an approval, this would need to be in legislation. Data requirements would need to be produced for applications.
<b>Capacity</b>	Regulator has to receive notifications.	The regulator only has to receive the additional evidence.	Would require significant regulator resources to make assessments and issue approvals. Exporters would need to provide the evidence to support applications. This burden could be reduced by tailoring the level of scrutiny to the importing country.
<b>Economy</b>	Does not address the reputational risks.	Goes some way to addressing the reputational risks.	Would fully address the reputational risk.

<b>Trust</b>	New Zealand may not be meeting international obligations in relation to the trade of counterfeit products.	This will go some way to meeting these obligations, which are not mandatory anyway.	May be more than what is required.
<b>Impacts Comment</b>	The safety risks are not to New Zealand consumers but the reputational risks are important for New Zealand Inc. This seems to strike the right balance.		

## Consultation

152. We have worked closely with NZ Customs on these proposals and consulted with the Ministry of Foreign Affairs and Trade and the Ministry for Business Innovation and Employment. There was general support, but concerns were raised about the evidence base for the proposals. MBIE particularly asked for more detail on the costs and benefits, some of which is provided in this document. The Ministry also intends to do further work in the lead up to the exposure draft being released to address these concerns and will test the approaches with industry. PHARMAC wanted to ensure that the Crown exemption for parallel importing was credible and this has been covered in the Cabinet paper. ACC asked for more detail on the personal use exception, which has also been added to the Cabinet paper.

## Conclusions and recommendations

### *Issue 1: Import controls*

153. It is proposed that importation become a licensed activity, which will make importing without a licence an offence. This will not prevent unscrupulous suppliers getting illegal product into the country, but it will mean that interventions can occur before those products get into the New Zealand supply chain. Collecting more information at the border will ensure that there is a more complete picture of the therapeutic products that come into the country and will also assist with the traceability of those products in the event of recalls. Import licences are required for products that pose comparable risks including prescribed foods, hazardous waste and products containing ozone depleting substances. This approach is consistent with what happens in other jurisdictions and it will help New Zealand to meet its WHO commitments in assisting to prevent the manufacture and sale of substandard and counterfeit medicines.

### *Issue 2: Export Controls*

154. It is proposed that the regime require notification of exports of therapeutic products accompanied by evidence that those products meet the regulatory requirements of the receiving country. Notification of exports is already a requirement for medical devices and natural health products, but not for medicines. Notification alone for all therapeutic products would improve information at the border, but would do little to mitigate the reputational risks associated with low-quality products. Adding a requirement that the exporter supply evidence that the product meets the standards of the importing country would provide some assurance that the exported product meets minimum standards. Requiring that all exported products be approved by the regulator would place too much of a burden on the export-only industry and on the regulator.

### *Other issues*

155. To facilitate trade and support the domestic therapeutic product market, the regulator should be able to issue certification of some kind for all therapeutic products that are exported. What it can attest to will depend on the circumstances. If an approval has been obtained, the regulator can confirm this. All products manufactured in New Zealand will have been produced in a licensed facility following GMP standards and

the regulator will be able to attest to this as well. Certificates of a similar nature can be issued under the natural health products legislation.

156. The parallel importation of all therapeutic products will be prohibited as a result of requiring approvals for all of these products. This is important, as the ability to parallel import with minimal regulatory control in Europe has resulted in counterfeit medicines in the legitimate supply chain on several notable occasions.
157. There is also currently a specific exemption for the Crown in the Medicines Act that allows it to parallel import medicines without the usual approval processes. This has never been used in practice, but it has been contemplated by PHARMAC on a number of occasions when available stocks of key medicines were running out. It has also provided useful leverage for PHARMAC when suppliers have threatened to withdraw vital products during commercial negotiations. It should be possible to retain the ability of the Crown to source alternative supplies of therapeutic products in emergencies without providing for a specific exemption for the Crown. For PHARMAC's purposes, it is important that this process is credible and has a high visibility in the new regime.

## 6. Detail of the proposed offence and penalty framework

### What are we regulating and why?

158. Cabinet was advised in November 2015 that the legislation would include flexible modern offences and penalties, commensurate with recent similar legislation. The proposed enforcement tools will allow the regulator a wide range of options, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances.

### Status Quo

159. The penalties attached to offences are out of step with modern legislation, with the maximum penalty for most offences being three months imprisonment or a \$500 fine. They are also too specific for primary legislation – it is an offence to “prepare a medicine for use in any room, or on any table or bench that is used for the purpose of packing, preparing, or consuming any food or drink”. Such detail should be in secondary instruments or conditions on licences, if needed at all. Also, there are no non-criminal sanctions in the Act except for a variable administrative penalty of up to \$40,000 that the medicines regulator may impose on a pharmacy licence holder who has breached a licence condition, and the regulator's ability to cancel a licence.

### Problem Definition

160. The compliance (offences, penalties, and powers of entry and search) in the Medicines Act do not support the aim of having flexible, responsive, and proportionate regulation. The provisions in the Act are confusing, and have been criticised by Parliamentary Counsel and the Courts.

### Options and impact analysis

161. The preferred option is to reconsider the offence and penalty structure as a whole, aligning it with similar recent legislation, providing for tiered offences and penalties allowing a proportionate response to varying seriousness of offending. The alternatives would be: to largely re-enact the current provisions, which is untenable in light of adverse judicial comment; to substantially re-enact them with larger penalties, which does not resolve the issues raised by Parliamentary Counsel or the Courts; or to have minimal offences related to licencing and rely on general powers to address risks to public health contained in other legislation, which does not address the specific risks posed by therapeutic products.
162. A tier of enforcement tools is proposed:
- 162.1. **Tiered criminal offences**, generally in 3 levels covering negligent or reckless conduct; conduct that poses a risk to human health, but is not negligent or reckless; and less serious non-compliance with regulatory requirements. There are intended to be separate categories of offence for misconduct by licence-holders (such as a failure to abide by the code of manufacturing practice), and for the unlicensed carrying out of a restricted activity (such as manufacturing medicines without a licence).
- 162.2. **Enforceable undertakings**, which allow the regulator to accept an undertaking from a license-holder, in lieu of more severe enforcement action. Such undertakings are then enforceable in the Courts and offer an interim step before suspension or cancellation of licenses, or even criminal charges.
- 162.3. **Infringement notices**, which will allow instant fines for low-level offending



24 MARCH 2016

### **Consultation**

163. The Ministry of Health will consult with the Ministry of Justice and the New Zealand Law Society during the development of the exposure draft.

### **Conclusions and recommendations**

164. A tiered approach to offences should be taken with further work done on the conduct that constitutes an offence and the associated penalty level.

## 7. Proposed institutional form of the Regulator

### What are we regulating and why?

165. The institutional form of the regulator and the stewardship functions that sit around it are critical to the success of the regulatory regime.
166. In order that the regime is effectively and sustainably delivered consistent with its agreed objectives and legislative principles the regulator will need:
- Independence - The Productivity Commission identifies the following four dimensions of independence:
    - *regulatory independence* (the degree to which the regulator can set and adjust regulatory requirements) has been agreed by Cabinet and the regulator will have the ability to set and adjust detailed regulatory requirements
    - *budgetary independence* (the degree to which the regulator is protected from political or sector pressure through funding arrangements). Cabinet has agreed that legislation will enable both cost recovery and Crown funding. Exactly how costs will fall is yet to be determined, however it is worth noting that the current regime is 80-90 percent cost-recovered. Cabinet has also agreed settings that aim to ensure there is no inappropriate pressure on the regulator through funding arrangements (eg, fees will be set by regulations, accountability arrangements promote transparency in respect of financial reporting, and legislation requires independent assessment of benefits and harms). Operational independence (discussed below) is a key factor in ensuring budgetary independence in practice
    - *operational independence* (the degree to which the regulator has operational independence or a broad discretion to exercise a range of powers). Cabinet has agreed that the regulator will exercise regulatory powers and associated administrative powers independently; and that it needs to be able to do so effectively. To fulfil this obligation it needs the operational independence to deploy resources as it sees fit to meet its obligations and responsibilities
    - *institutional independence* (the degree of distance in the regulator's relationship with Government and the rules governing the appointment and dismissal of governors or senior staff). This is the matter under consideration. In its detailed examination of the dimensions of independence the Productivity Commission observes that the choices about institutional form are important for what they signal about expected independence rather than for the legal constraints and freedoms associated with any particular form. For this reason the analysis below separates actual and perceived independence. It is also worth noting that a distinctive brand for the regulator would be consistent with international norms for respected regulators (as is the case for Medsafe currently).
  - Accountability – Cabinet has agreed a set of accountability arrangements for the regulator commensurate with its regulatory independence, desired operational independence, and likely high levels of third party revenue. The analysis below assesses the ability of the options for institutional form to give effect to these, namely, that:
    - except where already provided for by the Legislation Act, instruments made by the regulator will be disallowable instruments and subject to review by the Regulations Review Committee
    - in making legislative instruments, the regulator consult appropriately

- the regulator establish mechanisms for industry and consumer engagement
- the regulator be transparent about its processes
- there be financial and non-financial reporting
- the Minister of Health have the ability to direct the regulator on matters of government policy, but not in respect of a particular product or person.
- Capability and capacity – building and sustaining regulatory capacity will be an ongoing challenge for the regulator (recalling that addressing this challenge was one of the central reasons for joining forces with Australia under ANZTPA). All efforts need to be taken to position it as a desirable place to work and as a credible operator on the international stage. These factors will assist with addressing capacity constraints through attracting staff, engaging international expertise (eg, on committees) and enabling participation in international forums (eg, standards setting).
- A positive regulatory culture – identified by the Productivity Commission as a key factor in achieving effective regulation. The Commission identifies the importance of good foundational leadership.
- Organisational effectiveness and efficiency – this includes considerations such as the cost of establishment, cost effectiveness of ongoing operations, impact of size and connections within the Ministry, the health sector and the domestic and international regulatory communities. These connections are critical to effective regulation.
- Flexibility to incorporate other functions or for arrangements to be changed over time. It may be desirable for the regulator to administer other regulatory regimes, such as those for psychoactive substances and radiation. Over time the Government of the day may also wish to change institutional or other arrangements.

### **Status Quo and problem definition**

167. The Medicines Act is administered in the Ministry of Health by Medsafe and Medicines Control. These units are part of the Protection, Regulation and Assurance branch of the Ministry. Medsafe has 55 FTEs operating out of two offices (the bulk of staff are in Wellington and there is an office, focussed primarily on enforcement, in Auckland). Medicines Control has 14 FTEs. Until 2006 Medicines Control was part of Medsafe. It was separated in anticipation of the establishment of ANZTPA as its functions would not have been performed by the joint agency; and it has recently come back under Medsafe's management structure.
168. Medsafe also houses the Psychoactive Substances Regulator, has residual radiation safety responsibilities, and provides technical perspectives as part of the establishment of the natural health products regulatory scheme.
169. The new regulatory regime will differ from the status quo in a number of respects. Notably it will:
- be more comprehensive and have greater reach covering considerably more products (particularly medical devices) and will have a more comprehensive set of regulatory abilities
  - have greater regulatory independence and commensurately greater accountability as noted above
  - be larger (though still modest by international standards) and manage greater revenue. The Ministry's *working assumption* is that the regulator will have in the

region of 90-100 staff (the current FTE allocations for the administration of the Medicines Act, the Psychoactive Substances Act, and radiation safety, plus additional capacity for the administration of additional functions). The combined Medsafe and Medicines Control operating budget is currently \$12.2m of which \$10m is from third party revenue. These budgets are expected to increase in the new regulatory regime

By way of comparison, PHARMAC has approximately 100 FTEs, an operating budget of about \$24m and is a Crown Entity (Crown Agent).

170. While part of the Ministry, Medsafe was established as a separately branded business unit in the 1990s and it has a separate identity in the sector. However it does not have operational or budgetary independence, specific accountability arrangements, or well developed stewardship functions around it. These arrangements will not support the needs of the new regulatory regime or meet Government expectations of regulatory stewardship.

### **Options and impact analysis**

171. There are three options for the form of the regulator:

- Department (a unit of the Ministry of Health);
- Departmental Agency (an operationally autonomous agency headed by its own chief executive directly responsible to the appropriate Minister and hosted within the Ministry),
- Crown Entity (a separate entity accountable to the Minister. Of the Crown Entity forms, a Crown Agent is the most likely form for the regulator).

172. The following table contains an analysis of the options against the features identified above as necessary for the effective delivery of the regulatory regime.

	Department	Departmental Agency	Crown Entity
<b>Independence</b>			
Regulatory	<ul style="list-style-type: none"> <li>Cabinet has agreed that regulator can set and adjust many rules and this will be contained in legislation</li> </ul>	<ul style="list-style-type: none"> <li>Cabinet has agreed that regulator can set and adjust many rules and this will be contained in legislation</li> </ul>	<ul style="list-style-type: none"> <li>Cabinet has agreed that regulator can set and adjust many rules and this will be contained in legislation</li> </ul>
Budgetary	<ul style="list-style-type: none"> <li>Cabinet has agreed settings for budgetary independence</li> </ul>	<ul style="list-style-type: none"> <li>Cabinet has agreed settings for budgetary independence</li> </ul>	<ul style="list-style-type: none"> <li>Cabinet has agreed settings for budgetary independence</li> </ul>
Operational	<ul style="list-style-type: none"> <li>An internal agreement would be needed to provide for operational independence and care would be needed to ensure this capacity was not eroded over time</li> <li>Some feedback that health professionals are less willing to report adverse events to Medsafe because it is part of the Ministry due to concern that information about named health professionals would be shared with other parts of the MoH who may be obliged to investigate an individual practitioner's professional response.</li> <li>Risk that the Ministry's focus on regulatory business-as-usual diminishes over time</li> </ul>	<ul style="list-style-type: none"> <li>Operational independence is provided as a matter of form</li> </ul>	<ul style="list-style-type: none"> <li>Operational independence provided as a matter of form.</li> </ul>
<b>Signal of high levels of independence</b>	<ul style="list-style-type: none"> <li>Weakest signal – branding as a business unit would strengthen this signal as would a visible commitment to operational independence</li> </ul>	<ul style="list-style-type: none"> <li>Moderate-strong signal</li> <li>The model automatically brings a signal of independence as Departmental Agencies are operationally autonomous from the host department. These could be supported by provisions in statute eg conferring statutorily independent functions on the chief executive if appropriate.</li> </ul>	<ul style="list-style-type: none"> <li>Strongest signal – independence is clearly signalled as a matter of institutional form, however there is no platform for sending a very strong signal of real and perceived independence (for example, as existed with respect to the establishment of Worksafe)</li> </ul>
<b>Clear and robust accountability arrangements</b>	<ul style="list-style-type: none"> <li>Accountability arrangements for the regulator (separate to those for the Ministry, such as financial reporting) would need to be agreed and set out in regulations or agreed as a matter of practice (most likely approach)</li> </ul>	<ul style="list-style-type: none"> <li>Some accountability arrangements would come as a matter of form (eg. the requirement to produce an annual report). Others may need to be specified in regulations and/or in the departmental agency agreement</li> </ul>	<ul style="list-style-type: none"> <li>Accountability arrangements would be in statute as a matter of institutional form (are contained in the Crown Entities Act)</li> </ul>

<p><b>Capable and sustainable</b></p>	<ul style="list-style-type: none"> <li>Placing the regulator within the Ministry at lower than 2nd tier is likely to make it less attractive to staff and on the international stage as it may be perceived as not equal with peer regulators. This perception would need to be mitigated by strong branding and independence.</li> <li>Engagement domestically and internationally is likely to be easier as the regulator would be part of the Crown.</li> </ul>	<ul style="list-style-type: none"> <li>Likely to be more attractive to staff and on the international stage due to visibility of independence arrangements and the separate appointment of the chief executive</li> <li>Engagement domestically and internationally is likely to be easier as the regulator would be part of the Crown.</li> </ul>	<ul style="list-style-type: none"> <li>Potentially more attractive to staff and on the international stage due to visibility of independence arrangements although this is offset by being outside the legal Crown (other therapeutic product regulators tend to be operationally independent and close to central government)</li> </ul>
<p><b>Positive regulatory culture</b></p>	<ul style="list-style-type: none"> <li>Arrangements for operational independence would need to be visible in order to set the new regulator on a positive path under this model given its similarity in many respects to the status quo.</li> <li>Well implemented, the establishment of the new regulatory regime and the proposed approach to independence may provide a sufficient platform for a positive regulatory culture</li> </ul>	<ul style="list-style-type: none"> <li>A new entity form along with a new regulatory scheme provides a sound platform to establish a positive regulatory culture.</li> </ul>	<ul style="list-style-type: none"> <li>A new entity form along with a new regulatory scheme provides a sound platform to establish a positive regulatory culture</li> </ul>
<p><b>Organisational effectiveness and efficiency</b></p>			
<p>Cost</p>	<ul style="list-style-type: none"> <li>Establishment and ongoing costs would be lower than a Crown Entity and likely to be similar to a Dept Agency</li> </ul>	<ul style="list-style-type: none"> <li>Establishment and ongoing costs would be lower than a Crown Entity and likely to be similar to the Dept model</li> </ul>	<ul style="list-style-type: none"> <li>Highest cost to establish and run due to separation of back-room functions</li> <li>Unless established as a corporation sole there would be administration associated with a Board</li> <li>Board unlikely to add additional value to regulatory decision-making over that gained from using technical committees. And there is a risk of confusion between governance and regulatory responsibilities</li> </ul>
<p>Impact of size</p>	<ul style="list-style-type: none"> <li>Depending on location at 2<sup>nd</sup> or 3<sup>rd</sup> tier, may comprise a disproportionately large division</li> </ul>	<ul style="list-style-type: none"> <li>Would be separate from other MoH functions and easier to manage</li> </ul>	<ul style="list-style-type: none"> <li>Size is not out of step with other Crown entities eg, PHARMAC</li> </ul>

	<p>within the MoH which may fit awkwardly with other MoH functions</p> <ul style="list-style-type: none"> <li>• Would require good working relationship between the chief executive and the responsible manager to ensure independence of regulatory decision-making and operational independence were maintained</li> </ul>	<ul style="list-style-type: none"> <li>• Would require good ongoing working relationship between the chief executives</li> </ul>	<ul style="list-style-type: none"> <li>• Would require good working relationship between the chief executives of the Crown Entity and the Ministry of Health</li> </ul>
<p>Connections within the Ministry, the wider health sector and peer regulators domestically and internationally</p>	<ul style="list-style-type: none"> <li>• Largely a matter of regulator culture.</li> <li>• Connections with MoH would be readily established and maintained</li> <li>• Connections with the wider health sector would be relatively easily established and maintained</li> <li>• Connections with peer regulators would depend on the visibility of the regulator within the structure of the Ministry</li> </ul>	<ul style="list-style-type: none"> <li>• Largely a matter of regulator culture.</li> <li>• Connections with MoH, the wider health sector and peer regulators would be readily established and maintained</li> </ul>	<ul style="list-style-type: none"> <li>• Largely a matter of regulator culture.</li> <li>• Separation from the MoH may enhance the ability to connect with external health sector parties and weaken the ability to connect within the Ministry, and with peer regulators.</li> </ul>
<p><b>Flexibility to incorporate other functions or for form or other arrangements to change over time</b></p>	<ul style="list-style-type: none"> <li>• Other functions can readily be incorporated. Regulatory powers for other regimes are vested in the Director-General of Health and these would simply be delegated within the MoH</li> <li>• a change to form would require either legislation (Crown Entity) or an Order-in-Council (Dept Agency). Considerable flexibility to evolve the model. Changes would not necessarily be subject to external scrutiny</li> </ul>	<ul style="list-style-type: none"> <li>• Other functions can readily be incorporated. Regulatory powers for other regimes are vested in the Director-General of Health and these would simply be delegated to the chief executive of the Departmental Agency and necessary arrangements reflected in the departmental agency agreement</li> <li>• a change to form would require either legislation (Crown Entity) or an Order-in-Council (to change to the Departmental model). Whether other matters could be readily changed depends on whether they were part of the Dept Agency form (and thus set out in the State Sector Act) or were contained in the Departmental Agency Agreement. There is considerable scope to evolve the latter is more readily changed and requires the approval of Ministers and consultation with SSC and Treasury</li> </ul>	<ul style="list-style-type: none"> <li>• Other functions can be incorporated through delegation, contract or legislation.</li> <li>• a change to form would require legislation. How readily other matters could be changed would depend on how the regulator's functions and powers were designed. The vehicles for change would be Statement of Performance Expectations and Statements of Intent. These are public documents.</li> </ul>

<b>Other aspects of form types</b>	<ul style="list-style-type: none"><li>• It is appropriate that Cabinet decisions (in respect of procurement processes, or regulatory impact analysis for example) would apply</li></ul>	<ul style="list-style-type: none"><li>• It is appropriate that Cabinet decisions (in respect of procurement processes, or regulatory impact analysis for example) would apply</li></ul>	<ul style="list-style-type: none"><li>• The regulator does not need the financial powers (to borrow and invest for example) that Crown Entities have</li><li>• The regulator does not need the ability to engage in joint ventures</li></ul>
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## Organisational context

173. The above analysis focuses on how the three entity forms may meet the objectives of the regulatory regime for therapeutic products. The question of entity form for therapeutic product regulation also needs to be considered in the context of how the Ministry of Health approaches its wider span of regulatory functions and any changes to these settings as a result of the current organisational changes within the Ministry.
174. On 1 March 2016 a new organisational structure was put in place in the Ministry under a new, interim, Executive Leadership Team. The new executive is expected to begin a wider programme of change in the organisation with a focus on improved co-ordination and alignment of activity, improved focus on customer needs, and the delivery of the proposed New Zealand Health Strategy (the new regulatory regime for therapeutic products is a deliverable within the Strategy's roadmap of actions). As this change process unfolds there may be impacts on the analysis on the merits of the options for the institutional form of the regulator.
175. In particular there may be impacts in respect of how the Ministry wishes to organise its regulatory responsibilities for:
- products – therapeutic products, psychoactive substances, radioactive substances. The focus is on technical product assessment, individual product approval, licensing, audit, post-market monitoring, and enforcement
  - services – for example, through the administration of the Health and Disability Services Safety Act. Under this Act regulatory activity focuses on standards setting, accrediting third party auditors and enforcement
  - people – for example, through support for the Registration Authorities responsible for health practitioner regulation under the Health Practitioner's Competence Assurance Act
  - other matters – such as aspects of public health, compulsory treatment etc.
176. Alongside the Ministry is also considering how, irrespective of the form of the regulator, it will organise its stewardship functions such as strategic and operational policy, ongoing assessment and monitoring of the regulatory regime, and systems to keep the regime current.

## Conclusions and recommendations

177. The three options for organisational form are fundamentally distinguished by their status in relation to the Crown. Departments and Departmental Agencies are part of the legal Crown while Crown Entities are outside the legal Crown. The analysis above concludes that being part of the legal Crown has advantages in respect of delivering the regulatory regime objectives. In particular that it will facilitate domestic and international engagement – factors identified as important to effective regulation and for sustaining capacity.
178. Alongside this consideration, the analysis identifies that the Crown Entity model would also be the most expensive to establish and maintain, that it is not apparent that a Board would add value to regulatory decision-making over that gained through technical advisory committees, and it may be harder for a Crown Entity to incorporate other functions. A completely separate organisation also risks weakening the connection between the Ministry and the regulator to the detriment of both organisations. Officials also note that there is no burning platform, such as a serious

lack of public confidence, which requires separation from the Ministry of Health (such as existed in the decision to establish Worksafe as a Crown Entity rather than a Departmental Agency).

179. Officials conclude that initial analysis indicates that the therapeutic products regulator should not be established as a Crown Entity.
180. A decision between the remaining two options turns on the need for operational independence, the contribution organisational form can make to sustaining capacity, and the impact that structural changes within the Ministry may have on the overall organisation of regulatory functions.
181. The Departmental Agency form offers a number of advantages in respect of operational independence and sustaining capacity. Operational independence is provided as a matter of form, as are elements of the accountability framework, and the Departmental Agency Agreement provides a formal mechanism for setting out the relationship between the Ministry and the regulator to the advantage of both organisations. An independent organisation, with a separately appointed chief executive but located within a government department would assist with sustaining capacity.
182. That said, it is important to note that this is a new institutional form and that, while designed for this type of function, is relatively untested and has not yet been used for a regulator. The Ministry of Health, Treasury and the State Services Commission would need to work closely to ensure that, if this option were preferred, it was well designed in terms of working relationships (such as information requirements for reporting purposes) and well implemented.
183. The Departmental model could support the objectives of the regime. It is a known structure but it brings least as a matter of form and would require more to implement well and to sustain, particularly in respect of operational independence, regulator culture, and sustaining capacity.
184. The change process currently underway in the Ministry is significant. As it unfolds it may have implications for the analysis of the merits of the Departmental and Departmental Agency options. Ideally, these impacts would be known and able to be taken into account now. However this is not possible as the change process is unfolding concurrently.
185. In light of this uncertainty, the Ministry of Health considers that it would be prudent to delay making a decision between the Departmental and Departmental Agency options until any impacts resulting from the structural change process can be assessed. The downside of this approach is that this matter remains unresolved for the time being and stakeholders will not have clarity over the intended mechanisms for ensuring operational independence, accountability and sustainability. The Ministry considers that this risk can be mitigated by providing a clear assurance of the intention to provide for these matters and that the decision will be made by October 2016 in order that there is no undue delay to the development of the regulatory regime.
186. In order that the drafting of legislation is not impacted, officials advise that the Therapeutic Products Bill should be drafted so as to keep open the options of Departmental Agency and Department. This can be done by vesting the relevant powers in the chief executive as defined in the State Sector Act. That Act defines chief executive as the person holding office as the chief executive of the department or of the departmental agency.

## **Consultation**

187. The Treasury and the State Services Commission have been consulted and discussions have been held with officials involved in the establishment of Worksafe.
188. Treasury considers that the initial analysis indicates that a Departmental Agency is the preferred institutional form for the regulator but that further analysis of the three options should be undertaken to confirm this is the most appropriate form.
189. Central agencies are keen to see the preferred model implemented well, whichever from is agreed.
190. The State Services Commission advises that the regulatory powers and associated administrative powers of the regulatory regime should be vested in the 'chief executive' as defined in the State Sector Act. This approach enables drafting of the Bill to proceed while leaving open both the Departmental and Departmental Agency options.

## 8. Interface with Hazardous Substances and New Organisms Act

### What are we regulating and why?

191. The Hazardous Substances and New Organisms Act (the HSNO Act) covers both hazardous substances and new organisms, including genetically modified organisms. A therapeutic product may be, or contain, either of these things.
192. There are likely to be more therapeutic products containing new organisms, particularly vaccines, in the future. The new regime needs to ensure that there is an efficient and cost effective approval pathway for these types of products. The pathway will facilitate access for consumers, while also effectively managing the potential environmental risks the products pose.
193. For therapeutic products containing hazardous substances, the regulator would require the ability to set disposal requirements and to prohibit the importation or distribution of products that represent an unacceptable environmental risk. This is because finished dose form medicines are defined in regulation as not being hazardous substances and therefore outside the scope of the HSNO Act.

### Status Quo

#### *Product approval – medicines containing a live new organism*

194. If a medicine contains a live new organism, including a genetically modified (GM) organism, both Medsafe and the Environmental Protection Authority (EPA) must approve its use. Separate applications need to be made to both agencies. The EPA assesses the environmental risks, including public health risks, while Medsafe examines the efficacy and safety for consumers.
195. There have been several applications for veterinary medicines containing a new organism, but only one human medicine has been approved by EPA for use in New Zealand (Pexa-Vec). There were some unique features to this approval. Firstly, it was for use in a clinical trial and not for full public release. It also involved a virus that had a history of use in the unmodified form (ie, as a small pox vaccine).

#### *Regulating medicines containing hazardous substances*

196. The Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 state that a medicine (in finished dose form) is not hazardous for the purposes of the Act. The ingredients used to make medicines if imported to New Zealand may, however, be regulated as hazardous substances. The Medicines Act only empowers the prohibition of medicines that represent an unacceptable risk to public health, not environmental risks. There is also a gap in that disposal of medicines is not regulated.

### Problem definition

#### *Product approval – medicines containing a live new organism*

197. The medicines industry has indicated that the dual application pathway for these medicines represents a barrier to market entry. This may deter clinical trials of medicines containing new organisms being performed in New Zealand. Industry also says the data requirements for environmental impact assessments are costly and difficult to meet. In addition, it is possible that there may be some duplication in the

current process as both agencies assess public health and safety issues at a population level.

198. Industry has cited two vaccines that are available in Australia, but regulatory approval has not been sought in New Zealand. The vaccines are for dengue fever and Japanese encephalitis. There would be a limited market for these products in New Zealand as they would only be used by travellers visiting high risk areas for the diseases. It is therefore difficult to unpick the purely commercial considerations from the concerns about the processes. Research by the EPA does suggest that there are a number of products (mostly vaccines) that are available in other jurisdictions, but not here.

### *Regulating medicines containing hazardous substances*

199. Currently there is no legislated mandate under the HSNO Act or the Medicines Act to set disposal requirements of medicines or prohibit the importation and distribution of medicines that contain an environmentally hazardous substance. The HSNO Act exempts medicines in a finished product dose form and the Medicines Act only empowers the prohibition of medicines that represent an unacceptable risk to public health. In the future, medicines containing an ingredient with an extreme environmental risk profile may be identified. It would be unacceptable that New Zealand regulators are unable to adequately respond to such a risk if the ingredient is contained within imported finished dose form medicine. This lack of mandate also represents a reputational risk to New Zealand.

### **Options and impact analysis**

200. There are two distinct issues at the interface between the therapeutics and HSNO regimes.

### *Issue 1 – Approval process*

**Table 14: Should we retain the dual approval process, or can the risks around therapeutic products containing new organisms be managed through a single process?**

Question	Option 1 Status Quo	Option 2 Regulator cooperation and streamlining	Option 3 Full delegation to the new regulator
Should we retain the dual approval process, or can the risks around therapeutic products containing new organisms be managed through a single process?	Both EPA and the new regulator receive separate applications and consider them independently (see 'Status Quo' section for more detail)	A single application that the agencies collaborate on. EPA retains the decision-making but the new regulator would coordinate the process.	The new regulator would take over all the decision-making for the environmental impact assessments for therapeutic products.
<b>Strategic objectives</b>			
<b>Safety</b>	Safety concerns are fully addressed by the separate decisions.	Safety concerns are still addressed, but the assessment is shared between the two agencies.	Without the expertise of EPA, the new regulator may not be able to adequately assess the risks or propose appropriate conditions.
<b>Efficiency</b>	As the assessments are done separately but cover some of the same issues, there is duplication of effort.	There might still be some duplication, but the agencies collaborate to improve efficiency.	The new regulator would have to acquire the expertise. This would mean that there was duplication across government.
<b>Quality decisions</b>	Both regulators produce high-quality decisions.	The quality should be retained if the regulators can collaborate and make the decisions together.	The new regulator may not be able to maintain the same quality standards alone.

<b>Access</b>	Access is reduced by perceptions of barriers resulting in approvals not being sought for products.	The barriers should be reduced, improving access.	Access should be improved.
<b>Impacts Comment</b>	The preferred approach will reduce the barriers for industry and make the application process more seamless for the applicant.		

**Table 15: Should it be possible for the importation and distribution of medicines that contain an environmentally hazardous substance to be prohibited?**

*Issue 2 – How should medicines containing hazardous substances be regulated?*

<b>Question</b>	<b>Option 1 Status Quo</b>	<b>Option 2 New regulator can prohibit</b>	<b>Option 3 EPA can prohibit</b>
<b>Should it be possible for the importation and distribution of medicines that contain an environmentally hazardous substance to be prohibited?</b>	No. Currently this falls into a gap between the two regulatory regimes.	Yes, by the new regulator under the therapeutics regime, but on advice from the EPA.	Yes, but would require changes to the definition of hazardous substances and numerous operational changes that would require significant policy work to resolve.
<b>Strategic objectives</b>			
<b>Safety</b>	This creates serious risks.	Will address the safety risks.	Could also address the public safety risks.
<b>Quality decisions</b>	No decisions are being made.	The EPA is best placed to make the assessments of environmental risks but the new regulator will have broader expertise in assessing the safety of therapeutic products.	EPA would need to gain expertise in assessing the full safety risks of therapeutic products. It may be necessary to decide that the therapeutic benefit outweighs the environmental risk but the risk needs to be managed by more controls
<b>Capacity</b>	No impact at present.	It is best that the new regulator does not have to acquire additional environmental impact expertise.	The HSNO regime and its interface with therapeutic products would need to be significantly changed to facilitate EPA taking on this type of role. This would require significant additional development work.
<b>Trust</b>	This undermines New Zealand’s credibility. The public would find this unacceptable.	Consideration by either trusted regulator could satisfy the reputational risks.	Consideration by either trusted regulator could satisfy the reputational risks.
<b>Access</b>	Allows access to products that pose unacceptable safety risks to the environment.	Would reduce access, but only to products that pose an unacceptable environmental hazard	Would reduce access, but only to products that pose an unacceptable environmental hazard
<b>Impacts Comment</b>	EPA is best placed to provide the advice and the new regulator should have the power to intervene.		

**Consultation**

201. We have worked closely with EPA and the Ministry for the Environment in developing the proposed options.

**Conclusions and recommendations**

*Issue 1: Approval process - medicines containing a live new organism*

202. The Ministry’s view is that the barriers presented by the current process are largely perceived rather than real.

203. In relation to data requirements, other jurisdictions require evidence of environmental impacts for their assessments so material should be available. Companies do need to

provide information on the possible effect on New Zealand indigenous species, but this can be a literature based assessment rather than undertaking animal studies.

204. The preferred option for the approval process for medicines containing a live new organism is therefore to streamline the process as much as possible. The new therapeutics regulator and the EPA will work together to ensure that the application process for therapeutic products containing new organisms is efficient and effective, and streamlined from the applicants' perspective.

*Issue 2: Regulating medicines containing hazardous substances*

205. The environmental risks posed by medicines in a finished dose form are generally relatively low. However, there is a gap in ensuring effective disposal or prohibition in rare cases where medicine in finished dose form may have a material adverse impact on the environment.
206. The new regulator will be given the power in the legislation to prescribe disposal requirements and to prohibit the importation and distribution of medicines that contain an environmentally hazardous substance. The EPA will be best placed to provide technical advice on environmental harm and could be contracted to assess the environmental risk of finished dose form medication and provide advice to the new regulator. It is proposed the regulator could either arrange for the EPA to provide advice about the medicine or act on advice received proactively from the EPA.
207. The new regime will also establish regulation around the disposal of therapeutic products. This should assist in managing their potential impacts on the environment.

# Implementation plan

## Key considerations

208. The implementation plan needs to consider:

- how implementation risks will be being mitigated
- how compliance costs will be minimised
- the scope for reducing existing regulations
- enforcement.

209. The approach for the design of the new regulatory regime will eventually involve the wholesale replacement of the Medicines Act and regulations by a new Act and regulations together with tertiary instruments developed by the regulator.

210. Upgraded enforcement provisions (eg, revised offence and penalty provisions) will help to ensure that the regime achieves its public policy objectives.

211. In terms of mitigating implementation risks, and minimising compliance costs, the implementation plan adopts a staged approach for addressing these objectives.

## Approach to implementation

212. The approach to implementation accounts for a number of requirements and pressures:

- the sheer scale of the work involved in replacing the current Medicines Act and regulations, but the need to start the legislative process now given that work on the ANZTPA joint regulatory approach has ceased
- the importance of further consultation on the specific detail of the new regime - building on more general prior consultation - before a Bill is introduced, which will assist with industry engagement, identification of further issues, and thus improve the quality of the Bill introduced
- the multiple linkages with other regulatory regimes, and the need for careful legal review across a range of areas as part of the extensive drafting required
- the efficiency of sequencing given that much of the detailed work is critically dependent on the decisions taken on the major policy settings.

## Staged development

213. A staged, multi-year process has been developed for implementation as the best means of addressing all of these considerations. The timetable is as follows:

Stage	Requirements and linkages	Timing
Overall regulatory approach and core elements	<u>Policy decisions</u> Proposals presented to Cabinet in late 2015. These further proposals presented to Cabinet now. This	Late 2015 and



Stage	Requirements and linkages	Timing
	<p>enables decisions to be made on the overall framework for a new regime and the high-level policy settings.</p> <p><u>Drafting</u></p> <p>These decisions provide the basis for the drafting instructions for the preparation of an exposure draft.</p>	Early 2016
Exposure draft	<p><u>Exposure draft consultation</u></p> <p>An exposure draft of the proposed legislation is critical for consultation and policy review purposes. It is a key step in quality assurance and refinement of the policy settings and implications before a Bill is introduced. This will be accompanied by a consultation document describing how key issues will be addressed in the subordinate instruments.</p> <p>Outcome of consultation will include:</p> <ul style="list-style-type: none"> <li>• any refinement to the policy decisions</li> <li>• any further drafting instructions for the preparation of the Bill</li> <li>• early consideration of the tertiary instruments required by the regulator.</li> </ul>	Mid-2016
Bill introduction and enactment	<p><u>Bill</u></p> <p>The standard introduction and select committee process are expected to be followed. The process should benefit from the prior consideration of the exposure draft.</p> <p><u>Enactment</u></p> <p>Most aspects of the new regime will likely be implemented with delayed effect.</p> <p>The new Act will provide the necessary authority and clarity for work on tertiary instruments to be finalised by the regulator.</p>	Late 2016  2017/18
Transition / operational roll-out	<p>Some changes will be implemented quickly; others will take some years.</p> <p>The establishment of a new institutional form for the regulator could potentially be implemented during this period (or after the first major review, see below).</p>	From 2018 to 2020

## Monitoring, evaluation and review

### Formal review

214. The regulatory regime will not be fully operational until around 2020 at the earliest. This reflects the current timetable for further policy development, the legislative process, and the proposed transitional arrangements.

215. Given the scope of the new regime and its complexity, a review of the new legislation might be undertaken 5 years after the end of the transition period (ie, it would occur around 2025), and the legislation could include a provision that required this review.

### **Development review opportunities**

216. Before that time, however, there will also be opportunities for monitoring and evaluating the merits of the preferred approaches as the detail develops, and for taking into account and responding to the Government's evolving stewardship expectations.

#### The development of an exposure draft of the bill for consultation

217. In order that the Bill is robust, it is proposed that an exposure draft be released for consultation before introduction. Stakeholders will be particularly interested in the proposed content of the legislative instruments that would sit beneath the new Act and a description of the policy to be contained in these instruments should accompany the exposure draft.
218. Addressing such matters as the balance between primary and delegated legislation, and the exposure draft process, aims to improve the quality of legislation. This process is in accordance with the Legislation Advisory Committee's *Guidelines on the Process and Content of Legislation*.

#### The transition to full implementation

219. The arrangements for transition will need to ensure the regulator has time to develop the necessary tertiary instruments (notices and guidelines), and industry has time to prepare for and adjust to the new requirements. These arrangements will provide for the transition from the current Act to the new; and for the gradual application of the regime to newly regulated products (eg, medical devices and cell and tissue therapeutic products which will need to come into effect over a period of time).

### **Stewardship expectations**

220. The Government has signalled its core expectations for regulatory stewardship to agencies involved in designing and administering regulation. The Ministry of Health will be required to:
- 1) *actively monitor and periodically assess the performance and condition of the regulatory regimes it administers*, and to use that information to advise or act on problems, vulnerabilities and opportunities for improvement;
  - 2) *adopt best practice compliance strategies*, as part of a cross-government forum designed to share experiences and promote greater consistency between regulators; and
  - 3) *report publicly on its regulatory management strategy*, the state of the regulatory stock, and plans for improvement, including engaging actively with stakeholders and other regulatory agencies, and undertaking rigorous organisational self-review.
221. These requirements will impact on the stewardship of the current regulatory regime, and also influence the development of the new regime (ie, the design will need to enable and be compatible with effective stewardship).



# SUMMARY OF RECOMMENDATIONS

## 1. Clinical trials

- 222. The new regulator should have oversight of clinical trials for all therapeutic products and that coverage will also be expanded to encompass products that already have marketing approval.
- 223. The regulator should have wider powers to ensure that it has access to relevant information and can protect the safety of participants.
- 224. The current timeframe for considering applications should remain at 45 days. This period is comparable with other jurisdictions and should help retain New Zealand's attractiveness as a trial destination.
- 225. Officials should work together to streamline and improve the efficiency of the regulatory and ethical approve processes.

## 2. Cell and tissue therapeutic product regulation

- 226. The regime should include all cell and tissue therapeutic products, including minimally-manipulated tissue, with controls calibrated to the unique needs of these products.
- 227. While organs for immediate transplant will be included within the scope of the regime, no regulatory requirements are proposed at this time for services working with these products. This allows for the regulator to consider future innovations in organ products.
- 228. Xenotransplantation should be included in the regime.

## 3. Prescribing and dispensing

- 229. Controls over who is authorised to prescribe prescription therapeutic products and any conditions on that practice should sit under the Health Practitioners Competence Assurance Act 2003.
- 230. The Health Practitioners Competence Assurance Act 2003 should be amended to include mechanisms for prescribing authority to be part of a health practitioner's Scope of Practice (including amendments to prescribing authority). Mechanisms should include, inter alia, Ministerial approval of the prescribing aspects of the scope of practice.

## 4. Pharmacy licensing

- 231. Licensing of pharmacies remains the most efficient way of managing the risks associated with supply and use of therapeutic products. Applying conditions to licences is the most effective way for the regulator to manage risks, set expectations and drive desired behaviours.
- 232. Pharmacy licence applicants are currently restricted to physical premises. This restriction should be removed to allow innovation in distribution and supply models. The regulator should be able to assess the risks and approve applications if risks can be successfully managed in the conditions of a licence.

233. The current ownership restrictions should be removed and replaced with a requirement for applicants to name a pharmacist with responsibility for overseeing the implementation of pharmacy standards and licence conditions.
234. Prescribers (including pharmacist prescribers) should continue to be prohibited from having an interest in pharmacies where they may receive a financial benefit via their prescribing actions.
235. The regulator should have discretion to grant licences for up to 3 years, and should be able to grant licences for new ways to supply therapeutic products to the public other than through fixed premises.

## 5. Import and export

236. Importation of therapeutic products should become a licensed activity for which a licence would be required. An exception should be retained for personal use so long as regulatory requirements have been met and the import is not a controlled drug.
237. The controls for export should be a notification accompanied by evidence that the product meets the standards of the importing country.
238. The regulator should be able to issue certification for New Zealand exporters on request to facilitate export of therapeutic products to other jurisdictions.
239. The prohibition on the parallel importation of medicines is retained and expanded to cover all therapeutic products by virtue of the requirement to have an approval to import.
240. The current exemption permitting the Crown to parallel import medicines should be replaced with a credible alternative that will still allow the Crown to source alternative supplies of therapeutic products where options are constrained.

## 6. Offences and penalties framework

241. The Bill should include a hierarchy of enforcement tools that include tiered criminal offences:
  - **Tiered criminal offences**, generally in three levels covering negligent or reckless conduct; conduct that poses a risk to human health, but is not negligent or reckless; and less serious non-compliance with regulatory requirements.
  - **Enforceable undertakings**, which allow the regulator to accept an undertaking from a license-holder, in lieu of more severe enforcement action.
  - **Infringement notices**, which will allow instant fines for low-level offending

## 7. Regulator form

242. The regulator for the therapeutic products regulatory regime should not be established as a Crown entity.
243. Both the department agency model and the department model could, if well implemented, meet the objectives of the regime. The department agency model does so more readily and is the preferred approach based on initial analysis. Further work is to be done on these options.

244. The regulatory powers and associated administrative powers of the therapeutic products regulatory regime should be vested in the chief executive as defined by the State Sector Act, leaving both the department agency model and the department model options open.

## **8. Interface with the Hazardous Substances and New Organisms Act**

245. The approval process for therapeutic products containing a live new organism should be streamlined and for the EPA and new regulator to collaborate more. This will involve a single application coordinated by the new regulator.