

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.

Agency Disclosure Statement

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

It is associated with two Cabinet papers on Therapeutic Products Regulation: Paper 1 – Context and Overview; and Paper 2 – Proposals for a Therapeutic Products Bill.

The RIS provides an analysis of options to change the regulation of therapeutic products. These include medicines, medical devices, and cell and tissue therapies and combinations thereof. The purpose of change is to advance coverage, safety, quality and access objectives.

A key aspect of the proposed regime is the devolution of power to enable the regulator to set requirements relating to the approval of products and the licensing of activities on a product life-cycle and risk-proportionate basis. This would be supported by a clear and principled legislative mandate with robust accountability for the regulator's organisational performance and its regulatory decisions.

There are limitations on the extent to which the impacts of the proposals can be assessed specifically or quantitatively. This reflects a lack of information on some products and their risk profiles; that the specific regulatory approach in new areas has still to be developed by the regulator; and that the timetable for the development and implementation of the new regime is staged over several years. This involves the preparation of an exposure draft, consultation on the draft before the Bill is introduced, the development of regulations and other tertiary instruments, and an extensive transition after enactment.

The overall implications long term are predicted to involve:

- moderate increases in compliance costs for some parts of the regulated industry, most notably for the newly regulated products
- benefits for industry from having its products regulated and approved (eg, for PHARMAC purposes, for marketing in other countries)
- positive impacts on the management of therapeutic product risk, and on product availability and possibly pricing
- a positive impact fiscally for the Crown from the effects of product availability and risk management on the wider health budget and economy.

The design of the proposed regime has been informed by: a long-standing appreciation of the key problems that need to be addressed; accepted international practice; current public sector standards for legislative and regulatory design; and a measured timetable for decisions, development and implementation.

Further decisions will be sought from Cabinet on aspects of the regime in early 2016 in the following areas:

- Proposed institutional form of the regulator
- Regulatory approach to cell and tissue therapies
- Clinical trial arrangements
- Detail of the proposed offence and penalty framework
- Pharmacy ownership
- Import and export (including parallel importation)
- Prescribing and dispensing
- Interface with the Hazardous Substances and New Organisms Act
- Privileged statements (statements about therapeutic products during periods of data protection)
- Further advice on legislative placement of provisions if required.

Another RIS will be prepared to cover these issues.

The details of how the regime will operate in practice will be set out in regulations and subordinate instruments. The exposure draft of the legislation will be accompanied by a description of the policy to be contained in these instruments. The instruments themselves will be drafted throughout late 2016 and 2017 and a further RIS will be prepared for them.

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Contents

	<i>Page</i>
Executive Summary	4
Status quo and problem definition	5
Objectives	11
Options and impact analysis	11
<i>Part A: Issues and Options</i>	12
Strategic / framework	
Issue 1: Merits of therapeutic product regulation	12
Issue 2: Stand-alone versus joint regulation	16
Issue 3: Purpose and scope	17
Administrative / institutional	
Issue 4: Powers	20
Issue 5: Institutional form of regulator	22
Issue 6: Accountability	23
Issue 7: Cost recovery	25
Pre-market	
Issue 8: Product approvals	28
Issue 9: Controlled activities	30
Issue 10: Pharmacy licensing and control	32
Issue 11: Exemption issues	33
Post-market	
Issue 12: Monitoring	35
Issue 13: Enforcement	37
<i>Part B: Expected impacts for preferred approach</i>	39
<i>Part C: Overall impacts on costs and outcomes</i>	41
<i>Part D: Further points on approaches and impacts</i>	44
Consultation	46
Conclusions and recommendations	46
Implementation	47
Monitoring, evaluation and review	49

Executive summary

1. This RIS addresses the issues and options associated with replacing the Medicines Act 1981 and its Regulations with a new and comprehensive therapeutic products regulatory regime. The Therapeutic Products Bill has priority 6 on the Government's Legislation Programme [CAB Min (15) 5/7 refers].
2. Therapeutic products are vital for achieving health outcomes, and need to be regulated.
3. Deficiencies in the Medicines Act have been noted (for at least 20 years), and a joint approach with Australia was explored (over the last 15 years) to create a single trans-Tasman regime (ANZTPA). In November 2014, Minister Coleman and his Australian counterpart announced the cessation of efforts to establish ANZTPA. At that time, the Minister also announced that New Zealand would develop its own comprehensive domestic regulatory regime that covers medicines, medical devices and cell and tissue therapies [CAB Min (14) 36/22 refers].
4. New Zealand now needs to put in place an upgraded domestic regime for the regulation of therapeutic products. It is necessary to address the legislative framework and gaps and deficiencies in the policy settings, which increase the risks of adverse health outcomes, especially in relation to medical devices and cell and tissue therapies.
5. While this cannot be done in one stage, it is urgent to make a start now because it will involve some years of work.
6. The legislative framework problem may be best addressed by ensuring that product and licensing decisions are devolved to the regulator. This should be supported by a clear and principled legislative mandate with robust accountability for the regulator's organisational performance and its regulatory decisions.
7. Policy settings should be strengthened by bringing all therapeutic products and related activities within the scope of regulation, and taking an approach that is:
 - comprehensive and reflects a life-cycle approach, meaning all of the stages of a product or activity are considered for risk management purposes
 - risk appropriate, meaning that regulatory scrutiny and the information and assurance required are proportionate to the risks involved.
8. The powers of the regulator should be updated to ensure it is able to: determine requirements and to impose and modify conditions on approval and licensing decisions; and obtain information and take enforcement action, which is reasonable and necessary for effective regulation. This would be supported by updated sanctions and penalties for non-compliance.
9. Given the significant development work still to be undertaken, the full impacts of the proposals cannot be assessed quantitatively. Based on the framework and building blocks proposed, however, the implications long term are predicted to involve: moderate increases in compliance costs for some parts of the regulated industry (most notably for the newly regulated products); positive impacts on the management of therapeutic product risk, and on product availability and possibly pricing; and a potentially positive impact fiscally for the Crown from the effects of product availability and risk management on the wider health budget and economy.

Status quo and problem definition

Status Quo

Legislation

10. The Medicines Act 1981 and the Medicines Regulations 1984 provide for the regulation of certain products and activities.
11. In summary, the major focus of the legislation 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.

Size of the sector and the risks regulation seeks to manage

12. For therapeutic products, the annual sales in New Zealand are estimated to be around \$2 billion. Medicines and medical devices account for roughly \$1 billion each:
 - PHARMAC's combined pharmaceutical budget in 2015/16 is \$800 million, which is about 80% of total spending on medicines (ie, based on the overall average public/private share of health system spending).
 - The spending by DHBs on medical devices, a high-growth cost area, was estimated at around \$880 million four years ago.
13. Total reported adverse events for medicines and medical devices each year number around 4,450 (although this may be understated due to under-reporting).

Regulatory costs for industry and the Crown

14. Currently, the annual total cost for the regulatory bodies, Medsafe and Medicines Control, is about \$11.8 million. Of this figure, \$10.25 million is borne by industry through fees which are cost-recovered, and \$1.55 million is borne by the Crown.
15. Fees are paid by industry in respect of medicines and licences, but no fees are paid in respect of medical devices.

General regulatory approach

16. The Medicines Act 1981 provides for the regulation of products which come within a product definition.
17. The Act defines some types of therapeutic product:
 - medicines under section 3
 - medical devices under section 3A
 - xenotransplantation under section 96A.
18. Hybrid products are products which span more than one product category, including categories for which there is no product definition in the Act. The Act also defines therapeutic purpose.

19. Regulation provides a means of assessing risk in relation to the claimed benefits (often requiring significant scientific information and clinical testing), controlling the introduction of products to the market, licensing activities, together with monitoring and enforcement.

Medicines

20. Medicines primarily work through pharmacological, immunological or metabolic means. They are composed of active substances that interact with human physiological processes and there may be a narrow margin between the amount required to produce a therapeutic effect and a toxic effect.
21. Medicines are currently regulated pre- and post-market. The approval process will vary in accordance with whether it is considered to be a higher risk, intermediate risk or lower risk medicine. This will depend on the ingredients and intended purpose. The level of cost-recovery through fees is around 90%.
22. There are a number of innovative ways in which the approval process has already been made more efficient and cost effective. Truncated pathways have been developed to allow the regulator to leverage off previous work and data. There are abbreviated evaluations, where the applicant must provide the evaluation report of another trusted regulator, which is used as an adjunct to the assessment. Generic pharmaceuticals and biosimilars (the biological equivalent of a generic) can go through an accelerated approval pathway which allows the applicant to rely in part on the data submitted in respect of the innovator product. In addition, lower-risk medicines that have well-known risk profiles and are suitable for self-selection by patients go through an abridged application process that does not require clinical and toxicological data.
23. Medsafe currently processes approximately 200 new medicine applications (50 innovator, 100 generic/biosimilars and 50 over the counter (OTC) medicines) and 1,500 changed medicine notifications per year. Of the total medicines currently listed as approved, 4,735 are consented, 57 have provisional consent and 2219 are consented but not available (or actively marketed). Of prescription medicines, 1,795 are not available, and 3,450 are over the counter medicines. Just over 800 different unapproved medicines have been notified as having been supplied in New Zealand since January 2014, with a total of 253,325 packs. Around 4,000 adverse events from medicines are reported each year.

Medical devices

24. Medical devices work primarily through physical and electrical/electronic means. They include a wide range of apparatus, instruments and appliances, ranging from tongue depressors and latex gloves to implantable heart valves and machinery (such as ventilators and CT scanners). The term medical device also includes diagnostic equipment ranging from home pregnancy kits through to software.
25. There is no pre-market approval process for medical devices. Instead they must be notified to the Web Assisted Notification of Devices (WAND) database. Notification is free and there are no on-going fees. If there is a safety issue with a device, the WAND database can be used to identify sponsors of that device. The sponsor of the medical device must be a New Zealand legal entity with a physical address in New Zealand.
26. About 48,400 individual medical devices have been notified to Medsafe (around 5,000 more are added each year). Of the sponsors who have active notifications, 497 sponsors (56%) have five or fewer notifications, 275 (31%) have only one notification, 109 (12%) have 100 or more, and eight (1%) have more than 1,000 notifications. About 450 adverse events related to medical devices are reported each year.

Cell and tissue products

27. Cell and tissue therapeutic products are derived from living cells and tissues of human or animal origin. These products span whole tissues that are part of established clinical practice (eg, skin grafts) through to innovative and substantially manipulated gene and cellular therapies (eg, demineralized bone matrix for repair, reconstruction or replacement of cartilage, dental pulp-derived stem cells for tooth regeneration).
28. New Zealand does not have specific regulation for cell and tissue therapeutic products, although some cell and tissue products are currently regulated as medicines. These include products at the clinical trial stage, and various blood products. Products regulated as medicines must meet certain manufacturing standards, and the manufacturer must be licensed and undergo regular audit.
29. 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, there is a wide range of cell and tissue products on the market. It is characterised by significant innovation internationally and the range of products (including hybrid products) is likely to continue to grow.

Xenotransplantation

30. Xenotransplantation is the transplantation of living biological material from animals to humans. It carries the risk of transmission of disease, and can be controversial for ethical, cultural, spiritual or other reasons.
31. The Act only covers xenotransplantation in the clinical trial phase and requires the Minister of Health to be satisfied that robust safety and ethical criteria have been met. In addition to Ministerial approval, a xenotransplantation trial requires approval by the Gene Technology Advisory Committee (covering safety and risk management) and a Health and Disability Ethics Committee.
32. There is currently one company active in this field in New Zealand. To date, three Ministerial approvals have been issued for pig cell therapy clinical trials for type 1 diabetes and Parkinson's disease. Should these trials show promise, it will be necessary to develop an approval process that addresses the ongoing safety, manufacture and supply of the cellular product itself. The Medicines Act does not cater for this eventuality.

Medicines supply chain

33. Once a medicine is manufactured or imported into New Zealand it needs to be safely stored, distributed, dispensed or sold to the patient. Companies manufacture or sponsor the import of scheduled medicines and distribute them either directly to hospitals, pharmacies, and doctors, or distribute through national wholesalers.
34. All wholesalers require a Licence to Wholesale Medicines unless the medicines are classified as general sales medicines, in which case they can be distributed without restriction. Pharmacies require a licence to dispense and sell medicines. Retailers in remote areas who hold a range of pharmacy-only medicines require a Licence to Sell Medicines by Retail. Companies that "hawk" medicines for promotional purposes, for example professional samples to doctors, require a Licence to Hawk Medicines. Authorities and approvals to procure or possess medicines are also issued. In addition, the regulatory requirements for the dispensing of medicines in pharmacies are monitored as part of the pharmacy licensing regime.

35. Medicines Control currently processes 1036 pharmacy licences, 189 wholesale licences, 63 licences to sell medicines by retail, 32 hawk licences, 117 authorities and 16 approvals per year.

Institutional arrangements

36. Medsafe and Medicines Control are the two regulatory entities in New Zealand responsible for the regulation of therapeutic products and related activities. Both are business units within the Ministry of Health.

Medsafe

37. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is responsible for the regulation of medicines and medical devices and for ensuring that medicines and medical devices are acceptably safe.
38. In 2015/16 the total budget for Medsafe is \$10.1 million, with a personnel complement of 52 FTE staff. Industry meets approximately 90% of Medsafe's budget, with the balance met by the Crown.

Medicines Control

39. Medicines Control oversees the local distribution chain of medicines and controlled drugs within New Zealand. Its activities include the issuing of licences and authorities and monitoring compliance with legislation. It is the designated licensing authority for all licences issued under the Medicines Act 1981 and Medicines Regulations 1984 (except licenses to manufacture and pack medicines). This includes licences to operate a pharmacy. In addition, Medicines Control has responsibilities under the Misuse of Drugs Act 1977 and Misuse of Drugs Regulations 1977.
40. In 2015/16 the total budget for Medicines Control is \$1.7 million, with a personnel complement of 14 FTE staff. Industry meets close to 100% of Medicine Control's budget.

Problem definition

Reason for regulation

41. Therapeutic products provide a range of well-documented benefits, but also present a range of risks. To promote public health and welfare outcomes, the government needs to ensure therapeutic products are available and accessible, and the risks are sufficiently known and justified in relation to the benefits.
42. There is broad consensus and acceptance in New Zealand and internationally that the regulation of therapeutic products remains relevant and essential. In brief, this is because:
 - The market on its own does not always adequately manage risk, and users cannot judge risks without substantial further information.
 - The consequences of unsafe products can be devastating.
 - Some issues (eg, major ethical issues arising from new technology applications) require government consideration.
 - Proportionate regulation can be cost-effective (ie, identifying and managing risk without undue compliance costs).

43. The regulation of therapeutic products involves a range of activities designed to ensure consumers, health practitioners, and businesses have access to (and can confidently use) effective and safe therapeutic products. These activities include assessing whether such products can be marketed in New Zealand, and if so, on what basis.
44. The government may be seen to have a closer interest in therapeutic goods than it does for ordinary goods of commerce:
 - it wants to encourage their availability in New Zealand (it is less neutral than it is in relation to many other goods)
 - it is more concerned about their risks than it is for most goods.
45. In particular, the government is concerned to maximise the benefits of such goods relative to the risks as part of its strategic goal of promoting health outcomes. Thus, regulation of therapeutic products is beneficial for the users of those products (access to health benefits) and for the suppliers of those products (commercial benefits). Yet therapeutic products can present serious risks of harm, especially if used inappropriately.
46. All developed economies, including New Zealand, recognise that assuring the safety of therapeutic products is fundamental to the delivery of high quality health and disability support services (public and private) and to avoid diversion into illicit uses. United Nations member countries take their lead from the World Health Organization's framework, and member countries regulate to control the manufacturing chain, distribution chain, promotion/advertising, pre-market evaluation and approval, post-market surveillance and access. The challenge is to ensure that regulation is fit-for purpose and cost-effective.

Current problems

47. A range of specific and general concerns have been raised about the Medicines Act since at least the mid-1990s. These centre on issues of clarity, coverage, flexibility, and cost.
 - The legislation is dated and inflexible. This reflects the policy and legislative drafting of the 1970s when the types of products requiring regulation were simpler, industry was often locally-based, and it was usual to set out detailed processes in primary legislation. This prevents more efficient regulatory approaches.
 - There are significant gaps in coverage. The range and complexity of products is growing, but the legislation is unable to accommodate them.
 - The Act places many core regulatory powers with the Minister of Health (eg, approval of new medicines) which are exercised under delegation. This model does not enable a separation of responsibilities for accountability purposes, and also makes the Minister responsible for technical decisions that have significant impacts on private interests.
48. Specific examples of problems include:
 - The Act does not allow for unilateral recognition of decisions by other regulators in respect of new medicines applications. Medsafe does operate an abbreviated process for new prescription medicines that have already been approved by one or more trusted regulators. In this case, a reduced fee applies, but this stops short of the potential benefits possible if the Act were more flexible.

- There is no coverage of cell and tissue therapies that are not considered medicines, and medical devices are not fully regulated, which means risks are not being managed actively.
 - Under the Human Tissues Act 2008, cell and tissue therapies cannot be traded without a Ministerial approval and at present there is no mechanism to obtain an approval making it difficult for legitimate products to come to market.
 - New Zealand is moving to centralised procurement of medical devices under PHARMAC, but the issue of the safety and risks of such products and how they should be managed is unclear.
49. Over the course of the last 20 years, a number of partial solutions including amendments to the Medicines Act and other new legislation have attempted to manage some of these concerns, but the fundamental problems with the regulatory regime that were identified many years ago have still not been addressed. The Act does not fully enable flexibility to fully adopt a modern regulatory scheme (eg, fee setting provisions; changed medicine notifications).

Alternative approach to problem previously considered

50. Over the last two decades, a joint regulatory approach has been explored with Australia in the form of the Australia New Zealand Therapeutic Products Agency (ANZTPA). This initiative began in the late 1990s and in 2003 the Australian and New Zealand Governments signed a Treaty for the establishment of a joint regulatory scheme and agency.
51. In effect the arrangement would have created a single market for therapeutic products across the two countries. The agency was to have been jointly and equally governed by both countries. The objectives were to address capacity issues in New Zealand (which were also anticipated in Australia in the future), lower costs to industry and governments, and position both countries well on the international stage. It would also have resolved the issues with the Medicines Act and the temporary exemption for therapeutic products under the Trans-Tasman Mutual Recognition Arrangement (which has now become a permanent exemption).
52. Until 2007 a large amount of work was done to bring the ANZTPA initiative to fruition. Legislation was introduced in New Zealand (and released as an exposure draft in Australia) but could not be passed as there was a lack of political support. The lack of support largely reflected concern about the inclusion of complementary medicines within the scope of the joint scheme. (New Zealand has now developed a separate regime for these products in the form of the Natural Health Products Bill.) As a consequence the two governments put ANZTPA on hold. In 2011 the Prime Ministers of New Zealand and Australia recommitted to ANZTPA and work recommenced.
53. A few years later, however, following a comprehensive review of progress and assessment of the costs and benefits to each country of proceeding, the Prime Ministers of Australia and New Zealand announced in November 2014 to cease efforts on this major project.

Government expectations

54. On 17 November 2014 Cabinet noted that the Minister of Health would signal the next steps to upgrade New Zealand's regulation of therapeutic products. This involves "a new and comprehensive regulatory regime ... which will replace the Medicines Act 1981 and its Regulations" [CAB Min (14) 36/22 refers].

55. A Therapeutic Products Bill to repeal and replace the Medicines Act 1981 has priority 6 on the Government's Legislation Programme [CAB Min (15) 5/7 refers].

Objectives

56. The new regime is being designed to meet the needs of the health and disability support sector now and into the future, and to give effect to Government's expectations for regulatory systems (including international alignment or conformity as appropriate).
57. More specifically, the regime is being designed to:
- meet expectations of risk management and assurance of safety
 - result in efficient and cost effective regulation
 - be flexible, durable, up-to-date, and easy to use
 - ensure high-quality, robust and accountable decision-making
 - foster sustainable regulatory capacity
 - support New Zealand trade and economic objectives
 - be trusted and respected
 - support consumer access and individual responsibility for care.
58. These objectives will require:
- an enabling legislative framework that can be readily maintained and updated
 - regulatory requirements that are consistent with cost-effective risk management and accepted international practice
 - a regulator with capacity, independence, flexibility, and accountability.

Options and impact analysis

59. The proposal is to replace the Medicines Act 1981 and the Medicines Regulations 1984 with new legislation, regulations and subordinate instruments.
60. In approaching the analysis of options, the following key factors were considered:
- It is a major and wide-ranging proposal with a significant number of elements. The analysis needs to cover high-level strategic issues, as well as major design and policy issues. The focus must therefore be on the most significant areas - those that are expected to involve the most material changes or have the most significant impacts.
 - Some issues will not be presented for decision until 2016, including the institutional form of the regulator and pharmacy licensing and control (including ownership restrictions). For completeness, however, such issues and options are sketched in a preliminary way, and in order to provide assurance that their later consideration presents no impediment to other matters being decided now.
 - In some areas, detailed information on specific impacts is unknown (eg, in relation to products that would be brought within the scope of the regime). Currently, knowledge of cell and tissue therapies and medical devices is limited. The obligation to assure safety falls implicitly and variously on District Health Boards (DHBs), PHARMAC, and clinicians but without a clear framework of responsibility. Bringing them within scope provides the opportunity for more informed risk management.

61. The issues addressed in this RIS for option identification and impact analysis represent the high-level questions and potential building blocks for the proposed regime. They are as follows:

Strategic / framework

- Issue 1: Merits of therapeutic product regulation
- Issue 2: Stand-alone versus joint regulation
- Issue 3: Purpose and scope

Administrative / institutional

- Issue 4: Powers
- Issue 5: Institutional form of regulator
- Issue 6: Accountability
- Issue 7: Cost recovery

Pre-market

- Issue 8: Product approvals
- Issue 9: Controlled activities
- Issue 10: Pharmacy licensing and control
- Issue 11: Exemption issues

Post-market

- Issue 12: Monitoring
- Issue 13: Enforcement

62. Decisions on these issues – apart from institutional form of the regulator, and pharmacy licensing and control - are sought in the associated Cabinet papers. The following issues will be addressed substantively in advice in early 2016:

- Proposed institutional form of the regulator
- Regulatory approach to cell and tissue therapies
- Clinical trial arrangements
- Detail of the proposed offence and penalty framework
- Pharmacy ownership
- Import and export (including parallel importation)
- Prescribing and dispensing
- Interface with the Hazardous Substances and New Organisms Act
- Privileged statements (statements about therapeutic products during periods of data protection)
- Further advice on legislative placement of provisions if required.

Part A: Issues and options

Strategic / framework

Issue 1: Merits of therapeutic product regulation

63. Therapeutic products provide a range of well-documented benefits while also presenting a range of risks. The overall challenge is to ensure access to safe and effective products. This requires the risks to be sufficiently known, managed and justified in relation to the benefits.

64. Regulation of therapeutic products seeks to achieve this objective: it provides a means of assessing risk in relation to the claimed benefits (often requiring significant scientific information and clinical testing), controlling the introduction of products to the market, and monitoring use.
65. A key issue is whether regulation is necessary for this purpose.
66. New Zealand currently regulates a range of therapeutic products. The origins of the current approach to regulation are found in the 1950s and 1960s. Controls were first put in place around access to medicines (pharmacy restrictions). Then, with the development of the pharmaceutical industry – and the significant innovation and introduction of new medicines onto the world market – New Zealand, following the lead of other major countries, put in place a process to approve new medicines.
67. In particular, the devastating experience of the adverse effects of thalidomide highlighted the significant risks associated with medicines.
68. The current regulation of therapeutic products is governed by the Medicines Act 1981 and the Medicines Regulations 1984. The corresponding regulatory agencies are Medsafe and Medicines Control, business units within the Ministry of Health. Regulation currently focuses on medicines (reasonably fully) and medical devices (partially).
69. The management of risk in the public and private sectors has changed significantly since the 1960s. In brief, there is more awareness of risk, there is more concern about risk management, and there are stronger sanctions when products cause harm.
70. It would be hard to quantify or assess in precise or objective terms the net value added of therapeutic regulation in New Zealand. Nonetheless, the following considerations support the case for regulation.
 - There are inherent risks with therapeutic products given their nature and the ways in which they are used.
 - Major established companies producing such products do not always get it right despite the financial and reputational consequences they face when they get it wrong.
 - The catastrophic consequences of just one problem in one product (eg, if it gives rise to fatalities, deformities) suggest that regulation may be worthwhile even where it rarely finds problems with products, or rarely assesses them to be too risky to enter the market.
 - All developed countries regulate therapeutic products, and there is a broad similarity of approach across major jurisdictions, especially given the extent of global trade and the need for co-operation (eg, in relation to counterfeit product).
 - The experience with the regulation of therapeutic products in New Zealand does not suggest that regulation is unnecessary or is seen to be unnecessary. For example:
 - A number of products each year that have been approved in overseas markets are not approved in New Zealand (about 2%). This includes situations where Medsafe has identified issues and concerns unique to New Zealand.
 - There is no groundswell for the de-regulation of the therapeutic product industry.

- Regulation is consistent with the approach taken in other sectors where health and safety issues are at stake (eg, the Health and Safety Reform Bill has passed, with the Health and Safety at Work Act to come into force on 4 April 2016).
71. Cabinet has noted that the Minister of Health would signal the next steps to upgrade New Zealand’s regulation of therapeutic products (CAB Min (14) 36/22 of 17 November 2014).
 72. To this end, the following statement has been made on the Ministry of Health’s website: “The New Zealand Government is working on a new and comprehensive regulatory regime to regulate therapeutic products in New Zealand, which will replace the Medicines Act 1981 and its Regulations.”
 73. The above points indicate a high-level consensus and acceptance that the regulation of therapeutic products in some form is worthwhile.
 74. The goal then is to ensure that the regulatory regime is fit-for purpose and adds maximum value at least cost.
 75. Therapeutic product regulation must also be considered alongside other health and related regulation (eg, Health Practitioner Competence and Assurance Act 2003, Food Act 2014, Natural Health Products Bill). There are important connections between them, and mutual inter-dependencies in promoting wider health outcomes (eg, prescribing and dispensing in particular).

Merits of regulation: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	The status quo involves the continued regulation of only some therapeutic products (essentially medicines) on a basis where the regulator has little flexibility.	<ul style="list-style-type: none"> • Over time, under the status quo, there will be increased difficulty providing a satisfactory level of regulatory information and oversight. • In particular, as new and more complex products emerge, the regulator may not have the ability to assess and respond to risk (gaps in coverage, inadequate powers to act). • Regulator does not have the ability to optimise its resources across its various areas of responsibility (eg, the primary legislation may need to be more enabling and less prescriptive).
Option 1 - Enhanced status quo (preferred)	<p>This option involves the continued regulation of therapeutic products but on a more comprehensive basis.</p> <p>In particular, this would entail developing and implementing a clearer and more principled framework, more complete product coverage, and more flexible (and risk-appropriate) approval pathways alongside other regulatory improvements.</p>	<p>This option addresses the deficiencies noted under the status quo. For example:</p> <ul style="list-style-type: none"> • The regulator will be able to provide a more satisfactory level of regulatory information and oversight. • As new and more complex products emerge, the regulator will have the flexibility to assess and respond to risk (wider coverage, adequate powers to act).

Merits of regulation: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
		<ul style="list-style-type: none"> • The regulator will be able to recognise the decisions of trusted overseas regulators in relation to new medicines applications (with benefits in terms of timeliness of access, and lower compliance costs). • Regulator is able to optimise resources across areas of responsibility (eg, the primary legislation to be more enabling and less prescriptive).
Option 2 - No specific therapeutic product regulation	This option would allow therapeutic products to be marketed on more or less the same basis as general consumer products.	<ul style="list-style-type: none"> • This option represents a significant and radical departure from current New Zealand and international practice (which explicitly does not recognise therapeutic products as ordinary goods of commerce). • New Zealand would effectively not have a therapeutic products regulator. • This option is likely to have the most significant impacts (eg, cost reduction for industry, increased access to therapeutic products (mostly safe, but some potentially unsafe), increased risk of adverse reactions or events). • It would not be consistent with New Zealand's international obligations to play its part in promoting cross-border safety.
Option 3 - Minimalist regulation	<p>A range of minimalist approaches are possible.</p> <p>One example would be for the regulator to focus on market monitoring and enforcement only (ie, no explicit pre-market approval process).</p> <p>Under this option, the regulator would probably accept the decisions of other regulators without an assessment. It would only monitor and take appropriate action in response to any concerns about products entering or in use in the New Zealand market.</p>	<ul style="list-style-type: none"> • This option represents a less extreme version of option 2 above, with corresponding impacts. • In particular, while cost and access objectives may be met, risk management objectives and public expectations of safety are less likely to be consistently met. On occasion post-market action will be too late to prevent serious adverse outcomes. • New Zealand would not have a credible regulator that could participate in the international arena. Nor would it enjoy the benefits of WHO co-operation (eg, information sharing). • As above, this would not be consistent with New Zealand's international obligations to play its part in promoting cross-border safety.

76. The issues discussed below address whether the current approach to therapeutic product regulation, and the current settings, are fit for purpose or whether there are options for improving the operation and effectiveness of the regime.

Issue 2: Stand-alone versus joint regulation

77. The regulation of therapeutic products may be undertaken by New Zealand:

- on a stand-alone basis (ie, as a distinct, domestic New Zealand regime), or
- on a joint basis with another country or countries.

78. New Zealand has always operated a stand-alone regulatory regime for therapeutic products (as indeed it has for other areas subject to regulation).

79. During the last decade, however, the joint regulatory option has been considered actively as part of the Australia New Zealand Joint Therapeutics Agency (ANZTPA) project. It was progressed almost to the point of implementation.

80. In addition to addressing the problems identified, a joint approach was perceived to have the potential to deliver other benefits:

- regulatory capacity – as a small country there would be benefits for New Zealand, in terms of domestic regulation as well as international co-operation
- reduced costs for industry - through common definitions, classifications and processes for gaining approval and marketing products in either country (a single market)
- greater regional alignment and co-operation - with potential benefits for wider economic and trade development.

81. A review was undertaken of the merits of the joint approach in May 2014 by the respective Departments of Prime Minister and Cabinet. As a result of that review, Cabinet noted that the Prime Ministers of Australia and New Zealand agreed that the project to establish ANZTPA should cease (CAB Min (14) 36/22 of 17 November 2014).

82. At that meeting, Cabinet also noted that the Australian and New Zealand Health Ministers agreed that each country's therapeutic regulators would continue to co-operate where there are mutual benefits to be gained.

83. It is difficult to identify an alternative joint regulatory partner other than Australia with whom a joint approach would be a feasible or practical option for New Zealand. The ANZTPA option was able to be explored because Australia and New Zealand have close cultural and economic ties, and because of the Trans-Tasman Mutual Recognition Agreement.

84. A further option might be a combined approach with PHARMAC in order to leverage capacity. This might be an issue to consider in further reporting on institutional form. A particular issue would be the merits of having agencies with different objectives (or potentially conflicting objectives) under the one administrative umbrella.

Stand-alone versus joint regulation: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo (preferred)	Under the status quo, New Zealand would continue to develop its own domestic regulatory regime for therapeutic products.	<ul style="list-style-type: none"> • Can co-operate bilaterally and internationally at an operational level. • Provides maximum control of policy direction and settings to meet national interests. • Less aligned with Australia relative to joint approach. • Less regulatory capacity / economies at least in medium term.
Option 1 - Joint approach with Australia	Under this option, an arrangement along the lines of ANZTPA would be implemented involving a joint regulatory scheme.	<ul style="list-style-type: none"> • Capacity and cost benefits if successful. • Risks of lock-in or loss of leverage and higher costs over time. • This option has been actively and extensively explored since 1999. • Currently there is no mutual agreement on the merits of this approach.
Option 2 – Joint approach with another country	Under this option, a joint regulatory arrangement (analogous to ANZTPA) would be implemented with a country other than Australia.	<ul style="list-style-type: none"> • Apart from Australia, with whom New Zealand has close cultural and economic ties, it is difficult to identify an alternative joint regulatory partner with whom a joint approach would be a feasible or practical option. • New Zealand would need to find a willing and appropriate partner. • Thus there may be significant opportunity costs associated with this option and wasted resources.

Issue 3: Purpose and scope

85. The new Act will need to have a defined purpose and a set of principles to guide regulatory practice. This will influence the scope of the regulation, but different approaches are possible. Options are considered for scope.

Purpose

86. Regulatory and Legislation Advisory Committee guidance suggest effective modern statutes should have a clear purpose and not be cluttered with unnecessary detail.

87. The current Medicines Act does not contain a purpose statement or a coherent set of principles for guiding or circumscribing regulatory practice. Instead, it is very rule driven and prescriptive; and does not readily accommodate changes. This means

regulation cannot respond quickly or efficiently to changes in product technologies and markets, with adverse implications for effective and efficient risk management.

88. A purpose statement for the new Act might be directed at ensuring acceptable safety, quality and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare. The purpose might be further defined through principles which give effect to the overall purpose and set the parameters for the design and administration of the regulatory regime.
89. A range of principles are possible, drawing on concepts of: benefits outweighing risks, risk proportionality, impartiality and independence, market responsibility, access of information to consumers, international cooperation, compliance cost minimisation and supporting innovation and competition. In addition, and to the extent possible, it would be useful in shaping a coherent set of principles to:
- keep the principles focused (a long list of principles may be difficult to operationalise (the Health and Safety at Work Bill provides a good example of how to avoid this problem, focusing on health and safety outcomes, risks, costs, and reasonableness)
 - keep the principles high-level (ie, principles are not design features) in order to empower and enable the regulator to make trade-offs
 - ensure a level of compatibility with approaches to risk in other modern New Zealand statutes (in accordance with the Government's expectations)
 - take into account health consumer risk preferences where possible for defined patient groups or sub-groups (eg, those for whom particular products are specifically targeted and who may be much less risk averse than average)
 - have regard to opportunity costs - the implications of opportunities that must be forgone (eg, by the regulator, product applicants, consumers) as a result of particular regulatory actions.

Scope

90. Different approaches to scope are possible. For example:
- scope should be broad, covering all products and enabling all risks to be addressed, or
 - scope should be limited to the most risky products - those whose perceived risk exceeds some threshold level.
91. The current Act adopts the second approach. A limited number of therapeutic products are defined under the Act, essentially:
- medicines, new medicines, prescription medicines, pharmacy-only medicines, and restricted medicines under section 3 of the Act
 - medical devices under section 3A (subject to minimal controls only).
92. There is a concern that the current scope is too limited in that some therapeutic products (such as medical devices, and cell and tissue therapies) should be subject to regulation or more regulation (given their risk profiles). The current scope reflects the state of therapeutic regulation in the 1970s, but is now outdated.
93. An alternative approach is for the primary legislation to make clear that:

- all products and activities having a therapeutic purpose are subject to regulation
- the particular regulatory requirements will be risk-appropriate.

94. What is risk-appropriate will be determined by a balance of requirements that are:

- set out in primary legislation and in regulations where Ministerial oversight remains important
- determined by the regulator where decisions can appropriately be taken at that level.

95. The implications of this approach for product categories are:

- Medicines would continue to be regulated comprehensively, with additional approval methods able to be used (eg, unilateral recognition).
- Medical devices would be subject to risk-proportionate regulation (pre- and post-market), with the requirements calibrated to risk, involving a low-impact process (eg, self-certification) through to requiring conformity assessment against defined requirements.
- Some areas would become subject to regulation, such as cell and tissue therapies (CTT), which are currently not regulated unless they meet the definition of a medicine.
- Xenotransplantation, use of the living biological material of an animal in a human, is currently only regulated to the clinical trial stage under Part 7A of the Act (which expires on 30 September 2016). The intention is that xenotransplantation would be regulated as part of CTT on a risk-appropriate basis.
- Entirely new products, including hybrids, which are invented, developed and come onto the market, currently unforeseen, would be catered for – they would be subject to regulation in the same principled way as the products and activities above (ie, where they have a therapeutic purpose, and according to their risk) without any need to change the Act.

Scope: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	<p>The scope of therapeutic product regulation would remain limited.</p> <p>The focus would be on medicines (reasonably fully regulated at present) and medical devices (partially regulated at present).</p>	<ul style="list-style-type: none"> • Some potentially risky products are not covered (cell and tissue therapies, and medical devices). • Some products are not covered sufficiently for risk management purposes (medical devices).
Option 1 – Expanded scope	The scope of the regime would be expanded to include one or more defined products (eg, cell and tissue therapy). Some products, however, would remain outside of scope.	<ul style="list-style-type: none"> • Increase in compliance costs for industry whose products are brought within (or more within) the scope of regulation.

Scope: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
		<ul style="list-style-type: none"> • Benefits for risk detection and risk management with associated health and safety benefits. • A very-low risk product might be subject to very few or no requirements, whereas a high-risk product might be subject to more significant information and other requirements commensurate with its risk. • Excluding some products from the scope of regulation is itself risky (products seen as low-risk can turn out to be high risk). • In a complex and evolving market driven by technology, the nature and risk of products can change quickly (making fixed boundaries difficult to manage in practice).
Option 2 – Comprehensive scope (preferred)	The scope of the regime would be expanded to include all therapeutic products or all products having a therapeutic purpose.	<ul style="list-style-type: none"> • The impacts will be similar to those for Option 1 above. • The advantage of having all products within scope is that it requires the regulator to align the regulatory approach with the assessed (or pre-assessed) risk, and no products fall between the cracks (ie, future-proofed for products not yet invented).

Administrative / institutional

Issue 4: Powers

96. Decision rights for various regulatory requirements should be at the appropriate level with the supporting accountability between each.
97. This is an issue on which the Parliamentary Counsel Office and the Legislative Design Advisory Committee can provide expertise, but it is not solely a legislative design issue; it also needs to be informed by judgment on the policy/regulatory requirements.
98. The following structure illustrates a typical hierarchy of relationships:

Decision level	Legislative/administrative vehicle
Parliament	Act of Parliament (primary legislation)
Minister(s)	Regulations (secondary)
Government agency	Notices (tertiary instrument)
Delegated within agency	Administrative Practice Guidelines (also tertiary instruments)

99. In general:
- Significant issues (ie, major policy issues) should be decided by Parliament or Ministers.
 - Less significant issues (ie, issues which are operational or administrative in nature, and which are necessary to give effect to statutory and regulatory policy) should be decided by agencies or delegated within agencies.
 - Judgment is required in establishing the right balance between the different levels of decision rights.
 - The objective, however, is to ensure as far as possible that statutes and regulations are lean and do not contain unnecessary detail.
100. This requires a consideration of all the relevant powers in relation to the preferred policy settings for the regime.
101. The overriding design objectives of the new therapeutic products regulatory regime is to ensure that:
- the primary legislation has a clear purpose, provides robust principles to guide regulatory practice, is comprehensive, and enabling
 - the regulator has a clear mandate, powers, and accountability to achieve cost effective outcomes.
102. These objectives argue for:
- Ministers having the responsibility for setting the outcomes to be delivered and empowering the regulator to deliver them
 - the regulator being accountable to Ministers for the results.
103. This approach is consistent with the findings of the Productivity Commission which support new regimes being developed with regulatory detail contained in second tier and subordinate instruments, and the regulator empowered to keep the instruments up to date.
104. On this basis, and given the preferred options outlined in this document, many of the current powers of the Minister should be conferred by statute on the regulator.

Powers: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	<p>Under the status quo approach, there would be no change in the balance of powers held by the Minister versus the regulator in relation to regulatory decision making.</p> <p>Currently there is a “mixed model” (the Act currently splits powers between the Minister and the Director-General).</p>	<ul style="list-style-type: none"> • Because significant power is held formally by the Minister, this impacts on the costs, timeliness, and perceived independence of the regulatory decision process.

Powers: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Option 1 Enhanced status quo	<p>There would be some (limited) devolution of powers to the regulator.</p> <p>This might include a range of regulatory approval and licensing decision powers.</p>	<ul style="list-style-type: none"> The impacts under this approach would be similar to (and smaller than) those listed under Option 2 below.
Option 2 Significant devolution (preferred)	<p>There would be more significant devolution of powers to the regulator.</p> <p>The Minister would retain powers in relation to major policy issues, and some committee appointments.</p> <p>The Minister should also retain power to decide issues where major ethical or public interest issues are involved.</p>	<ul style="list-style-type: none"> Where the regulator has a clear mandate, powers, and accountability a number of beneficial impacts are possible relative to the status quo. The Minister is more able to focus on issues relating to the accountability of the regulator, and on issues of major public interest. More timely decision making. Less costly decision making in some cases. Reduced risk of perceived lack of independence. Greater conformity with public sector legislative and regulatory standards / requirements (with cost, accountability, transparency benefits). Ability to keep technical detail current.

Issue 5: Institutional form of regulator

105. The preferred institutional form of the regulator will be addressed in advice to be included in the Cabinet paper in early 2016. The discussion and identification of options below is for illustrative purposes.

106. The appropriate institutional form for a regulator will vary with the nature of its role and responsibilities. Decision making is currently delegated, although some powers remain with the Minister. The preferred options for the new therapeutic products regulatory regime would involve significant devolution of powers to the regulator. The main change is the ability of the regulator to design subordinate instruments. Given the role the regulator is expected to perform, a key concern is to ensure that the regulator has sufficient:

- independence (from the party or parties to whom it is accountable)
- capacity and credibility (technical expertise, appropriate culture)
- cost-effectiveness and accountability.

107. Such factors alone, however, do not point conclusively to a particular preferred institutional form. Other factors to consider are:
- the costs associated with setting up a new entity
 - continuity of regulatory performance and change management issues (the timing of any institutional change, alongside the change in powers and policy settings)
 - whether the merits of institutional form are likely to be influenced by experience operating the new regulatory regime (ie, where the status quo is “a safe pair of hands” meantime).

Institutional form of regulator: example of options	
<i>Options</i>	<i>Description</i>
The development of options and any proposals for change will be part of advice in early 2016. The options set out below illustrate some of the alternatives available.	
Status quo	Under the status quo, the regulator (Medsafe and Medicines Control) would continue as a separate business unit within the Ministry of Health.
Option 1 – Departmental agency	The business units would be established as a Departmental Agency. Powers would be vested directly in the CE of the agency, or in the Director-General of Health and delegated.
Option 2 – Crown entity	The business units would be established as a Crown entity (eg, Crown agent). The regulatory powers would be vested directly in the Board.

Issue 6: Accountability

108. Accountability includes:
- accountability for overall organisation performance which will significantly be shaped by the requirements which attach to organisational form, although these may be supplemented or modified as necessary (not addressed further here)
 - accountability for the design of requirements in regulator-made instruments
 - accountability for all regulatory decisions, including those on product approvals, licensing (and licensing conditions), and enforcement action.
109. The latter involves review and appeal provisions which are an essential part of the legislative and institutional design for a regulatory regime.
110. The objective is to ensure that the decision-making process and the decisions of the regulator are subject to appropriate quality control and review processes.
111. Such processes include:
- General and prescribed reviews. This comprises all quality assurance processes, and all other processes that precede a final, substantive decision being made by (or under the authority of) the regulator. This could include reference to

committees established, or required to be established, under primary legislation (eg, equivalent of the current Medicines Classification Committee).

- Regulations Review Committee. This would include legislative instruments made by the regulator being disallowable instruments subject to review by the Regulations Review Committee.
- Judicial review. This process exists as a common law right whereby the High Court reviews a decision (or proposed decision, or refusal to exercise a power of decision) to determine whether it is unauthorised or invalid.
- Appeal. An appeal exists when a statute provides for a decision to be appealed to a court. In an appeal the focus is on the merits of the decision being appealed.

112. Currently:

- the proposed decisions of the regulator (when close-call decisions are put up for review) are generally supported by expert review
- the final decisions of the regulator are very rarely appealed.

113. If the current allocation of powers remained the same, the review and appeal provisions need no fundamental change.

114. If, however, the allocation of powers were substantially changed, as is being proposed, review and appeal provisions would need to be updated accordingly. In particular:

- the regulator would take direct responsibility for all internal review
- a new specialist appeals body would sit between the regulator and the courts
- the role of the High Court (and potentially the Court of Appeal) could continue - modified only as necessary to reflect that the Minister would not be making regulatory decisions, and the decisions of the regulator would first be considered by the specialist appeals body).

Accountability: Establishment of specialist appeal body		
<p>If powers are substantially delegated to the regulator, the review and appeal structure would need to be modified.</p> <p>In particular, a revised specialist appeal body would be required. A range of design issues arise, with options for each.</p> <p>Note: the status quo would no longer be viable.</p> <p>Further advice from the Ministry of Justice will be obtained.</p>		
<i>Design issue</i>	<i>Alternative approaches</i>	<i>Issues to be considered / reason for preferred approach</i>
Administering agency	Ministry of Health, or Ministry of Justice	The Ministry of Justice has greater expertise in the management of such bodies, and may provide for greater independence. Practical issues of cost and capacity, however, would also need to be considered.

Accountability: Establishment of specialist appeal body		
Appointment of members	by Minister of Health, or by other person or body	Either approach may be appropriate. Further advice will be obtained.
Membership numbers and skills	Predefined, or Flexible	Retaining flexibility (within some bounds) would provide for the necessary capability and capacity to be provided in the particular circumstances and for different products.
Type of appeal	by way of re-hearing, or by other type of hearing	Appeal by way of re-hearing may provide for the most efficient process: previous evidence and new evidence can be brought to bear.
Who may appeal	Only applicants, or Those having an interest	Allowing appeals from those who can establish an interest might be preferred in principle. However, practical considerations might lead to "applicants only". This may vary depending on the nature of the decision (eg, product approvals versus licensing decisions).
Charging	Charging applies, or No charging	Charging may deter genuine cases from being heard. No charging may encourage cases without sufficient merits. A <i>de minimis</i> or moderate charge might be indicated.
Complaints	Have a complaints mechanism, or No mechanism.	It may be more efficient to have a complaints mechanism operated by the regulator. This would ensure that only the most significant issues are escalated to the appeal body.

Issue 7: Cost recovery

115. Cost-recovery is guided by *Charging fees for public sector goods and services* (Controller and Auditor-General, 2008) and *Guidelines for Setting Charges in the Public Sector* (The Treasury, 2002).
116. The extent to which the cost of therapeutic product regulation is borne by industry or the Crown should depend on the type of regulatory work involved. In principle, where the regulatory activities represent:
- public goods – where the benefits can be shared by all (non-excludable, non-rival) - the Crown should fund the activity
 - private goods – where the benefits of the activity can be directly attributed (eg, a company seeking approval to market a product, or authorisation to undertake an activity) – industry should pay through a fee for service

- industry or club goods – which have some public good element but also a defined group of beneficiaries or risk-makers – industry should pay through an industry levy.
117. The activities of therapeutic product regulation (ie, activities undertaken by Medsafe and Medicines Control) for which costs must be funded by the Crown or by cost-recovery from industry, are:
- policy related activity (and possibly general enforcement activity) – public goods
 - approvals, licensing, and specifically related activities – private goods
 - standards and industry-wide requirements, general compliance, audit surveillance and monitoring – industry good.
118. At present:
- regulatory activities by Medsafe are largely cost-recovered from industry (ie, just over 90% of costs are recovered), although the split appears to reflect practice as it has evolved rather than a precise public/private/industry split, and activities by Medicines Control are fully cost-recovered
 - there is no industry levy.
119. In practice, industry and the Crown are the only realistic funding alternatives. It is not practicable, in the foreseeable future, for reasons of administrative cost and complexity, to require consumers to directly fund therapeutic product regulation.
120. Key points to be considered going forward include:
- the regulator's expected total costs, and breakdown of costs across various activity types, under the new regime
 - the Government's stance on industry funding versus Crown funding for enforcement activity (and if Crown funding, the level it wishes to fund).
121. These matters will be influenced by decisions on the various policy settings for the new regime to be considered in further reporting in early 2016.
122. In general, however, the new Act should provide for the necessary fees and charges to be set. Options include:
- The approach adopted for the Natural Health Products Bill, and the Food Act 2014, whereby the regulator is empowered to set fees and charges (eg, by notice in the Gazette).
 - Fees set in Regulations. Given the magnitude of some fees, and that fees will be influenced by how efficient the regulator is in managing costs within budget (for which the regulator is accountable to the Minister for its performance), this approach should be preferred.

Cost recovery: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
<p>The development of options and any proposals for change will affect the financial implications and will be part of advice in early 2016. The options set out below illustrate alternative approaches to cost-recovery (ie, assuming the new Act permits fees and levies to be set by Regulations).</p>		
<p>Status quo – Mixed model (currently 90% cost-recovery from industry)</p>	<p>Under the status quo, the regulator would continue to recover the bulk of its costs from industry, and be funded by the Crown for the balance.</p> <p>There would be no industry levy.</p>	<ul style="list-style-type: none"> • Costs would continue to be recovered on the basis of a 90/10 split as between industry and the Crown. • This split would not reflect a precise, principled assessment of the appropriate share based on the types of regulatory goods involved (public/private/industry). • A version of the mixed model may be the most practicable in the medium term.
<p>Option 1 – Recover all costs from industry except defined public good activities</p>	<p>Fees for private goods; levy for club goods.</p> <p>Public good activities might be defined as certain kinds of policy-related activities and/or enforcement activities.</p> <p>Government would determine level of public good activity from time to time.</p> <p>Power to set industry fees and levy in Regulations.</p>	<ul style="list-style-type: none"> • It is not clear how the share of costs as between industry and the Crown would alter without further investigation. • The share of costs borne by the Crown would increase (decrease) if public good activities were assessed as representing more than (less than) 10% of the regulator's costs. • Even with full investigation, however, the distinction between different types of goods for cost-recovery purposes can be difficult to draw. • Strategic considerations may also be brought to bear. For example, a New Zealand approval might be extremely valuable to an applicant wishing to enter another more lucrative market (eg, which uses unilateral recognition).
<p>Option 2 – Full cost-recovery from industry</p>	<p>Under this option, industry would meet the full costs of the regulator.</p> <p>This would likely include cost-recovery through a combination of fees and levies.</p> <p>This option reflects the judgement that under the regulatory regime all regulatory activities are either private goods or industry/club goods.</p>	<ul style="list-style-type: none"> • This would increase costs to industry and reduce costs to the Crown. • There are issues related to new or low-volume, high-cost areas (eg, cell and tissue therapy) where cost-recovery may simply be unaffordable for industry (particularly if development costs of the approval process also need to be recovered). • Unapproved product in the market also raise issues where monitoring and enforcement by the regulator is important but where it may be difficult to sheet home the regulatory costs to an industry, supplier, or responsible person.

Pre-market

Issue 8: Product approvals

123. Product approval is a key regulatory control point. It is the process for considering whether, and subject to what limits or conditions, therapeutic products may be marketed in New Zealand.
124. Under the preferred approach:
 - All therapeutic products (as defined) will need to be approved by the regulator in order to be marketed.
 - The process for approval will be risk-appropriate to the products in question, meaning the higher the level of risk the greater will be the regulatory scrutiny and the information required.
 - The regulator will require the necessary flexibility (supported by accountability) in order to operate approval processes flexibly (in response to emerging new and hybrid products) and in accordance with the cost-effective management of overall risk.
125. The requirements will largely be determined by the type of product (medicine, medical device, cell and tissue therapy, combination etc). Within each category of product, the detailed technical requirements will be determined by the risks posed, consistent with international norms.
126. In practice, the use of product categories can be managed in a way that gives best effect to a risk-appropriate approach.
127. The regulatory regime needs to provide clarity, at the same time as being responsive and up-to-date. It will therefore be important for product categorisations and technical requirements to be expressed through an effective combination of primary, secondary and tertiary instruments.
128. For a new Therapeutic Products Act, changes in the following areas should be considered:

Responsibilities of the regulator

129. The regulator needs to have the necessary ability to:
 - determine the process for approval and the information requirements (including modifying technical standards and requirements as necessary)
 - determine the basis of the approval that is the most risk-appropriate and cost-effective in the circumstances of each case (eg, full assessment, partial assessment, unilateral recognition)
 - determine the conditions which may apply to, and the duration of, the approval
 - modify, suspend, or revoke an approval.

Responsible person

130. There are problems under the current regime in pinpointing a person or entity responsible when quality and safety issues need to be resolved quickly and effectively in relation to both product approvals and licences (including withdrawing a product from

market). There are a range of accountabilities, but, in respect of products, no person has overall accountability and a duty to:

- respond to queries and requests for information in relation to the approval, monitoring, and use of the product
- maintain distribution standards (including record keeping and product monitoring)
- ensure there is an effective system to take market action, including recall, and information being available about the distribution chain.

131. An option is for legislation to define the responsible person to make clear who is responsible for an individual product or licensed activity at any point in time. The legislation would also need to define Approval Holder and Licensee.

132. The Approval Holder or Licensee would need to ensure that the responsible person meets reasonable requirements. This would include demonstrating the necessary technical knowledge, or quick access to it, and meeting character requirements.

Classification

133. Classification is the process of specifying conditions on availability and particularly whether a product should only be available via a health practitioner.

134. Classification under the current Act applies to medicines only which, on approval, are classified as prescription, restricted (pharmacist-only), pharmacy-only, or general sale (these categories are also defined in the Act). It also involves an expert committee established under the Act.

135. In the future, classification may need to apply to other types of therapeutic product and this development should be enabled legislatively.

Product approvals: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	The approval process for therapeutic products would be set out in primary legislation.	<ul style="list-style-type: none"> • The limitations of this approach are that it will not enable the regulator to take a risk-appropriate approach, and will quickly become rigid and out of date. • The key consequence is limited effectiveness in managing costs and in promoting access.
<i>Areas of possible change</i>	<i>Alternative approaches (the second is preferred in each case)</i>	<i>Reason for preferred approach (most reasons relate in some way to the benefits of flexibility in managing risk)</i>
Approval process	Process pre-defined, or Regulatory flexibility to modify process if necessary	<ul style="list-style-type: none"> • Flexibility enables processes to be risk appropriate and cost appropriate.
Product categories / risk sub-categories	Set out in primary or secondary legislation, or	<ul style="list-style-type: none"> • Flexibility enables categories to be kept up to date, or kept up to date more efficiently (legislation – when it can be

Product approvals: options and impacts		
	Set out in a combination of primary, secondary, and tertiary instruments	changed - is costly to change), while ensuring appropriate accountability.
Basis of approval	Regulator must conduct its own technical assessment, or Mixed model – full assessment, partial assessment, unilateral recognition	<ul style="list-style-type: none"> Flexibility enables regulator to determine best approach based on all the circumstances (including capacity). Mixed model provides full spectrum of alternatives, with benefits for effective cost management.
Approval conditions	Conditions must conform with a pre-defined approach, or Conditions may be determined and imposed as the regulator sees fit	<ul style="list-style-type: none"> Flexibility enables the regulator to align the conditions with the particular circumstances and risk assessment for a particular product or activity. Less certainty for industry (in terms of type of conditions), but more certainty that risks will be managed proportionately (which is not without some benefit to industry).
Change in approval	Approvals must conform with a pre-defined approach, or Approval may be modified, suspended or revoked as the regulator sees fit	<ul style="list-style-type: none"> Flexibility enables the regulator to modify approach to better address or contain risks. Greater uncertainty for supplier, but changes would only be occasioned when risks justify change.
Responsible person	Status quo (mixed accountabilities), or Responsible person	<ul style="list-style-type: none"> More effective risk management is possible when a responsible person is designated as a condition of an approval or licence. Increases compliance costs potentially, but more costs are proportionate. Reduction in riskier products brought to market.
Classification categories	Status quo (categories defined in Act), or Categories defined through use of primary, secondary and tertiary instruments	<ul style="list-style-type: none"> Sole reliance on primary legislation risks rigidity as products evolve. Use of spectrum of instruments provides more flexibility to keep up to date at lower cost.

Issue 9: Controlled activities

136. In addition to the control of therapeutic products through the approval process discussed above, activities relating to therapeutic products are currently also subject to regulatory control in order to manage their risks.

137. Control is by means of licensing (subject to conditions) and general rules. In brief:

- Section 17 of the Act requires manufacturers, wholesalers, packers of medicine, and operators of pharmacies to be licensed. Part 3 of the Act sets out a range of requirements governing the application process and the granting of licences (eg, the need to be a fit and proper person, or an entity of good repute). The regulator may set and vary conditions on a licence, and suspend or revoke a licence.
- Other activities are not licensed but controlled by general rules. For example, anyone selling medicines is bound by the regulations on storage.

138. The control of therapeutic product related activities by licensing and general rules:

- is the norm internationally
- appears to be working effectively for the most part in New Zealand at present.

139. On this basis, whether under the present Act or a new Act, the use of licensing and general rules for regulating such activities should continue. There are, however, some areas where the merits of a change in approach should be considered:

- Entry powers to ensure compliance. Currently the regulator does not have the right kinds of powers of entry and inspection to assure compliance with a licence. It appears that this is an oversight which might be remedied in order to strengthen the effectiveness of monitoring and enforcement and the incentives for general compliance.
- Licence period. Currently licences must be issued for one year. A longer period (eg, three years), or allowing the regulator to specify a period (including a period shorter than one year), might be more compatible with minimising compliance costs for industry, and with targeting regulatory effort on licence-holders with a history of non-compliance. It is also practical for times when there is a change in business ownership.
- Powers to determine activities to be licensed, and general rules.

Controlled activities: options and impacts		
<i>Option</i>	<i>Description</i>	<i>Impacts</i>
Status quo	A range of activities related to therapeutic products would continue to be licensed and subject to general rules.	<ul style="list-style-type: none"> • The limitations of the status quo are the lack of powers and flexibility in a few areas. This detracts from the ability of the regulator to take a risk-appropriate approach. • The key consequence is limited effectiveness in managing risk and in promoting and ensuring compliance.
<i>Areas of possible change</i>	<i>Alternative approaches (the second preferred in each case)</i>	<i>Reason for preferred approach (most reasons relate in some way to the benefits of additional powers and flexibility in managing risk)</i>
Entry powers for licence compliance	Incomplete entry powers (status quo), or	Providing the regulator with a fuller range of entry powers would better enable the

Controlled activities: options and impacts		
	Fuller entry powers	regulator to obtain the necessary information to verify the extent of compliance.
Licence period	One year (status quo), or Three years (or other period specified by the regulator)	Providing the regulator with the flexibility to determine the appropriate licence period allows a more risk appropriate approach, and may lower compliance costs in some cases.
Powers to determine activities to be licensed	Set out in primary Act (status quo), or Set out in Regulations	Enabling the activities to be licensed to be set by Regulation provides a cost-effective means for the regulator to manage risk.
Powers to determine general rules	Set out in primary Act (status quo), or Set by Regulation	Similarly, enabling general rules to be set by Regulation provides a cost-effective means for the regulator to manage risk.

Issue 10: Pharmacy licensing and control

140. The licensing and control of pharmacies will be addressed in advice to be included in the Cabinet paper in early 2016. The following discussion illustrates the key issues.

Objectives

141. Licensing of pharmacies is intended to ensure the safe supply and effective use of therapeutic products.
142. It is a mutual goal of the pharmacy profession and the Government to move toward better, and more integrated consumer-centred care. These elements are an important part of innovation in the sector.
143. Thus, key objectives are:
- to ensure the safe supply and effective use of therapeutic products
 - to ensure the regulatory environment enables innovation in pharmacy services, and enhances the contribution of pharmacist skills in a range of settings
 - to enhance the accessibility of pharmacy services within an environment that enables the development of innovative services provision.
144. The primary method of ensuring safety and efficacy in the use of therapeutic products in the new regime will be through licensing requirements, including continuing with the “supervision and control” requirements placed on qualified pharmacists. Additional requirements relating to safe pharmacy practice should also be able to be set by the Regulator as part of licence conditions.

Current requirements

145. Prescription, restricted and pharmacy-only medicines must be under the supervision and control of a pharmacist. Practising pharmacists must be suitably qualified, registered with the Pharmacy Council, and subject to the Health Practitioners Competence and Assurance Act 2003.

146. In addition, the Medicines Act 1981 imposes further requirements in the form of ownership restrictions:
- 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).
 - There are also restrictions on other health professionals (authorised prescribers, delegated prescribers) holding an interest in a pharmacy.
147. The issue is whether the ownership restrictions are necessary in order to ensure that objectives of the regime are met.

Whether ownership restrictions necessary

148. The genesis of these ownership restrictions dates 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).
149. The ownership restrictions appear to be unnecessary for ensuring safe supply and effective use. There is no direct link between majority (or level of) ownership of a pharmacy by a pharmacist and patient safety. This goal may be better met by the requirements that registered pharmacists oversee the control, compounding and dispensing of therapeutic products.
150. The ownership restrictions appear more likely to hinder rather than promote the objective of innovation as they reduce the scope for competition and may inhibit pharmacy investment. Moreover, the restrictions encourage attempts to enter into various arrangements to work-around the formal requirements (which can be difficult to monitor and control).

Consultation

151. The Ministry of Health has discussed changes to the pharmacy licensing regime with the Pharmacy Steering Group, which includes broad representation from the pharmacy profession.
152. The Ministry of Health is also presently consulting with pharmacy stakeholders on a draft Pharmacy Action Plan 2015-2020 which sets out a future direction for pharmacy services as part of a person-centred and fully integrated health and disability system (closing 25 November). The consultation includes a question about pharmacy ownership legislation requirements to guide the future direction.

Issue 11: Exemptions

153. The current Act sets up an approach where products need to be approved before they can be marketed in New Zealand and certain activities are licensed which authorises them to be carried out.
154. The Act then provides for a range of exemptions where, for example, unapproved medicines may be prescribed and supplied because of particular circumstances.
155. Issues with current exemptions provisions include:

- a perceived excessive use of exemptions (eg, the volume of product supplied through the s29 exemption is higher than anticipated when the exemption was originally introduced)
 - not all situations where exemptions are justified are covered under the Act (eg, keeping stocks of unapproved medicines for future emergency use by unnamed patients)
 - quality standards for large-scale local compounding of products by pharmacists (the question is whether this activity should be subject to licensing as for local manufacturing of approved products);
 - supply chain quality assurance for unapproved medicines (ie, assurance that the medicine is what it claims to be, and has been manufactured to standard).
156. The approach taken to exemptions is affected by views about the overall role and reach of regulation.
157. For example, if the objective is to ensure as many products are approved as possible, and as few unapproved products are used as possible (eg, because the regulator does not have the resources to monitor them) then exemptions should be tightly controlled.
158. If, however, the view is that there is often sufficient information available for unapproved products to be judged safe and effective by accountable health professionals, exemptions might simply represent another valid and helpful pathway to product use.
159. The challenge is to:
- facilitate access to worthwhile (and sometimes essential) products that will never be submitted for approval in New Zealand given the small size of this market
 - protect the integrity of the approval process (ie, contain the use of unapproved products, and encourage sponsors to submit products for approval).
160. The pressure to use unapproved products, however, may be reduced if the costs (direct fees and compliance costs) of obtaining an approval are reduced as a result of the regulator having more options available in the approval process (see Product approvals section above).
161. Further, it may be possible for intermediate approaches to be developed where, under certain circumstances, the regulator may specify the basis on which products may be used (but not marketed) without an approval.

Exemptions: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	Prescribing and use of unapproved products in a range of circumstances.	<ul style="list-style-type: none"> • Current problems continue without any amendment. • For example, desirable exceptions not legally provided for (with consequential adverse effects for health and safety outcomes): <ul style="list-style-type: none"> - emergency use;

Exemptions: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
		<ul style="list-style-type: none"> - use by veterinarians. • Further, some undesirable use of the exemption provisions will continue, potentially undermining the approval process itself (ie, products that would otherwise be submitted for approval will not be submitted), with adverse implications for the overall effectiveness of the regime (access to safe products).
Option 1 – Enhanced status quo via updated categories (preferred)	<p>Retain exemption provisions but strengthen.</p> <p>For example:</p> <ul style="list-style-type: none"> - Emergency use exemption. - Specification of products not needing to be approved. - Continue to permit small-scale compounding by pharmacies, but require large-scale compounding to be separately licensed. - Require unapproved product to have appropriate supply chain certification, with attached responsibilities. - Other prescribers included (eg, veterinarians). 	<ul style="list-style-type: none"> • Would involve targeted changes to address known issues as identified in the status quo with consequential beneficial effects on health and safety outcomes. • Makes for a more complicated scheme (defining and delimiting the circumstances with sufficient precision). • Would move New Zealand approach on to a basis more consistent with international practice.
Option 2 – Comprehensive exemption	<p>An exemption for health professionals acting within scope and accountable for their actions.</p> <p>Would be used where they judge an unapproved product to be the most appropriate all things considered.</p>	<ul style="list-style-type: none"> • In principle, an effective low-cost regulatory approach. • Very different from international practice. • May place excessive burden for evaluating technical risk issues, and staying up-to-date on therapeutic good developments, on health professionals.

Post-market

Issue 12: Monitoring (by the Regulator)

162. Monitoring needs to cover all products and activities where compliance is required, or where there is the potential for risk in terms of safety, quality and efficacy.
163. Information is critical to effective monitoring. The regulator needs to have access to all the necessary information in order to analyse developments and to inform judgments about the nature and level of risks.

164. Current monitoring issues include, for example, whether the regulator:

- has a clear mandate and necessary information to monitor unapproved products (eg, those that may have been supplied under exemption provisions)
- the necessary powers to obtain all the information it requires.

165. To the extent that it is agreed that a more comprehensive approach to monitoring is preferred, it would be necessary to ensure in the primary legislation that the regulator:

- has a wide monitoring mandate (eg, including unapproved products)
- the necessary powers to obtain information reasonable for monitoring purposes.

166. This would enable the regulator to set its priorities and pursue different strategies at different times depending on judgments about risk and optimal resource use. Post-market monitoring is particularly important when greater use is made of unilateral recognition and partial recognition processes pre-market.

Monitoring: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	Monitoring will continue with focus on approved products.	<ul style="list-style-type: none"> • Uncertainty about the powers of the regulator to address unapproved product issues. • Regulator not able to obtain all the information it needs to manage risk.
Option 1 – Enhanced status quo (preferred)	<p>The regulator engages in more comprehensive monitoring.</p> <p>A clearer mandate.</p> <p>Enhanced information gathering powers.</p>	<ul style="list-style-type: none"> • Enhanced risk management by regulator. • Some additional compliance costs for industries subject to information requests. • Increased voluntary compliance. • Possible increase in costs to Crown if monitoring separately funded as public good.
Option 1a – Focus on selected areas only	<p>As for option 1 above – plus:</p> <p>Regulator highly selective in the areas monitored.</p> <p>Prioritising attention and resources to particular areas only (eg, areas judged to be higher risk).</p>	<p>Impacts as for option 1 above – plus:</p> <ul style="list-style-type: none"> • Potential for more effective risk management in areas more intensively monitored. • Potential for adverse events in areas not monitored even though judged to be low risk.
Option 1b – Reduced focus on monitoring in favour of public health	<p>As for option 1 above – plus:</p> <p>Regulator less proactive in monitoring, focusing on pre-market regulatory activities.</p>	<ul style="list-style-type: none"> • Reduced compliance costs for industry in responding to regulator requests (eg, for information). • Increased costs where adverse events arise as a result of lack of monitoring and the costs of responding are greater than the

Monitoring: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
rapid response	Objective to minimise post-market problems, and develop a capability enabling a robust response to any post-market issues that emerge.	<p>costs that would have been incurred in monitoring (and detecting the problem earlier in the piece).</p> <ul style="list-style-type: none"> • (Note, however, it is not possible to know everything about a product at the stage of approval. Information is often gained only when products are used in real patient populations (this is a particular issue for medical devices). • This option and Option 1b may impact negatively on the goal of “a trusted and respected” regulator.

Issue 13: Enforcement

167. This involves a range of regulatory actions in response to the information received and analysed during the monitoring process.
168. The need for action can arise for different reasons, including negligent non-compliance, or as a result of risks that were latent and could not have been reasonably foreseen or pre-empted.
169. It is important for the regulator to have a spectrum of actions available depending on the nature and seriousness of the issue in question.
170. In general, the objectives are for the regulator to:
- create an environment of voluntary compliance
 - take appropriate action as necessary (the consequences of which support voluntary compliance in future).
171. Sustainable, long-term voluntary compliance, however, requires industry to appreciate, as a result of the regulator’s monitoring and enforcement activities:
- that non-compliance will be detected and acted upon (even in relation to small issues on occasion)
 - that compliance and strong safety management is the most cost-effective strategy overall.
172. Examples of regulatory action along the spectrum of increasing seriousness include:
- requests for additional information
 - “please explain” letters
 - advisories
 - warnings
 - product recalls / withdrawals / bans
 - imposition of extra conditions on licences (usually to limit activities)
 - fines
 - prosecutions.

173. Offences and penalty provisions are a vital backstop for effective enforcement. Current provisions need to be updated and aligned with other comparable legislation. Consultation with the Ministry of Justice on these matters will inform further reporting in early 2016.

Enforcement: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
Status quo	No change to existing enforcement powers.	<ul style="list-style-type: none"> Enforcement will continue to be a challenge (risks more difficult to manage). Uncertainty about the powers of the regulator to address unapproved product issues. Regulator not able to take all the actions it needs to in order to manage risk (eg, in relation to recalls, bans).
Option 1 – Enhanced status quo (preferred)	<p>Enhanced and calibrated powers for regulator to take enforcement action.</p> <p>Strategic use of the full spectrum of regulatory actions available.</p> <p>Strengthened offence and penalty provisions.</p>	<ul style="list-style-type: none"> Increased voluntary compliance as a result of strengthened regulator powers and enhanced offence and penalty provisions. Greater ability to take appropriate action commensurate with the offence (ie, low, medium, high). Enhanced effectiveness in treating non-compliance issues (eg, the regulator is able to ban unsafe products), with associated benefits for safety and health. Reputational benefits for the regulator, which also leads to lower costs over time (eg, because industry is more responsive).
Option 1a – Focus on specified areas only	<p>As for option 1 above (enhanced powers and penalties) – plus:</p> <p>Regulator highly selective in the areas enforced.</p> <p>Prioritising attention and resources to particular enforcement areas only (eg, areas judged to be higher risk).</p>	<p>This is a sub-option relating to how the regulator might operationalise its approach (the regulator has the same powers as under Option 1).</p> <p>It would be up to the regulator to decide the most cost-effective approach overall, and to modify that approach as necessary in the light of experience.</p>
Option 1b – Reduced focus on enforcement	<p>As for option 1 above (enhanced powers and penalties) – plus:</p> <p>Regulator less proactive in enforcement, focusing on pre-market regulatory activities.</p> <p>Objective to minimise post-market problems, and to a capability that would enable a</p>	<p>This is also is a sub-option relating to how the regulator might operationalise its approach (the regulator has the same powers as under Option 1).</p> <p>Similarly, it would be up to the regulator to decide the most cost-effective approach overall, and to modify that approach as necessary in the light of experience.</p>

Enforcement: options and impacts		
<i>Options</i>	<i>Description</i>	<i>Impacts</i>
	rapid/robust response to any post-market issues that emerge.	

Part B: Expected impacts for preferred approach

Area	Change	Impacts / incidence / risks
Legislation and regulations	Replace the Medicines Act and Regulations with new legislation.	<ul style="list-style-type: none"> • Administrative cost for government in developing and implementing new legislation. • Potential efficiencies over time (eg, with leaner, more streamlined primary statute, reduced need to change legislation). • Minor costs for industry (eg, consultation). • Costs largely managed within existing baseline budgets.
Purpose	Develop a purpose statement and principles to guide decisions by the regulator (none at present).	<ul style="list-style-type: none"> • Life-cycle approach to therapeutic products and related activities. • More risk-appropriate approach. • Regulatory scrutiny risk-proportionate. • More effective risk management (regulator optimises resources across the spectrum of its responsibilities).
Scope		
<i>Medical devices</i>	Bring all medical devices within regime.	<ul style="list-style-type: none"> • Impact will depend on regulatory approach. • Development and ongoing operational costs for regulator. • More information required on numbers and types and risk profiles. • Significant transition possible. • Likely large number of products affected / low to high compliance costs per product (depending on risk / complexity – the majority of products by value are at the low end).
<i>Cell and tissue therapies (CTT)</i>	Bring all CTT within regime for first time.	<ul style="list-style-type: none"> • As above with respect to approach, costs, information required, and transition. • Likely very small number of products affected / low to high compliance costs per product.
<i>All hybrids, all other products defined as therapeutic products</i>	Clarifies how such products will be regulated.	<ul style="list-style-type: none"> • Similar to CTT above. • Few products now, but growing. • More customisation of regulatory approach possible.
Powers	Decisions on all product approvals and activity control to be taken by regulator, and ability to set regulatory requirements.	<ul style="list-style-type: none"> • Significant devolution of all powers for product and licensing decisions from Minister to regulator. • Minister retains powers in relation to major policy issues, some committee appointments, and issues where major ethical or public interest issues involved. • Minister oversees regulator's overall performance. • Regulator given flexibility to manage risk, subject to robust accountability (including appeal).

Area	Change	Impacts / incidence / risks
		<ul style="list-style-type: none"> • More timely and less costly decision making. • Greater conformity with public sector legislative and regulatory design standards / requirements. • Reduced risk of perceived lack of political independence in decision making.
Institutional form	It is not yet clear what if any changes to the institutional form of the regulator are preferred.	<ul style="list-style-type: none"> • The main alternatives are business unit within Ministry (status quo), departmental agency, or Crown entity. • This will be subject to further reporting in early 2016.
Accountability	<p>Updated organisational accountability for regulator.</p> <p>Updated review/appeal committees structure.</p>	<ul style="list-style-type: none"> • Additional financial and performance reporting might be expected. • This would be aligned with the regulator's expanded role. • The costs of change in accountability structures are expected to be small and managed within baseline budgets. • New committee structure necessary in response to the devolution of powers. • Review and quality control would continue to be robust. • Appeal processes would not change in substance. • No increase in appeals (or change in appeal outcomes) expected.
Cost recovery	<p>Provision for approval/licensing fees and an industry levy (levy would be new).</p> <p>Potential for Crown funding to be set on public good grounds.</p>	<ul style="list-style-type: none"> • Private goods should be subject to fees. • Industry/club goods (eg, standards, industry-wide requirements) could be subject to levy. • Balance between the two will affect Incidence of costs within industry (eg, levy will increase share of costs borne by companies with few new products being approved). • Government may choose to fund public good activity (eg, enforcement). • Costs to industry / Crown will be affected accordingly.
Product Approval	<p>Regulator has more ability to choose the right process and conditions.</p> <p>Role established for a "responsible person".</p> <p>Other changes (eg, information for consumers).</p>	<ul style="list-style-type: none"> • Graduated compliance costs (depending on risk and cost of process). • More timely decisions. • Better risk management. • Increased compliance costs. • Possible reduction in (riskier) products submitted for approval, and subject to post-market activities. • Better risk management. • Minor impact. • Large number of products affected. • Low compliance costs.

Area	Change	Impacts / incidence / risks
Controlled activities	More flexibility for regulator to impose conditions when licensing.	<ul style="list-style-type: none"> • Compliance costs may be higher or lower depending on conditions, length of licence etc). • In general, minor impacts for industry as a whole.
Pharmacy licensing and control (including ownership restrictions)	This will be subject to further reporting in early 2016.	<ul style="list-style-type: none"> • The key issues is whether ownership restrictions are necessary. • Under all options to be considered, pharmacists would retain the responsibility for the supervision and control of medicines. • Further reporting will be informed by consultation on the draft Pharmacy Action Plan 2015-2020.
Exemptions	Some refinements to exemption provisions.	<ul style="list-style-type: none"> • Clarification of basis on which exemptions (ie, supply and use of unapproved products) are permitted. • Impact will be assessed during further sector engagement. Aim is minimal compliance impact and increased safety. • May be a reduced need for exemptions in light of other changes (eg, more flexible approval process).
Monitoring and enforcement	<p>Monitoring: additional powers to obtain information.</p> <p>Enforcement: wider range of actions regulator can take, and strengthened offences and penalty provisions.</p>	<ul style="list-style-type: none"> • Greater voluntary compliance (with the powers rarely needing to be used). • When they are used, such information (or absence of information) will assist compliance and enforcement action with positive effects for safety management. • Overall, some small increase in compliance costs for industry. • As with monitoring, the key impact is likely to be greater voluntary compliance (with the more serious sanctions rarely needing to be used). • When they are used, the demonstration effect will assist in promoting general industry compliance with positive effects for safety management. • Calibrated responses based on the seriousness of offending. • Greater consistency with information and enforcement provisions in comparable legislation.

Part C: Overall impacts on costs and outcomes

174. The effects of the preferred options, as discussed in the preceding table, are now summarised in terms of their overall implications for costs and outcomes.

175. The critical outcomes are: the availability of products, their quality and prices, levels of product risk and risk management, and health outcomes. The critical costs are the compliance costs for industry and the fiscal costs for the Crown.

Compliance costs on industry

176. The compliance costs on industry are predicted to increase slightly to moderately overall depending on a range of factors. The main influences are:

- First, a wider range of products will be subject to regulation. Newly or more extensively covered areas will be medical devices (a category with a large number and wide range of products), cell and tissue therapies (a small number of complex products), and hybrid products (a small but increasing number of complex products). For the majority of medical devices, which are not complex and are low risk, the compliance costs are expected to be very low or modest (eg, self-certification as meeting technical and performance standards may be sufficient). Note also that there may be benefits for industry from having its products regulated and approved (eg, for PHARMAC purposes; for marketing in other countries).
- Secondly, for all products including medicines – the category most comprehensively regulated currently – there will be a range of new requirements or powers to which they will be subject. These include: various conditions that may be placed on an approval, placing duties and obligations on a responsible person for each product, powers to require industry to provide information, and strengthened offence and penalty provisions. The implications of some of these changed requirements – eg, the ability of the regulator to licence for longer periods – are likely to reduce compliance costs.
- Thirdly, more flexible approval processes are expected to provide some overall benefit in terms of medicines, where the costs of approval can be high (ie, in the vicinity of \$100,000 for full assessments). Medsafe is, however, already very efficient and timely in its decisions and the costs of approval in New Zealand are very competitive by international standards (ie, the comparable cost in the US is USD260,000, and in Australia AUD220,000). There is also a stepped fee schedule for applications depending on the complexity and amount of work required, with reductions for the truncated pathways where previous work or data is relied upon or some requirements have been waived. For products that it will be appropriate to accept through unilateral recognition, there should be reduced compliance costs, but it is not expected that there will be many of these.

Product availability and pricing

177. The overall effect of the new regime on product availability and pricing is expected to be slightly favourable:

- First, the supply of innovative products will be assisted by the more flexible (and lower cost) methods of approval that may be employed. More efficient processes by the regulator over time should also assist all products. Further, the extra compliance costs per product may in many cases (eg, medical devices) be so low (eg, self-certification) as to have little bearing on the product's pricing.
- Second, where there are higher compliance costs, these will not all be able to be passed on to consumers, and the incidence of cost between industry and consumers will vary across products.
- Third, depending on advice in early 2016 on pharmacy ownership restrictions, there is the potential for positive effects on pricing given that pharmacists and pharmacies represent such a critical interface. For example, if it were decided to remove such restrictions, this could lead to more active product management, and bulk buying, and greater innovation in the delivery of services to consumers (eg, opening hours, more integration with other medical services).

Management of risk

178. The overall effect of the preferred options on the levels of therapeutic product risk and management of risk is expected to be favourable:

- First, it is expected that fewer unacceptably risky products will be able to be marketed (eg, as a result of the wider product coverage, the better targeting of risk). High-risk is not a problem of itself where the benefits are significant and satisfactory controls and monitoring are in place.
- Secondly, more active monitoring and greater information powers for the regulator will result in increased risk detection. An increase in voluntary compliance is also expected (eg, in response to strengthened offence and penalty provisions) which should reduce risk and lead to more timely detection where risk is encountered (also assisted by the role of the responsible person).
- Finally, the regulator will have an enhanced ability to take more timely and appropriate actions (potentially recall or banning of products) across a wider range of products where regulatory action is required.

Fiscal costs to the Crown

179. The fiscal effects on the Crown are predicted to be slightly favourable overall in the long term:

- First, there will be costs in developing and implementing the new Act, but there should be reduced costs over time in operating under the new regime (more efficient processes for Ministers and officials as a result of the devolution of powers; and a reduced need to amend the Act or change Regulations given that less detail would be in primary legislation and greater use made of tertiary instruments).
- Secondly, the new regime envisages a potentially larger regulator (to regulate products not currently regulated) and a regulator that is enabled to manage its resources more flexibly and efficiently in order to take a risk-appropriate approach.
- Finally, and most importantly, the success of the new regime in preventing, detecting and responding to risk should lead to safer and better quality products, and fewer and less serious adverse events. This will have positive flow-on effects in reducing costs and cost pressures on the health system as a whole, with some favourable fiscal effect on the Crown, and positive implications for the wider economy (output and productivity from better health outcomes). This effect need only be small to outweigh or dominate the other less favourable fiscal effects identified.

Summary table

Critical Areas of Impact	Cause of impact (arising from preferred options for change)	Impact (see key below)
Compliance costs on industry	More products subject to regulation	-
	More flexible, timely approval processes	+
	More conditions on approval	= / -
	Introduction of "Responsible person"	= / -
	More information required	-
	Strengthened sanctions and penalties	=
	Overall impact	= / -

Critical Areas of Impact	Cause of impact (arising from preferred options for change)	Impact (see key below)
Product availability and pricing	General availability of products	=
	Supply of innovative products	= / +
	Supply prices	=
	Retail prices	=/+
	Consumer access and services	+
	Overall impact	= / +
Management of risk and confidence in system integrity	Pre-market risk detection	+
	Post-market risk detection	+
	Post-market response to risk	+ or ++
	Confidence in products and system integrity	+
	Overall impact	+
Fiscal costs on Crown	Development and implementation of new Act	= / -
	Devolution of powers	= / +
	Larger regulator	= / -
	More efficient regulator	= / +
	Better health outcomes	+
	Overall impact	= / +

Key:

very unfavourable	unfavourable	slightly unfavourable	neutral impact	slightly favourable	favourable	very favourable
--	-	= / -	=	= / +	+	++

Part D: Further points on approaches and impacts

180. A key challenge is to minimise compliance and other costs while still ensuring the regulatory regime is effective. It is useful to highlight some contextual points and indicative impacts in relation to medical devices – the main area where compliance costs are expected to increase.

Regulation of medical devices

181. Medical devices is the main product area where compliance costs can be expected to increase under the proposed new regime. There are two reasons for this:

- increased regulatory requirements for medical devices. Medical devices are subject only to a notification process at present irrespective of the level of risk (which provides product and contact information); they are not subject to an approval process of any kind
- more consistent application of cost recovery for private or industry goods in accordance with public sector cost recovery principles. There is no cost-recovery at present (ie, of the costs of operating the WAND database and of monitoring medical devices in the market).

182. Of products currently notified to the WAND database, approximately:
- 50% are class I or low-risk (eg, re-usable surgical instruments)
 - 40% are class II or medium risk (eg, hypodermic needles)
 - 10% are Class III or high risk (eg, drug eluting cardiac stents, implantable pacemaker).
183. The intended regulatory approach for medical devices will be risk-appropriate and likely focus on conformity assessment. This means that costs should be low or moderate for most products:
- As noted, 90% of products are low or medium risk and the regulatory approach will reflect this.
 - For higher risk and generally more complex products, the significant majority will be expected to have some form of conformity or similar assessment (eg, by a regulator or conformity assessment body).
 - The costs of obtaining an independent conformity assessment would generally be regarded as part of the normal costs of developing a product for market, and is required in many other markets (eg, Fisher & Paykel meet the EU requirements). Users of the product require such an assurance, especially where it is high cost and is used for complex and risky procedures. The interests of the regulator and the interests of the users of the products are very closely aligned. Thus, in this respect any regulatory impost over and above what users require should be minimal.
184. The additional regulatory costs for Medsafe from medical devices regulation will depend on the number of additional FTE staff members required. On a fully-allocated cost basis (ie, including overheads), the annual staff cost for Medsafe is around \$200,000 per FTE. It is unclear, however, at this stage how many additional staff will be required.

New PHARMAC role: medical devices

185. PHARMAC also has a new role in relation to medical devices, and this will need to be taken into account in developing the preferred regulatory approach.
186. In 2012 the Government agreed that PHARMAC should take on the management of hospital medical devices. District health boards spend about \$1 billion a year on medical devices, and in the recent past costs have been rising faster than economic growth.
187. PHARMAC's aim is national consistency in access to treatment, greater transparency in decision making, and improved cost-effectiveness of public spending. In particular, the work involves putting in place national contracts for items already used in New Zealand. These contracts are optional for DHBs, but offer savings benefits if they switch or increase their mix of better value brands. The range of products and the number of supplies will also probably narrow as a consequence.
188. In relation to the safety and quality of devices, PHARMAC is still working through how these factors should feature in its decision making process, although DHBs will remain responsible for assuring themselves of the quality and safety of individual devices. An enhanced ability to regulate medical devices by Medsafe will therefore provide more information about safety and quality of devices to inform PHARMAC and DHB decisions.

Consultation

Health sector and industry

189. There are a significant number of organisations and groups (50 plus) from the public, private and non-profit sectors with an interest in the therapeutic product regulation.
190. A range of consultations with these groups have taken place over the course of the last 10 years in relation to the ANZTPA process, and more recently there has been ongoing contact and regular discussions with some groups on selected issues.
191. The main general concerns of industry groups relate to the detail of the regulatory requirements and compliance costs (including cost recovery by the regulator). The main concerns of health professionals relate to prescribing practice and pharmacy control.
192. There has not been sector-wide consultation on the specific set of proposals currently under consideration. The reasons for this are:
 - it will be more efficient to consult on the exposure draft of the bill as that will provide the necessary detail for informed and comprehensive engagement
 - ANZTPA and more recent consultations have covered similar ground with respect to the major design elements of the regime (eg, streamlined legislation, broader product coverage, more risk-appropriate approach, more flexible processes).

Government agencies

193. Government agencies with an interest have been consulted on the proposals contained in the Cabinet papers. Some technical considerations were raised during the course of discussions, but no major issues.

Conclusions and recommendations

194. The key conclusions from the analysis of options, and the recommended approach, may be summarised as follows:
 - New Zealand should continue to regulate therapeutic products and related activities in order to maximise the benefits of such products and activities relative to the risks.
 - It is timely to address two overarching problems with current regulation:
 - the legislative framework, which is now unfit for purpose
 - gaps and deficiencies in the policy settings, which increase the risks of adverse health outcomes (eg, especially in relation to medical devices and cell and tissue therapies).
 - The legislative framework problem may be best addressed by ensuring that product and licensing decisions should be devolved to the regulator, supported by a clear and principled legislative mandate with robust accountability for the regulator's organisational performance and its regulatory decisions.
 - Policy settings should be strengthened by bringing all therapeutic products within the scope of regulation and by adopting:

- a comprehensive life-cycle approach, meaning all of the stages of a product or activity are considered for risk management purposes
 - a risk appropriate approach, meaning that regulatory scrutiny and the information and assurance required should be proportionate to the risks involved.
- The powers of the regulator should be updated to ensure it is able to determine requirements and to impose and modify conditions on approval and licensing decisions, obtain information, and to take enforcement action, which is reasonable and necessary for effective regulation, supported by updated enforcement powers together with sanctions and penalties for non-compliance.
195. The above conclusions support the approach recommended by the Minister of Health in the two Cabinet papers: Therapeutic Products Regulation: Paper 1 – Context and Overview; and Paper 2 – Proposals for a Therapeutic Products Bill.
196. Given the significant development work still to be undertaken, there are limitations on the extent to which the impacts of the proposals can be assessed quantitatively. On the basis of the framework and building blocks proposed, however, the implications long term are predicted to involve:
- moderate increases in compliance costs for some parts of the regulated industry (mostly notably for the newly regulated products)
 - positive impacts on the management of therapeutic product risk, and on product availability and possibly pricing
 - a potentially positive impact fiscally for the Crown from the effects of product availability and risk management on the wider health budget and economy.
197. The overall approach represented by the preferred options for the new regime has been informed by:
- a long-standing appreciation of the key problems that need to be addressed
 - accepted international practice
 - current public sector standards for legislative and regulatory design
 - a measured timetable for development, consultation, decision making, and implementation.

Implementation plan

Key considerations

198. 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.
199. As highlighted above, the preferred approach for 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.

- 200. Upgraded enforcement provisions (eg, revised offence and penalty provisions) will help to ensure that the preferred option achieves its public policy objectives.
- 201. In terms of mitigating implementation risk, and minimising compliance costs, the implementation plan adopts a staged approach for addressing these objectives.

Approach to implementation

- 202. The preferred approach to implementation has had to have regard to 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

203. 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	<p><u>Policy decisions</u></p> <p>Proposals presented to Cabinet in late 2015. Further proposals presented to Cabinet in early 2016. This 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 will provide the basis for the drafting instructions for the preparation of an exposure draft.</p>	Late 2015 and Early 2016
Exposure draft	<p><u>Exposure draft consultation</u></p> <p>An exposure of the proposed legislation is critical for consultation and policy review purposes. It is key step in quality assurance and refinement of the policy settings and implications before a Bill is introduced.</p> <p>Outcome of consultation will include:</p> <ul style="list-style-type: none"> • any refinement to the policy decisions • any further drafting instructions for the preparation of the Bill 	Mid-2016

Stage	Requirements and linkages	Timing
	<ul style="list-style-type: none"> early consideration of the tertiary instruments required by the regulator. 	
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>	<p>Late 2016</p> <p>2017/18</p>
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

204. The preferred 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.
205. 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

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

Further advice on elements of the regime

207. From March 2016 there will be further advice to Cabinet on other key elements and implications of the regime (eg, institutional form, prescribing and dispensing, interface issues with other legislation, and financial considerations).
208. Reporting at that time provides a further opportunity to consider and provide assurance on the extent to which all of the elements of the regime (those addressed in March 2016, and those addressed now) will work together and be effective as a whole.

The development of an exposure draft of the bill for consultation

209. 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.
210. 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

211. 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 therapies which will need to come into effect over a period of time).

Stewardship expectations

212. The Government has recently signalled its core expectations for regulatory stewardship to agencies involved in designing and administering regulation. These are still being developed although it is clear in this context the Ministry of Health will be required to:
- *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;
 - *adopt best practice compliance strategies*, as part of a cross-government forum designed to share experiences and promote greater consistency between regulators; and
 - *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.
213. 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).