In Confidence

Office of the Minister of Health

Chair, Cabinet Social Policy Committee

Therapeutic Products Regulation Paper 1: Context and Overview

Proposal

1 That Cabinet agree the objectives for a new comprehensive, cost effective regulatory regime for therapeutic products in New Zealand and how they will be achieved. The new regime will replace the Medicines Act 1981.

Executive Summary

2 Medicines, medical devices, and cell and tissue therapies (and hybrids thereof) are collectively known as therapeutic products and they aim to treat or prevent ill health in humans. All developed countries regulate these products across their lifespan to ensure, as far as possible, that the benefits of their use outweigh the risks.

3 Since the early 1990s there have been attempts to address problems and weaknesses with New Zealand's regulatory regime and in late 2014, concurrent with announcing the cessation of work on Australia New Zealand Therapeutic Products Agency (ANZTPA), I announced that work would commence on a new comprehensive regime to replace the Medicines Act 1981 and its Regulations.

4 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]. Advice in this paper, the companion paper *Therapeutic Products Regulation: Paper 2 Proposals for a Therapeutic Products Bill* and further advice in March 2016 will enable drafting of the Bill. It is proposed that an exposure draft of the Bill be released for consultation during 2016, followed by introduction to the House in late 2016 and passage in 2017.

5 The new regime is being designed to meet the needs of the health and disability support sector now and into the future, to give effect to Government's expectations for regulatory systems and mindful of the global settings for therapeutic products. Reflecting this context the objectives for the regime are that it:

5.1 meets expectations of risk management and assurance of acceptable safety

5.2 results in efficient and cost effective regulation

5.3 is flexible, durable, up-to-date, and easy to use

5.4 ensures high-quality, robust and accountable decision-making

5.5 is able to sustain capable regulatory capacity

5.6 supports New Zealand trade and economic objectives

5.7 is trusted and respected

5.8 supports consumer access and individual responsibility for care.

6 These objectives will be best met by:

6.1 regulatory requirements that are consistent with international approaches and effectively administered

6.2 a regulator that can exercise regulatory powers effectively, is accountable, and that can engage internationally

6.3 an enabling legislative framework that can be readily maintained and updated.

7 A challenge to designing such a regime is ensuring sustainable regulatory capacity into the future and all opportunities should be taken to support capacity development and retention, while not unduly compromising other objectives. This involves, for example, implementing a mixed model for pre-market assessment where the regulator is able to do full assessments, partial assessments, and recognise the work of other regulators.

Background

8 Therapeutic products are used for humans for a therapeutic purpose.[1] Currently they can be grouped into the broad categories set out below.

8.1 **Medicines** (including blood and blood products) work primarily through pharmacological, immunological or metabolic means. They comprise substances that interact with human physiological and pathological processes and there may be a narrow margin between the amount required to produce a therapeutic effect and the amount that can cause a toxic effect.

8.2 **Medical devices** work primarily through physical and electrical/electronic means and include a vast range of apparatus, instruments and appliances from tongue depressors and bandages to implantable devices such as pace makers, diagnostic tools, software, robotic surgery machines, MRI scanners, and in-vitro diagnostics.

8.3 **Cell and tissue therapies** are derived from living cells and tissues of human or animal origin and include products such as skin grafts, ligaments, demineralised bone matrix, and dental-pulp derived stem cells.

9 There are also hybrids which combine these product types. For example, a metal stent coated with a matrix and endothelial cells is a medical device-cell and tissue hybrid, and a coronary stent with a heparin coating is a medicine-medical device hybrid.

10 Therapeutic products are not ordinary goods of commerce and can present serious risks of harm, especially if used inappropriately. All developed countries, 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 regulate to control the manufacturing chain,

[1] Internationally, therapeutic purpose means actions such as treating, preventing, monitoring or diagnosing a disease or condition, modifying a physiological process, testing for a disease or condition, investigating, replacing or modifying parts of the human anatomy, influencing, controlling, preventing pregnancy.

distribution chain, promotion/advertising, pre-market evaluation and approval, post-market surveillance and access.[2]

11 There is rapid development of new products. Nanotechnology, information technology, and gene technology are examples of drivers of this development. It is expected that the numbers of technologically advanced medicines, medical devices and cell and tissue therapies, hybrid products, and new categories of product will continue to grow. These developments are challenging the capacity and currency of regulatory systems globally.

12 The key problems New Zealand faces are:

12.1 The Medicines Act 1981 and its Regulations are no longer fit-for-purpose.

12.1.1 They are dated and inflexible, reflecting policy and legislative drafting of the late 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.

12.1.2 There are significant gaps in coverage. There is no coverage of cell and tissue therapies that are not considered medicines, and medical devices are not fully regulated. The numbers and complexity of these products is growing and New Zealand is moving to centralised economic / clinical / commercial assessment, prioritisation and procurement of medical devices under PHARMAC.

12.1.3 The prescriptive nature of the Medicines Act 1981 prevents regulatory efficiencies.

12.1.4 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.

12.2 Difficulties with ensuring regulatory capacity and flexibility into the future for the pre-market assessment of innovative new products (such as those using nanotechnology).

12.3 The Medicines Act 1981 places many core regulatory powers with the Minister of Health which are exercised under delegation. This model does not enable an easy separation between performance and monitoring, and it also makes the Minister responsible for technical decisions that have significant impacts on private interests.

13 Successive governments have sought to address problems with New Zealand's regulatory regime. Domestic reform in the 1990s was overtaken by the initiative to establish a joint regulator with Australia (ANZTPA). The ANZTPA[3] initiative began in the late 1990s, faltered in 2007, was revived in 2011 and was then reviewed in 2014. In November 2014 my Australian counterpart and I and announced the cessation of efforts to establish ANZTPA. At that time I also announced that New Zealand would now develop its own comprehensive domestic regulatory regime that covers medicines, medical devices and cell and tissue therapies [CAB Min (14) 36/22 refers].

[2] http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf.
[3] Australia New Zealand Therapeutic Products Agency

14 The extent of the changes needed to give effect to new policy settings and the difficulty of attempting to amend the Medicines Act 1981 point to repealing and replacing it with a new Act. This has also been the view of the Parliamentary Counsel Office during previous attempts at domestic reform and remains its view. A Therapeutic Products Bill has Priority 6 on the Government's Legislative Programme. Priority 6 is that drafting instructions are issued to the Parliamentary Counsel Office this year [CAB Min (15) 5/7 refers].

15 Advice on the new regime will be provided to Cabinet in three tranches:

15.1 contextual overview and objectives – contained in this paper

15.2 proposals for the key elements of the new legislation with a view to drafting instructions being issued – contained in the accompanying paper: *Therapeutic Products Regulation: Paper 2 Proposals for a Therapeutic Products Bill*

15.3 proposals for other matters required for the legislation – to be reported to Cabinet by March 2016. This paper will cover prescribing, dispensing and administration, clinical trial arrangements, the detail of the proposed offences and penalties provisions, the proposed form of the regulator and other matters.

16 It is intended that the Bill be introduced in late 2016 for passage during 2017. In order that the Bill is robust and well understood by stakeholders it is recommended that an exposure draft is 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.

17 Concurrent with developing the new regime, Cabinet has agreed to the drafting of a Statutes Repeal Bill that includes repealing provisions of the Medicines Act 1981 that were introduced through the Medicines Amendment Act 2013. These provisions have a default commencement date of 1 July 2017 and, with the development of the new regime, it is no longer necessary or desirable for them to come into force [EGI-15-MIN-0027 refers]. The Treasury is leading work on this Bill and is currently seeking feedback on an exposure draft of the Bill.

Context and objectives for the new regime

18 Internationally regulatory regimes put risk-proportionate controls at key points across the lifespan of products. These controls are supported by compliance and enforcement powers and requirements and systems to monitor the use of products and to respond to any safety concerns. These arrangements are aimed at ensuring that the benefits of using products as intended outweigh the risks of harm, that products are high quality throughout their lifespan (ie, they do not degrade or fail), are traceable, appropriately used and accompanied by good information about their use.

19 This type of regime is proposed for New Zealand with the objectives that it:

19.1 meets expectations of risk management and assurance of acceptable safety

19.2 results in efficient and cost effective regulation

19.3 is flexible, durable, up-to-date, and easy to use

19.4 ensures high-quality, robust and accountable decision-making

19.5 is able to sustain capable regulatory capacity

19.6 supports New Zealand trade and economic objectives

19.7 is trusted and respected

19.8 supports consumer access and individual responsibility for care.

20 These objectives have been derived from an analysis of the broader context in which the regime will sit. That is:

20.1 the need of the health and disability support sector now and into the future to have a regime that protects health and safety while supporting changes in the ways services are delivered and health practitioners are used;

20.2 the Government's increased focus on the design, stewardship and maintenance of regulatory systems; and

20.3 the international arena.

21 In designing proposals for the regime, considerable use has been made of the Productivity Commission's report on *Regulatory Institutions and Practices* (2014) alongside the Government Statement on Regulatory Stewardship and correspondence from Business Growth Agenda Ministers to regulators about international settings and participation in the international arena (26 May 2015).

22 The international arena has a considerable influence on the design of the new regime and it is critical that New Zealand is responsive to these settings. Therapeutic products are, for the large part, global commodities and regulation in developed countries is guided by international standards for the safety and quality of products. Developed countries also have formal and informal obligations in respect of global safety concerns (eg counterfeit products). Internationally, regulators are looking for ways to respond to regulatory challenges such as capacity constraints driven by innovative products, increasingly complex supply chains (eg a product may have components from many sources or supply may be many steps removed from manufacture), and the desire for continued efficiencies.

23 Achieving the objectives requires:

23.1 **regulatory requirements** that are consistent with international approaches and effectively administered

23.2 **a regulator** that can exercise regulatory powers effectively, is accountable, and that can engage internationally

23.3 an enabling **legislative framework** that can be readily maintained and updated.

24 A central challenge to putting this type of regime in place is ensuring sufficient regulatory capacity. One of the main gains of ANZTPA for New Zealand was the potential to address capacity constraints. With that initiative off the table, all opportunities to build and sustain capacity need to be taken in the design of the new regime while not unduly compromising other objectives.

Regulatory requirements

25 As noted, there are international standards and frameworks for the regulation of products[4]. Standards have been adopted internationally to facilitate the preparation of dossiers for pharmaceuticals by industry for assessment by regulators. There are similar standards for medical devices and emerging norms for cell and tissue therapies. New Zealand should align with these international norms (as we do now to the extent possible under the Medicines Act 1981). There will also need to be local standards for matters usually covered domestically, such as product labelling and product classification.

26 Using these standards will support efficiency and will go some way to assisting with capacity challenges. Maintaining capacity to assess an individual product against the standards remains and it is worth commenting on whether New Zealand should maintain a full-service regulator for medicines (ie, one that is able to do full pre-market assessments). It is proposed that it is in our best interests to do so, and to also enable and expect the regulator to make use of the work of overseas regulators where sensible. While possibly, *prima facie*, attractive, a regulatory regime that is heavily or completely weighted toward simple recognition of overseas approvals will not be in New Zealand's interests as it risks compromising:

26.1 **international reputation and credibility as a first world country** – there would be reputational damage from being seen as a free-rider. In addition, the World Health Organization specially urges developed countries to have developed regulatory systems rather than rely on others. We are also unlikely to be able to meet our international obligations in relation to combating counterfeit products[5].

26.2 **longer-term capacity and sustainability** – our ability to attract and retain staff with suitable skill sets to administer the regulatory regime would be limited. In turn this would erode our capacity to effectively ensure acceptable quality, efficacy and safety of therapeutic products in New Zealand. This would be particularly acute with respect to post-market activities (which would be more important under a recognition model).

26.3 **access** – we could not access products until they had been approved by one or more other jurisdictions (New Zealand is first-in-world for some product applications, particularly those seeking to be funded through the PHARMAC tender process), overseas approvals may also be more restrictive than considered necessary (particularly in respect of classification where New Zealand is more willing than other countries to move medicines from prescription to non-prescription status). There is also the difficulty of determining what decisions of overseas regulators would be recognised as it is not uncommon for jurisdictions to make different decisions with respect to the same product – that is to approve (or not), set conditions, and revoke.

26.4 **ensuring acceptable quality, efficacy and safety** – the regulator would be poorly placed to fulfil regulatory responsibilities for local matters (labelling, packaging, and potentially also classification) and respond to post-market safety concerns as there

[4] Such as those promulgated by the International Conference of Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, the Pharmaceutical Inspection Cooperation Scheme, and the International Medical Device Regulators Forum.

[5] WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1999).

would have been no, or limited, scrutiny of data in New Zealand pre-market and thus light knowledge about the product.

26.5 **domestic industry** – New Zealand has a small manufacturing capacity for all types of therapeutic product that may be disadvantaged by reliance on full recognition of overseas approvals.

27 While a regime that is heavily or completely dependent on simple unilateral recognition is not desirable, unilateral recognition will have its place in the new regime and should be used judiciously. For example, when a highly innovative product first comes to the international market, New Zealand is unlikely to be able to assess this type of 'cutting edge' product and would need to recognise an approval from another jurisdiction. (It is worth noting that this type of recognition is currently prevented by the Medicines Act 1981.) This is not ideal, but it is pragmatic; and is a conclusion being reached by other small and medium therapeutic product regulators (including Australia). Over time, as the 'cutting edge' technology becomes established and the international knowledge base develops New Zealand would develop capacity to assess (or partially assess) these products. International engagement in technical regulatory forums, work-sharing, and staff development in overseas regulators are examples of ways to develop capacity.

28 It is also expected that the regulator will, as Medsafe does now, use aspects of other regulator's work to inform its pre-market evaluation of a product (including work sharing and harmonisation of processes). It may also be the case that self-certification (where the supplier declares to the regulator that requirements have been met and the regulator is able to audit to ensure compliance) may be appropriate for some low-risk products.

29 For medical devices the international trend is away from full evaluation of a product by the regulator and toward the regulator accrediting third parties to undertake this process. The evaluations of third party Conformity Assessment Bodies are then assessed by regulators as required. This is the European model and is increasingly being adopted or actively considered by other jurisdictions (Australia has recently signalled moves toward this model). This movement is driven by the challenge of government regulators maintaining the capacity and investment required to robustly assess this vast and complex group of products. Third parties are able to specialise in assessing a particular type of medical device or against a particular set of standards and are thus better able to keep pace with rapid technological advances. New Zealand should follow suit.

30 The choice of approach (unilateral recognition, use of others work, or full assessment) would be determined by the regulator and would depend on the nature of the therapeutic product and its risk profile. For the majority of products the international standards for risk classification will guide the choice of process. The accountability arrangements proposed for the regulator in the companion paper provide the opportunity to ensure that the regulator is using the most efficient regulatory approach at any point in time.

31 Capacity issues are not as pressing with respect to post-market and licensing activities.

Regulator

32 Decisions will be needed on who holds regulatory powers, what accountability arrangements sit around the exercise of those powers, and the form that the regulator takes. Advice on the first two of these is contained in the companion paper. That paper recommends that regulatory powers (and associated administrative powers) are held independent of the Minister of Health and that there be arrangements to ensure accountability for the exercise of powers.

33 Proposals on the form of the regulator will be provided in March 2016. The options include the status quo, a Departmental Agency or a Crown Entity. The March paper will assess the benefits of the different models and give an indication of the likely size of the new regulator (a modest increase in size is expected, noting that our regulator is currently small by international norms). The March paper will recommend an approach taking into account the extent to which the options support independent decision-making, accountability, maintaining capacity, a positive regulatory culture, effectiveness and efficiency.

Legislative framework

34 One of the key problems with the Medicines Act 1981 is that it has failed to keep pace with changing regulatory practice and types of products as much of the detail about products and the regulatory requirements are contained in the primary statute.

35 The Productivity Commission found, despite guidance from the Legislation Advisory Committee, this problem is common and regulators across government are working with dated legislation. The Commission's analysis supports new regimes being developed with regulatory detail contained in second tier and regulator-made instruments and regulators being provided the ability to keep these instruments up to date. This is the approach that is recommended for the new therapeutic products regime. Paper two sets out the types of matters that would be contained in each type of instrument following the basic approach that:

35.1 **Primary legislation** should set out the purpose of the statute, provide a set of principles to set the parameters of the regulatory regime (and, importantly set boundaries for the scope and development of subordinate legislative instruments), contain the primary elements of the regulatory regime, provide enforcement powers, and set out accountability arrangements. The principles would include concepts such as risk-proportionality, cost-effectiveness, impartiality, and appeals and reviews.

35.2 **Regulations** will contain further detail on matters not appropriately dealt with in regulator-made instruments (such as fee-setting), matters to do with accountability (as these things will remain relatively stable and are not the jurisdiction of the regulator) and key elements of the regulatory regime that will remain relatively stable and which are significant to the design of the regulatory requirements.

35.3 **Regulator-made instruments** with the force of law should contain the detail of the regulatory requirements and should be made by the regulator. These instruments should, if not already the case as a matter of law, be disallowable instruments and subject to review by the Regulations Review Committee.

New regime compared to the status quo

36 The new regime would result in a modern, comprehensive and sustainable regulatory regime for therapeutic products and would draw to a close the uncertainty that has surrounded this area for nearly two decades. The key changes proposed in the new regime compared to the status quo are:

36.1 **Product coverage**: medicines are currently regulated pre- and post-market and the changes for this sector are relatively small. Medical devices are subject to minimal regulatory controls and no fees currently. The change to full pre- and post-market regulation will be significant, as will any cost recovery. The medical devices industry recognises the need for regulation and is supportive of New Zealand following the international trend to use conformity assessment bodies. The sector will need time for consultation on the detailed requirements and to adjust to full regulation. The cell and tissue sector is largely unregulated and the shift to full regulation is significant. Paper 2 comments on transition arrangements and sector engagement.

36.2 **Regulatory powers**: the proposal that regulatory (and associated administrative powers) be held independent of the Minister of Health is a change from the status quo (these powers are currently held by the Minister of Health and the Director-General of Health[6]) as is the proposal to have specific accountability arrangements for the regulator. These changes will reflect the current practice whereby all regulatory powers are exercised under delegation by the Group Manager Medsafe and the Manager Medicines Control in the Ministry of Health. The Minister currently holds administrative power to appoint advisory committees on technical matters and the proposals would change this arrangement. The accountability arrangements currently are those that apply to the Ministry of Health (eg financial reporting) with voluntary provision of information (eg about approval times).

36.3 **Regulator**: the regulators currently are Medsafe and Medicines Control within the Ministry of Health. Proposals will be provided in March 2016 on the best option for the form of the regulator into the future.

36.4 **Legislative framework**: as signalled, the shift to a lean, principles-based legislative framework will be a significant, and welcome, change from the status quo.

Interfaces with other statutes

37 The new regime will interface with a number of other regulatory regimes and general legislative frameworks, as the Medicines Act 1981 does now (eg, Biosecurity Act, Agricultural Compounds and Veterinary Medicines Act, Fair Trading Act); these interfaces will be examined as the new regime is developed. Key interfaces include those with the:

37.1 **Hazardous Substances and New Organisms Act** – currently medicines that contain new organisms require approval under HSNO as well as under the Medicines Act; officials will examine the impact of and need for two approval processes. Products may also contain ingredients banned under HSNO because of their environmental impact and provision may be needed to clarify that both ingredients and whole products can be banned as well.

[6] The Minister holds powers in respect of new medicines (those that have not previously been available in New Zealand) and the Director-General of Health holds powers in respect of changes to medicines with approvals, clinical trials, activities (eg pharmacy licensing), and medical devices.

37.2 **Food Act 2014** – this Act sets out the meaning of *food* under that Act and states that food does not include any substances used as medicines under the Medicines Act 1981. The new regime will not fundamentally change this arrangement. Any impacts on food regulation from broadening of the scope of the new regime from medicines to therapeutic products will be worked through with the Ministry of Primary Industries to ensure a consistent approach is taken to products at the interface between regimes.

37.3 **Natural Health Products Bill** – care will be taken to ensure that there is clarity about the scope of the Natural Health Products Bill and the new Therapeutic Products regime. The Bill provides that a natural health product may not be, or contain, a scheduled medicine. It is proposed that the therapeutic products regulator must consult the Natural Health Products Authority before scheduling a natural substance as a prescription or pharmacy medicine. There is likely to be interest in reconsidering the status of existing scheduled medicines which fall within the definition of natural substance (for example, vitamin D is a prescription medicine at daily doses above 25 mcg). There are likely to be products that could be sold as natural health products or medicines. The decision of which regulatory scheme to sit under will be up to the person bringing the product to market.

37.4 **Misuse of Drugs Act** – controlled drugs used for therapeutic purposes (eg, morphine for pain management) are regulated under both the Misuse of Drugs Act and the Medicines Act. Medsafe assesses controlled drug products for approval as medicines as for any other medicine but the Misuse of Drugs Act sets out the classification framework for controlled drugs, requirements for import and supply (to protect the supply chain from diversion for illicit uses), and prescriber and dispensing restrictions. The Ministry of Health reviewed the current arrangements for the legitimate uses of controlled drugs earlier this year and concluded a comprehensive review of the Misuse of Drugs Act was not warranted at this time. It also concluded that there is merit in reviewing the Misuse of Drugs Regulations to integrate labelling and packaging requirements for controlled drugs with those for other therapeutic products (current inconsistencies are a legitimate cause of complaint from pharmacy and manufacturers) and pharmacy requirements (ie, audit, stock management and period of supply for prescriptions). This work will be done alongside the development of subordinate instruments for the therapeutic products regulatory regime.

37.5 **Human Tissue Act** – this Act requires an exemption from the Minister of Health to trade in human tissue. The prohibition on trading is designed to prevent inappropriate trade in body parts, but it creates an access issue as an exemption from the Minister is required where trade is legitimate. It is envisaged that the new therapeutic products regime would provide mechanism for exemption without the need for additional Ministerial approval.

Consultation

38 The Government agencies consulted on this paper were: The Treasury; State Services Commission; Ministries of Business Innovation and Employment, Justice, Primary Industries, Environment, Women, Social Development; Te Puni Kokiri, PHARMAC; ACC; Health Quality and Safety Commission; Environmental Protection Authority; and New Zealand Customs. Agency views are reflected in this paper. Agencies will also be consulted on the March 2016 paper and the detail of interfaces with their areas of responsibility.

39 The Government agencies informed about this paper were: The Department of Prime Minister and Cabinet.

40 The Ministry of Health has processes in place for testing the proposals for the new regime with the regulated industry and health practitioners. These groups have also been well consulted on the issues through previous attempts at legislative reform. Industry's key interest is in the detail of the regulatory requirements and the cost recovery proposals. It is proposed that these are largely contained in regulations and regulator-made instruments and that policy proposals for these instruments should be available for consultation with industry at the same time as the exposure draft of the bill.

Financial Implications

40 There are no financial implications associated with this paper.

Human Rights

41 The proposals in this paper are not inconsistent with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Legislative Implications

42 This paper proposes the repeal and replacement of the Medicines Act 1981 and its regulations with a Therapeutic Products Act and associated subordinate instruments. This proposal has Priority 6 on the Government's Legislative Programme and the companion paper seeks approval to issue drafting instructions to Parliamentary Counsel consistent with this priority.

Regulatory Impact Analysis

43 A regulatory impact statement is attached to Paper 2.

Gender Implications and disability perspective

44 There are no gender implications or disability issues associated with this paper.

Publicity

45 In November 2014 I announced the cessation of efforts to establish ANZTPA and the commencement of work on a new domestic regulatory regime for therapeutic products. There is considerable interest in this initiative from the industry and health sector stakeholders. The Ministry of Health is engaging actively with interested parties and I propose making further announcements at the time the exposure draft is released for consultation.

Recommendations

The Minister of Health recommends that the Committee:

1 **Note** that in November 2014 the Minister of Health announced the cessation of work on a joint regulator with Australia (ANZTPA) and the commencement of work on a comprehensive domestic regulatory regime for therapeutic products covering medicines, medical devices and cell and tissue therapies [CAB Min (14) 36/22 refers]

2 **Note** that a Therapeutic Products Bill to repeal and replace the Medicines Act 1981 Priority 6 on the Government's legislative programme (drafting instructions to be issued this year) [CAB Min (15) 5/7 refers] and that this paper, and its companion *Therapeutic Products Regulation: Paper 2 Proposals for a Therapeutic Products Bill* will enable drafting instructions to be developed for the key elements of the Bill

3 **Note** that the Minister of Health will report to SOC in March 2016 on a range of other matters, including prescribing dispensing and administration of therapeutic products, clinical trial arrangements and the proposed form of the regulator; with a view to further drafting instructions being issued

4 **Note** that the Minister of Health intends to introduce the Therapeutic Products Bill to the House in late 2016 for passage during 2017

5 **Agree** that, prior to the introduction of the Bill, the Minister of Health release an exposure draft of the Bill for consultation along with a statement of the policy to be contained in subordinate legislative instruments

6 **Note** that Cabinet has also agreed to repeal, via the Statutes Repeal Bill, provisions of the Medicines Act 1981 that were introduced through the Medicines Amendment Act 2013 that have a default commencement date of 1 July 2017 as these are no longer necessary or desirable in light of the development of the new regulatory regime [EGI-15-MIN-0027 refers].

7 **Agree** that the objectives for the therapeutic products regulatory regime are that it:

7.1 meets expectations of risk management and assurance of acceptable safety

7.2 results in efficient and cost effective regulation

7.3 is flexible, durable, up-to-date, and easy to use

7.4 ensures high-quality, robust and accountable decision-making

7.5 is able to sustain capable regulatory capacity

7.6 supports New Zealand trade and economic objectives

7.7 is trusted and respected

7.8 supports consumer access and individual responsibility for care.

8 **Agree** that these objectives will be best met by:

8.1 an enabling legislative framework where primary legislation sets the purpose of the regime, principles that set boundaries for the scope and development of subordinate legislative instruments, enforcement powers and accountability arrangements

8.2 regulatory requirements that reflect international norms, standards and frameworks

8.3 a regulator that can exercise regulatory powers and associated administrative powers effectively, is accountable, and able to engage internationally.

9 **Note** that the regulatory approval processes will involve a mix of unilateral recognition, use of other regulators work, and assessment by the regulator.

Hon Dr Jonathan Coleman
Minister of Health

In Confidence

Office of the Minister of Health

Chair, Cabinet Social Policy Committee

Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill

Proposal

1 Approval is sought to issue drafting instructions for a comprehensive, cost effective regulatory regime for therapeutic products to replace the Medicines Act 1981.

Executive Summary

2 This is the second of two papers about Therapeutic Products Regulation. The first, *Therapeutic Products Regulation Paper 1: Context and Overview* has described the context within which the new regulatory regime for therapeutic products is being developed, the objectives of the new regime, and how they can be achieved. This paper seeks agreement to key elements of the legislation to give effect to the need for:

2.1 a lean, principles-based Act containing the central regulatory requirements and the parameters for regulations and regulator-made instruments that contain the detail of regulatory requirements.

2.2 a regulator that is responsible for the design of the technical regulatory requirements and the exercise of regulatory powers independent of the Minister of Health with associated accountability arrangements that balance regulator independence and enable scrutiny of regulator performance by Ministers and stakeholders.

2.3 regulatory requirements that are consistent with international approaches and effectively administered. The regulatory requirements for product approval and licensed activities will be based around a set of clearly stated principles set around consumer safety and delivery of health outcomes. Therapeutic product classifications and license conditions for supply will be based on risk. In both cases a Responsible Person is required to be named that can take action in relation to the product or licensed activity. Provisions will also be made for advertising controls, compliance, audit, post-market vigilance, and enforcement. Exceptions may be approved by the regulator consistent with the principles.

Background

3 This is the second of two papers being provided concurrently to Cabinet with a view to decisions being taken on the key elements of new legislation to regulate therapeutic products (medicines, medical devices, cell and tissue therapies, hybrids, and new technology) in New Zealand.

4 Paper one has described that the regulatory regime should comprise regulatory requirements, a regulator and an enabling legislative framework.

5 This paper focuses on the key elements proposed for the new Therapeutic Products Bill and is organised as follows:

5.1 purpose and principles

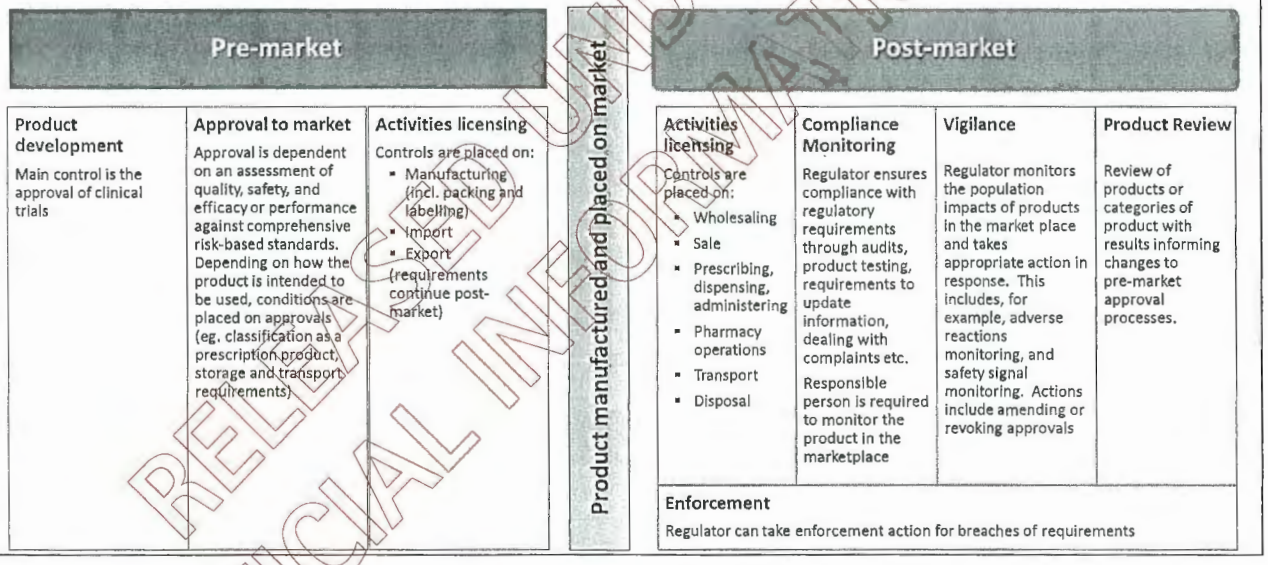
5.2 regulatory requirements, including definitions, product approval, activities licensing, post-market vigilance, and enforcement

5.3 administration arrangements, including regulatory powers and accountability

5.4 transition.

6 Internationally, regulatory regimes put risk-proportionate controls at key points across the lifespan of products (refer diagram below). These controls are supported by compliance and enforcement powers; and requirements and systems to monitor the use of products and to respond to any safety concerns. These arrangements are aimed at ensuring that the benefits of using products as intended outweigh the risks, that products are high quality throughout their lifespan (ie, they do not degrade or fail), are traceable, appropriately used and accompanied by good information.

Regulatory control points across the therapeutic product lifespan



Purpose and Principles

7 The key purpose of the new legislation will be to ensure acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare. In particular this requires the regulation of manufacture, supply, import, export and promotion of therapeutic products; the setting of standards in relation to therapeutic products; the post-market monitoring of therapeutic products, and the enforcement of requirements.

8 It is proposed that the legislation contain a purpose statement that encompasses this concept.

9 The purpose statement would be supported by a set of principles that give effect to the overall purpose and set the parameters for the design and administration of the regulatory regime. The following general principles are proposed.

9.1 The expected benefits of therapeutic products should outweigh their known risks of causing harm in the treatment population.

9.2 Regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use.

9.3 Regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests.

9.4 An identified person is responsible for managing the risks associated with each therapeutic product on the market, and will generally be the person who is responsible for marketing that product.

9.5 Regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public.

9.6 The regulator should co-operate with international peer regulators and take relevant international standards and practice into account.

9.7 Compliance costs should be appropriate to the benefit:risk profile.

9.8 Regulation should support innovation and competition.

10 These principles will be of central interest to stakeholders and considerable feedback is expected during consultation on the exposure draft. Care will be taken in the final drafting to ensure that the final set of principles provide appropriate parameters to the regime and certainty to industry, but are not too prescriptive or too broad.

Regulatory Requirements

Definitions

Therapeutic product and therapeutic purpose

11 The legislation should define *therapeutic product* and *therapeutic purpose*. These definitions will bound the regime, give a level of certainty to industry, and clarify boundaries with other regulatory regimes (eg, food, natural health products).

12 Legislation should also enable the regulator to determine whether something is, or isn't, a therapeutic product and to exclude things from the scope of the Act if needed. This will enable the regulator to assess whether a product meets the definition of a therapeutic product and to exclude things captured within the scope of the regime that are better regulated elsewhere. For example, fireman's clothing could inadvertently be captured through the concept that a therapeutic product 'prevents a condition'.

13 The definitions in the Medicines Act 1981 and international norms provide useful starting points for these definitions.

Responsible person, Approval holder, and Licensee

14 The legislation should define a *responsible person* as a legal person (natural person or company) for both products and licences. That person should be readily contactable and able to take action; this is particularly important in product recall situations.

15 In the current regulatory scheme, it is not always clear who is responsible for a therapeutic product on the New Zealand market. The Medicines Act 1981 refers in several places to the manufacturer or importer of a medicine, in one place to the proprietor and to sponsors of medical devices. Various obligations are placed on those people – for example reporting adverse effects of a product, and withdrawing products from sale if ordered by the Director-General of Health.

16 It is proposed that identifying a *responsible person* be a condition of a product approval (refer discussion at paragraph 22). That person would be the first port of call for any issues arising with an individual product and would be responsible for ensuring that those issues can be responded to.

17 The legislation should also define *approval holder*. This concept is contained in the current Medicines Act. The *approval holder* would be ultimately responsible for ensuring that the terms of an approval are adhered to. The legislation will need to provide the regulator with legal reach to these people in order that it can enforce the terms of an approval if necessary. The *approval holder* would be responsible for:

17.1 responding to queries and requests for information in order that the product can be assessed for approval

17.2 ensuring products distributed in New Zealand meet requirements. This will include manufacture, distribution, record keeping and product monitoring carried out according to prescribed standards

17.3 ensuring that there is an effective system to take market action, including recall, including information being available about the distribution chain

17.4 ensuring product information is available for the regulator, health care professionals and the public.

18 The *approval holder* may delegate some of these responsibilities to the *responsible person*, or they may be one and the same person.

19 Similar arrangements should be put in place in respect of holding licences (refer paragraph 41). The legislation should define *licensee* and impose obligations on that person, including the requirement to identify a *responsible person.* In regards to licences, the *responsible person* must be a natural person.

20 *Approval holders* and *licensees* would be responsible for ensuring that *responsible persons* meet reasonable requirements. This could include demonstrating the necessary technical knowledge or quick access to it, understanding the obligations of the approval or licence (including any hazards) and meeting character requirements.

21 The legislation should identify a *Responsible Person* for unapproved products where there is no application or approval holder (this may be the prescribing health practitioner or the supplier).

Approval to Market

Product approval

22 Product approval is the key point of control in the regulatory regime and the legislation should:

22.1 require therapeutic products to have an approval and enable the regulator to issue an approval

22.2 require material changes to approved therapeutic products to also be approved

22.3 enable conditions to be placed on an approval

22.4 enable approvals to be modified, suspended or revoked

22.5 enable approvals to be for a defined duration

22.6 enable recognition of other jurisdictions assessments/approvals and third party evaluators

23 To obtain an approval a product will need to meet technical requirements (eg, for pharmacology, toxicology, electrical safety, labelling) and there will need to be processes in place for post-market vigilance, the ability to conduct product recalls etc. These technical requirements are largely set out in international standards such as those promulgated by the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* and the *International Medical Device Regulators Forum* (previously the Global Harmonisation Taskforce). There will also be domestic standards for local matters such as labelling and classification.

24 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. Specific requirements will be given effect through conditions being placed on the approval. Conditions will include matters such as classification status (discussed below), requirements to use licensed facilities (eg, for manufacture), and obligations with respect to ensuring market recall action can be taken, that the product can be verified locally before distribution, that quality and technical information is available etc.

25 While currently relatively stable, it is anticipated that the categorisation of products as medicine, medical device or cell and tissue therapy will need to evolve in response to a growing number of hybrid products and the arrival of new products. Detailed technical requirements will evolve in tandem.

26 In terms of legislative placement a balance needs to be struck between ensuring the regulatory regime remains flexible and current (which argues for placement of these key categories in regulator-made instruments) and ensuring that the Government and regulated industry are provided with certainty over regulatory settings (which argues for more detail in the primary statute).

27 It is proposed that this balance be struck by legislation containing a high-level definition of the product categories with detail contained in regulator-made instruments. The

definitions in the primary act will need to be sufficiently high-level so as to allow evolution in the detail contained in regulator-made instruments over time. There will also need to be accountability arrangements in respect of the regulator's processes for making instruments and these are discussed at paragraph 69.

28 The Ministry of Health will discuss this placement issue further with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and I will report back on the outcome of that process in March 2016 if any change is proposed. That discussion will include considering whether placing more precise category definitions in regulations would be appropriate.

Classification

29 Classification is the process of specifying conditions on availability, for example, whether a product should only be available via a health practitioner. Currently classification applies to medicines which, on approval, are classified as prescription, restricted (pharmacist-only), pharmacy-only or for general sale. Classification often changes (usually – but not always – to be less restrictive) as a new medicine becomes established and its risk profile is better understood; classification may also change in response to changes in prescribing authority.

30 Classification decisions are significant in that they have a material bearing on consumer access to products, revenue (for prescribers, pharmacists and retail outlets), and costs to the health system.

31 Classification may need to apply to other types of therapeutic product over time and this development should be enabled through the legislative arrangements.

32 It is proposed that:

32.1 the principles of medicines classification be adapted to apply to all therapeutic products and that these be set out in legislation (eg 'prescription' could be adapted to 'available on the authority of a health practitioner')

32.2 legislation enable regulations to be made that set out additional precision specific to product types (eg, prescription medicine)

32.3 legislation enable the regulator to set out any further detail in regulator-made instruments.

33 Given the significance of classification decisions it is also proposed the legislation require the regulator to establish a technical advisory committee to inform these decisions. Further information on the establishment of this, and other committees is contained in paragraph 73. A classification committee is part of the Medicines Act currently and is common internationally.

Exceptions to the approval process

34 The regime will need to provide the ability for unapproved products to be available in certain circumstances. This is a common arrangement in regulatory regimes internationally and facilitates access to products when a prescriber judges that the particular clinical circumstances of an individual patient require the use of an unapproved product.

35 Section 29 of the Medicines Act currently provides for unapproved medicines to be supplied and administered to particular patients under the care of a medical practitioner. It also requires the use to be reported to the Director-General of Health. Section 29 is problematic in that it is increasingly being used for the supply of medicines for use in routine, non-exceptional circumstances; these are contrary to the spirit and intention of the provision and give rise to risks to patient safety. Section 29 also prevents provision of unapproved products to unknown patients. This is impractical when a section 29 medicine may be required with urgency and thus needs to be held in stock by a hospital pharmacy (eg anti-venom).

36 The intention is that under the new regime there will be less need for exceptions to be made, as the regime will be more appropriately calibrated for a range of circumstances. For example, accelerated approval processes, use of recognition, and potentially fee relief for small volume products. The Ministry of Health will also explore what incentives can be put in place during the transition from the current regime to the new regime to encourage suppliers of currently unapproved products to apply for approval.

37 The new regime should, in addition to requiring all products to have an approval (paragraph 22), enable regulations to set out the circumstances when a therapeutic product may be made available without an approval, by whom, the requirements that sit around provision of the product (eg, responsibilities, duration of provision, record keeping, notification, informed consent). The regulations should also set out responsibilities on the regulator to monitor the use of the product and the ability of the regulator to require an exempted product to go through the assessment process with a view to obtaining an approval. The requirements may differ between the types of therapeutic product and who can access them is likely to be expanded to cover a broader range of prescribers, including veterinarians, who sometimes need access to unapproved human medicines to treat animals.

38 A related consideration is products compounded (prepared) in a pharmacy, usually in small batches. Currently any pharmacist can do this under section 26 of the Medicines Act and product approval is not required. These provisions reflect the era of the Medicines Act when pharmacy compounding was common and changes are proposed to reflect more modern practice and products. It is proposed that the regulations enable, within parameters, unapproved products to be made by specialised facilities with the right expertise. Parameters should be set in regulator-made instruments and relate to the types of operation, the permitted volumes of products, and the responsibilities in relation to the fact the products are unapproved.

Data protection

39 New Zealand is required by the Trade-Related Aspects of Intellectual Property Rights agreement (known as TRIPS) to provide protection for the information supporting a regulatory approval of a new medicine. New Zealand provides five years data protection for all medicines from the date regulatory approval is granted. This means that a 'generic' that has the same active ingredient as an approved product cannot rely on that data for an 'accelerated' approval during the data protection period. It is proposed that the new regime retain the same settings as in the current Medicines Act for data protection. This will also satisfy our Trans-Pacific Partnership obligations which can be met within existing law and practice.

Activities Licensing

40 Pre- and post-market activities relating to therapeutic products (eg, manufacturing, supply chain management) are currently largely controlled via licensing, as is the standard model around the world, and recommended by the World Health Organization. There is no compelling reason to depart from this model.

41 Some activities are controlled by general rules, without being licensed. For example, anyone selling medicines is bound by the regulations on storage, which require, for example, that medicines are kept clean and protected from vermin. I propose regulation-making powers similar to those in the current Medicines Act to allow such rules to be made.

42 It is proposed that the legislation require licences for controlled activities, including the following, and be otherwise prohibited:

42.1 manufacturing, including packing and labelling

42.2 supplying, including wholesale, hawking, and retail sale (licence holders must also undertake these activities consistent with product classification)

42.3 operating a pharmacy.

43 It is proposed that the regulator have powers of entry and inspection to assure compliance similar to those in the current Medicines Act, discussed more fully in enforcement below. I further propose that the regulator have powers to set and vary conditions on a licence, and to suspend or revoke a licence, as is the case now.

44 It is proposed that licenses generally last for three years, rather than the current one year. The regulator would be able to specify a shorter period, or revoke a license for non-compliance. This will reduce the compliance burden on industry, while allowing for more frequent relicensing for licence-holders with a history of non-compliance.

45 The detailed requirements in respect of obtaining licences should be contained in Regulations and regulator-made instruments.

Pharmacy licensing

46 The overarching objective for the regulation of pharmacies is to ensure the safe supply and effective use of therapeutic products, and to enhance their accessibility within an environment that enables the development of innovative ways of providing pharmacy services.

47 The primary method of ensuring this in the new regime will be through licensing requirements, including that they are under the supervision of qualified pharmacists. Additional conditions related to safe pharmacy practice should also be able to be set as in the terms of a license by the regulator.

48 My initial view is that the current restrictions on pharmacy ownership are not necessary to achieve the safety objectives of the regulatory scheme – that includes restrictions on medical practitioners having an interest in pharmacies. The current restriction is that a pharmacist must hold 51 percent of the shares in a pharmacy and may hold this majority share in up to five pharmacies. Professional bodies, as well as licence conditions are well

placed to address and identify potential issues - and should have sufficient regulatory authority to do so.

49 The Ministry of Health is presently consulting with 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 support system (closing 25 November 2015). This consultation includes a question about the place of pharmacy ownership in the future delivery of pharmacy services. Following the completion of this consultation I will report to Cabinet on the pharmacy licensing arrangements for the inclusion in the Therapeutic Products Bill. It is expected that there will be a strong reaction from parts of the pharmacy sector to the suggestion that ownership requirements may no longer be necessary.

Promotion/advertising

50 The legislation should set high level requirements in respect of the promotion/advertising of therapeutic products and enable enforcement action for breaches. The internationally accepted parameters are that advertisements should be truthful, not misleading and socially responsible. The legislation should also enable regulator-made instruments to be made that set out how these requirements are given effect, including classes of people or products to whom requirements apply.

51 This legislative framework should continue to be supported by the existing self-regulatory systems for the control of advertising of therapeutic products. The Advertising Standards Authority issues a Code of Practice consistent with the legislation and regulations and the Therapeutic Advertising Pre-vetting System reviews advertisements for compliance with the Code.

52 This system results in most breaches of requirements being dealt with simply and effectively and the regulator retains the ability to take enforcement action for serious breaches or non-compliance. The section on enforcement below proposes a graded system to enforcement; this would provide medium level enforcement tools that would be appropriate for advertising breaches.

53 The Ministry of Health is exploring whether changes are needed to the current policy settings in respect of direct-to-consumer and direct-to-health practitioner advertising and I will advise Cabinet if any changes appear warranted.

Compliance, monitoring and enforcement

54 In general, current legislation has worked reasonably well and Medsafe and Medicines Control have been able to intervene to protect public safety in respect of products and the supply chain. It is proposed that the new regime include improvements. The main change proposed is identifying a *responsible person* and imposing obligations on *approval holders* and *licensees* in respect of that person, as discussed in paragraph 14.

55 Only minor changes are proposed to enforcement powers to provide explicit intermediate steps before suspending or cancelling a licence or withdrawing consent for a medicine to be distributed, including fines. The ability of the regulator to vary conditions on activity licences and marketing authorisation for goods will provide the controls necessary.

56 The regulator needs the ability to check and enforce compliance with regulatory requirements, both for licenses and illicit activity. That requires powers of entry, search

and seizure, as well as the power to demand information. These powers are present in the current Medicines Act. Enforcement officers have a warrantless search power where they reasonably suspect articles subject to the Act are made, stored or available for sale.

57 A warrantless search power continues to be justified on the ground that the risk to public safety posed by non-compliant medicines, and the ease of destroying or removing evidence mean a requirement to obtain a warrant will unreasonably interfere with the aims of the legislation. I propose adding a warranted search power for dwellinghouses and marae where an offence against the Act is reasonably suspected, and retaining the existing warrantless search and seizure powers for other premises, but ensuring they follow the provisions of the Search and Surveillance Act 2012.

58 The penalties in the current Medicines Act are out of step with more recent similar legislation. I propose offences and penalties broadly commensurate with those in recent similar legislation. The Ministry of Health will work with the Ministry of Justice to develop detailed offence and penalty provisions for consideration by Cabinet in March 2016.

Vigilance

59 Even with pre-market review and approval of therapeutic products, they present risks when in the market. It is not possible to have perfect information at the time of approval (eg, clinical trial data may cover a limited time period). It is therefore proposed to require post-market monitoring of therapeutic products by the *approval holder*, and the regulator; and to provide the regulator with intervention powers to require effective action to be undertaken when a safety concern is identified. The present arrangement for medicines is that the importer or manufacturer of a medicine must report 'substantial untoward effects of that medicine'. This implies an obligation to actively monitor the safety and quality of products in order to be able to fulfil the legislative responsibility, but there is no explicit requirement in legislation.

60 It is proposed that the new legislation impose obligations on the *approval holder* and the regulator to monitor the safety of therapeutic products, according to standards. Therapeutic product vigilance is a highly technical area, so the detail of requirements will be in regulator-made instruments, rather than the primary act or regulations. The regulator will have powers of search and seizure to support enforcement.

61 It is further proposed to add obligations to share information, including an obligation on *approval holders* to create information under some circumstances (paragraph 14 refers). This would enable the regulator to require the *approval holder* to carry out safety studies where a concern is identified. At present, Medsafe does not have such a power, meaning it must rely on the goodwill of pharmaceutical companies where such studies are warranted.

Administration arrangements

62 Decisions are sought about who holds decision rights, how they are held to account, review and appeal rights, and how technical advice and public input is sought. Proposals on the form of the regulator will be provided in March 2016.

Holding powers

63 Decisions about these arrangements flow from a decision about the degree of independence the regulator should have. Regulatory independence is explored in-depth

in the Productivity Commission's 2014 report on *Regulatory Institutions and Practices*. The Commission puts forward strong arguments for independence as a key factor to regulators adopting effective regulatory strategies and creating an impartial and stable regulatory environment over the longer term. The Commission notes that independence is particularly desirable when there are powerful private interests weighed against a dispersed public interest, when a substantial degree of technical expertise is required and when public confidence that the regulator is impartial is important.

64 Regulatory decisions about therapeutic products impact significantly on:

64.1 consumers in terms of access to products

64.2 health professionals in terms of how they are able to provide care to patients and (for some) their personal financial gain

64.3 the therapeutic products industry and other private interests (eg, supermarkets) in terms of revenue and reputation in the domestic and international markets

64.4 the provision of publicly-funded products through the Pharmaceutical Schedule.

65 While in practice the Minister's powers are exercised under delegation by the appropriate officials, the status quo places ultimate responsibility for many technical decisions that have significant third party impacts with the Minister of Health[1]. This is problematic because:

65.1 the Minister is responsible but poorly placed to assess the relevant technical information and make a risk:benefit judgement

65.2 Ministers may be put under undue pressure to make decisions contrary to technical analysis, resulting in safety concerns (for example a decision to approve a product for market, or to withdraw or not withdraw a product from the market)

65.3 the Minister is less able to independently monitor the overall performance of the regulatory regime and the regulator.

66 The Minister also holds administrative power to appoint advisory committees on technical matters to provide proposals and recommendations in respect of regulatory decisions, these are:

66.1 the Medicines Assessment Advisory Committee and the Medicines Adverse Reactions Committee (appointed under a general power to appoint advisory and technical committees)

66.2 the Medicines Classification Committee

66.3 the Medicines Review Committee.

67 It is proposed that regulatory powers and associated administrative powers (for example those to appoint technical committees) are held independent of the Minister of Health.

[1] Under the Medicines Act 1981 the Minister holds powers in respect of new medicines (those that have not previously been available in New Zealand) and the Director-General of Health powers in respect of changes to medicines with approvals, clinical trials, activities (eg, pharmacy licensing), and medical devices.

This would mean that the Minister had no influence over regulatory decisions in respect of particular products, or persons.

68 As a counterbalance to regulatory independence and reflecting the Minister's role in overseeing the performance of the regime, it is proposed that the legislation also provide a limited power for the Minister to be able to direct the regulator. Direction should be limited to matters of government policy that relate to the delivery of the regulatory regime and for any directions to be tabled in the House (ie there would be no ability to direct in respect of particular products or persons). The Productivity Commission notes that such ability can, somewhat counterintuitively, enhance regulatory independence while also recognising the fact that there are times when political imperatives diverge from the objectives of regulators.

Accountability

69 In order to balance the independence of the regulator and reflecting the likelihood that the costs of the regulatory regime will be largely (and potentially fully) recovered from the regulated industry it is recommended that there are accountability arrangements around regulatory design, decision-making and performance. The arrangements below will apply as a matter of law:

69.1 the requirement that the contents of regulator-made legislative instruments be consistent with the principles of the Act. In turn the principles require risk proportionality, cost effectiveness etc.

69.2 judicial review

69.3 process requirements in respect of the making of regulations.

70 In addition it is proposed that the legislation include the following requirements:

Regulator making instruments

70.1 that, except where already provided for by the Legislation Act, regulator-made legislative instruments be disallowable instruments and subject to review by the Regulations Review Committee

70.2 that, in making legislative instruments, the regulator consult appropriately

Regulatory practice

70.3 that the regulator establish mechanisms for industry and consumer engagement (this may involve, for example, formalising the existing bi-annual industry forum)

70.4 that the regulator be transparent about its processes including how committee appointments are made, decision-making processes and reasons for decisions

Performance

70.5 mechanisms for review and appeal of regulatory decisions in addition to judicial review (refer paragraph 75)

70.6 financial and non-financial reporting.

71 It is proposed that detail in relation to these matters be set out in regulations enabled by the primary legislation.

72 Precisely how the proposed accountability arrangements are set out in the legislation will depend to some extent on decisions on the form of the regulator as some of the requirements would apply automatically if the regulator is established as a Crown Entity. Advice on merits of establishing the regulator as a Crown Entity, a Departmental Agency or within the Ministry of Health will be provided in March 2016. That advice will analyse the options and the extent to which they support independent decision-making, accountability, maintaining capacity, a positive regulatory culture, effectiveness, and efficiency.

Obtaining specialist advice and consumer input

73 As is the case now under the Medicines Act 1981, the new regime will require consideration of issues where the advice of external experts will be valuable. Committees provide a relatively simple way to obtain additional expert input to regulatory decisions and ensure that the full range of considerations are taken into account. It is proposed that the regulator be required to establish certain committees for certain purposes. Mindful of the costs of establishing and running committees, and of the challenge in finding suitable candidates for them, this requirement should however be kept to a minimum. I propose that the legislation:

73.1 Require the regulator to establish a committee or committees to provide advice, as needed, on therapeutic product:

73.1.1 assessment

73.1.2 classification

73.1.3 safety monitoring.

73.2 Require the regulator to ensure committee members have suitable skills including (but not limited to) knowledge of medicine, pharmacy, and consumer perspectives

73.3 Enable the regulator to establish other technical advisory committees as it requires

73.4 Enable committee processes (including the management of conflicts of interest, remuneration) to be determined by the regulator as a matter of policy. These policies would, as a matter of Government process, include consideration of the Cabinet Fees Framework and governance policy.

74 These arrangements aim to provide flexibility in how committees are appointed and used while also signalling the types of issues that to be considered by a committee. The accountability requirements in paragraph 69 will ensure that the regulator can be held to account for its decisions over what committees are established, how they are used, and how appointments are made.

Review and appeal

75 The legislation should establish an independent review committee administered by the Ministry of Health to hear appeals against regulatory decisions. This will provide a

mechanism for review in addition to judicial review. There will be a further right of appeal to the High Court.

76 The committee will have a broad and flexible membership appointed by the Minister of Health. It will be able to hear appeals on the papers. The form of appeal will generally be by re-hearing, which means new evidence can be submitted. Only the applicant will be permitted to appeal a declined application for approval. Someone whose interests are affected will be permitted to appeal a licencing decision.

77 The regulator will also establish an internal complaints mechanism to help resolve complaints about regulatory decisions.

Cost recovery

78 Generally, and consistent with Treasury guidelines, it is likely that the costs of the regime will largely be cost-recovered from the regulated industry. There may be some activities that should be funded by appropriation from general taxation. This might include fee-exemptions for low-volume but necessary medicines; consideration will also need to be given to the appropriate mechanism for funding enforcement. In the event that Crown funding is desirable, it would be arranged through standard Budget processes. The fee-setting provision will oblige the recovery of costs that are not provided for by Crown funding, leaving open the possibility of such funding, if desirable. Currently just over 80 percent of the costs are recovered from industry. It is proposed that fees and levies are set in regulations.

79 Legislation should also require a review of the fees and levies within 3 years of them first being set as it is likely that they will need adjusting as volume assumptions (and thus regulatory costs) are tested.

Transition and review

80 Legislation will need to set out how currently regulated products move from the Medicines Act 1981 to the new regime and it is proposed that drafting instructions be prepared for these transitional provisions. Legislation will also need to enable the regulatory requirements for medical devices and cell and tissue therapies to come into effect over a period of time and to be different for the different product types. This approach will allow industry to adjust to the new requirements in a reasonable fashion. Implementation will include examining incentives for industry to bring products under the new regime early.

81 Given the scope of the new regime and its complexity, it is recommended that the legislation should require a review to be undertaken about 5 years after the end of the transition period.

Consultation

82 The Government agencies consulted on this paper were: Treasury; State Services Commission; Ministries of Business, Innovation and Employment, Justice, Primary Industries, Environment, Women, Social Development; Te Puni Kokiri; PHARMAC; ACC; Health Quality and Safety Commission; Environmental Protection Authority; and New Zealand Customs. Agency views are reflected in this paper. Agencies will also be consulted on the March 2016 paper and the detail of interfaces with their areas of responsibility.

83 The Government agencies informed about this paper were: Department of Prime Minister and Cabinet.

84 The Ministry of Health has processes in place for testing the proposals for the new regime with the regulated industry and health practitioners. These groups have also been well consulted on the issues through previous attempts at legislative reform. Industry's key interest is in the detail of the regulatory requirements and the cost recovery proposals. This paper proposes that these are largely contained in regulations and regulator-made instruments and that policy proposals for these instruments should be available for consultation with industry at the same time as the exposure draft of the bill.

85 Paragraph 46 notes the consultation currently underway with the pharmacy sector on the Draft Pharmacy Action Plan.

86 Agency comment: the Ministry of Business Innovation and Employment, PHARMAC and Treasury note their support for the removal of restrictions on pharmacy ownership and for allowing increased overlap between prescriber/dispenser roles with appropriate safeguards. Treasury notes that any financial implications of this change will need to be considered as the further advice is developed.

87 The Parliamentary Counsel Office notes that the timeframe for developing the new legislation is reasonably tight.

Financial Implications

88 This paper proposes that legislation enable both cost recovery and Crown funding to meet the costs of the regulatory regime. An indication of these costs and how they should fall will be contained in policy proposals to accompany the exposure draft. This will include whether there should be any recovery of establishment and start-up costs.

89 The costs of developing the new regime are currently met from within the Ministry of Health's baseline funding (including some funding from the Ministry's third party revenue baseline funding). It is likely that there will be implementation costs, such as the development of new IT infrastructure, that cannot be reasonably met from these sources and consideration will be given as to whether these will be managed within usual budget processes or factored into fee-setting for the new regulatory regime. It is expected that any bids would be part of the 2017 Budget process.

Human Rights

90 The proposals in this paper are not inconsistent with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 (NZBoRA) and the Human Rights Act 1993.

91 While the proposals include search and seizure proposals, the restriction in NZBoRA is on *unreasonable search and seizure*. Care will be taken in developing the proposals to ensure they do not transgress s21 of NZBoRA. Review of the Bill for consistency with the Bill of Rights Act will be undertaken as part of usual legislative processes.

Legislative Implications

92 This paper proposes the repeal and replacement of the Medicines Act 1981 and its regulations with a Therapeutic Products Act and associated subordinate instruments. This proposal has Priority 6 on the Government's Legislative Programme and this paper

seeks approval to issue drafting instructions to Parliamentary Counsel consistent with this priority [CAB Min (15) 5/7 refers].

Regulatory Impact Analysis

93 The Regulatory Impact Analysis (RIA) requirements apply to the proposal in this paper and a Regulatory Impact Statement (RIS) has been prepared and is attached.

94 The Regulatory Impact Analysis Team (RIAT) has reviewed the RIS prepared by the Ministry of Health and associated supporting material, and considers that the information and analysis summarised in the RIS meets the quality assurance criteria.

95 RIAT notes that the full impact of the proposed changes will depend on the detail of the arrangements, which is yet to be decided. RIAT understands that further decisions will be sought from Cabinet on this detail and a RIS will be completed for these decisions.

Gender Implications and Disability Perspective

96 There are no particular matters with respect to gender implications or disability perspectives. The overall regime is designed to facilitate access to safe, high-quality therapeutic products. Where there are gender or disability issues with respect to any given therapeutic product (for example, access to pregnancy test kits, products with contraceptive uses) the regime contains mechanisms for these to be considered (eg, the requirement that consumer perspectives are considered in classification decisions).

Publicity

97 In November 2014 I announced the cessation of efforts to establish ANZTPA[2] and the commencement of work on a new domestic regulatory regime for therapeutic products. There is considerable interest in this initiative from the industry and health sector stakeholders. The Ministry of Health is engaging actively with interested parties and I propose making further announcements at the time the exposure draft is released for consultation.

Recommendations

The Minister of Health recommends that the Committee:

1 **agree** that drafting instructions be provided to the Parliamentary Counsel Office for a Therapeutic Products Bill that includes the following settings.

Purpose and principles

1.1 A statement encompassing the concept that the purpose of the Bill is to ensure acceptable safety, quality and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare; and

1.2 That the concept in 1.1 includes the regulation of manufacture, supply, import, export and promotion of therapeutic products; on the setting of standards in relation to therapeutic products; the post-market monitoring of therapeutic products, and the enforcement of requirements.

[2] Australia New Zealand Therapeutic Products Agency

1.3 A set of principles that give effect to the purpose and set the parameters for the regulatory regime and that express the intention that:

1.3.1 the expected benefits of therapeutic products should outweigh the known risks of causing harm in the treatment population

1.3.2 regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use

1.3.3 regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests

1.3.4 an identified person is responsible for managing the risks associated with each therapeutic product on the market, and will generally be the person who is responsible for marketing that product

1.3.5 regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public

1.3.6 regulator should co-operate with international peer regulators and take relevant international standards and practice into account

1.3.7 compliance costs should be appropriate to the benefit:risk profile

1.3.8 regulation should support innovation and competition.

Definitions

1.4 Definitions of the terms *therapeutic product*, *therapeutic purpose, responsible person, approval holder,* and *licensee.*

1.5 High-level definition of categories of therapeutic products.

1.6 The ability for the regulator to declare something to be, or not to be, a therapeutic product and the category of product.

Approvals

1.7 A requirement that therapeutic products are approved, unless an approval is not required, and the ability for the regulator to issue an approval.

1.8 A requirement that material changes to approved therapeutic products also be approved.

1.9 The ability for the regulator to place conditions on an approval.

1.10 The ability for the regulator to modify, suspend or revoke an approval.

1.11 The ability for approvals to be issued for a defined duration.

1.12 Definitions of generic classifications that apply to therapeutic products based on those that apply to medicines currently (prescription, restricted, pharmacy-only, general sales).

1.13 The ability for the regulator to classify products as a condition of approval.

1.14 Enable recognition of other jurisdictions assessments/approvals and third party evaluators.

Data protection

1.15 Provisions for the protection of information supporting an application for regulatory approval of a new medicine from the date the approval is granted, consistent with New Zealand's obligations under the Trade-Related Aspects of Intellectual Property Rights agreement and as set out in the Medicines Act 1981.

Activities licensing

1.16 A requirement that, unless done under licence issued by the regulator, controlled activities are prohibited in respect of therapeutic products, including:

1.16.1 manufacturing, including packing and labelling

1.16.2 supply, including wholesale, hawking, and retail of therapeutic products (licence holders must also undertake these activities consistent with product classification)

1.16.3 operating a pharmacy.

1.17 The ability for the regulator to issue licenses for up to a three year period and set and vary conditions on a licence within that time.

Promotion/advertising

1.18 A requirement that advertisements and promotions in respect of therapeutic products be truthful, not misleading and socially responsible.

Compliance, enforcement and penalties

1.19 Inspection powers, including the ability to require information.

1.20 Search and seizure powers based on those in the Medicines Act 1981 and the Search and Surveillance Act and including a warranted search power for dwelling houses and marae where an offence against the Act is reasonably suspected.

Vigilance

1.21 Obligations on the regulator to monitor the safety of therapeutic products and to provide information to approval holders (noting that obligations for vigilance are also imposed on approval holders through the approvals process).

Administration arrangements

1.22 That regulatory powers and associated administrative powers are held independent of the Minister of Health.

1.23 An ability for the Minister of Health to direct the regulator on matters of government policy and not in respect of a particular product or person.

1.24 The following accountability arrangements:

1.24.1 that, except where already provided for by the Legislation Act, instruments made by the regulator be disallowable instruments and subject to review by the Regulations Review Committee

1.24.2 that, in making legislative instruments, the regulator consult appropriately

1.24.3 that the regulator establish mechanisms for industry and consumer engagement

1.24.4 that the regulator be transparent about its processes

1.24.5 financial and non-financial reporting.

1.25 The ability for the regulator to establish technical advisory committees as it requires.

1.26 A requirement that the regulator establish a committee or committees to provide advice, as needed, on therapeutic product assessment, classification, and safety monitoring.

1.27 A requirement that the regulator ensure committees have members with suitable skills, including (but not limited to) consideration of the need for members with knowledge of medicine, pharmacy and consumer perspectives.

1.28 The ability for committee processes to be determined by the regulator as a matter of policy.

Review and appeal

1.29 The establishment of an independent review committee administered by the Ministry of Health to hear appeals against regulatory decisions.

Cost recovery

1.30 A requirement that the regulator recover its costs through fees and levies where these costs are not met through Crown funding.

1.31 A requirement that fees and levies are reviewed within three years of first being set.

Transitional provisions

1.32 Provisions which enable products regulated under the Medicines Act 1981 to transition to the new regulatory regime.

1.33 Provisions which enable regulatory requirements to apply in a staged manner to medical devices and cell and tissue therapies.

1.34 Provisions that require a review of the Therapeutic Products Act within 5 years of the end of the transition period.

Regulations

1.35 The ability for regulations to be made in respect of:

1.35.1 Review Committee matters including who can apply for review and the ability to charge for review

1.35.2 classification

1.35.3 fees and levies

1.35.4 accountability arrangements

1.35.5 exempted products (including pharmacy compounding)

1.35.6 licensing.

Regulator-made instruments

1.36 The ability for instruments to be made by the regulator in respect of:

1.36.1 how an application for an approval should be made

1.36.2 closer definition of categories of product

1.36.3 standards and requirements that will apply to products and associated activities (including for example, manufacture, product recall, vigilance)

1.36.4 the application of classifications

1.36.5 exempted products

1.36.6 requirements to be met in respect of obtaining licenses

1.36.7 requirements to be met in respect of meeting advertising requirements.

2 **Note** that the Ministry of Health will discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments further with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and I will report back on the outcome of those discussions in March 2016 if any changes are proposed.

3 **Note** that the obligations in the TransPacific Partnership on data protection for pharmaceuticals (including biological pharmaceuticals) can be met within New Zealand's current policy settings and practice.

4 **Note** that the Minister of Health's initial view is that current restrictions on pharmacy ownership as a condition for licensing are not necessary to achieve the safety objectives of the regulatory scheme (including restrictions on medical practitioners having an interest in pharmacies) **and** that the Minister of Health will report to Cabinet and seek agreement on the most appropriate licensing arrangements for the Bill following sector consultation on the Draft Pharmacy Action Plan.

5 **Note** that the costs of developing the regime are currently met from the Ministry of Health's baseline funding (including some funding from the Ministry's third party revenue baseline funding) and that the costs of implementation will be managed within usual budget processes or factored into fee setting for the new regulatory regime.

6 **Note** that the Minister of Health will report to the Social Policy Committee during March 2016 on further policy issues with a view to further drafting instructions being authorised; these include prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework and the form of the regulator.

Hon Dr Jonathan Coleman
Minister of Health

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20151082
File number: AD10-53-2
Action required by: routine

Therapeutic Products Regulatory Regime: Policy related to pharmacies

To: Hon Dr Jonathan Coleman (Minister of Health)

Hon Peter Dunne (Associate Minister of Health)

Purpose

To seek your agreement on an approach for the regulation of pharmacies, including pharmacy ownership, and to seek your approval for consultation with the sector.

Key points

- The development of the new therapeutic products regulatory regime includes the legislative provisions in the Medicines Act 1981 that relate to the control and ownership of pharmacies. Pharmacy ownership remains a contentious issue with the sector and any decisions on future settings are likely to attract attention.
- The recently released *Implementing Medicines New Zealand 2015 to 2020* (Medicines Action Plan) and the Pharmacy Roadmap will set out the government's vision for the future of pharmacy. The new legislative regime should provide a modern and flexible framework to enable this vision to be achieved.
- There are two main elements of the new therapeutic regulatory scheme that will influence pharmacy practice: the framework for prescribing and dispensing of therapeutic products; and the regulation of pharmacies themselves. Prescribing and dispensing will be covered in a future briefing. This briefing proposes a high level framework for the regulation of pharmacies.
- The overarching objectives for the regulation of pharmacies are to ensure the safe supply and effective use of therapeutic products and to enhance their accessibility within an environment that enables the development of innovative ways of providing pharmacy services.
- It is proposed that the key features of the regulation of pharmacies should include licensing of pharmacies and that every pharmacy must be under the supervision of a qualified pharmacist.
- The Ministry considers that the restrictions on who may own community pharmacies are unnecessary to achieve the objective of safe supply and effect use, and may hinder future innovation.
- Deregulation of pharmacy ownership may lead to a general increase in the accessibility of medicines. There will also be risks around the disruption of the pharmacy market that will need to be considered and mitigated.
- We seek to consult on the proposed regulatory framework, including the implications for pharmacy ownership, with the pharmacy sector as part of wider discussions on the Pharmacy Roadmap.
- This briefing has been provided to ensure your comfort with our intended approach, ahead of your meeting with the Ministry and members of the Pharmacy Steering Group that is scheduled for 29 July.

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	Hannah Cameron, Manager, Sector and Services Transformation Team	021 783 574

Health Report number: 20151082

Therapeutic Products Regulatory Regime: Policy related to pharmacies

Recommendations

The Ministry recommends that you:

a) **Note** that the Ministry is considering the future regulation of pharmacies as part of the development of the new therapeutic products regulatory regime.

b) **Note** that pharmacy ownership remains a contentious issue with the sector and any decisions on future settings are likely to attract significant attention.

c) **Agree** that the new regulatory regime should be positioned to enable the future direction for pharmacy as set out in *Implementing Medicines New Zealand 2015 to 2020* (Medicines Action Plan) and the developing Pharmacy Roadmap. **Yes / No**

d) **Agree** that the overarching objectives for the regulation of pharmacies are to ensure the safe supply and effective use of therapeutic products, and to enhance their accessibility within an environment that enables the development of innovative ways of providing pharmacy services. **Yes / No**

e) **Agree** that the key features of the regulation of pharmacies should be to licence pharmacies and ensure they are under the supervision of qualified pharmacists. **Yes / No**

f) **Agree** that the pharmacy ownership restrictions are not necessary to achieve the objectives required of the regulatory scheme. **Yes / No**

g) **Agree** that the Ministry should consult first with the Pharmacy Steering Group on the regulatory framework, including pharmacy ownership, as part of discussions on the Pharmacy Roadmap, and then with the wider pharmacy and health sector. **Yes / No**

Teresa Wall
Acting Deputy Director-General
Policy Business Unit

Minister's signature

Date:

Health Report number: 20151082

Therapeutic Products Regulatory Regime: Policy related to pharmacies

Background

1. A new comprehensive, domestic therapeutic products regulatory regime is being developed with a view to legislation being introduced to Parliament in 2016. The regime will repeal and replace the Medicines Act 1981 and its regulations (HR 20150290 refers).
2. Ministers have agreed that the new legislation should be based on the Treasury's principles of best practice regulation. These include principles of proportionality and support for growth and are part of wider government goals for the regulatory environment to be as efficient and least restrictive as possible.
3. We will be providing you with a series of briefings in the coming months about various aspects of the new regime. This first briefing focuses on the future regulation of pharmacies.

The pharmacy environment

4. There are longstanding restrictions in New Zealand on who may own pharmacies. The Medicines Act provides that pharmacies must be majority owned and controlled by pharmacists, who may own a majority interest in up to five pharmacies. These types of restrictions are unique to the pharmacy profession.
5. New Zealand currently has around 1020 pharmacies, most of which are community pharmacy practices. It is estimated that pharmacies wholly owned by a single pharmacist are declining, but these still represent the majority of all pharmacies. Green Cross Health Ltd is the major corporate player, representing more than 300 pharmacies under the Unichem and Life Pharmacy banners and with shareholdings of up to 49% in 70 of these pharmacies.
6. We understand that owning a pharmacy does not appear to be a strong motivator for many young pharmacists. There are approximately 3400 pharmacists currently practising and numbers have increased steadily in recent years. More than 75 percent of pharmacists work in community pharmacies; others work in hospitals, primary care, industry and government. The pharmacy profession is in a healthy position in terms of the qualification and registration pathways, new entrants and retention – and we expect this to continue. Pharmacy has a relatively young demographic compared with other health professions.
7. The original policy rationale for the ownership restrictions was that ownership as well as control by pharmacists was necessary to ensure effective control of pharmacies. The ownership requirements have proved difficult to administer as, in practice, a range of company arrangements have been put in place to get around the restrictions, to the point that there are serious questions about whether the intent of the policy is being met and should be retained.
8. Previous considerations of pharmacy ownership provisions have resulted in government choosing not to make legislative amendment. This has reflected strong objection to change from some parts of the pharmacy sector.
9. The repeal of the Medicines Act creates a different scenario as the Government will have to proactively choose the shape of the new regulatory framework. Together with the current work on defining a future direction for pharmacy, this provides an opportunity to consider a new approach to the issue.

What do we want to achieve?

10. A series of strategic initiatives will together set the future direction for pharmacy. The Government recently released a new plan, *Implementing Medicines New Zealand*, which outlines the actions required over the next five years to achieve the outcomes for the use of medicines (quality, access and optimal use) set out in *Medicines New Zealand*, the Medicines Strategy. The refresh of the New

Zealand Health Strategy encompasses broader health settings, but also has implications for future pharmacy practice.

11. A draft Pharmacy Roadmap is being developed by the Ministry in consultation with the Pharmacy Steering Group. The Roadmap will set out how the pharmacy sector can be most effectively used to deliver quality, accessible and cost-effective services. It focuses specifically on how to maximise the capability and capacity of the pharmacy workforce in order to make best use of pharmacists' specialist skills and knowledge as medicines experts.
12. These initiatives share an overall vision for pharmacy of enabling more innovative practice. The Ministry considers them as a package aimed at providing safe and effective high-quality health care services with consumers at the centre and making the best use of pharmacists' specialist skills working with other health professionals in a more integrated way.
13. The future direction established by these documents will be achieved by a combination of non-regulatory measures underpinned by legislation. There are two main elements of the new regulatory scheme that will influence pharmacy practice: the framework for prescribing and dispensing of therapeutic products; and the regulation of pharmacies themselves. Prescribing and dispensing will be covered in a future briefing. This briefing proposes a high level framework for the regulation of pharmacies.

The regulation of pharmacies

14. Based on the strategic framework provided by the documents highlighted above, we propose that the overarching objectives for pharmacy regulation are to ensure the safe supply and effective use of therapeutic products and to enhance their accessibility within an environment that enables the development of innovative ways of providing pharmacy services.
15. In order to ensure safety, the storage and supply of therapeutic products need to be controlled. It is proposed that the primary means to achieve this in the pharmacy segment of the supply chain are:
    - that the storage, sale, supply or distribution of prescription medicines, restricted medicines and pharmacy-only medicines are generally restricted to pharmacists, pharmacies and hospitals
    - that pharmacies are licensed
    - that every pharmacy must be under the supervision of a qualified pharmacist
    - that every person who operates a pharmacy must ensure therapeutic products are held in secure storage under appropriate environmental conditions.
16. Under the licensing model being considered, the regulator will be able to issue licences allowing suitably qualified persons to undertake certain activities. There will likely be general conditions on who may be issued a licence, such as a fit and proper person, or a body corporate of good repute. This represents international best practice.
17. Appropriate auditing arrangements would be put in place to ensure safe and effective pharmacy practice is maintained.

Ownership restrictions are not necessary for safety and may hinder innovation

18. We do not consider that pharmacy ownership restrictions are necessary to achieve the objective of ensuring safe supply and effective use of therapeutic products.
19. The need for professional control of pharmacies by pharmacists is not in dispute. Pharmacists must continue to oversee the control and dispensing of medicines and provide health services and advice. However, the day-to-day discharge of their professional responsibilities has been, and will likely be, little affected by who actually holds majority ownership.
20. In practice, there is not necessarily a link between ownership and quality of service provision and there is no evidence of any increase in health and safety concerns or poor service in 'chain' pharmacies, ie, those with shareholdings by large companies. In almost every case of poor service provision under Ministry investigation, the pharmacy is owned by a sole pharmacist and perhaps his or her family trust.

21. More flexible ownership arrangements could assist in achieving the mutual goal of the pharmacy profession and the Government of helping the sector move toward better, integrated, and consumer centred care. Ownership restrictions may be more likely to hinder rather than enable these developments.

Risks created by a change in the current pharmacy market can be mitigated through regulatory and non-regulatory tools

22. Pharmacy stands alone in New Zealand as an industry which restricts business ownership to specified professionals. No comparable economic models exist that enable us to predict the exact impact that would occur to the pharmacy market.

23. Overall, it can be expected that deregulation of pharmacy ownership would lead to further corporatisation of the sector. It could also lead to a general increase in the accessibility of medicines, related to the establishment of new pharmacies or increased opening hours. Greater economies of scale and more buying power may result in lower distribution costs and therefore lower prices, particularly for pharmacy only medicines. There will be risks around the disruption of the pharmacy market that will need to be considered and mitigated.

24. It is possible that some pharmacies in smaller population centres may close if competition from large outlets in neighbouring towns renders them unviable, meaning a reduction in access to pharmaceuticals. Access issues can be mitigated through licensing provisions such as allowing medicine depots and non-pharmacy retail licences for remote places. There would also be the possibility for smaller pharmacies becoming attached to GP practices, with travelling pharmacists visiting several of these pharmacies in a week.

25. The possibility of a pharmacy being attached to a GP practice which owns the pharmacy raises the possibility of blurring of the separation between prescribing and dispensing. We will need to investigate ways to manage any conflicts of interest and ensure consumers' rights of choice under the Health and Disability Commissioner's Code of Rights are maintained.

26. Other identified risks include sharp commercial practices such as selling unnecessary or inappropriate medicines or misleading marketing. Those risks are mitigated through advertising rules and the professional ethics of pharmacists, who will still control dispensing and pharmacy practice as a whole.

Next steps

27. We need to consult with the health sector to inform the development of regulatory provisions that will achieve the objectives outlined above, and appropriately mitigate any risks.

28. We advise that careful consideration is given to consultation on the issues contained in this briefing. There is a significant portion of the pharmacy profession who have objected to similar proposals in the past. In addition, we are aware of ongoing tensions within the sector in relation to the current re-contracting of the Community Pharmacy Services Agreement between DHBs and pharmacies and separate deliberations on the issue of the Pharmaceutical Margin – the contribution to stockholding and supply of medicines that is funded by DHBs.

29. The Pharmacy Roadmap is leading discussion on the future of pharmacy. You are meeting with officials and members of the Pharmacy Steering Group to discuss the roadmap and future consultation processes on 29 July.

30. We propose to discuss the regulatory framework as an enabler for change within the context of the roadmap. This will include raising the proposal that pharmacy ownership restrictions are not necessary to achieve wider goals for pharmacy. We would first engage with the Pharmacy Steering Group, who have started to position themselves as agents for change across the pharmacy sector, and then with the wider pharmacy and health sector.

31. The results of our consultation will inform more detailed policy proposals to be included in recommendations to Cabinet regarding the new therapeutic products regulatory regime.

END.

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20150290
File number: AD10-53-01
Action required by: routine

Therapeutic Products Regulatory Regime: overview

To: Hon Dr Jonathan Coleman (Minister of Health)

Purpose

To inform a discussion between yourself, Minister Dunne, and officials on 16 April 2015 at 10:30am about the new regulatory regime for therapeutic products, its interfaces with other work areas and the decisions which will need to be made on the new regime over the coming months.

Key points

- A new, comprehensive, domestic therapeutic products regulatory regime (the regime) is being developed with a view to legislation being introduced to Parliament in 2016.
- The regime will repeal and replace the Medicines Act 1981 and its regulations, and considerably change the status quo. As well as replacing, modernising and changing the regulatory arrangements for medicines, it will also encompass medical devices and cell and tissue therapies which currently are not adequately regulated in New Zealand.
- Over the coming months you will be asked to make decisions about pre-market approval processes, arrangements for regulating activities (such as manufacturing), post-market surveillance of products, funding and cost recovery arrangements, scheme administration, dispensing and prescribing arrangements, and other matters such as appeal mechanisms, enforcement and pharmacy ownership.
- Policy proposals for each of these areas will be developed mindful of the needs of the health sector, the reality of the global marketplace, and ensuring good regulatory practice. The central challenge will be to design robust regulatory arrangements that can be sustained within our small market.
- The new regime interfaces with Minister Dunne's review of aspects of controlled drug legislation and work on the Medicines Strategy action plan.

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Health Report number: 20150290

Therapeutic Products Regulatory Regime: overview

Recommendations

The Ministry recommends that you:

a) **Note** that you are meeting with officials and Mr Dunne to discuss the new regulatory regime on 16 April 2015 at 10:30am.

b) **Forward** a copy of this report to Associate Minister Dunne ahead of that meeting. **Yes / No**

Don Gray
Deputy Director-General
Policy Business Unit

Minister's signature

Date:

Minister's feedback on quality of report

Very poor (1)	Poor (2)	Neutral (3)	Good (4)	Very good (5)

Health Report number: 20150290

Therapeutic Products Regulatory Regime: overview

1. In November 2014, following your public announcement of the cessation of the ANZTPA initiative, we proposed the process and timeline for developing a new therapeutic products regulatory regime (Health Report 20141547 refers). You are discussing the project to develop the new regime with Minister Dunne and officials on 16 April 2015. To inform that discussion this report:
   a. sets out the areas where decisions will be sought over the coming months
   b. proposes a framework that will guide our analysis of the issues
   c. signals linkages with other streams of work.

Background

2. Therapeutic products are medicines, medical devices, cell and tissue therapies, and blood and blood products. They are not ordinary goods of commerce and present serious risks of harm especially when used inappropriately. A robust regulatory regime is a prerequisite to the delivery of high-quality services (public and private). All developed economies regulate to a greater or lesser extent. Regulation for medicines is widespread and began following the 1960s thalidomide tragedy in Europe. It has extended to the other therapeutic products over time.
3. While Medsafe and Medicines Control are respected regulators, there are serious inadequacies in New Zealand's regime that need to be addressed concurrently.
   a. A regulatory scheme that is no longer fit for purpose, creates the potential for risk, and does not enable efficient regulation.
   b. Inadequate capacity to comprehensively regulate complex new products.
4. As advised in HR 20141547, it is desirable but not essential that the regime be in place before provisions of the Medicines Amendment Act 2013 come into force on 1 July 2017. The broad timeline is that the regime will be developed over 2015, legislative processes will occur over 2016 and implementation in 2017. The timeframe is reasonably tight and the Ministry will advise you on contingency plans should they appear necessary.

Regulating therapeutic products

5. There are two key aspects to the regulatory regime: the scheme (ie, the rules and controls applied) and its administration (who makes decisions, regulator culture, and implementation).
6. The scheme will apply controls on products and related activities across a product's lifespan: from clinical trials, through manufacturing processes, the distribution chain and use, to disposal. Controls are aimed at ensuring that benefits of products outweigh the risks, that products are high quality, traceable throughout the distribution system, appropriately used and accompanied by good information. Appendix One contains further information.
7. Over the coming months you will be briefed on the following aspects of the regime with a view to advice being prepared for Cabinet:
   a. Pre-market approvals processes – the pathways for approval of medicines, medical devices and cell and tissue therapies. This will include advice on the extent to which we should do full evaluations, as compared to relying to some extent on overseas evaluations.
   b. Proposed arrangements for regulating activities such as manufacturing, wholesaling, supplying and advertising therapeutic products.
   c. Post-market surveillance – this refers to the way in which the use and performance of therapeutic products is monitored and safety issues are identified and responded to.
   d. Funding and cost recovery arrangements – including the extent to which the scheme should be cost recovered from industry and how any cost recovery should be structured.

e. How the scheme should be administered, including who should hold regulatory decision-making powers and administrative powers (eg, to appoint committees).

f. The framework for dispensing and prescribing products.

g. Other matters including the legislative arrangements for safety in community pharmacy (pharmacy ownership), appeal mechanisms, enforcement, and information protection.

h. Implementation – including transition arrangements for products, establishing administrative arrangements, and costs and off-setting savings.

Designing the new regime

8. In designing the new regime we are aiming to meet the needs of the health and disability support sector and ensure good regulatory practice. We are also mindful of the influential global settings for therapeutic products and our small marketplace. Taking these considerations into account, the table in Appendix Two contains a set of proposed desired features for the new regime and the main mechanisms that will enable them to be achieved. We wish to discuss this table with you at the meeting on 16 April with a view to it guiding the Ministry's work on the detail of the regime.

9. Key issues to discuss include:

   a. the extent to which we should do pre-market evaluation of products ourselves compared with relying on evaluations done by others; and whether we should approach this issue differently for different types of products

   b. ensuring that we keep the regulatory regime up-to-date and flexible over time

   c. ensuring sustainable regulatory capacity.

Linkages

10. The regime has linkages with the following projects:

    a. Natural health and supplementary products (NHSP) regulation – the NHSP Bill that will regulate these products is due to be passed this year. The new regime will need to interface effectively with the NHSP regime particularly in terms of definitions of products and in ensuring that there are no gaps between the NHSP regime and the new therapeutic products regime as both schemes will commence at different times.

    b. Review of aspects of controlled drugs legislation – this project is looking at the therapeutic uses (eg, controlled drugs as medicines, addiction services, and clinical trials) and non-therapeutic uses (eg, cultivation and production of industrial hemp seed and drug testing kits) of controlled drugs. It is envisaged that some or all of the changes from this work would be given affect through the new regime.

    c. Refreshed Medicines Strategy Action Plan – the core objectives of the Medicines Strategy are that medicines are safe, accessible, and optimally used. The new regime is critical to achieving these outcomes. The Medicines Strategy action plan focuses on pharmacy issues that intersect with those aspects of the regime that are to do with patient access and use of the workforce.

11. Associate Minister Dunne has lead responsibility for the latter two initiatives. We recommend that you forward a copy of this report to him ahead of the meeting on 16 April.

END.

Health Report number: 20150290

APPENDIX ONE: Overview of scheme controls

The scheme will control products and activities by ...	in order that ...
• assessing products and issuing approvals (or approving exemptions) • licensing and auditing activities - manufacture, supply, promotion, import and export • setting standards (eg, labelling, manufacturing) • setting and changing access limits (eg, scheduling medicines) • monitoring products in the market-place (eg, adverse reactions, product testing) and responding to safety issues (eg, recalls, complaints) • monitoring compliance and taking action for non-compliance (eg, suspending, modifying, or revoking marketing approvals) • communicating with the public and health practitioners about safety matters • approving clinical trials.	• the **benefits** of products outweigh the **risks** when used as intended • products are high **quality** and maintain their quality throughout their lifecycle • products are **traceable** throughout the distribution chain so that problems can be quickly addressed • the appropriate product is used for the **correct purpose** • products are **not diverted** into illicit uses • consumers and health practitioners have **good information** about products so that benefits are maximised