[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

1. 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.
2. 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.
3. 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.
4. 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:
   1. meets expectations of risk management and assurance of acceptable safety
   2. results in efficient and cost effective regulation
   3. is flexible, durable, up-to-date, and easy to use
   4. ensures high-quality, robust and accountable decision-making
   5. is able to sustain capable regulatory capacity
   6. supports New Zealand trade and economic objectives
   7. is trusted and respected
   8. supports consumer access and individual responsibility for care.
5. These objectives will be best met by:
   1. regulatory requirements that are consistent with international approaches and effectively administered
   2. a regulator that can exercise regulatory powers effectively, is accountable, and that can engage internationally
   3. an enabling legislative framework that can be readily maintained and updated.
6. 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

1. Therapeutic products are used for humans for a therapeutic purpose.[[1]](#footnote-1) Currently they can be grouped into the broad categories set out below.
   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.
   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.
   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.
2. 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.
3. 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, distribution chain, promotion/advertising, pre-market evaluation and approval, post-market surveillance and access.[[2]](#footnote-2)
4. 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.
5. The key problems New Zealand faces are:
   1. The Medicines Act 1981 and its Regulations are no longer fit-for-purpose.
      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.
      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.
      3. The prescriptive nature of the Medicines Act 1981 prevents regulatory efficiencies.
      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.
   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).
   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.
6. 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]](#footnote-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].
7. 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].
8. Advice on the new regime will be provided to Cabinet in three tranches:
   1. contextual overview and objectives – contained in this paper
   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*
   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.
9. 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.
10. 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

1. 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.
2. This type of regime is proposed for New Zealand with the objectives that it:
   1. meets expectations of risk management and assurance of acceptable safety
   2. results in efficient and cost effective regulation
   3. is flexible, durable, up-to-date, and easy to use
   4. ensures high-quality, robust and accountable decision-making
   5. is able to sustain capable regulatory capacity
   6. supports New Zealand trade and economic objectives
   7. is trusted and respected
   8. supports consumer access and individual responsibility for care.
3. These objectives have been derived from an analysis of the broader context in which the regime will sit. That is:
   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;
   2. the Government’s increased focus on the design, stewardship and maintenance of regulatory systems; and
   3. the international arena.
4. 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).
5. 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.
6. Achieving the objectives requires:
   1. **regulatory requirements** that are consistent with international approaches and effectively administered
   2. **a regulator** that can exercise regulatory powers effectively, is accountable, and that can engage internationally
   3. an enabling **legislative framework** that can be readily maintained and updated.
7. 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. **Redacted under s.6(a)** 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

1. As noted, there are international standards and frameworks for the regulation of products[[4]](#footnote-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.
2. 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:
   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]](#footnote-5).
   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).
   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.
   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 would have been no, or limited, scrutiny of data in New Zealand pre-market and thus light knowledge about the product.
   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.
3. 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 **Redacted under s.6(a)** . 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.
4. 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.
5. 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.
6. 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.
7. Capacity issues are not as pressing with respect to post-market and licensing activities.

## Regulator

1. 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.
2. 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

1. 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.
2. 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:
   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.
   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.
   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

1. 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:
   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.
   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]](#footnote-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).
   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.
   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

1. 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:
   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.
   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.
   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.
   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.
   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

1. 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.
2. The Government agencies informed about this paper were: The Department of Prime Minister and Cabinet.
3. 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

1. There are no financial implications associated with this paper.

## Human Rights

1. 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

1. 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

1. A regulatory impact statement is attached to Paper 2.

## Gender Implications and disability perspective

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

## Publicity

1. 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 instructionsto 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:
   1. meets expectations of risk management and assurance of acceptable safety
   2. results in efficient and cost effective regulation
   3. is flexible, durable, up-to-date, and easy to use
   4. ensures high-quality, robust and accountable decision-making
   5. is able to sustain capable regulatory capacity
   6. supports New Zealand trade and economic objectives
   7. is trusted and respected
   8. supports consumer access and individual responsibility for care.
8. **Agree** that these objectives will be best met by:
   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
   2. regulatory requirements that reflect international norms, standards and frameworks
   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

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. [↑](#footnote-ref-1)
2. http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf. [↑](#footnote-ref-2)
3. Australia New Zealand Therapeutic Products Agency [↑](#footnote-ref-3)
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. [↑](#footnote-ref-4)
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). [↑](#footnote-ref-5)
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. [↑](#footnote-ref-6)