In Confidence

Office of the Minister Health

Chair, Cabinet Social Policy Committee

# Therapeutic Products Regulation: further policy approvals

## Proposal

1. That Cabinet agree to further drafting instructions being issued for the Therapeutic Products Bill. The Bill is due for introduction in late 2016.

## Executive Summary

1. In November 2015, Cabinet agreed the strategic context and key elements of a new therapeutic products regulatory regime. This paper seeks agreement to issue further drafting instructions on the following discrete matters:
   1. **Clinical trials** – as is the international norm, trials of all types of products will be covered and regulatory powers will provide adequate protection.
   2. **Cell and tissue therapeutic product regulation** – all such products should be within the scope of the regime with the ability for the most minimally-manipulated tissue to be exempted from pre-market controls.
   3. **Prescribing and dispensing** – controls on prescribing authorities should sit under the Health Practitioners Competence Assurance Act 2003. Final approval of prescribing authority should rest with the Minister of Health.
   4. **Pharmacy licensing** – restrictions on pharmacy ownership should be replaced by licence conditions that require professional pharmacy standards to be implemented; ownership controls are needed only to limit prescriber interests in pharmacies.
   5. **Import and export** – these activities require regulatory oversight via licencing and notification respectively.
   6. **Offences and penalties framework** – a hierarchy of tools is required – criminal offences, enforceable undertakings, and infringement notices.
   7. **Regulator form** – a Crown Entity is not supported and I will seek final decisions on institutional arrangements by October 2016.
   8. **Interface with the Hazardous Substances and New Organisms Act 1996** – addressing a gap with respect to the environmental risks of finished-dose-form medicines.
   9. **Placement of provisions** – officials will work with the Legislation Design Advisory Committee and the Parliamentary Counsel Office.
2. The next step for the Bill is the development and release of an exposure draft for consultation.

## Background

1. Following the decision in 2014 to cease work on the joint regulatory scheme with Australia (ANZTPA) Cabinet agreed to a new regulatory regime for therapeutic products. The new regime will replace the Medicines Act 1981 and its regulations. It will be comprehensive and modern, reflect the needs of the health sector now and into the future, be cognisant of international regulatory and market settings (and New Zealand’s unique market), and the Government’s expectations for regulatory regimes. It will also contribute to delivering the proposed New Zealand Health Strategy. The Smart System theme in the strategy aims for the system to be well placed to take advantage of new technologies; this requires a robust regulatory framework to provide assurance of the safety of products and accountabilities in respect of them.
2. In November 2015 Cabinet agreed the objectives of the regime, the key means to achieve them (see below), and its main elements. It also noted that I would report back on the issues discussed in this paper (SOC-15-MIN-0050 and SOC-15-MIN-0049 refer).
3. Cabinet agreed that the objectives of the regime will be best met by:
   1. an enabling legislative framework
   2. regulatory requirements that reflect international norms
   3. a regulator able to exercise regulatory powers and associated administrative powers effectively and independently, that is accountable, and able to engage internationally.
4. The regime will sit alongside those listed below. Care is being taken to ensure that the regimes work together, are fit-for-purpose, and that there is clarity for industry and practitioners as to their requirements.
   1. **Food** and **psychoactive substances** are regulated by the Food Act 2014 and the Psychoactive Substances Act 2013 respectively. These Acts are clear that food and psychoactive substances do not include any substances used as medicines under the Medicines Act 1981. These arrangements will be updated and carried into the new regime.
   2. **Natural health products** (NHPs)will be regulated under the Natural Health Products Act (once passed). There will be a clear boundary between the two regimes in that NHPs may not be, or may not contain, prescription, pharmacy, or pharmacist-only substances or medicines (known as scheduled substances or medicines). The NHP Bill also requires the therapeutic products regulator to consult the NHP Authority before scheduling a natural substance (ie, a potential NHP ingredient). NHPs will be able to make low-level health claims only whereas therapeutic products will be able to make therapeutic claims. Guidance will be developed for industry on these matters.

There are likely to be products that could be sold as NHPs or as general-sales medicines. The person bringing these products to market will choose which regime to comply with according to their assessment of where they want to position their product in the market and compliance costs. The NHP Bill is currently before Parliament.

* 1. **Controlled drugs** will continue to be regulated under the Misuse of Drugs Act 1975 and work will be done to streamline detailed requirements (eg, labelling) as subordinate instruments are developed.
  2. **Human tissue** is regulated under the Human Tissue Act 2008. That Act is primarily concerned with consent to use tissue from deceased persons. It also controls trade in tissue from living and deceased donors. Importantly, it prevents trade in tissue without a ministerial exemption. Currently there is no process for gaining a ministerial exemption and it is therefore difficult for legitimate products to be available for patient treatment. The new regime will enable the approval of cell and tissue therapeutic products from a safety perspective, which could form the basis for a ministerial exemption for all approved cell and tissue therapies. Cell and tissue therapeutic product regulation is discussed in this paper.
  3. **Hazardous substances and new organisms**, may also be therapeutic products. The interface with the Hazardous Substances and New Organisms Act 1996 is discussed in this paper.
  4. **Health practitioners** are regulated under the Health Practitioners Competence Assurance Act 2003. The interface with respect to prescribing practice is discussed in this paper.

## Comment

1. Cabinet has agreed that the therapeutic products regulatory regime will regulate all therapeutic products (medicines, medical devices, cell and tissue therapeutic products and hybrids) across their lifespan. The objectives of the regime, and other contextual information is set out at Appendix 1. This paper proposes arrangements for the following matters:
2. clinical trials;
3. cell and tissue therapeutic product regulation;
4. prescribing and dispensing;
5. pharmacy licensing;
6. import and export;
7. offences and penalties framework;
8. regulator form;
9. interface with the Hazardous Substances and New Organisms Act;
10. placement of provisions.
11. The arrangements have been designed to give effect to the objectives for the regime, including that it meet expectations of risk management, be efficient, flexible and sustainable, and support wider New Zealand trade and regulatory aims.

## Clinical trials

1. Clinical trials conducted within a robust regulatory framework offer social and economic benefits. For example, they attract and help retain high-quality, innovative clinicians, academics, and scientists; and bring investment and employment opportunities. New Zealand’s high quality infrastructure makes it a desirable location for clinical trials and the new regime aims to facilitate New Zealand-based trials under a robust regulatory regime.
2. Clinical trials are regulated under the Medicines Act 1981 (scientific matters) and the New Zealand Public Health and Disability Act 2000 (ethical matters) in separate but parallel processes. The therapeutic products regulatory regime is concerned only with the former and changes are needed to current settings in respect of scope and regulatory powers. While outside the scope of the regime, it is worth noting that the National Ethics Advisory Committee is currently reviewing its guidelines. I have instructed officials to take the opportunity to streamline and improve co-ordination between the two parts of the approval processes in the interests of enhancing New Zealand’s international competitiveness for trials.

### Scope

1. Currently regulatory approval is needed for trials of new medicines only. I propose that the new regime cover trials of all therapeutic products: medicines, medical devices, cell and tissue therapeutic products and hybrids. This includes medicines that have marketing approval, but are being trialled for new uses. The new regime will also provide clarity over the distinction between a clinical trial and innovative clinical practice (where new approaches are being used but formal investigational research is not being carried out). This is the norm internationally and there is no case for less coverage.

### Regulatory powers

1. There are currently gaps in the regulator’s tool kit. The regulator needs to be able to set the requirements for approval, issue approvals, set and change conditions on approvals, require reporting and information, inspect trial sites, audit, act to ensure safety and compliance and revoke or suspend approval.
2. The detailed requirements to be met before approval can be granted will follow international norms and will be commensurate with risk. Low-risk trials are expected to require simple notification and higher-risk trials assessment by the regulator. All trials will need to have an identified person in New Zealand during the trial who is responsible for meeting the conditions of approval and other requirements. These are likely to include, for example, registration on an approved registry and a long-term commitment that participants receive treatment. Agencies such as PHARMAC will be involved as requirements are developed.
3. A short time frame for regulatory approval of trials is critical to maintaining New Zealand’s attractiveness as a trial destination. I propose that the current timeframe remain at a mandatory maximum of 45 *working* days. For future flexibility, this should be set out in a subordinate instrument.
4. Cabinet has agreed that the regulator can establish expert advisory committees and must establish them for some purposes. I propose that the regulator be required to establish a committee to provide advice, as needed, on clinical trials. The relationship between this committee and the existing (non-statutory) Health Research Council committees will be examined as part of implementation.

## Cell and tissue therapeutic product regulation

1. Cell and tissue therapeutic products are derived from living cells and tissues of humans or animals. They span whole tissues that are part of established clinical practice (eg, kidney transplants, skin grafts) through to innovative and substantially manipulated cellular products (eg, demineralized bone matrix for repair, dental pulp-derived stem cells for tooth regeneration). While some are regulated as medicines (eg, cellular products in clinical trials and blood products) there is no specific regulation of these products.
2. The sector is a mix of non-profit entities (universities and health services) and commercial companies. Although volumes are generally low, a wide range of cell and tissue products are on the market, which is characterised by significant innovation internationally (eg, stem cells used for cardiac muscular repair) and continued growth is expected.
3. Since Cabinet’s decisions in November 2015, the overall regulatory approach has been tested with the sector to determine if it needs any modification for cell and tissue therapeutic products. The conclusion is that all these products should be included in the regulatory regime and that regulatory requirements will need to be graded according to the degree of manipulation of the tissue and the clinical realities of donation and transplantation services. This would mean that:
   1. **Minimally-manipulated tissue for immediate transplantation** (eg, kidney transplants) would not be subject to pre-market approvals and activity licences. They are not products in the conventional sense. They are individual (non-uniform), need to be transplanted in short timeframes, and are subject to clinical decision-making processes that recognise the acute scarcity of organs for transplant and target safety issues accordingly. In this context it is not clear that pre-market controls would assist with managing risks or result in benefits.

These tissues should, however, be included in the regulatory regime as post-market controls may be appropriate, inclusion avoids difficult boundary issues, and pre-market controls may be desirable in the future to respond to technological developments (eg, organs grown for transplant) or new public health issues (eg, new infectious diseases that warrant controls and that can be screened for within the necessary timeframes).

The sector is relatively comfortable with this approach and I am supportive of its desire that there be clear processes governing how any decisions to put regulatory requirements in place are made. This can be done through the design of legislative instruments (such as using regulations) and through the accountability framework for the regulator previously agreed by Cabinet.

* 1. **Minimally-manipulated tissue that is stored** (eg, banked bone) would not require an approval. Activity licences covering matters such as infectious disease testing, storage, labelling, and transport would be required; and some post-market controls would apply.
  2. **Tissue that is more than minimally-manipulated** (eg, expanded mesenchymal stem cells to repair cartilage) would require approval, activity licences and post-market controls. These products are akin to medicines in many ways and similar controls are appropriate.
  3. **Blood and blood products**would continue to be subject to full regulatory controls.

### Import and export

1. Import and export controls are discussed later in this paper. I note here however that import and export controls are not proposed for minimally-manipulated tissue for immediate transplantation as this would impact unnecessarily and negatively on the New Zealand–Australia transplantation programme.

### Xenotransplantation

1. Xenotransplantation (using live animal cells in human therapy) is a developing technology and clinical trials are underway in New Zealand. Xenotransplantation is controversial with some people, and under the Medicines Act there is robust scrutiny of these trials and ministerial approval of applications. As yet there are no xenotransplantation products ready for the market. When they emerge, however, the Medicines Act will not necessarily cover them. This gap will be addressed by the therapeutic products regulatory regime.

1. As a separate matter I will bring advice to Cabinet before June 2016 proposing an Order-in-Council to extend the controls in the Medicines Act on xenotransplantation clinical trials. These controls will expire in September 2016.

## Prescribing and dispensing

1. Who may prescribe and under what conditions is controlled under the Medicines Act and its regulations. Prescribing authorities are changed periodically in order to improve care, health outcomes, patient convenience, or to make better use of the workforce; while not compromising safety.
2. In the new regime, as is the case now, products will be classified according to their risk profile. The highest risk products will continue to be available on the prescription of an authorised health practitioner only. These practitioners have the qualifications, training and competence to make the necessary clinical judgements. The competence and registration of health practitioners is the remit of the Responsible Authorities (eg, Medical Council, Nursing Council) under the Health Practitioners Competence Assurance Act 2003 (HPCA Act).
3. While closely connected with the therapeutic products regulatory regime, prescribing is part of a health practitioner’s clinical practice. I therefore propose that controls on prescribing authority shift to the HPCA Act and to the jurisdiction of the Responsible Authorities.
4. The detail of who is authorised to prescribe (including any conditions) will be set out in the relevant Scopes of Practice. Scopes of Practice bound the roles of health practitioners and the HPCA Act contains a process for establishing and changing them. This process will need some amendments to ensure sufficient oversight of prescribing. Once amended, the process required would be:
   * a Responsible Authority develops (consultation is required) the appropriate parameters of prescribing activity (including training and qualifications) for inclusion in a Scope of Practice
   * the Ministry considers the proposal in line with the strategic objectives of the health system
   * the Minister of Health makes a decision whether to approve the parameters of prescribing proposed for inclusion in a Scope of Practice. Under the general power of delegation in the State Sector Act 1988 this ability could be delegated if the Minister wished
   * the Responsible Authority publishes the parameters in the Gazette.
5. The Ministry has consulted the Responsible Authorities and key representative groups on this proposal. The majority supported the proposed approach. The Medical Council has decided to await the draft Bill before providing a position. Issues raised in consultation, such as the need to protect against the risk that Responsible Authorities seek to advance their own profession, will be addressed as the changes are implemented.
6. Current prescribing authorities will be directly translated into this new approach. Delegated prescribing and Standing Orders (where prescription medicines can be administered without a prescription by paramedics for example) will also continue.

## Pharmacy licensing

1. Cabinet has agreed that operating a pharmacy will continue to require a licence. In November 2015, when this decision was made, I advised that I would report back on the arrangements and that my initial view was that restrictions on pharmacy ownership are not necessary to achieve safety objectives.
2. Pharmacy licensing is a critical part of ensuring the integrity of the supply chain and I propose that the regulator continue to have the ability to:
   * issue a licence
   * set conditions on licences
   * require information
   * assess whether the applicant is a fit-and-proper person or, if a corporate, of good repute to hold a licence
   * require that a Responsible Pharmacist be identified and be responsible for the day-to-day operations of the pharmacy.
3. In addition, I propose that pharmacy licence applicants be required to name a Supervisory Pharmacist with responsibility for advising owners on, and overseeing, the implementation of professional pharmacy standards and licence conditions. The role of Supervisory Pharmacist is aimed at ensuring that professional practice standards are upheld in a commercial environment and would be additional to the current requirement for a Responsible Pharmacist.
4. In practice, in a small pharmacy, an individual pharmacist could be the Supervisory Pharmacist and Responsible Pharmacist. Where an owner(s) holds multiple pharmacy licenses a single Supervisory Pharmacist should be named to enable a single point of contact.
5. To ensure that the Supervisory Pharmacist can effectively perform their role, the regulator will need the ability to put conditions on a licence with respect to:
   * requiring licence owners to adequately resource the Supervisory Pharmacist to perform their role across a number of pharmacies
   * managing risks that may arise if a Supervisory Pharmacist is responsible to different pharmacy owners.
6. Both the Supervisory Pharmacist and the Responsible Pharmacist will be accountable to the licence holder who would be accountable to the regulator. A breach of professional practice standards may result in enforcement action against the licence holder. It may also result in disciplinary action against the Responsible or Supervisory Pharmacist through the Health Practitioners Disciplinary Tribunal (established under the HPCA).
7. These arrangements, and particularly the new requirement for a Supervisory Pharmacist, mean that the ownership restrictions in the Medicines Act are not needed. The current requirement that a pharmacy must be majority owned by a pharmacist (51 percent) and that a pharmacist can hold a majority stake in up to five pharmacies is an anomaly. Licences do not normally seek to restrict business owners, but rather regulate the risk of an activity via conditions. Conditions on a licence, rather than ownership restrictions, better manage risks and enable a competitive market. These ownership controls are unnecessary to ensure the integrity of the supply chain and manage risks to public health.
8. The Medicines Act also contains provisions restricting prescribers from taking any interest in pharmacies, unless granted an exception by the regulator. While designed to prevent prescribers benefitting financially from their prescribing decisions, the current wording may negatively affect the development of integrated health services. I support the intention of the provision and propose that a more focussed prohibition on prescribers benefitting from their prescribing decisions through investment in pharmacies is developed that also enables prescribers and pharmacies to develop more patient-centred integrated services (for example, shared systems, staff, or working space). This would apply to all prescribers, including pharmacists, nurses, and others.
9. I also propose that:
   * pharmacy licences be issued for up to three years (currently 12 months) as has been agreed for other licences (such as for wholesaling)
   * the regulator accommodate different distribution and supply arrangements and different models of pharmacy practice. For example, by not tying licences to fixed physical premises, and setting minimum pharmacy standards to be met under a licence.
10. As a related matter, I do not propose any change to the division between licensing and funding. Pharmacy licensing will be the jurisdiction of the therapeutic products regulator while funding decisions are made by District Health Boards. A pharmacy licence carries no entitlement to a services contract.

## Import and export of therapeutic products

1. Therapeutic products are freely-traded global commodities and supply chains are complex (for example, parts of the manufacture and packing process may occur at different locations). Through the internet consumers also have direct access to global suppliers. The regulatory regime needs to have import and export controls that appropriately manage the risks to patient safety, protect New Zealand’s reputation and support trade and economic objectives.

### Import

1. Imported products that are counterfeit, adulterated, or not subject to regulatory scrutiny pose a safety risk to New Zealand consumers. Currently this risk is inadequately managed as prosecution requires a sale to occur or an intention to sell to be established. There is also a lack of information about who is importing products, in what quantities and where the product is going.
2. I propose that importation be a licensed activity: importation without a licence would be an offence and intervention could occur before products get into the New Zealand supply chain. Collecting more information at the border will also give a more complete picture of the products in New Zealand and will assist with product recall. This approach is consistent with that in other jurisdictions, for other products in New Zealand (eg, prescribed foods and hazardous waste) and it will help New Zealand meet its World Health Organization commitments[[1]](#footnote-1).
3. I am however mindful of compliance costs (many of which are ultimately borne by the health system) and seek for import licensing to be as automated and streamlined as possible. Import licensing will be a significant change for the medical devices and cell and tissue sectors, but may be welcomed by compliant and trusted suppliers as it will protect the integrity of the market.
4. I propose to retain the current ability for individuals to bring in small quantities of therapeutic products for personal use. In respect of prescription medicines an individual needs to have an authorisation from a prescriber in order to receive imported goods. A similar arrangement will continue.

### Export

1. In addition to export by New Zealand manufacturers, there is some transactional export where products from overseas are imported, potentially repackaged or relabelled, and exported again. The issues of concern are protecting New Zealand’s reputation and supporting the domestic industry:
   * unapproved and possibly low-quality products may be transacted through New Zealand to nations with less ability to pay for products (eg, the Pacific Islands)
   * products may be exported claiming or implying New Zealand regulatory approval
   * New Zealand’s wider reputation may be damaged if it is seen as a source or transit point for low-quality or counterfeit product
   * New Zealand may not be meeting its international commitments.
2. I propose to address these risks while not imposing burdensome requirements or impeding the flow of therapeutic products to Pacific countries for legitimate reasons by requiring exports to be notified accompanied by evidence that the products meet the regulatory requirements of the receiving country.
3. Notification of exports is already a requirement in some cases for medical devices and will be for natural health products, but is not for medicines. The requirement that the exporter supply evidence that the product meets the standards of the importing country would provide some assurance that the exported product meets minimum standards. I propose that the current ability of the regulator to issue export certificates on request continue. These certificates are currently required by some jurisdictions (eg, China) and provide an assurance that the product can be marketed in New Zealand.
4. No changes are proposed to requirements in respect of the import and export of controlled drugs.

### Parallel importation

1. For therapeutic products, parallel importation would mean the importation and marketing of products by a supplier that does not hold a regulatory approval for those products. Even if they appear to be the same as an approved product, the safety of these products could not be assured and it would be impossible to hold the approval holder to account for them. The ability to parallel import with minimal regulatory control in Europe has resulted in counterfeit medicines in the legitimate supply chain on several notable occasions.
2. Parallel importing of medicines is prohibited now as a result of the requirement for a regulatory approval. This will be the case for other products (eg, medical devices) under the new regime as they will also require approval.
3. The Medicines Act currently allows the Crown to parallel import medicines. The Crown has contemplated using this in emergencies when stocks of key medicines were low. It has also provided useful leverage for PHARMAC when suppliers have threatened to withdraw vital products during commercial negotiations. I propose that the new regime include a credible mechanism to make it possible for the Crown to source alternative supplies of therapeutic products in appropriate circumstances.

## Offence and penalty framework

1. Cabinet was advised in November 2015 that the legislation would include flexible modern offences and penalties, aligned with recent similar legislation (such as the Food Act 2014 and the Health and Safety at Work Act 2015). The proposed enforcement tools will allow the regulator a wide range of options, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances.
2. I propose a hierarchy of enforcement tools:
   1. Tiered **criminal offences**, generally in three levels covering 1) negligent or reckless conduct; 2) conduct that poses a risk to human health, but is not negligent or reckless; and 3) less serious non-compliance with regulatory requirements. There will be separate categories of offence for misconduct by licence-holders (such as a failure to abide by the code of good manufacturing practice) and for the unlicensed carrying out of a restricted activity (such as manufacturing medicines without a licence) with penalties calibrated to the type of licence.
   2. **Enforceable undertakings**, which allow the regulator to accept an undertaking from a licence-holder, in lieu of more severe enforcement action. Such undertakings are then enforceable in the courts and offer an interim step before suspension or cancellation of licences, or even criminal charges.
   3. **Infringement notices**, which will allow instant fines for low-level offending.

## Regulator form and vestment of powers

1. The form of the regulator and its supporting infrastructure are important to achieving the objectives of the regime; noting that the new regulatory regime will be different to the status quo in that it will be larger, more comprehensive and have greater reach and that the regulator will have greater regulatory independence and commensurately greater accountability.
2. As Cabinet was advised last November, there are three options for the form of the regulator:
   1. Department (a unit of the Ministry of Health – the status quo);
   2. Departmental Agency (an operationally autonomous agency headed by its own chief executive, directly responsible to the appropriate Minister and hosted within the Ministry), or
   3. a Crown Entity (a separate entity accountable to the Minister).
3. To meet the objectives of the regulatory regime, the most appropriate form is that which best supports operational independence, accountability, sustaining capacity, a positive regulatory culture, organisational effectiveness, and flexibility to incorporate other functions.
4. I recommend that the therapeutic products regulator not be established as a Crown Entity. The key difference between the Department and Departmental Agency options, and a Crown entity is status in relation to the Crown. Departments and Departmental Agencies are part of the legal Crown while Crown Entities are outside the legal Crown. Being part of the legal Crown has advantages in respect of delivering the regulatory regime objectives in that it will facilitate domestic and international engagement – factors important to effective regulation and sustaining capacity. While a Crown Entity has a number of advantages, it would be the most expensive to establish and maintain and it may be harder for a Crown Entity to incorporate other functions.
5. A decision between the remaining two options turns on the need for operational independence and the contribution organisational form can make to sustaining capacity. The Departmental Agency form offers a number of advantages in these respects. It is, however, a new institutional form that, while designed for this type of function, has not yet been used for a regulator. The Departmental model could support the objectives of the regime. It is a known structure but it brings least as a matter of form and would require more to ensure that the objectives were met in an enduring and focussed way.
6. An additional important consideration is that, as part of an internal change process, the Ministry of Health is examining the optimal delivery of its broad set of regulatory functions. This includes the fit between its other responsibilities (such as the regulation of services) and the new therapeutic products regulatory regime; and how stewardship functions are organised. While this work is carried out, I propose that both remaining options are kept open. This can be done without delaying the preparation of the exposure draft of the Bill by vesting the relevant powers in the chief executive as defined in the State Sector Act. That Act defines chief executive as the person holding office as the chief executive of the department or of the departmental agency. A decision on the form of the regulator should however be taken by October 2016 to avoid undue delay to the development of the regulatory regime and its implementation (which requires long lead times).
7. Treasury considers that further analysis of all three options, including the Crown Entity option, should be undertaken as part of the further consideration indicated above. However, I consider that there are advantages in providing certainty to stakeholders on at least the question of a Crown Entity. I am also conscious that a Crown Entity would require additional legislative change and I am keen that the exposure draft published for consultation is as complete as possible.

## Interface with the Hazardous Substances and New Organisms Act 1996

1. If a therapeutic product contains a new organism (including a genetically modified organism) or a hazardous substance it also falls within the jurisdiction of the Hazardous Substances and New Organisms Act 1996 (HSNO).

### Approval process for products containing a live new organism

1. Medicines containing live new organisms require approvals from the Environmental Protection Authority (EPA) which assesses the environmental and public health risks, and from Medsafe which assesses the safety, quality and efficacy of the product. Two applications are made. Currently, only one relevant human medicine has been approved by the EPA for use in New Zealand (Pexa-Vec), with that approval restricting use of the medicine to a clinical trial. The medicines industry has indicated that the dual processes are a barrier to market entry and deter clinical trials. There is also a potential risk of duplication in the current process as both agencies assess public health and safety risks.
2. I propose that the new therapeutics regulator and the EPA continue to work to ensure the application process is efficient and effective, including minimising where appropriate the transactions required. This would recognise the separate roles of each agency in an applications process while streamlining it from the applicants’ perspective.

### Products containing hazardous substances

1. The HSNO Regulations exempt finished-dose-form medicines from the HSNO Act. The Medicines Act empowers the prohibition of medicines that represent an unacceptable risk to public health. Officials advise this interface is generally working well. However, there is no regulation to control the disposal of medicines and there is no ability to prohibit the importation and distribution of medicines in a finished-dose-form that contain an environmentally hazardous substance. Were a finished-dose-form product with a high environmental risk to be identified in the future, New Zealand regulators would be unable to adequately respond.
2. Accordingly I propose that the new therapeutics regulator be able to prohibit the importation and distribution of medicines that contain an environmentally hazardous substance and to prescribe disposal requirements on the advice of the EPA. The regulator could request an assessment of the environmental risks or this advice could be provided on the initiative of the EPA. The new regime will establish regulation around the disposal of therapeutic products. These changes should assist in managing potential impacts on the environment from finished-dose-form medication.

## Placement of provisions

1. In November 2015, Cabinet agreed to a flexible legislative framework and to as much detail as possible being contained in regulator-made instruments. It also agreed that the placement of key provisions – particularly the categorisation of products as medicines, medical devices, cell and tissue therapeutic products, or hybrids – should be discussed with the Parliamentary Counsel Office and the Legislation Design Advisory Committee and that the Minister should report back if any changes were proposed as a result. Discussions conclude that the desire for flexibility to change categorisations in response to changing technology does not outweigh the need for certainty in these settings: they should not be included in third tier legislation. Officials will resolve this issue as the Bill is drafted.

## Consultation

1. The following agencies were consulted on this paper and their views are reflected: Parliamentary Counsel Office; Treasury; State Services Commission; Ministries of Business, Innovation and Employment, Justice, Primary Industries, Environment, Women, Social Development, Foreign Affairs and Trade; Te Puni Kokiri; PHARMAC; ACC; Environmental Protection Authority; and New Zealand Customs. The Department of Prime Minister and Cabinet was informed.
2. Agency comment:
   1. The Parliamentary Counsel Office notes that the timeframe to develop, consult on, and introduce the Bill is tight.
   2. Treasury and the Ministry of Business, Innovation and Employment continue their support for the removal of pharmacy ownership restrictions.
3. The Ministry has had targeted engagement on the issues in this paper with a range of industry and sector stakeholders. Further engagement is planned before the release of the exposure draft for consultation. Including with the research community, the Health Research Council, ethics committees and the cell and tissue sector.

## Financial Implications

1. Cabinet has agreed that the new regulatory regime can be funded through both cost recovery and Crown revenue. An indication of how these costs should fall will be contained in the policy proposals that accompany the exposure draft.
2. 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). Consideration will be given to whether implementation costs that cannot be met from these sources 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

1. The proposals in this paper are consistent 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 that further drafting instructions for the Therapeutic Products Bill be issued. The Bill will repeal and replace the Medicines Act and has priority 5 on the legislation programme (to be introduced in 2016).

## Regulatory Impact Analysis

1. 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.
2. The Regulatory Impact Analysis Team (RIAT) has reviewed the RIS for the above legislative/regulatory proposal and considers that the information and analysis summarised in the RIS **meets** the quality assurance criteria.
3. The RIS describes an extensive consultation process and careful consideration of points raised by stakeholders. It will be important to continue this level of engagement through the rest of the development and implementation process.

## Gender Implications and Disability Perspective

1. There are no particular matters with respect to gender implications or disability perspectives.

## Publicity

1. The Ministry continues to engage with sector stakeholders on the design of the regulatory regime and there is considerable interest in it.

### Release of Cabinet papers and regulatory impact statements

1. To facilitate further engagement, I intend to proactively release this Cabinet paper, the two considered by Cabinet in November 2015 (SOC-15-SUB-0049, SOC-15-SUB-0050), and the associated regulatory impact statements before May 2016. The Ministry will assess whether redactions, consistent with the grounds for withholding information under the Official Information Act 1982, should be made.

### Exposure draft

1. Cabinet has agreed that I will release an exposure draft of the Bill for consultation along with a statement of the policy to be contained in subordinate legislative instruments (SOC-15-MIN-0049 refers). In order that the maximum possible time is allowed for developing and consulting on the draft Bill, I propose that Cabinet agree that I approve the release of this package of material (the draft Bill and consultation document). I will report back the key outcomes from the consultation at the time that I seek approval to introduce the Bill (unless there are matters of particular significance that should be addressed by Cabinet before introduction).
2. I intend to make a media statement at the time the exposure draft and consultation material are released.

## Recommendations

1. The Minister of Health recommends that the Committee:

### Previous consideration

1. **note** that, as recorded in SOC-15-MIN-0050 and SOC-15-MIN-0049, Cabinet has:
   1. agreed the objectives for a new therapeutic products regulatory regime, the means to achieve those objectives, and that drafting instructions be provided for the key elements of a Therapeutic Products Bill to repeal and replace the Medicines Act 1981;
   2. noted that the Minister of Health would report to the Social Policy Committee during March 2016 on policy issues to inform further drafting instructions. These include prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework, the form of the regulator, and pharmacy licensing arrangements;
   3. notedthat the Ministry of Health would discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments with the Parliamentary Counsel Office and the Legislation Design Advisory Committee, and that the Minister of Health would report back if any changes were proposed.

### Clinical trials

1. **note** that clinical trials are conducted within a robust safety and ethical framework can offer a number of social and economic benefits to New Zealand;
2. **agree** that the therapeutic products regulatory regime cover trials of all therapeutic products (all medicines, medical devices, cell and tissue therapies, and hybrid products) with requirements commensurate with the risk each trial presents;
3. **agree** that the regulator have the necessary powers to enable it to set requirements, approve trials, change conditions, access information, inspect, audit and take action to ensure safety (including revoking approval);
4. **agree** that the regulator be required to establish a committee to provide advice, as needed, on applications for clinical trials;
5. **agree** that the current timeframe for considering clinical trial applications remain at 45 working days and that this be contained in a subordinate instrument;
6. **note** that I have instructed officials to streamline and improve co-ordination and co-operation between theregulatory and ethical approval processes for clinical trials;

### Cell and tissue therapeutic product regulation

1. **confirm** that all cell and tissue therapeutic products be within the scope of the therapeutic products regulatory regime (including minimally-manipulated tissue for immediatetransplantation and xenotransplantation) with requirements calibrated to the risk of the products and the way they are used in clinical practice;
2. **agree** that the regime include a mechanism to enable minimally-manipulated tissue (both for immediate transplantation and banked for later transplantation) to not be subject to the requirement for pre-market approval;
3. **agree** that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to the requirement for activities licences;
4. **agree** that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to import and export requirements;
5. **agree** that recommendations 9-11 be drafted so as to allow these settings to be changed in the future should issues arise that warrant it;
6. **note** that both legislative placement and the accountability arrangements agreed by Cabinet for the regulatory regime will ensure that there is appropriate Government oversight of, and sector engagement about, any proposal to put additional regulatory requirements in place for minimally-manipulated tissue for immediate transplantation;

### Prescribing and dispensing

1. **agree** that controls on prescribing authority (including conditions on that practice) should sit under the Health Practitioners Competence Assurance Act 2003;
2. **agree** that the Health Practitioners Competence Assurance Act 2003 be amended to include mechanisms for prescribing authority to be part of a health practitioner’s Scope of Practice (including amendments to prescribing authority);
3. **agree** that those mechanisms include the Minister of Health deciding whether to approve the parameters of prescribing proposed for inclusion in a Scope of Practice;
4. **note** that current prescribing authorities will be carried over into the new regime;

### Pharmacy licensing

1. **note** that pharmacy licensing is aimed at ensuring the integrity of the supply chain of therapeutic products and that Cabinet has previously agreed to continue the international norm of licensing pharmacies;
2. **agree** that the therapeutic products regulatory regime provide for the regulator to:
   1. issue licences, for up to three years
   2. require information
   3. assess whether applicants for licences are fit-and-proper persons (or of good repute to hold a licence)
   4. require licence applicants to identify a Responsible Pharmacist for the day-today oversight of the licenced pharmacy
   5. require licence applicants to also identify a Supervisory Pharmacist with responsibility for overseeing the implementation of professional pharmacy standards and licence conditions
   6. set conditions on licences as appropriate to maintain pharmacy standards and manage and monitor risks.
3. **agree** that requiring pharmacist ownership of pharmacies is unnecessary to achieve the objectives of the regime and that the provisions in recommendation 19 provide sufficient mechanisms to ensure that professional pharmacy practice standards are upheld;
4. **agree** that licences for supply not necessarily be restricted to fixed physical premises, and that additional conditions may be set to manage risks associated with new supply models;
5. **agree** that the therapeutic products regulatory regime prohibit prescribers from benefitting from their prescribing activities through an investment in pharmacies, but not prevent sensible integrated service initiatives from developing;
6. **note** that the separation between pharmacy licensing and contracting will continue and that a pharmacy licence does not entitle the holder to a services contract;

### Import and export

1. **agree** that importing therapeutic products be a licensed activity;
2. **agree** that an exception to the requirement to hold an import licence should be provided for personal use, so long as other regulatory requirements are met;
3. **agree** that the export of therapeutic products require notification accompanied by evidence that the product meets the regulatory standards of the importing country;
4. **note** that the regulator will continue to issue export certificates for therapeutic products for New Zealand exporters on request to facilitate export to other jurisdictions;
5. **note** that parallel importing of all therapeutic products will be prohibited as a result of requiring approvals for all therapeutic products;
6. **agree** that the exemption permitting the Crown to parallel import medicines be replaced with a credible alternative that will enable the Crown to source alternative supplies of therapeutic products in appropriate circumstances;

### Offences and penalties framework

1. **agree** that the Therapeutics Products Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings, and infringement notices;

### Regulator form

1. **agree** that the regulator not be established as a Crown Entity;
2. **agree** that the powers of the regulatory regime (and associated administrative powers) be vested in the chief executive as defined in the State Sector Act 1988;

### Interface with the Hazardous Substances and New Organisms Act 1996

1. **agree** that the new therapeutics regulator and the Environmental Protection Authority will work together to ensure the application process for therapeutic products containing new organisms is efficient and effective;
2. **agree** that the Therapeutic Products Bill provide the ability to prescribe disposal requirements and prohibit the importation and distribution of medicines that contain an environmentally hazardous substance on the recommendation of the Environmental Protection Authority, on its own initiative or at the request of the regulator

### Drafting instructions

1. **authorise** drafting instructions being provided to the Parliamentary Counsel Office to give effect to the decisions in recommendations 2 – 34
2. **agree** that the Minister of Health make further policy decisions for the purposes of preparing the exposure draft of the Bill where the matter is consistent with the decisions made by Cabinet on the Therapeutic Products Bill;
3. **agree** that the Ministry of Health issue drafting instructions in respect of straight-forward matters that are in the Medicines Act that should be carried through to the new regulatory regime (with appropriate adjustments to reflect decisions made by Cabinet on the new regulatory regime);

### Placement of provisions

1. **agree** that officials continue to work with the Parliamentary Counsel Office and the Legislation Design Advisory Committee on placement matters with a view to the legislation being as enabling as possible, while also providing certainty as to the scope of the regulatory regime and its requirements;

### Report backs

1. **agree** that the Minister of Health report to Cabinet Social Policy Committee on institutional arrangements for the regulator, including whether the regulator should be the Department or a Departmental Agency, no later than October 2016;
2. **agree** that the Minister of Health report to Cabinet Social Policy Committee by June 2016 on extending Part 7A of the Medicines Act that controls specified biotechnical procedures (including xenotransplantation);

### Process matters

1. **agree** that the Minister of Health approve the release of the Therapeutic Products Bill exposure draft and supporting consultation material later in 2016, and that the Minister of Health report on the outcomes of consultation when approval is sought to introduce the Bill (unless there are significant matters to be addressed by Cabinet earlier);
2. **agree** that, to facilitate stakeholder engagement, the Ministry of Health release this paper, those considered by Cabinet in November 2015 (SOC-15-SUB-0049, SOC-15-SUB-0050), and associated regulatory impact statements before May 2016 with any necessary redactions made consistent with the Official Information Act 1982).

Hon Dr Jonathan Coleman

**Minister of Health**

1. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs (1999). [↑](#footnote-ref-1)