[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.

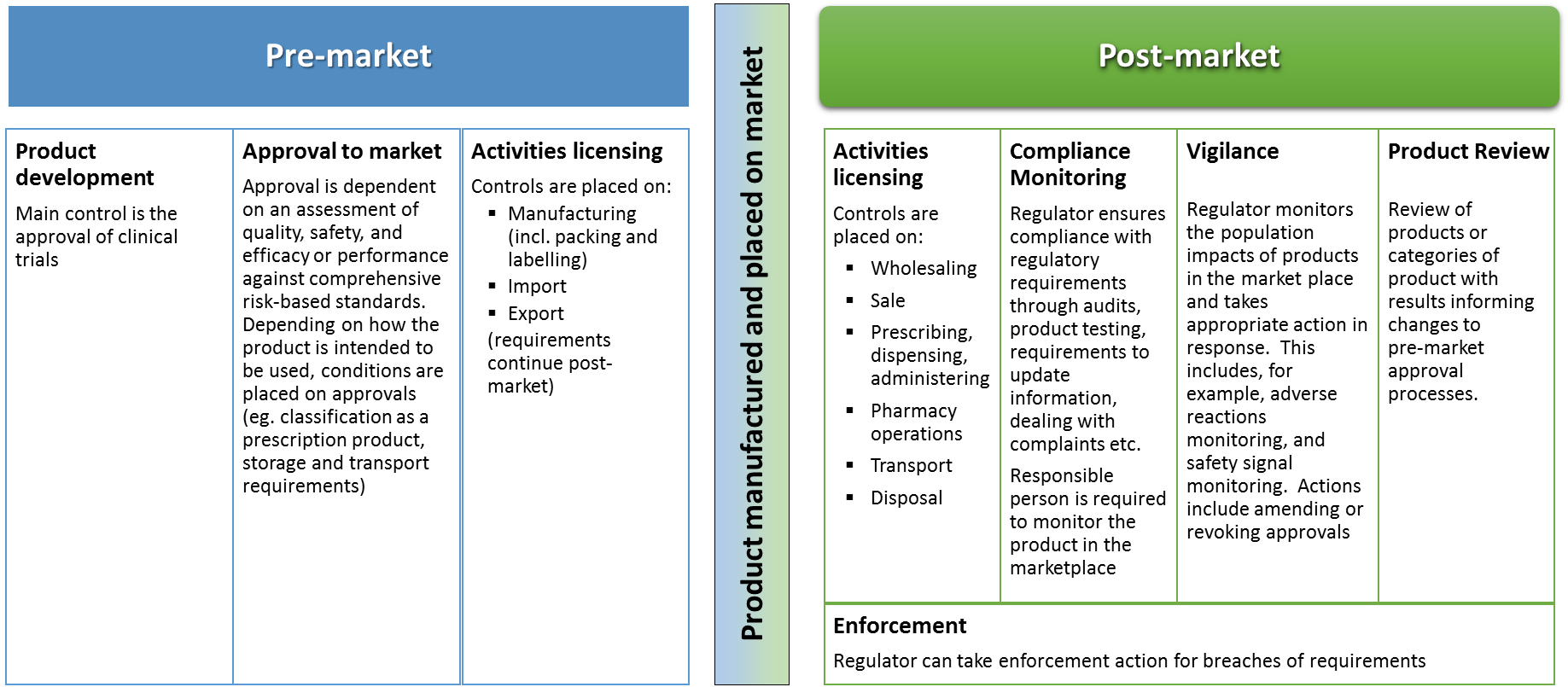
## Executive Summary

1. 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:
   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. 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.
   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

1. 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.
2. Paper one has described that the regulatory regime should comprise regulatory requirements, a regulator and an enabling legislative framework.
3. This paper focuses on the key elements proposed for the new Therapeutic Products Bill and is organised as follows:
   1. purpose and principles
   2. regulatory requirements, including definitions, product approval, activities licensing, post-market vigilance, and enforcement
   3. administration arrangements, including regulatory powers and accountability
   4. transition.
4. 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

1. 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.
2. It is proposed that the legislation contain a purpose statement that encompasses this concept.
3. 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.
   1. The expected benefits of therapeutic products should outweigh their known risks of causing harm in the treatment population.
   2. Regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use.
   3. Regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests.
   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.
   5. Regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public.
   6. The regulator should co-operate with international peer regulators and take relevant international standards and practice into account.
   7. Compliance costs should be appropriate to the benefit:risk profile.
   8. Regulation should support innovation and competition.
4. 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

1. 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).
2. 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’.
3. The definitions in the Medicines Act 1981 and international norms provide useful starting points for these definitions.

#### Responsible person, Approval holder, and Licensee

1. 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.
2. 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.
3. 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.
4. 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:
   1. responding to queries and requests for information in order that the product can be assessed for approval
   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
   3. ensuring that there is an effective system to take market action, including recall, including information being available about the distribution chain
   4. ensuring product information is available for the regulator, health care professionals and the public.
5. The *approval holder* may delegate some of these responsibilities to the *responsible person*, or they may be one and the same person.
6. 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.
7. *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.
8. 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

1. Product approval is the key point of control in the regulatory regime and the legislation should:
   1. require therapeutic products to have an approval and enable the regulator to issue an approval
   2. require material changes to approved therapeutic products to also be approved
   3. enable conditions to be placed on an approval
   4. enable approvals to be modified, suspended or revoked
   5. enable approvals to be for a defined duration
   6. enable recognition of other jurisdictions assessments/approvals and third party evaluators
2. 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.
3. 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.
4. 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.
5. 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).
6. 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.
7. 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

1. 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.
2. 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.
3. Classification may need to apply to other types of therapeutic product over time and this development should be enabled through the legislative arrangements.
4. It is proposed that:
   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’)
   2. legislation enable regulations to be made that set out additional precision specific to product types (eg, prescription medicine)
   3. legislation enable the regulator to set out any further detail in regulator-made instruments.
5. 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

1. 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.
2. 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).
3. 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.
4. 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.
5. 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

1. 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

1. 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.
2. 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.
3. It is proposed that the legislation require licences for controlled activities, including the following, and be otherwise prohibited:
   1. manufacturing, including packing and labelling
   2. supplying, including wholesale, hawking, and retail sale (licence holders must also undertake these activities consistent with product classification)
   3. operating a pharmacy.
4. 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.
5. 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.
6. The detailed requirements in respect of obtaining licences should be contained in Regulations and regulator-made instruments.

#### Pharmacy licensing

1. 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.
2. 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.
3. 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.
4. 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

1. 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.
2. 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.
3. 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.
4. 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

1. 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.
2. 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.
3. 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.
4. 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.
5. 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

1. 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.
2. 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.
3. 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

1. 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

1. 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.
2. Regulatory decisions about therapeutic products impact significantly on:
   1. consumers in terms of access to products
   2. health professionals in terms of how they are able to provide care to patients and (for some) their personal financial gain
   3. the therapeutic products industry and other private interests (eg, supermarkets) in terms of revenue and reputation in the domestic and international markets
   4. the provision of publicly-funded products through the Pharmaceutical Schedule.
3. 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]](#footnote-1). This is problematic because:
   1. the Minister is responsible but poorly placed to assess the relevant technical information and make a risk:benefit judgement
   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)
   3. the Minister is less able to independently monitor the overall performance of the regulatory regime and the regulator.
4. 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:
   1. the Medicines Assessment Advisory Committee and the Medicines Adverse Reactions Committee (appointed under a general power to appoint advisory and technical committees)
   2. the Medicines Classification Committee
   3. the Medicines Review Committee.
5. 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. This would mean that the Minister had no influence over regulatory decisions in respect of particular products, or persons.
6. 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

1. 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:
   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.
   2. judicial review
   3. process requirements in respect of the making of regulations.
2. In addition it is proposed that the legislation include the following requirements:

##### Regulator making instruments

* 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
  2. that, in making legislative instruments, the regulator consult appropriately

##### Regulatory practice

* 1. that the regulator establish mechanisms for industry and consumer engagement (this may involve, for example, formalising the existing bi-annual industry forum)
  2. that the regulator be transparent about its processes including how committee appointments are made, decision-making processes and reasons for decisions

##### Performance

* 1. mechanisms for review and appeal of regulatory decisions in addition to judicial review (refer paragraph 75)
  2. financial and non-financial reporting.

1. It is proposed that detail in relation to these matters be set out in regulations enabled by the primary legislation.
2. 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

1. 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:
   1. Require the regulator to establish a committee or committees to provide advice, as needed, on therapeutic product:
      1. assessment
      2. classification
      3. safety monitoring.
   2. Require the regulator to ensure committee members have suitable skills including (but not limited to) knowledge of medicine, pharmacy, and consumer perspectives
   3. Enable the regulator to establish other technical advisory committees as it requires
   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.
2. 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

1. 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.
2. 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.
3. The regulator will also establish an internal complaints mechanism to help resolve complaints about regulatory decisions.

### Cost recovery

1. 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.
2. 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

1. 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.
2. 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

1. 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.
2. The Government agencies informed about this paper were: 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. 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.
4. Paragraph 46 notes the consultation currently underway with the pharmacy sector on the Draft Pharmacy Action Plan.
5. 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.
6. The Parliamentary Counsel Office notes that the timeframe for developing the new legislation is reasonably tight.

## Financial Implications

1. 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.
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). 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

1. 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.
2. 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

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

## 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 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.
3. 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

1. 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

1. In November 2014 I announced the cessation of efforts to establish ANZTPA[[2]](#footnote-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. 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
  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.
  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. the expected benefits of therapeutic products should outweigh the known risks of causing harm in the treatment population
     2. regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use
     3. regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests
     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
     5. regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public
     6. regulator should co-operate with international peer regulators and take relevant international standards and practice into account
     7. compliance costs should be appropriate to the benefit:risk profile
     8. regulation should support innovation and competition.

##### Definitions

* 1. Definitions of the terms *therapeutic product*, *therapeutic purpose,* *responsible person, approval holder,* and *licensee.*
  2. High-level definition of categories of therapeutic products.
  3. The ability for the regulator to declare something to be, or not to be, a therapeutic product and the category of product.

##### Approvals

* 1. A requirement that therapeutic products are approved, unless an approval is not required, and the ability for the regulator to issue an approval.
  2. A requirement that material changes to approved therapeutic products also be approved.
  3. The ability for the regulator to place conditions on an approval.
  4. The ability for the regulator to modify, suspend or revoke an approval.
  5. The ability for approvals to be issued for a defined duration.
  6. Definitions of generic classifications that apply to therapeutic products based on those that apply to medicines currently (prescription, restricted, pharmacy-only, general sales).
  7. The ability for the regulator to classify products as a condition of approval.
  8. Enable recognition of other jurisdictions assessments/approvals and third party evaluators.

##### Data protection

* 1. 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. A requirement that, unless done under licence issued by the regulator, controlled activities are prohibited in respect of therapeutic products, including:
     1. manufacturing, including packing and labelling
     2. supply, including wholesale, hawking, and retail of therapeutic products (licence holders must also undertake these activities consistent with product classification)
     3. operating a pharmacy.
  2. 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. A requirement that advertisements and promotions in respect of therapeutic products be truthful, not misleading and socially responsible.

##### Compliance, enforcement and penalties

* 1. Inspection powers, including the ability to require information.
  2. 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. 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. That regulatory powers and associated administrative powers are held independent of the Minister of Health.
  2. 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.
  3. The following accountability arrangements:
     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
     2. that, in making legislative instruments, the regulator consult appropriately
     3. that the regulator establish mechanisms for industry and consumer engagement
     4. that the regulator be transparent about its processes
     5. financial and non-financial reporting.
  4. The ability for the regulator to establish technical advisory committees as it requires.
  5. A requirement that the regulator establish a committee or committees to provide advice, as needed, on therapeutic product assessment, classification, and safety monitoring.
  6. 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.
  7. The ability for committee processes to be determined by the regulator as a matter of policy.

##### Review and appeal

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

##### Cost recovery

* 1. A requirement that the regulator recover its costs through fees and levies where these costs are not met through Crown funding.
  2. A requirement that fees and levies are reviewed within three years of first being set.

##### Transitional provisions

* 1. Provisions which enable products regulated under the Medicines Act 1981 to transition to the new regulatory regime.
  2. Provisions which enable regulatory requirements to apply in a staged manner to medical devices and cell and tissue therapies.
  3. Provisions that require a review of the Therapeutic Products Act within 5 years of the end of the transition period.

##### Regulations

* 1. The ability for regulations to be made in respect of:
     1. Review Committee matters including who can apply for review and the ability to charge for review
     2. classification
     3. fees and levies
     4. accountability arrangements
     5. exempted products (including pharmacy compounding)
     6. licensing.

##### Regulator-made instruments

* 1. The ability for instruments to be made by the regulator in respect of:
     1. how an application for an approval should be made
     2. closer definition of categories of product
     3. standards and requirements that will apply to products and associated activities (including for example, manufacture, product recall, vigilance)
     4. the application of classifications
     5. exempted products
     6. requirements to be met in respect of obtaining licenses
     7. requirements to be met in respect of meeting advertising requirements.

1. **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.
2. **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.
3. **Note** that the Minister of Health’s initial view is thatcurrent 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.
4. **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.
5. **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

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. [↑](#footnote-ref-1)
2. Australia New Zealand Therapeutic Products Agency [↑](#footnote-ref-2)