

In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Therapeutic products regulatory scheme: overview and consultation on Bill exposure draft

Proposal

- 1 A Therapeutic Products Bill to replace the Medicines Act 1981 s9(2)(f)(iv) [REDACTED]. This paper provides an overview of the proposed new regulatory scheme for therapeutic products, and
 - 1.1 draws your attention to key policy issues: including next steps with natural health products regulation and consultation on options for pharmacy licensing criteria
 - 1.2 seeks to reaffirm the 2016 decision that the Minister of Health approve the release of an exposure draft of the Bill and supporting consultation material.

Executive Summary

- 2 A Therapeutic Products Bill is being developed to repeal and replace the Medicines Act 1981. The Medicines Act provides insufficient coverage of the many products used in modern healthcare delivery, is inefficient to administer, and is no longer fit-for-purpose. This has been the case for many years and the need to progress new legislation is now pressing if New Zealanders are to be assured of safe and reliable products.
- 3 This new regulatory scheme will ensure all therapeutic products are subject to appropriate levels of regulation and enable improvements and innovation in Government and Health priority areas. Appendix A sets out the framework of the draft Bill.
- 4 An exposure draft of the new Bill is nearing completion. Consistent with sector expectations, I propose releasing the draft Bill and a consultation document by the end of the year for consultation until April 2019. This will give the many interested stakeholders an opportunity to work through the complex and detailed provisions and for the Bill to be refined ahead of it being introduced to the House in 2019.
- 5 The policy decisions that would be given effect by the Bill were largely taken in 2015 and 2016. Those decisions were to put in place a comprehensive regulatory scheme that covers all therapeutic products and is aligned with international regulatory norms. The new scheme would place risk-proportionate controls at key points across the lifespan of products, and support them with compliance, enforcement powers and requirements, systems to monitor the use of products and to respond to any safety concerns.
- 6 I have reviewed the previous policy decisions and, with a few exceptions, they are sound. These policy proposals are set out in this paper. The exceptions are areas where I consider a change in policy is required or should be consulted on. In this regard this paper seeks your approval for the draft Bill to contain policy proposals to: include a category of product (type-4) for future therapeutic products that are not medicines or medical devices, curtail the personal importation of prescription medicines via the post, enable health practitioners to supply pharmacy-only medicines to their patients, and technical changes to provisions on

the establishment of expert advisory committees and arrangements for merits review of regulator decisions.

7 The following matters are controversial and likely to attract significant attention during consultation:

7.1 Pharmacy licensing – pharmacy businesses would continue to be licensed under the Bill. Currently to get a licence a pharmacist has to have the majority ownership of a pharmacy and has to be in ‘effective control’ of the pharmacy. However as they are currently expressed in the Medicines Act 1981 these provisions don’t work well and they are unsuitable to be rolled into the new Bill. There are two options for the Bill; (1) to retain the ownership requirements and improve how they work, or (2) to remove them and require pharmacists to be in control of the quality systems and practices in the pharmacy. The previous government decided on option two. I however am concerned that this proposal may not meet safety objectives and [REDACTED] s9(2)(g)(i) [REDACTED] My inclination is to retain the ownership requirement and improve how it works (option one). I am aware that this is a complex issue however and before these provisions are drafted into the Bill I intend to consult on the policy options through the consultation document. I will report back following consultation on my recommended approach.

7.2 Direct-to-consumer advertising of named prescription medicines (DTCA) – the Bill gives effect to the previous decision that DTCA continue to be permitted. This contentious practice is only permitted in New Zealand and the USA. I have been aware of this issue for some time and that strengthened regulation may be warranted. I expect considerable consultation feedback on this issue and will review this policy following consultation.

7.3 Natural health products (NHPs) – under the previous administration these products were to have been regulated by the Natural Health Products Bill. That Bill was not reinstated by this Government and this has had the unintended consequence of bringing NHPs within the ambit of the Therapeutic Products Bill. In order that the Government can consider how it wishes to regulate NHPs into the future, this paper recommends that NHPs are, as far as is possible, excluded from the Therapeutic Products Bill. The consultation document would make it clear that the intention is to develop an exclusion for NHPs before the Bill is introduced. s9(2)(g)(i) [REDACTED]
[REDACTED]

8 I propose reporting back to Cabinet on the outcomes of consultation and the matters noted in the paragraph above. I also propose reporting back on the institutional form of the regulator and cost recovery policy.

Background

9 Medicines (including cell and tissue therapeutic products) and medical devices are collectively known internationally as therapeutic products and they aim to diagnose, treat or prevent ill health in humans.

10 The Medicines Act 1981 is widely acknowledged as not fit-for-purpose. It is inflexible, prescriptive and prevents regulatory efficiencies; creates difficulties for some legitimate cell and tissue based products to come to market; and is poorly suited to the delivery of modern healthcare.

- 11 There are also significant gaps in what it covers. For example, there are no pre-market controls on medical devices (which include high risk products that are implanted) and there is only regulatory oversight of clinical trials of new medicines. With the increasing range of complex therapeutic products being developed, New Zealand needs a new scheme that is comprehensive and flexible enough to respond to and regulate these products.
- 12 Successive governments have recognised these problems and there have been attempts to address them since the 1990s. For much of this time efforts were focussed on establishing a joint New Zealand-Australia regulatory scheme and agency. However, in late 2014 this initiative ceased and work on a new regulatory scheme for New Zealand commenced.
- 13 Three papers approved by Cabinet in 2015 and 2016 established the key elements of the new regulatory scheme, how it would be set out in legislative instruments, and that an exposure draft of the Bill would be released for public consultation before the Bill was introduced to the House. This work was informed by the long history of reform attempts and by the comprehensive review of regulatory systems and institutions published by the Productivity Commission in 2014. The minutes of those papers are appended for reference [SOC-15-MIN-0049, SOC-15-MIN-0050 and SOC-16-MIN-0025].
- 14 Since 2016 the Parliamentary Counsel Office and the Ministry of Health have been drafting a Therapeutic Products Bill and undertaking tailored stakeholder engagement. Therapeutic products regulation is a complicated and very detailed matter and the drafting process has taken considerably longer than initially anticipated.
- 15 I have been briefed on the Bill and the policy decisions taken by the previous administration. Aside from a few exceptions that are discussed in this paper, these policies provide the basis for a comprehensive, modern, cost-effective regulatory scheme. I am also supportive of the process that public consultation happen before the Bill is introduced.

NEXT STEPS: PUBLIC CONSULTATION

- 16 Before turning to the regulatory scheme itself, it is useful to set out my proposed next steps for finalising the Bill for introduction to the House.
- 17 Consultation on a draft of the Bill will enable stakeholders to review the detail, to express their perspectives and to help identify any further issues to be resolved or the need to reconsider policy decisions. Consultation now is likely to smooth progress of the Bill through the House when it is introduced. Consultation on an exposure draft is also consistent with the recommendations of the Productivity Commission that exposure drafts be published and consulted on before introducing into Parliament legislation that creates a new regulatory scheme or significantly amends existing schemes. I also note that stakeholders are expecting, and keenly anticipating, this opportunity.
- 18 Given the high level of stakeholder interest, and the length of time it has taken to get to this point, I want to consult as soon as practical. Officials are currently working to have the draft Bill and a consultation paper ready for release by the end of the year.
- 19 In order that stakeholders have sufficient time to work through the detail, and in recognition that consultation will span the end-of-year holiday period, I propose that consultation be for until April 2019.
- 20 The usual process would be for Cabinet to approve the final consultation paper and draft Bill before they are released. Given the complex and technical nature of this Bill, the previous government agreed that the Minister of Health would approve the release of the Bill exposure draft and supporting consultation material [SOC-16-MIN-0025 refers]. I would also

like to take this approach and will ensure that our Coalition and support partners have an opportunity to review the material before it is released. I attach the current working draft of the Bill for your information.

- 21 I therefore seek your agreement that I approve the release of the exposure draft of the Bill and supporting consultation material; and that I report back on the outcomes of consultation within four months following the close of consultation.

THE NEW REGULATORY SCHEME

- 22 Therapeutic products regulation is aimed at ensuring the safety, quality, and efficacy or performance of products over their lifecycle. The new regulatory scheme is designed to meet these objectives for New Zealanders while being mindful that we are a small part of a highly competitive global market and that our size brings constraints on our technical regulatory capacity. We need a regulator that can ensure safety for our citizens by having in-house expertise and capacity where needed and by being connected to the global regulatory community and able to leverage its expertise. It is worth emphasising that therapeutic products regulators across the world are challenged by the speed of change and complexity of products that technology is creating. In order to meet the ongoing needs and expectations of New Zealanders it is critical that we have a modern regulatory scheme that is administered by a credible and respected regulator.
- 23 The new scheme is aligned with international norms and places risk-proportionate controls at key points across the lifespan of products. It supports these controls with compliance and enforcement powers and requirements, and systems to monitor the use of products and to respond to any safety concerns. These arrangements aim to ensure that the benefits of using products (as intended) outweigh the risks of harm, that products are high quality throughout their lifespan (ie, they do not degrade or fail), are traceable, appropriately used and accompanied by good information about their use. They also aim to avoid diversion from the licit supply chain. There would be controls on:
- 23.1 Products, which in general must be approved before being imported or supplied
 - 23.2 Access; to prescription medicines for example
 - 23.3 Information provision such as factual product information and advertising
 - 23.4 Certain activities (eg, manufacturing, clinical trials, pharmacy)
 - 23.5 Conduct of key people (eg, sponsors of products).
- 24 Appendix A includes a diagram of the various controls that would apply across a product's lifespan.
- 25 To keep pace with technological change and changes in regulatory practice the new scheme would comprise a principles-based Act that is high-level and enables the making of regulations, rules, and notices. These subordinate instruments would contain the detailed regulatory requirements. The Act would also, where not otherwise provided for, contain process requirements for how these subordinate instruments are made. This would ensure appropriate transparency, accountability, and certainty to consumers and to those regulated.

Overview of the new scheme

- 26 An overview of the new scheme is set out below. A small number of matters are in bold. These are matters where, since the decisions on the scheme were taken in 2015 and 2016,

a new policy direction is recommended, or where a matter is contentious and should be noted, or where further work is needed and I will report back to Cabinet, if necessary.

Product controls: medicines, medical devices, active medicinal ingredients, and type-4 products

- 27 The Bill would regulate all therapeutic products. There are two main types: medicines (including most cell and tissue therapeutic products) and medical devices. This is the general approach taken internationally and enables us to use international standards and share work with international peer regulators. Active medicinal ingredients (AMIs) will continue to be covered, but are included as a separate product type so that specific controls can be applied where appropriate.
- 28 To ensure the regulatory scheme can appropriately regulate new, currently unknown types of therapeutic products, **the draft Bill contains a placeholder for a type of product termed 'Type-4 products'**. Type-4 products are currently unknown, but may emerge and not fall within the definition of 'medicine' or 'medical device' meaning that they would not be subject to many controls. This type of provision would have been beneficial in 2002 when xenotransplantation products looked to be emerging and a hurried amendment to the Medicines Act was required to ensure some form of regulatory coverage¹.
- 29 Product controls fall into two main areas: pre-market approval and on-market monitoring. Currently we have pre-market approval for medicines only and on-market monitoring for both medicines and medical devices. The lack of pre-market controls on medical devices is a significant gap that would be filled by the new scheme.
- 30 In the new regulatory scheme, unless an exception applies, products would need to be approved by the regulator before they can be imported or supplied. The Bill would enable the regulator to establish different pathways to approval depending on the type of product, its risk profile, and other features. The ability to have different risk-calibrated pathways to approval is an important feature of the new scheme and one that it is difficult to do under the Medicines Act now. This approach would enable the regulator to make its own decisions, either based on its own assessment of the data, a review of another body's assessment, or a mix of these.
- 31 The standards and requirements that products would need to meet in order to be approved would be set in subordinate instruments as these things change over time and tend to be technically detailed. They would align with international norms to the extent that they are applicable in our context. Stakeholders will be very interested in the detail of these requirements and there will be consultation and engagement as they are developed.
- 32 The new regulatory scheme would also contain obligations on product 'sponsors' and on the regulator for monitoring, reporting and other vigilance activities aimed at ensuring the ongoing safety, quality and efficacy/performance of products that are in the market.
- 33 The new scheme would enable the supply of products that have not been approved by the regulator ('unapproved' products) where there is a clinically demonstrated need for them. This is an important feature of the Medicines Act now and regulatory schemes internationally. The control in the new scheme would be somewhat tighter than that in the Medicines Act now as there is concern that the current provisions are relatively easily circumvented.

Import and export

¹ Xenotransplants will be included within the Therapeutic Products Bill as a type of medicine. The scheme will be able to apply appropriate controls on these products.

- 34 The new regulatory scheme includes import and export controls that more appropriately manage the risks to patient safety, protect New Zealand's reputation internationally, and support trade and economic objectives. This includes, for the first time, regulating import. This is done by requiring imported products to be approved or otherwise authorised so that intervention could occur before products enter the New Zealand supply chain. This approach is consistent with that in other jurisdictions and with World Health Organization commitments.
- 35 Concern has increased over the years about the personal importation of prescription medicines by individuals and volumes have increased with the advent of online sellers overseas. Many of the prescription medicines crossing the border as personal imports have not been prescribed or may be of poor quality, adulterated or counterfeit. The Bill aims to strike a balance between personal freedoms and protecting consumers from unknowingly purchasing unsafe or ineffective products.
- 36 It does this by retaining the policy under the Medicines Act for:
- 36.1 non-prescription medicines – allowing individuals to import a three-month supply (by either bringing the medicine into the country with them or ordering them by post)
 - 36.2 prescription medicines – allowing someone to carry on their person a reasonable quantity for personal use when entering New Zealand, if they have been lawfully prescribed.
- 37 The Bill proposes to **remove the ability for individuals to import prescription medicines from overseas through the post/courier**. It is important to note that individuals would still be able to obtain unapproved prescription medicines under other provisions of the Bill. Where there is a clinical need for a particular unapproved product, a medical practitioner could issue a special clinical needs supply authority. That would authorise the medical practitioner, a pharmacist, or a wholesaler with an appropriate licence to import the product on the patient's behalf. These people are better able to identify suitably accredited suppliers. The regulator would also be able to issue a permit authorising the personal import of prescription medicines in situations where it is considered appropriate.
- 38 Personal importation of medical devices is not currently regulated. The Bill provides that a person may import a medical device for personal use unless there is a specific restriction on that device (akin to a medicine being a prescription medicine).
- 39 Concerns in relation to the export of therapeutic products are centred on protecting New Zealand's reputation and supporting the domestic industry. The new export scheme addresses these risks, while avoiding imposing burdensome requirements or impeding the flow of therapeutic products to developing countries, such as those in the Pacific, for legitimate reasons. The new scheme would require those exporting products to obtain a product approval. For export-only products this is likely to be through a notification system involving requirements for Good Manufacturing Practice and a declaration that the products meet the regulatory requirements of the receiving country.

Access controls

- 40 The Bill would enable access controls to be placed on products to ensure that those of low risk are readily available and those of higher risk are accessible with the appropriate level of clinical oversight. The current categories (prescription, pharmacist-only, pharmacy-only, and general sale) would continue for medicines (termed category 1 - 4 in the Bill).

- 41 At present, products classified as 'pharmacy-only' can only be supplied from a licensed pharmacy or a place that holds a special retail licence. The Bill would **widen access to pharmacy-only medicines by allowing health practitioners (who may not be prescribers)**, and their staff, to supply pharmacy-only medicines to patients of their practice. The medicines they could supply would be limited to those that are appropriate for the treatment of a condition covered by their scope of practice. Currently health practitioners are able to administer these types of medicines, but not supply them to patients for follow-up care. If a health practitioner has the competencies required to administer these medicines, it follows that they also have the competencies required to safely supply them.
- 42 The Bill would also enable use or supply restrictions to be placed on medical devices if risks were identified.

Information provision

- 43 The Bill would also control information provision in respect of products and information sharing for enforcement. It would control advertising of products and enable requirements to be placed on product sponsors to provide information about the safe and effective use of their product (eg, Consumer Medicine Information).
- 44 I am aware that there is considerable interest in the advertising controls on medicines. The Bill would continue the current requirements that only approved products can be advertised and advertisements must be truthful and not misleading.
- 45 **The issue of particular interest is whether we should continue to permit named prescription medicines to be advertised to consumers;** this advertising is known as DTCA (direct-to-consumer advertising). Currently New Zealand and the USA are alone in the developed world in allowing DTCA of prescription medicines (DTCA of non-prescription medicines is permitted). DTCA is a contentious issue, views are split, and the evidence base on its impacts is mixed. The previous government agreed that DTCA would continue to be permitted in New Zealand and the Bill is drafted on this basis. Since being in office I have heard concern from health practitioners about DTCA. In light of that concern I am interested in exploring whether increased regulation is warranted. I expect that there will be considerable consultation feedback on this issue and following consultation I will report back to Cabinet on this issue.

Activity controls

- 46 The Bill would control those activities that impact on the safety, quality, and efficacy or performance of products. The activities controlled include manufacturing, wholesale and non-wholesale supply, prescribing, administering, conducting clinical trials, and operating a pharmacy business.

Pharmacy licensing

- 47 For safety reasons operating a pharmacy would continue to require a licence. **What the criteria for obtaining a pharmacy licence should be is a contentious issue and I intend to consult on the policy options.**
- 48 Strategically pharmacy is an important point of primary care service delivery and pharmacists are highly skilled health professionals that we want to utilise better within the health system – both in bricks and mortar pharmacies and elsewhere in the community. Publicly-funded pharmacy and pharmacist services are often delivered through a commercial and competitive private market. Pharmacy licensing controls are targeted at ensuring the

integrity of the medicines supply and distribution chain in that environment; they need to do this while supporting the evolution of service delivery.

- 49 Currently, to be eligible for a pharmacy licence the Medicines Act 1981 requires that a pharmacy be majority owned by a pharmacist and that a pharmacist has 'effective control' of the pharmacy. An individual pharmacist may have the majority shareholding in up to five pharmacies. These arrangements are based on the policy premise that safety objectives will be best met and negative impacts of commercial influences minimised, by having pharmacist ownership of pharmacies. When a pharmacist owns and controls a pharmacy, they are required to uphold the Medicines Act, and are also bound by the Health Practitioners Competence Assurance Act 2003 to uphold professional standards.
- 50 There are however challenges to the way that the current provisions work in practice. Key terms such as 'effective control' are not defined in the Medicines Act and there is a lack of clarity about the concept of majority ownership and the 5 pharmacy limit when there is joint ownership. There is a wide variety of business structures in place in the sector and complex ownership structures have raised questions about whether the current provisions have achieved the expectation that the pharmacist owner has effective control of the pharmacy. The current provisions could not be rolled into the new regulatory scheme.
- 51 There is no question that key medicine-related activities within a pharmacy need to be under the control of a pharmacist to ensure the integrity of the medicines supply chain. This control can be achieved in different ways. The previous government decided to move away from an ownership control of a pharmacy and to allow open ownership with targeted licence requirements focused on ensuring a pharmacist was empowered and responsible for the quality systems and practices within the pharmacy that relate to the supply of medicines. In addition they were going to continue the current requirement that there be a pharmacist identified on the licence as responsible for the day-to-day operations of the pharmacy. This change was considered to allow for more flexibility in how pharmacist services are delivered, and encourage competition in the pharmacy sector. This approach was discussed with the pharmacy sector with an understandably mixed response and considerable concern.
- 52 Since coming into office I have heard the concerns of the sector about the previous government's proposed approach and my initial inclination is that it would be preferable to retain the policy of pharmacist ownership and to ensure that the legislative provisions work effectively to give effect to this policy. While I understand that there are mixed incentives in the sector I share some of the sector's reservations about whether moving to open ownership, albeit with other controls, would meet safety objectives; s9(2)(g)(i)
- 53 I am aware that this is a complex issue that will impact on the sector now and, along with changes to pharmacy contracts, will influence how the sector and service delivery evolves. I therefore propose that the sector be consulted on the options before provisions are drafted for the Therapeutic Products Bill. Consultation on the policy options and key issues will enable the sector to consider the issues and impacts. For example, issues that will benefit further exploration are whether an ownership control should relate to just those aspects of a pharmacy that are medicines-related, or all activities within the pharmacy (eg. sales of other products such as cosmetics) and how an ownership control can be cast to support flexible pharmacies (not tied to bricks and mortar premises).
- 54 The consultation document will set out both options as follows and will seek feedback on the issues associated with each, how to best give effect to them and the potential risks, benefits, and impacts:

- 54.1 Strengthened accountability through pharmacist ownership and effective control (including the five pharmacy limit) (my initial preference)
- 54.2 Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

55 I will report back to Cabinet on pharmacy licensing following consultation.

56 **A related matter is whether we should continue the restriction that prescribers cannot hold an interest in a pharmacy**, unless granted an exception by the regulator. The previous government considered that this provision should be retained, but drafted in a way that did not prevent sensible integrated service initiatives from developing. The drafting process has raised a number of issues about the practicality of such a provision and on the impact it may have on current pharmacy owners who are pharmacists and wish to become qualified to prescribe. Internationally there is a notable increase in the types of pharmacist prescriber roles. These trends support improved access to services and better use of health practitioners and need to be borne in mind when designing the licensing system. I intend to seek further feedback on the workability of this provision during the consultation and will report back to Cabinet on the above, if necessary.

Prescribing

57 Prescription medicines are higher risk and should only be available on the advice of a health practitioner with the qualifications, training and competence to make the clinical judgements necessary to balance the benefits and risks of use. Currently the Medicines Act and its regulations control which health practitioners may prescribe and under what circumstances. The overall controls on the competence and registration of health practitioners is the remit of Responsible Authorities (eg, the Medical Council) established under the Health Practitioners Competence Assurance Act 2003 (HPCA Act).

58 In the Bill, the authorisation to prescribe would be established in the relevant professions' scope of practice, under the HPCA Act. This approach reflects the fact that prescribing is part of a health practitioner's clinical practice. That said, prescribing is a particularly sensitive aspect of clinical practice and the HPCA Act would be amended so that the final decision about which professions have authority to prescribe rests with the Minister of Health.

Clinical trials

59 Clinical trials are research studies that explore whether a therapeutic product is safe and/or effective for humans, including those with certain illnesses or other characteristics. Currently regulatory approval is only needed for clinical trials of new medicines and not for new uses for already approved medicines. This minimal coverage is out of step with international norms and expectations.

60 The new scheme aligns with OECD guidance on the governance of clinical trials for medicinal products and international norms for Good Clinical Research Practice. It covers trials of all therapeutic products, and the approval would be risk-based and take the form of a licence. Clinical trials would require ethics approval (unless exempted by the ethics system). The Bill will also contain new powers to monitor and audit the conduct of trials.

61 Alongside ensuring safety and integrity of trials, timeliness and streamlined approval processes are important to maintaining New Zealand's attractiveness as a place to do trials. It is intended that on-line tools would be used to expedite the submission of applications and that there would be performance targets for the regulator.

Compliance and enforcement

- 62 Compliance and enforcement activities are a core part of any regulatory regime and the powers and penalties in the Medicines Act 1981 are insufficient to address and deter poor behaviour.
- 63 The tiered approach for criminal offences and penalties in the Bill is aligned with similar recent legislation. The enforcement tools would also include infringement notices, and enforceable undertakings (which offer an interim step before criminal charges).
- 64 **The Ministry of Health is also discussing with the Ministry of Justice whether civil pecuniary penalties would be appropriate for this scheme.** This discussion will continue while the Bill is being consulted on. I will seek Cabinet approval to amend the Bill to include this type of penalty if deemed appropriate.

Administrative arrangements

Regulatory powers

- 65 **The institutional form of the regulator is yet to be decided.** A decision was taken in 2016 that the regulator not be a Crown Entity and that further consideration be given to establishment as a Departmental Agency or within the Department (Ministry of Health). With the passage of time, restructuring within the Ministry of Health, and recent experience of regulatory systems this issue warrants further reconsideration. The Minister of State Services and I will report to Cabinet on the proposed institutional form of the regulator in March 2019.
- 66 **It was envisaged that the Bill would need to contain a requirement on the regulator to establish committees for certain matters and a requirement that consideration be given to membership from medicine, pharmacy and consumer perspectives.**
- 67 As drafting has progressed, the Ministry has been advised by the drafters that this requirement is not necessary. This is because the regulator would have the ability to establish committees or seek other forms of external advice whenever and for whatever circumstances it needs as a matter of course. There is also a risk that if specific provision is made the regulator may feel compelled to use a committee when it is not necessary or efficient to do so.
- 68 I am aware however that specific provisions may provide comfort that there would be an external voice in particular matters and that it may be sought for accountability reasons. This accountability can be achieved through other mechanisms that do not bring the risk of additional cost or bureaucracy. The precise mechanisms depend to an extent on the institutional form chosen for the regulator.
- 69 For the purposes of consultation, I recommend that the Bill not contain a requirement on the regulator to establish committee(s) for specific matters and that this issue be revisited, if necessary, as part of the work on institutional form.

Review and appeal

- 70 Specified decisions of the regulator (eg, a refusal to approve a product or issue a licence) would be subject to a formal merits review process. **The previous government had agreed that a review committee would be independent of the regulator and administered by the Ministry of Health.** Further work on this issue however indicates that this is not the best approach to ensuring an efficient and effective system for reviews of decisions.

- 71 Currently the Medicines Act provides for a Medicines Review Committee. In practice this committee has met very infrequently since its commencement in 1984. Disputed matters tend to be resolved through engagement between the party and the regulator.
- 72 After further consultation with the Ministry of Justice, and review of their publication 'Tribunal Guidelines', an independent standing committee with set membership is no longer considered appropriate. Instead it is proposed that the Bill provide for a review to be conducted by a panel of at least three people appointed by the regulator that have not previously been involved in the decision. One of the panellists must be a lawyer with at least seven years legal experience. Panels would be convened as and when needed, and their membership constituted in relation to the issues in dispute. This approach reflects the fact that the regulatory scheme would be wider and flexibility is needed to ensure members have appropriate knowledge and allow for the inclusion of external experts as required.
- 73 The panel would not re-make decisions made by the regulator, but would either confirm the original decision, or refer the matter back with recommendations for consideration of a new decision. Decisions of the regulator and the panel could be appealed to the District Court. The process the regulator undertook to reach a decision would also be subject to Judicial Review by a judge of the High Court.
- 74 The Bill has been drafted for this new approach and I consider the new provisions, taken together with rights of judicial review, provide applicants an appropriate and robust path to seek reconsideration of the regulator's decisions. I recommend that they are included in the exposure draft of the Bill released for consultation.

INTERFACES AND NATURAL HEALTH PRODUCTS

- 75 There is an array of products that are used or ingested with the aim of improving health, promoting wellness, improving appearance, or other aspects of human experience. Regulation to manage harms and ensure safe access spans this Bill (and the current Medicines Act), the Food Act and Dietary Supplements Regulations, the Misuse of Drugs Act, the Psychoactive Substances Act, tobacco control legislation, the developing medicinal cannabis regulatory scheme, Hazardous Substances and New Organisms Act (cosmetics, live vaccines), and the work underway on whether there should be greater regulation of the appearance industry.
- 76 The Therapeutic Products Bill would interface with all these other regulatory schemes and care is being taken to ensure that the interfaces work smoothly. In this context we need to decide how to manage the challenging interface between the Therapeutic Products Bill and natural health products (NHPs) as there is not a clean definable boundary between these product types.

Natural health products

- 77 NHPs are a broad group of products that are marketed for maintaining wellness, or treating or managing illnesses or health conditions. They include dietary supplements, complementary and traditional medicines, herbal preparations and other products (such as homoeopathic products). They come in a range of medicinal dose forms including tablets, capsules, creams, ointments, oral liquids and some injections, pessaries and suppositories. They generally contain ingredients derived from nature and/or their synthetic equivalents and may be simple vitamins or minerals through to herbal medicines and substances derived from animals (eg, deer velvet) or, commonly, a combination of substances. Most products on the New Zealand market are imported or manufactured in New Zealand by a small number of medium to large companies. Small producers in New Zealand tend to supply products made from locally grown plants or from animals such as bees or deer. Increasingly,

they are also being manufactured and supplied by pharmaceutical companies as companion products to be sold with one of their more potent medicines.

- 78 In terms of risk they generally (but not exclusively) sit between food and medicines. NHPs currently come under either the Dietary Supplements Regulations or the Medicines Act, but the regulation that is in place is poorly suited to the products, there is widespread non-compliance, and widespread non-enforcement. The Dietary Supplements Regulations are also due to expire in early 2021.
- 79 There is general agreement that NHPs need better regulation in order to support health objectives (obtaining benefits and managing risks) and industry growth (especially export). Opinion within the sector is, however, starkly divided on the appropriate method and level of regulation to achieve these objectives. There has been strong opposition from parts of the industry (and strong support from others) to regulatory proposals by successive governments in this area. This mirrors the experience in other countries which have updated regulation of these products.
- 80 In response to sector concern the previous government promulgated a Natural Health Products Bill (NHP Bill) that would have regulated these products separately from medicines. This government did not reinstate the NHP Bill and this would have the unintended consequence of bringing natural health products within the ambit of the Therapeutic Products Bill if appropriate risk mitigation is not undertaken. This is because the Therapeutic Products Bill's definitions of therapeutic product and medicine are such that NHPs are caught. The definitions are internationally accepted and permeate the Therapeutic Products Bill.
- 81 The Minister for Food Safety and I have sought advice from officials about the regulatory options for NHPs into the future. There are several options and these need careful consideration within government and with stakeholders. The need for the Therapeutic Products Bill is pressing and it has been a long time in development already. I do not wish to delay it while the difficult matter of the regulation of NHPs is addressed. I recommend that:
- 81.1 The consultation document make clear that the Government is considering options for the regulation of natural health products and that in order for that work to be done NHPs will, as far as is possible, be excluded from the Therapeutic Products Bill.
 - 81.2 The Ministry of Health will work with the Parliament Counsel Office to develop an approach for excluding NHPs before the Therapeutic Products Bill is introduced.
 - 81.3 The Minister for Food Safety and I report back to Cabinet in May 2019 on the options for the regulation of NHPs.

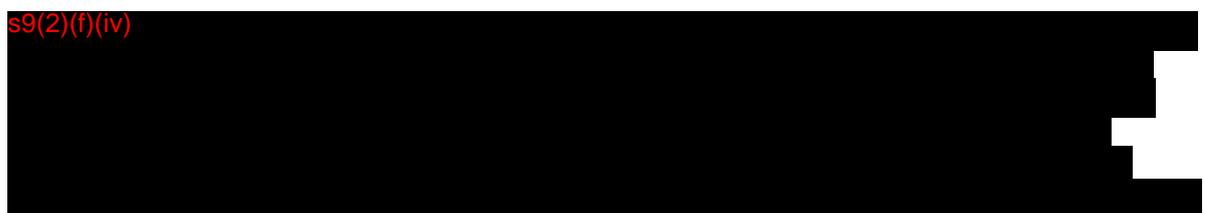
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s9(2)(f)(iv)

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83

s9(2)(f)(iv)

A large black rectangular redaction box covers the text for item 83. The text 's9(2)(f)(iv)' is visible in red at the top left of the redaction.

84

s9(2)(f)(iv)

85

s9(2)(f)(iv)

Consultation

- 86 The following agencies were consulted on this paper: Department of Prime Minister and Cabinet, Treasury, Ministry of Business Innovation and Employment (MBIE), Ministry of Justice, Ministry for Primary Industries, New Zealand Customs Service, Ministry for the Environment, Ministry of Social Development, Ministry for Women, Commerce Commission, State Services Commission, Environmental Protection Authority, Accident Compensation Corporation, Pharmac, and the Health Quality and Safety Commission.
- 87 MBIE provided the following comment for inclusion in this paper. MBIE supports the general intent of the Therapeutic Products Bill, and the release of an exposure draft and consultation document. However, MBIE has concerns about the proposal to tighten restrictions on pharmacy ownership and strongly prefers the option to allow open ownership and have targeted licence requirements that a pharmacist be in control of quality systems and practices within the pharmacy. In particular, MBIE considers that tightening ownership restrictions has the potential to undermine competition and the development of innovative business models in the sector. This could result in an increase in the prices of pharmacy-provided goods and services to consumers and a reduction in service quality. MBIE notes that, in the UK, modest relaxation of pharmacy entry regulations were found to produce a number of benefits for consumers, including increased choice and convenience, better service levels, and reduced costs for some non-subsidised products. MBIE also notes that no clear link has been established between shareholding in a pharmacy, entitlement to dividend rights or membership of the board of a company, and the quality of systems and practices for the safe dispensation of medicines. As such, even if further restrictions on ownership are introduced, it is not clear to MBIE that this will result in an improvement in the supervision of a pharmacy's systems and practice, or improved compliance with a pharmacy's licensing requirements.
- 88 Officials at the Commerce Commission emphasised that it is important to consider the impact of any changes on competition. Staff at the Commission have also acknowledged the current lack of regulation of natural health products and the impact this has on consumers. They have welcomed future work in this area and are likely to raise points concerning competition and consumer policy as the Bill progresses.

Sector consultation

- 89 This paper proposes public consultation on an exposure draft of the Bill and on a consultation document. That process would build on consultation undertaken over many years under the umbrella of previous attempts at regulatory reform. It would also build on the open discussions the Ministry of Health has had with stakeholders over the last few years as work has been undertaken on this Bill.

- 90 In general there is a high level of support for the Bill and stakeholders are likely to welcome the modern regulatory approach it enables. That said, there will be comment on the details from all sectors and issues to work through. I also expect that the sector will be keen to see the next levels of detail of the regulatory scheme (ie, the regulations, rules and notices). There will be further consultation and engagement as these instruments are developed.
- 91 As indicated earlier in this paper, I expect considerable feedback on pharmacy licensing, DTCA and NHP regulation. I also expect considerable feedback on the need to ensure costs are managed and transition processes are realistic for industry. Officials are cognisant of these concerns and they will be taken into account as those matters are worked through.
- 92 The consultation process is being designed to ensure that the many stakeholders interested in the Bill have an opportunity to participate. Even though the Bill is highly technical, consumers (such as those involved in the surgical mesh issue) have a key interest in it and the protections it will offer them. The Ministry is working to ensure that consumers are able to be involved.

Financial Implications

- 93 The Bill provides for the regulator to recover its costs through fees and levies where these costs are not met through Crown funding. Further information on cost recovery policy will be provided as part of the report back on institutional form of the regulator.
- 94 The costs associated with establishing the new regulatory scheme (before any cost recovery occurs) will be considered through Budget processes.

Human Rights

- 95 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

- 96 It is anticipated that the Therapeutic Products Bill will be ready for introduction by late-2019.

Regulatory Impact Analysis

- 97 The Ministry of Health produced regulatory impact statements to inform the main policy decisions taken by the Government that form the basis of the draft Bill. These are available on the Ministry's website.
- 98 The Ministry has sought an exemption for the more minor policy proposals contained in this paper. A regulatory impact analysis for the proposal to curtail the personal import of prescription medicines via the post/courier is attached. The Ministry of Health and the Regulatory Quality Team at the Treasury has reviewed the Regulatory Impact Assessment "Therapeutic Products Bill – Personal import of Medicine by mail/courier" produced by the Ministry of Health and dated November 2018. The review team considers that it meets the Quality Assurance criteria.
- 99 The analysis is commensurate with the scale of the issue. While there are some uncertainties about the scale of the problem, as identified in the analysis, this proposal will form part of the consultation on the exposure draft of the wider Therapeutic Products Bill. We expect any insights gained from this consultation will inform revised analysis
- 100 Following consultation further regulatory impacts analyses are likely to be needed.

Gender Implications

- 101 The new regulatory scheme aims to ensure the safety, quality, and efficacy/performance of all therapeutic products for all people. In recent times there have been safety issues with devices that particularly affect women's health (such as surgical mesh) and improvements for this population could be expected as a result of the new scheme.

Disability Perspective

- 102 The proposals in this paper are consistent with the New Zealand Disability Strategy. They would support disabled people accessing and using therapeutic products that are safe, of high quality and effective; and them having accurate information about the products they use. As the new regulatory scheme is operationalised it will be important to ensure that consumers (including disabled people and their carers) understand any changes (for example to the personal importation arrangements).

Proactive Release

- 103 I intend to release this Cabinet paper at the time the Ministry begins consultation on the exposure draft and accompanying discussion paper. The Ministry will assess whether redactions, consistent with the grounds for withholding information under the Official Information Act 1982, should be made.

Recommendations

The Minister of Health recommends that the Committee:

Previous consideration

1. Note that the Medicines Act 1981 is no longer fit-for purpose and a new regulatory scheme for therapeutic products is required
2. Note that in 2015 and 2016 policy decisions were taken on matters to be covered in a new Therapeutic Products Bill that would repeal and replace the Medicines Act 1981 with a modern, comprehensive regulatory regime for therapeutic products in New Zealand [SOC-15-MIN-0049, SOC-15-MIN-0050 and SOC-16-MIN-0025 refer]
3. Note it was agreed in 2016 that, because of the technical and complex nature of the Therapeutic Products Bill, the Minister of Health would release an exposure draft of that Bill and supporting consultation material [SOC-16-MIN-0025 refers]

Next Steps

4. Note that the Minister of Health has reviewed the policy decisions taken by the previous administration and, with some exceptions, recommends that the draft Bill giving effect to the decisions in SOC- 15-MIN-0049, SOC-15-MIN-0050 and SOC-16-MIN-0025 proceed to public consultation as an exposure draft
5. Note that there is a high level of stakeholder interest in the Bill and an expectation of public consultation
6. Agree that the Minister of Health release an exposure draft of the Therapeutic Products Bill and a consultation document by the end of the year for consultation

7. Note that an exposure draft will be supported by a consultation document and questions and answers to assist discussion
8. Agree that coalition and support partners have an opportunity to review the exposure draft of the Therapeutic Products Bill and consultation document before they are released

Policy changes/new policy

9. Note that as the Minister of Health has reviewed the work to date and as drafting has proceeded a small number of issues have emerged where a different approach is now recommended
10. Agree that the Bill include provision for an unknown type of therapeutic product (currently called 'Type-4') to be regulated should such a thing emerge in future
11. Agree that the Bill provide for individuals to carry into the country a reasonable quantity of a lawfully prescribed prescription medicine for personal use, but that the ability for individuals to receive prescription medicines from overseas through the post be curtailed
12. Agree that the Bill enable health practitioners to supply pharmacy-only (or category 3) medicines in certain circumstances
13. Agree that, in order to inform further advice to Cabinet the consultation document seek views on the following two options for pharmacy licensing in the new regulatory scheme:
 - a. Strengthened accountability through pharmacist ownership and effective control (Minister of Health's initial preference)
 - b. Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy
14. Agree that the Bill provide for review of specified regulatory decisions by:
 - a. requiring the regulator to convene a review panel that comprises at least three people with suitable skills, who were not involved in the original decision, and at least one of whom is a lawyer with at least 7 years' experience
 - b. requiring that the panel review the merits of the original decision on the basis of the information available when the decision was made
 - c. enabling the panel to confirm the original decision or set the decision aside and refer the matter back to the regulator to be reconsidered and a fresh decision made
 - d. enabling appeal to the District Court in respect of review panel and regulator decisions
15. Agree that the Bill not contain a requirement on the regulator to establish committee(s) for specific matters and that this issue be revisited, if necessary, as part of the work on institutional form.

Natural health products

16. Note the non-reinstatement of the Natural Products Bill would have the unintended consequence of bringing natural health products within the ambit of the Therapeutic Products Bill if appropriate steps to mitigate this are not undertaken

17. Agree, in order to not unduly further delay the Therapeutic Products Bill and to allow due process in respect of the ongoing work on the regulation of natural health products, that natural health products be excluded from the Therapeutic Products Bill as far as is possible
18. Agree that the consultation document to be released with the exposure draft of the Bill make clear that the Government is to consider options for the regulation of natural health products and that it will therefore exclude them from the Therapeutic Products Bill as far as is possible
19. Note that the exclusion will be drafted and included in the Bill that is introduced to the House
20. Note that this issue will attract considerable attention during the consultation process and during the Select Committee stages of the Bill

Reports-back

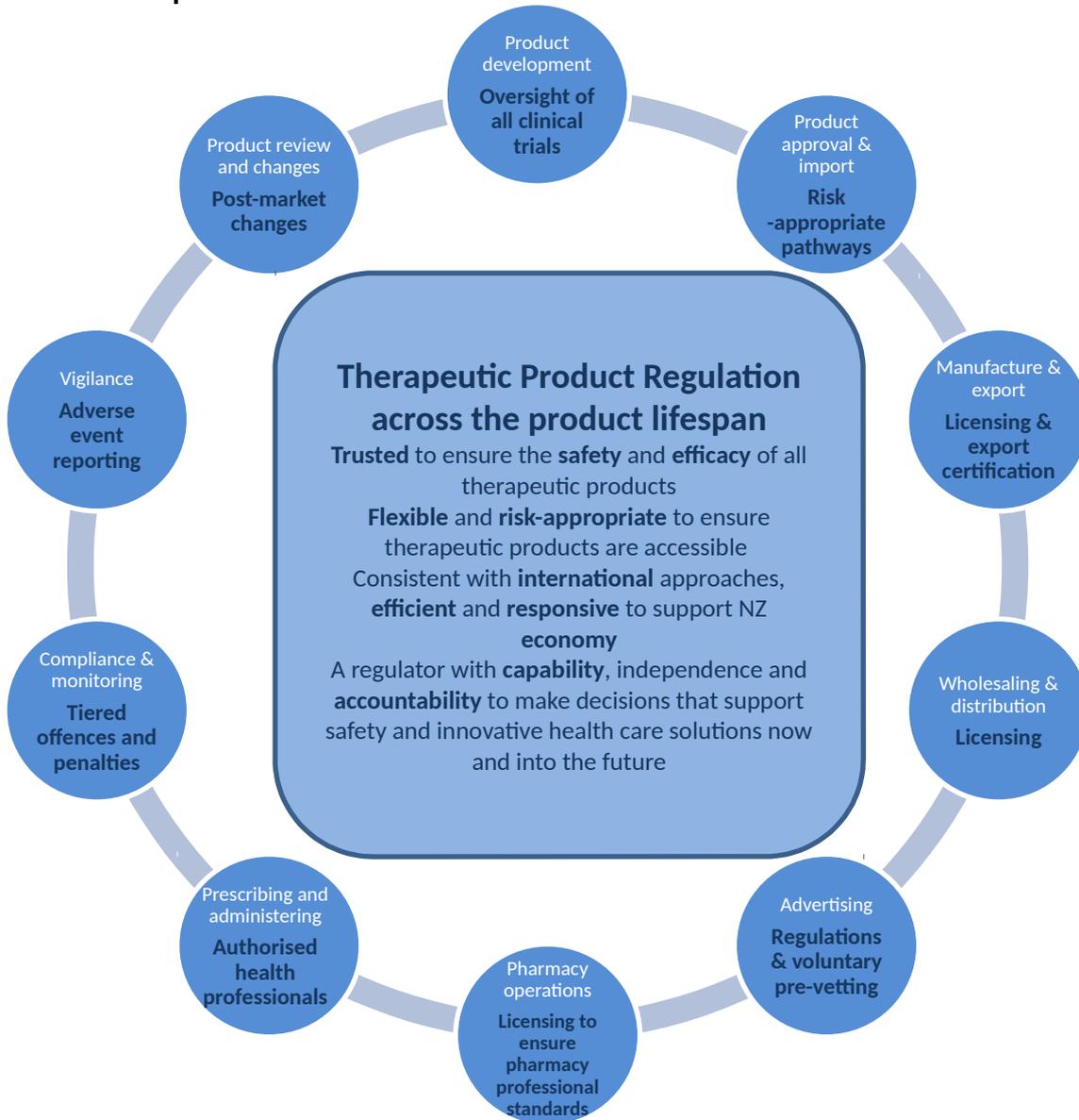
21. Invite the Minister of Health and Minister of State Services to report back to the Social Wellbeing Committee in March 2019 on the recommended institutional form of the therapeutic products regulator and cost recovery policy for the regulatory scheme
22. Invite the Minister of Health and the Minister for Food Safety to report back to the Social Wellbeing Committee in May 2019 on the options for the regulation of natural health products
23. Invite the Minister of Health to report back to the Social Wellbeing Committee within four months following the close of consultation on the following matters:
 - a. the overall outcomes of consultation on the Exposure Draft of the Bill and consultation document
 - b. whether increased regulation of direct-to-consumer advertising of named prescription medicines is warranted
 - c. a recommended approach to pharmacy licensing criteria.

Authorised for lodgement

Hon Dr David Clark

Minister for Health

Appendix A: Overview of the various controls that would apply across a therapeutic product's lifespan



Appendix B: Minutes of previous Cabinet decisions