In Confidence

Office of the Minister of Health

Cabinet Legislation Committee

Therapeutic Products Bill: Approval for Introduction

Proposal

1. This paper seeks approval for the introduction of the Therapeutic Products Bill (the Bill).

Policy

2. Cabinet has agreed to repeal the Medicines Act 1981 (Medicines Act) and Dietary Supplements Regulations 1985 (made under the Food Act 2014) and replace them with new legislation that will regulate medicines, medical devices, active pharmaceutical ingredients, and natural health products (therapeutic products). The Bill modernises the therapeutic products regulatory regime to enable better and more equitable health outcomes for all New Zealanders. Providing for flexible and risk-proportionate approval pathways will ensure New Zealand can access necessary and life-saving medicines, for example vaccines to respond to a public health emergency.

3. Cabinet has previously agreed that the objectives for the new therapeutic products regime include risk management, efficiency, ease of use, quality and accountable decision making, capable regulator capacity, support for New Zealand trade and economic objectives, trust and respect, and support for consumer access and individual responsibility for care. Past Cabinet decisions on the Bill are summarised in Appendix One.

4. The Bill is classified as a category 4 priority on the 2022 Legislation Programme (to be referred to a Select Committee in 2022).

Why is the Bill necessary?

5. It has been recognised by successive governments, industry and practitioners for more than a decade that New Zealand's regulatory regime for medicines and medical devices is out of date, not fit for purpose, inflexible and increasingly out of step with comparator countries. The Medicines Act currently provides insufficient coverage of the many products used in modern healthcare delivery. It also lacks the necessary surveillance and enforcement tools that are proportionate to the risk of, or actual harm, caused by the inappropriate supply and use of therapeutic products. This creates a number of challenges for Medsafe, the current regulator.

6. Likewise, the regulation of natural health products needs reform. Previously, a Natural Health Products Bill was introduced into Parliament in September 2011 and progressed to the Committee of the Whole House, before lapsing in November 2017.

Current regulatory arrangements are making it increasingly difficult for New Zealand's industry to export and innovate. They also do not provide an appropriate level of assurance that products imported and supplied in New Zealand are safe for consumers or made to the appropriate quality standards.

7. Our response to COVID-19 over the past two years has also demonstrated how the lack of a modern and robust therapeutics regime can adversely affect the Crown's ability to prevent or respond to future health emergencies, such as pandemics and natural disasters. The World Health Organisation (WHO) has identified emerging trends and technologies that will play an important role in global public health over the next two decades. Most of these technologies (e.g., software application for disease screening, biosensor-based point-of care diagnostic methods, artificial intelligence-assisted clinical reasoning support systems, and microbiome-based therapies) are not currently provided for under either the Medicines Act 1981 or other legislative mechanisms.

8. Without legislation and regulatory guidance to evaluate and test emerging health technologies, New Zealand will continue to face difficulties developing or introducing to market necessary and high-quality therapeutic products. One current example is the ongoing work to find a viable way of regulating COVID-19 Point-of-Care Test products and practices before the new therapeutic product regime comes into force.

9. Regulation that ensures a safe and effective supply of therapeutic products for consumers is fundamental to a well-functioning health system and to delivering the Government's vision of Pae Ora for all New Zealanders. Reforming the law governing therapeutic products is a major missing piece in the regulatory framework that underpins our public health system and will enable it to become fit for purpose into the future.

What is covered by the regulatory scheme?

10. The purpose of the Bill is to protect, promote and improve the health of all New Zealanders by providing for:

    10.1 acceptable safety, quality, and efficacy or performance of medicines, medical devices and active pharmaceutical ingredients across their lifecycle;

    10.2 acceptable safety and quality of natural health products across their lifecycle.

11. The Bill takes a risk-proportionate approach to regulating therapeutic products across their life span, which includes pre-market, in-market and post-market risk management and control measures. Essentially, the scheme consists of two broad components:

    11.1 market authorisation requirements that regulate which products may be imported into, supplied in, or exported from New Zealand;

    11.2 'controlled activity' and supply chain activity requirements, which regulate how therapeutic products are to be dealt with, and by whom.

12. The Bill also:

    12.1 establishes an independent statutory officer as a regulator within the Ministry of Health (Manatū Hauora), and confers functions, powers and responsibilities on them [CBC-21-MIN-0017];

    12.2 establishes a range of enforcement tools, including enforceable undertakings, injunctions, an infringement fine regime, criminal penalties (including strict liability offences), a civil pecuniary regime [CBC-21-MIN-0017] and extends criminal liability to Crown organisations [SWC-22-MIN-11]. Defences are also included, recognising that supply chains involve multiple parties, are global, and operate through contractual relationships;

    12.3 empowers the development of risk-proportionate secondary legislation that will provide most of the structure for the new regulatory regime;

    12.4 places obligations on the Minister and regulator to consult when developing regulations and secondary legislation, including with Māori;

    12.5 authorises cost recovery through fees, charges and levies [CBC-21-MIN-0017];

    12.6 continues direct-to-consumer advertising of prescription medicines, with the regulator able to develop robust controls where appropriate [CBC-21-MIN-0017];

    12.7 retains the current restrictions on pharmacy ownership, as well as exemptions to those restrictions in certain circumstances [SWC-22-MIN-0156].

13. A broad outline of the Bill's core elements is included in the General Policy Statement.

Likely areas of interest at Select Committee

14. Due to the size and scale of the Bill and future regulatory regime, I expect that many individuals and groups will seek to make submissions on the Bill after it is introduced to Parliament. While many groups (including industry) supported the 2018 exposure draft of the Bill and the need for reform, change in this area is still likely to be contentious, particularly in relation to the inclusion of natural health products [SWC-21-MIN-0109]. Some of these concerns may be at a general level (e.g., offences and penalties or the level of fees and charges), while others may be unique to specific sectors.

Rongoā Māori requires careful consideration, and separate work has been commissioned

15. An issue that has arisen in the drafting process, and our consultation with Māori clinicians, practitioners and Te Aka Whai Ora – the Māori Health Authority, is the degree to which the Bill intersects with, and affects the practice of, rongoā Māori. The intersection centres on how the Bill applies to products used in rongoā or made by

rongoā practitioners. Like all products that are intended for a therapeutic purpose or make health benefit claims, the Bill will apply to these products.

16. The Bill does not mention rongoā explicitly. However, the regulation of natural health products by ingredients will capture ingredients used by rongoā practitioners. It is important that the legislation overall supports the traditional practice of rongoā, while balancing this objective against the need to provide assurances for patient safety and export market access for rongoā practitioners. The Associate Minister of Health, Hon Peeni Henare, and I have commissioned a stream of work to consider how these objectives with respect to rongoā may be achieved. This work will be led by Te Aka Whai Ora and Manatū Hauora.

17. The workstream will be announced at the same time as the Bill is introduced and I will brief Cabinet on the subject at that time.

Outstanding policy matters for agreement

18. Although the Bill has been in development for many years since the Cabinet decision to replace the Medicines Act in 2015, two small policy matters remain outstanding for Cabinet's decision.

Act to bind the Crown

19. Although Cabinet has previously agreed to extend criminal liability to the Crown [SWC-22-MIN-0011], no explicit Cabinet decision has been made for the Bill to be binding on the Crown. For the avoidance of doubt, this paper seeks agreement that the Act will be binding on the Crown.

Including an offence on improper inducements to health practitioner prescribers

20. The current Medicines Act makes it an offence for a pharmacist, person licensed to operate a pharmacy, or operator or manager of a pharmacy to give or offer money or other consideration to a prescriber as a 'commission on prescriptions'. This offence is intended to deter improperly inducing a health practitioner to prescribing a medicine. I intend to bring this provision over to the new Bill and to extend its scope so that it applies to product sponsors and suppliers, as well as pharmacists who seek to improperly induce a health practitioner or veterinarian to make a favourable clinical decision in relation to a therapeutic product. The new provision would not be limited to prescription medicines or prescribing.

Areas for further development during the House process

21. This large and complex Bill affects many interests, including competing interests. While there has been more than a decade of policy work and consultation, I nevertheless anticipate it will result in ongoing interest and significant discussion and feedback from stakeholders as it progresses through Parliament, during the development of regulations and rules, and through the transition period. This will be particularly so for sectors that gain better awareness of the outgoing regime, or that will be newly regulated, or where significant change will occur for them. Therefore, some issues will require further work while the Bill is the in House. Manatū Hauora

and Parliamentary Council Office (PCO), with input from other agencies, have identified the following key areas where they expect further work will be needed:

21.1 The definition of natural health products, especially as it relates to food, and the regulation of natural health products and practitioners generally;

21.2 The regulation of therapeutic products that are both medicines and devices;

21.3 The transitional, savings, and related provisions;

21.4 The relationship between the Bill and other Acts;

21.5 Changes to address substantive and editorial issues identified by PCO's review processes (which will only be partially completed when the Bill is introduced).

22. Manatū Hauora and PCO will continue to assess the Bill following introduction in order to identify and address any further issues during the House process.

Impact analysis

23. Five Regulatory Impact Statements have previously been considered by Cabinet:

23.1 Therapeutic Products Regulation – Replacement of the Medicines Act 1981 and the Medicines Regulations 1984 with a new legislative scheme for therapeutic products [November 2015]

23.2 Therapeutic Products Regulation – Replacement of the Medicines Act 1981 and the Medicines Regulations 1984 with a new legislative scheme for therapeutic products – Analysis of specific issues and options [March 2016]

23.3 Therapeutic Products Bill – Personal Import of Medicine by mail/courier [November 2018]

23.4 Regulation of natural health products under the Therapeutic Products Bill [May 2021]

23.5 Pharmacy ownership and licensing [May 2021].

24. The above Regulatory Impact Statements have been published as required.

25. I am attaching two supplementary Regulatory Impact Statements that have been prepared for the Cabinet decisions made in October 2021 and February 2022 [CBC-21-MIN-0117; SWC-22-MIN-11]:

25.1 Therapeutic Products and Natural Health Products Regulation – Supplementary Analysis (Pecuniary penalties and Crown liability);

25.2 Therapeutic Products and Natural Health Products Regulation – Supplementary Analysis (Entity form and cost recovery).

26. Manatū Hauora's Papers and Regulatory Committee has reviewed the supplementary analysis on civil pecuniary penalties and Crown liability which meets the quality

assurance criteria, and the analysis was clear and concise, and the analysis convincing.

27. The Committee has reviewed the supplementary analysis on the form of the regulator and cost-recovery options and advised that it partially meets the quality assurance criteria. While the paper meets most of the criteria, the Committee considered that there could have been further clarification to make the analysis and scoring of the options more robust.

Compliance

28. The Bill complies with each of the following:

    28.1 the principles of the Treaty of Waitangi, noting they are woven throughout the Bill, and through the additional workstream that will be announced relating to rongoā Māori;

    28.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;

    28.3 relevant international standards and binding obligations, noting that New Zealand's international obligations under the United Nation Convention on the Rights of Persons with Disabilities and the United Declaration on the Rights of Indigenous People will be considered as part of the rongoā workstream;

    28.4 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

29. A disclosure statement has been prepared and is attached to the paper.

30. The Bill contains several clauses (for example, clause 206) which override the Privacy Act 2020. In addition, the Bill contains a regulation making power which would allow the Regulator to make regulations that override the Privacy Act. The Privacy Commissioner has raised some initial concerns about the breadth of these overrides and will work with officials to address these as the Bill proceeds through Parliament and during the development of secondary legislation.

Consultation

Government departments and public bodies

31. The following agencies were consulted on the Bill: Te Arawhiti; Ministry of Business, Innovation and Employment; New Zealand Police; the Public Service Commission; Accident Compensation Corporation; the Crown Law Office; Ministry for the Environment; Ministry for Foreign Affairs and Trade; Department of Internal Affairs; Whaikaha – Ministry of Disabled People; Ministry for Primary Industries; Te Puni Kōkiri; New Zealand Defence Force and the Department Defence; Ministry for Women; Ministry of Justice; the Office of the Privacy Commissioner; the Commerce Commission; Ministry for Ethnic Communities; Ministry for Pacific Peoples; and the New Zealand Customs Service. The Department of the Prime Minister and Cabinet and the Treasury were informed.

32. Within the health sector, the following public entities were consulted on the Bill and this paper: Te Whatu Ora – Health New Zealand, Te Aka Whai Ora, the New Zealand Blood and Organ Service, Pharmac, the Health Research Council of New Zealand.

33. Introduction of such a large and complex Bill this year has meant that consultation with, and consideration by, government departments and public bodies (including with the current Regulator, Medsafe) has been limited. I anticipate that amendments will need to be made to the Bill to deal with the issues identified at paragraph 22 above, to ensure the regime can be operationalised and the Bill can function as intended.

34. s 9(2)(h) [redacted]

35. s 9(2)(h) [redacted]

Public consultation

36. In 2018 an exposure draft of the Bill, which did not include natural health products, was consulted on. Targeted consultation and engagement with many sector organisations (e.g., exporters, importers, practitioners and researchers) has occurred throughout development of the Bill.

37. There was considerable consultation and engagement on the Natural Health and Supplementary Products Bill, which lapsed in 2017. This Bill builds on the significant work done then, taking into consideration previous contentious issues.

38. Manatū Hauora has had initial engagement with Te Aka Whai Ora, Te Puni Kōkiri, Te Arawhiti, rongoā practitioners and Māori clinicians on ways to reflect the principles of Te Tiriti o Waitangi in the Bill and to recognise and protect rongoā appropriately.

Government caucus and other parties represented in Parliament

39. I have consulted with the Government caucus.

Creating new agencies or amending law relating to existing agencies

40. No new agency is created by the Bill. The Bill establishes an independent statutory officer to be the Regulator and confers functions, powers and responsibilities on them [CBC-21-MIN-0117].

Allocation of decision-making powers

41. The Bill does not allocate decision-making powers between the executive, the courts, and tribunals.

Associated regulations

42. Operational and procedural requirements that will shape the implementation of the new regulatory regime will be set out in secondary legislation (e.g., regulations and rules and Regulator's notices). The Bill includes provisions empowering the making of regulations by Order in Council for anything that this Bill says must or may be provided for by regulations, including anything incidental for carrying out or giving full effect to this Bill. The Bill includes similar provisions allowing the Regulator to make rules.

43. I anticipate that developing regulations and rules will be a large and complex task due to the need for regulations and rules to be appropriately designed for the relevant product category (e.g., medicines, medical devices, natural health products) and controlled activities (e.g., enabling the provision of blood products by the New Zealand Blood and Organ Service). The regulations and rules are expected to take two to three years to develop following enactment of the Bill.

Other instruments

44. The Bill includes provisions empowering the making of other instruments that are secondary legislation. These other instruments are needed to provide the detail to support the regulations (e.g., market authorisation approval pathways, product standards, licence criteria, lists of permitted natural health product ingredients and health benefit claims, transitional rules).

45. The explanatory note in the Bill sets out the reasons for provisions empowering the making of other instruments.

Definition of Minister/department

46. The Bill includes a standard definition of Minister or department.

Commencement of legislation

47. The Bill is drafted with a commencement date of 2026. This is because the Dietary Supplements Regulations 1985 will expire on 1 March 2026, by which time new regulations are intended to replace them.

48. I intend that the Therapeutic Products Act will commence in stages.

    48.1.1 To allow for the development of necessary secondary legislation and the establishment of the new Regulator, the Act will commence via an Order in Council.

48.1.2 the explanatory note to the bill sets out the reasons for commencement by Order in Council.

Parliamentary stages

49. The Bill will be introduced by 30 November 2022, subject to Parliament's timetable and confirmation from the Leader of the House. The Bill will then be referred to the Health Select Committee. I intend for the Bill to be passed this Parliamentary term.

Proactive Release

50. This paper will be proactively released according to standard processes under Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982.

Communications

51. A proactive communications and engagement approach is already underway and will continue as the Bill is introduced into the House, with a particular focus on supporting factual and timely communication regarding the intent and content of the Bill as it progresses through the Select Committee process. For example, regular newsletter updates will continue to be sent out to over 1,000 stakeholders to pre-empt issues ahead of time and provide timely and accurate information.

Recommendations

I recommend that the Cabinet Legislation Committee:

1 **note** that the Therapeutic Products Bill is classified as a category 4 priority on the 2022 Legislation Programme (to be referred to a Select Committee within 2022);

2 **note** that the purpose of the Bill is to protect, promote, and improve the health of all New Zealanders by providing for— (a) acceptable safety, quality, and efficacy of medicines or performance of medical devices, and active pharmaceutical ingredients across their lifecycle; and (b) acceptable safety and quality of natural health products across their lifecycle;

3 **agree** that the Act will bind the Crown;

4 s 9(2)(h) [redacted]

5 **agree** to include in the Therapeutic Products Bill a prohibition on sponsors and suppliers from offering improper inducements to health practitioners to make favourable decisions in relation to a product;

6 **approve** the Therapeutic Products Bill for introduction, subject to the final approval of the government caucus and sufficient support in the House of Representatives;

7 **note** that the rongoā workstream the Associate Minister of Health, Hon Peeni Henare and I have commissioned will be announced at the same time as the Bill is introduced;

8 **agree** that the Minister of Health may make minor and technical amendments to the Bill prior to introduction;

9 **agree** that the Therapeutic Products Bill be introduced by 30 November 2022;

10 **agree** that the government propose that the Bill be:

10.1 referred to the Health Committee for consideration;

10.2 enacted by 31 August 2023.

Authorised for lodgement

Hon Andrew Little

Minister of Health

Appendix One. Summary of Cabinet decisions relating to the Therapeutic Products Bill

The following provides a summary of decisions made by Cabinet from 2015-2022:

- repeal and replace the Medicines Act with a new Therapeutic Products Bill (the Bill). Agreement was also reached on key regulatory objectives for the new Bill [SOC-15-MIN-0049];
- draft policies on purpose and principles, definitions, approvals, data protection, activities licensing, promotion/advertising, compliance, enforcement and penalties, vigilance, administrative arrangements, review and appeal, cost recovery, regulations and Regulator made instruments [SOC-15-MIN-0050];
- draft policies on clinical trials, cell and tissue therapeutic product regulation, prescribing and dispensing, pharmacy licensing, import and export, offences and penalties framework, Regulator form, and the interface with the Hazardous Substances and New Organisms Act 1996 [SOC-16-MIN-0025];
- release an exposure draft of the Bill for public consultation, draft policy changes and new policies, and not regulate natural health products as part of the Bill to not unduly delay the Bill and to allow due process in respect of the ongoing work in that area [SWC-18-MIN-0176];
- regulate natural health products as part of the Bill [SWC-21-MIN-0109];
- establish the Regulator as a branded business unit within Manatū Hauora with an independent statutory officer, include a civil pecuniary penalty regime, continue current policy settings for regulating direct-to-consumer advertising of prescription medicines, and enhance enforcement tools [CBC-21-MIN-0117];
- further improve the offence and penalty framework, including extending criminal liability to the Crown [SWC-22-MIN-0011];
- retain the current pharmacy ownership provisions and related exemption provisions in the Medicines Act to allow time for pharmacies to embed changes under the new health system and continue addressing the ongoing impacts of COVID-19 [SWC-22-MIN-0156].