MANATŪ HAUORA
MINISTRY OF HEALTH

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

24 May 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023023391

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora, the Ministry of Health (the Ministry) on 11 April 2023, for information regarding the pharmacy ownership model and the Therapeutic Products Bill (the Bill). Please find a response to each part of your request below.

> *Copies of all advice, policies, directives, Cabinet papers, communications and other correspondence from 1 April 2019 through to 5 March 2023, to or from the Ministry, the Office of the Minister of Health, and Te Whatu Ora, or internally within the Ministry, related to or concerning:*
> 1. *the community pharmacy ownership model, specifically in relation to the policy intention/considerations for the Ministry's recommendation of an 'open ownership' model in the regulatory impact statement on pharmacy ownership and licensing (May 2021), as opposed to the existing majority pharmacy ownership model;*
> 2. *the change to the definition of "dispensing" in the TPB (cl 38), specifically in relation to the policy intention/considerations for the change;*
> 3. *the introduction of the new term "pharmacy licence" and the language used to define this term in the TPB (cl 152), and the policy intention/considerations for this; and*
> 4. *the introduction of provisions in the TPB relating to the ability of health practitioners to sell / dispense medicines and health practitioners' staff to sell medicines (cls 83,86 and 92), specifically in relation to the policy intention/considerations for the introduction of these provisions."*

On 19 April 2023, you were contacted in accordance with section 18B of the Act, as your request was for a very large volume of information. In order to provide you with the information sooner, and to work within a more manageable request, you were asked and agreed to refine the scope of your request.

> *"Copies of advice, policies, Cabinet papers, aide-memoires, report items and memos from 1 April 2019 through to 5 March 2023 regarding:*
> 1. *the community pharmacy ownership model, specifically in relation to the policy intention/considerations for the Ministry's recommendation of an 'open ownership' model in the regulatory impact statement on pharmacy ownership and licensing (May 2021), as opposed to the existing majority pharmacy ownership model;"*

Manatū Hauora has identified three documents within scope of this part of your request. All documents are itemised in Appendix 1 and copies of the documents are enclosed. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

There are also a number of proactively released documents from the period of April 2019 to 5 March 2023 regarding pharmacy ownership, which can be found on the Manatū Hauora website at the following links below:

- www.health.govt.nz/system/files/documents/information-release/publication_-_ris_pharmacy_ownership_and_licencing_2021.pdf.
- www.health.govt.nz/system/files/documents/pages/pharmacy_ownership_and_licensing_1_redacted.pdf.
- www.health.govt.nz/system/files/documents/pages/swc-22-min-0156.pdf.
- www.health.govt.nz/system/files/documents/pages/therapeutic_products_and_natural_health_products_regulatory_scheme_1_redacted.pdf.

We understand the basis of your request is to understand the 'policy intention/consideration' for the Ministry's advice on pharmacy ownership. As per the above documents, Manatū Hauora recommended the removal of current restrictions on pharmacy ownership. As outlined in the Regulatory Impact Statement (11 May 2021), and after weighing various criteria set out in the statement, removing ownership requirements was identified as better enabling some of the innovative patient care models intended by the Bill. However, as discussed in the above Pharmacy Ownership Report to the Cabinet Social Wellbeing Committee (September 2022), the Government ultimately decided to retain the status quo statutory settings regarding pharmacy ownership rules as changes to this model would create additional uncertainty for the sector. This was particularly so at a time when the sector was already facing significant reforms.

> *"Copies of advice, policies, Cabinet papers, aide-memoires, report items and memos from 1 April 2019 through to 5 March 2023 regarding:*
> 2. *the change to the definition of "dispensing" in the TPB (cl 38), specifically in relation to the policy intention/considerations for the change;*
> 3. *the introduction of the new term "pharmacy licence" and the language used to define this term in the TPB (cl 152), and the policy intention/considerations for this; and*
> 4. *the introduction of provisions in the TPB relating to the ability of health practitioners to sell / dispense medicines and health practitioners' staff to sell medicines (cls 83,86 and 92), specifically in relation to the policy intention/considerations for the introduction of these provisions."*

Manatū Hauora has interpreted your requests describing changes to definitions and introductions of terms or provisions to mean changes from the 2018 consultation draft of the Therapeutic Products Bill to the version of the Therapeutic Products Bill introduced to Parliament 30 November 2022 (Government Bill 204—1). This consultation draft is publicly available here: www.health.govt.nz/system/files/documents/publications/therapeutics-products-bill.pdf.

With the exception of clause 38 (Dispense) Manatū Hauora did not make or request any changes to the clauses described in the requests as a result of a change in policy or intention.

As defined in the Bill as introduced, dispensing a medicine means to bring it to a state ready for immediate supply to a specific patient in response to a request for that supply. Dispensing does not include preparing a medicine for administration. For example, interpreting the prescription or order, verifying the accuracy of the medication and dosage, preparing the medication and providing instructions for use to the patient or their caregiver would be considered part of dispensing. This differs from 'compounding', which means 'to produce a quantity of [a medicine] ready for supply to a specific patient in response to a request for that supply'. The Bill states that compounding a medicine is part of manufacturing.

Since the 2018 consultation, the Ministry made some changes to clause 38 of the introduced version of the Bill (clause 29 in the consultation draft) to explicitly remove 'dispensing' from being part of manufacturing. This was to reflect the existing use of terminology of a range of

activities involved in 'producing' and 'handing out' medicines in practice more correctly. This change also clarifies the original policy intention to enable people in the supply chain to carry out certain activities (e.g., required for immediate supply of a medicine for a specific patient without having to seek a manufacturing licence).

Changes to areas covered by clauses 83, 86, 92 and 152 were for a range of editorial purposes such as to enhance legibility, readability and accessibility and do not reflect a change policy intent from Manatū Hauora. These changes may also have been required to ensure the final Bill was consistent with Cabinet's decision to maintain the current rules around pharmacy ownership.

The term "pharmacy licence" is not new and was present in the 2018 consultation draft. Clause 152 largely mirrors clause 124 of the consultation draft. There were no policy intentions behind changes to this clause from Manatū Hauora.

Manatū Hauora is unable to comment further on potential changes to the Bill while it is under active consideration. However, the Ministry encourages you to check regularly for further proactively released documents regarding the Bill on the Manatū Hauora website at: www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Maree Roberts
Deputy Director-General
Strategy Policy and Legislation | Te Pou Rautaki

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	14 December 2020	Health Report: Initial briefing on the Therapeutic Products Regulatory Scheme (HR20202242)	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons.
2	6 June 2022	Cabinet Social Wellbeing Committee Summary: Pharmacy Ownership and Licensing	Released in full.
3	15 September 2022 to 13 October 2022	Weekly Report – Therapeutic Products Bill: update	Excerpt released under section 16(1)(e) of the Act by giving an excerpt or summary of the contents. Some information withheld under section 9(2)(a) of the Act.

Document 1

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report

Initial briefing on the Therapeutic Products Regulatory Scheme

Date due to MO:	14 December 2020	**Action required by:**	January 2021
Security level:	In Confidence	**Health Report number:**	20202242
To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	S9(2)(a)
Fiona Ryan	Manager, Therapeutics, System Strategy and Policy	S9(2)(a)

Action for Private Secretaries

Return the signed report to the Ministry of Health.

Date dispatched to MO:

MINISTRY OF HEALTH
MANATŪ HAUORA

Initial briefing on the Therapeutic Products Regulatory Scheme

Purpose of report

1. This report provides you with an update on the draft Therapeutic Products Bill (Bill), outstanding policy decisions; and options for progressing this work, including a proposed pathway for Bill progression and introduction. It also addresses options to regulate natural health products which can be considered within the scope of therapeutic products.

Summary

2. Therapeutic Products (medicines, including biologics[1] and medical devices) are used by all New Zealanders in their everyday lives and in all parts of the health system. They are also used to treat and prevent COVID-19.

3. The Medicines Act 1981, which currently regulates these products, is outdated and has not kept pace with technological change. Therapeutic products present significant risks and should be regulated to ensure the benefits of their use outweigh the risks.

4. There are longstanding gaps in the regulation of some therapeutic products (advanced therapy medicinal products and medical devices) in New Zealand. The response to COVID-19 has particularly highlighted the lack of regulation of medical devices. A lack of modern therapeutics regulation in New Zealand is also impacting the ability to make progress in other important programmes such as the response to surgical mesh.

5. The Therapeutic Products Bill is well aligned with any implementation of the Government's response to the Health and Disability System Review, as it addresses significant gaps in one of the foundations of a well-functioning, patient-focused health and disability system. It will provide assurance of the safety, quality and efficacy or performance of therapeutic products across their lifecycle and that are used in all parts of the system and in everyday life.

6. The Therapeutic Products Bill will repeal and replace the Medicines Act 1981.

7. There is broad support among stakeholders and a desire for progress and increased certainty.

8. The Therapeutic Products Bill is well advanced but there is still technical policy work to complete to address stakeholder issues raised in consultation, and some outstanding policy decisions on specific areas including direct to consumer advertising of prescription medicines, pharmacy ownership and licensing, and options to regulate natural health products. We will provide you with further advice early in 2021.

9. Options to regulate natural health products include as a standalone Bill or under the Therapeutic Products Bill. We now consider that regulating natural health products under the Therapeutic Products Bill is the option most likely to ensure natural health

[1] Biologics include gene, cell and tissue products and are defined on page 5.

products are suitably regulated before the proposed extension to the Dietary Supplements Regulations would expire again in 2026.

10. Any new therapeutic products regulatory scheme will also need a regulator with a wider remit than Medsafe, the current regulator. There are choices still to be made about the institutional form of the future therapeutics' regulator, and an outstanding Cabinet report back. We recommend delaying the Cabinet report back until at least mid-2021.

11. We propose two options for timeframes to progress the Therapeutic Products Bill, one would see the Bill introduced to Parliament in late 2021 or early 2022, the other would take a slower track with introduction likely in late 2022 or early 2023. Both options are subject to the timing of Cabinet decisions and PCO drafting time which is hard to predict.

Recommendations

We recommend you:

a) **note** the Medicines Act 1981, which currently regulates medicines and medical devices, is out of date, has not kept pace with technological change and does not regulate important therapeutic product categories such as medical devices

b) **note** the Therapeutic Products Bill would repeal and replace the Medicines Act and provide a modern, comprehensive regulatory scheme that aligns with international practice, is future proofed and provide assurance of the safety, quality and efficacy or performance of therapeutic products

c) **note** that the Therapeutic Products Bill is well advanced, with an exposure draft having undergone public consultation but the Bill still requires further technical policy work and final policy decisions for Cabinet which include:

   i. direct to consumer advertising of prescription medicines

   ii. pharmacy ownership and licensing

   iii. options to regulate natural health products

d) **note** that officials will report back to Cabinet in early 2021 on the overall outcome of the consultation on the Therapeutic Products Bill and other outstanding policy decisions including for direct to consumer advertising and pharmacy ownership and licensing

e) **note** that officials consider the option to regulate natural health products under the Therapeutic Products Bill would provide for safety and quality of these products. It is also most likely to ensure natural health products are suitably regulated before the proposed extension to the Dietary Supplements Regulations expire again in 2026

f) **discuss** the proposal to include natural health products within the scope of the Therapeutic Products Bill with Hon Dr Verrall, Associate Minister of Health **Yes/No**

MINISTRY OF HEALTH
MANATŪ HAUORA

g) **indicate** your preference for the pace you would like to progress the Therapeutic Products Bill to either:

   i. seek to introduce the Bill to Parliament in late 2021 or early 2022 **Yes/No**

   OR

   ii. seek to introduce the Bill to Parliament in 2022 or early 2023 **Yes/No**

h) **note** there are choices still to be made about the institutional form of the future therapeutics' regulator and an outstanding Cabinet report back

i) **agree** to discuss with the Minister for Public Services, delaying the report back on the institutional form of the therapeutic products regulator and cost recovery policy for the regulatory scheme, until at least mid-2021 **Yes/No**

j) **direct** officials to report to you on key policy issues and recommendations in February 2021. **Yes/No**

Maree Roberts
Deputy Director-General
System Strategy and Policy
Date:

Hon Andrew Little
Minister of Health
Date:

Hon Dr Ayesha Verrall
Associate Minister of Health
Date:

MINISTRY OF HEALTH
MANATŪ HAUORA

Initial briefing on the Therapeutic Products Regulatory Scheme

Why is therapeutic product regulation important?

1. Therapeutic products are used to diagnose, treat or prevent ill health, and to compensate for symptoms or disability in humans. The Medicines Act 1981, which currently regulates these products, is outdated and has not kept pace with technological change. Therapeutic products can present significant risk of harm and need to be regulated to ensure the benefits of their use outweigh the risks.

2. There are longstanding gaps in the regulation of a range of therapeutic products (advanced therapy medicinal products and medical devices) in New Zealand. The Medicines Act does not provide the modern regulatory instruments necessary to facilitate timely, safe access to therapeutic products and new health technologies for New Zealanders, nor does it provide the compliance and enforcement tools necessary to address modern issues. The response to COVID-19 has further highlighted this.

3. The Therapeutic Products Bill (the Bill) addresses significant gaps in the foundation of a well-functioning patient-focused health and disability system by providing assurance of the safety, quality and efficacy or performance of therapeutic products that are used in all parts of the system and in everyday life.

What are therapeutic products?

4. These products can be grouped into three broad categories:

    a. **Medicines:** are substances taken into or placed on the body that cure a disease or condition, treat or relieve a medical condition or prevent disease. They can be prescription and non-prescription products. They work primarily through pharmacological, immunological or metabolic means. Examples include vaccines, antibiotics and anti-cancer medicines, over the counter and general sale medicines such as paracetamol. Some countries also include complementary and traditional medicines, which are called natural health products in New Zealand.

    b. **Biologics such as gene, cell and tissue products:** are derived from living cells and tissues of human or animal origin. They are any product manufactured in or extracted from biological sources. They can work by the same means as medicines or medical devices. Examples include blood and blood products, organs for transplant, skin grafts, ligaments, and advanced therapy medicinal products such as gene editing, stem cell therapy and regenerative medicine.

    c. **Medical devices:** are a wide range of products, that are generally used on, in or by a person for a diagnostic, prevention, monitoring, or treatment purpose or for the alleviation of disease. They work primarily through physical and electrical/electronic means. Examples include tongue depressors, cotton swabs, clinical personal protective equipment, implantable devices like artificial joints or pacemakers, and complex equipment like home dialysis machines, diagnostic

software, and diagnostic testing equipment used in medical laboratories and by consumers.

The Medicines Act is no longer fit for purpose

5. Medicines and medical devices are currently regulated under the Medicines Act 1981. The Medicines Act is no longer fit for purpose. It is out of step with international regulatory practice, consumer expectations, and has not kept pace with significant technological changes in medicines, advanced therapies and medical devices[2].

6. The Medicines Act has significant gaps in coverage, does not support efficient, robust regulatory practice, and does not support innovation. For example, the Act:

   a. does not provide any scrutiny of medical devices before they enter the New Zealand market and provides patchy coverage of advanced medicinal therapeutic products, and of clinical trials for therapeutic products

   b. has an inadequate enforcement framework to deter poor behaviour and support compliance.

7. A lack of significant regulatory reform in this area means that New Zealand is increasingly diverging from international expectations[3] for the regulation of therapeutic products.

8. Countries with modern regulation consistent with international practice are better able to engage in and leverage important international regulatory cooperation arrangements, including those available under Free Trade Agreements. The benefits can lead to improved information sharing among regulators to support efficient approvals and market surveillance, as well as significantly reducing compliance costs through recognising third party inspection and audits.

9. Technological change in medical and health technologies is rapid and accelerating. New Zealand does not currently have modern regulation able to respond to technological change, which is necessary to ensure New Zealanders have timely access to new and emerging pharmaceuticals, advanced therapies and medical devices, while ensuring the safety, quality and efficacy or performance of the products.

Limitations of the Medicines Act

10. The COVID-19 pandemic has brought the importance of regulation of therapeutic products into the public awareness globally and has made it front of mind for ordinary New Zealanders. The pandemic has further clarified the urgent need for change in New

---

[2]Examples of new and emerging technologies include immunotherapies, personalised medicines, nanotechnology, gene therapies, insulin pumps, computer assisted and robotic surgery, machine learning and Artificial Intelligence as part of integrated software and the increased use of 3D printing.

[3] The World Health Organization regulatory frameworks for medicines and medical devices, provide the model for international regulatory practice and is the basis for therapeutic products regulation in developed and developing countries. There is ongoing reform in Australia, European Union, UK, Canada and increasingly developing countries in South East Asia which have outpaced New Zealand's legislation and regulatory scheme.

Zealand and has highlighted both the strengths and significant weaknesses of the Medicines Act.

11. Therapeutic products regulators around the world[4] are, in the course of their normal business, playing a key role in supporting public trust and confidence through approval requirements for COVID vaccines, new and repurposed medicines, and assurance of the safety and performance of medical devices for the diagnosis, treatment and prevention of COVID-19. Medsafe is no exception.

12. Key strengths of the Medicines Act include the approval pathways for new and repurposed medicines and vaccines. Medsafe have a reputation as a competent regulator and a track record of providing timely and responsive consideration of medicines and vaccine applications, including in emergency situations. Medsafe also have a key role in post-market vigilance for possible adverse events.

13. Medsafe engage internationally and are a founding member of the International Collaboration of Medicines Regulatory Authorities (ICMRA) and a member of the Pharmaceutical Inspection Cooperation Scheme (PICS)[5]. In the absence of legislation that fully regulates medical devices Medsafe are currently limited in their ability to engage internationally in the forum for medical devices regulators, the International Medical Devices Regulatory Forum. It is important that New Zealand has modern therapeutics legislation to ensure we can retain our regulatory integrity and international reputation, a condition of membership in these international fora.

14. As noted previously the Medicines Act also has some significant gaps which have significantly limited the ability to respond to rapidly changing technology. With no requirement for pre-market assessment and approval of medical devices there is no protection against a potential influx of poor quality, unacceptable medical devices. This lack of protection extends to clinical personal protective equipment used to prevent infection spread, COVID-19 testing kits and sophisticated intensive care unit equipment. The Ministry and Medsafe are aware of this issue and acted quickly using an awkward mechanism in the Medicines Act to prohibit consumer COVID-19 test kits, however, modern legislation would have dealt more effectively with this issue.

15. Other issues the Medicines Act is not able to address are the ability to provide regulatory safety oversight and assurance of implantable devices such as surgical mesh or orthopaedic joints, radiopharmaceuticals, clinical trials, including those involving vulnerable populations such as children, and limited controls on the use and establishment of clinics providing advanced therapies such as stem cell or gene editing treatments which remain largely unregulated. It is also having real impacts on the

[4] Like minded regulators include the European Medicines Agency (EMA), UK Medicines and Healthcare Products Regulatory Authority (MHRA), US Food and Drug Administration (FDA), Health Canada and the Australian Therapeutic Goods Administration (TGA).

[5] ICMRA and PICS provide important benefits for Medsafe to keep up with latest technical information, maintain trusted relationships and credibility among other regulators, which supports information exchange on pre- and post-market intelligence and regulatory action; enables mutual recognition and participation in conformity assessment networks that provide important credibility, and provides significant cost-savings (cost and time) for firms and for the regulator.

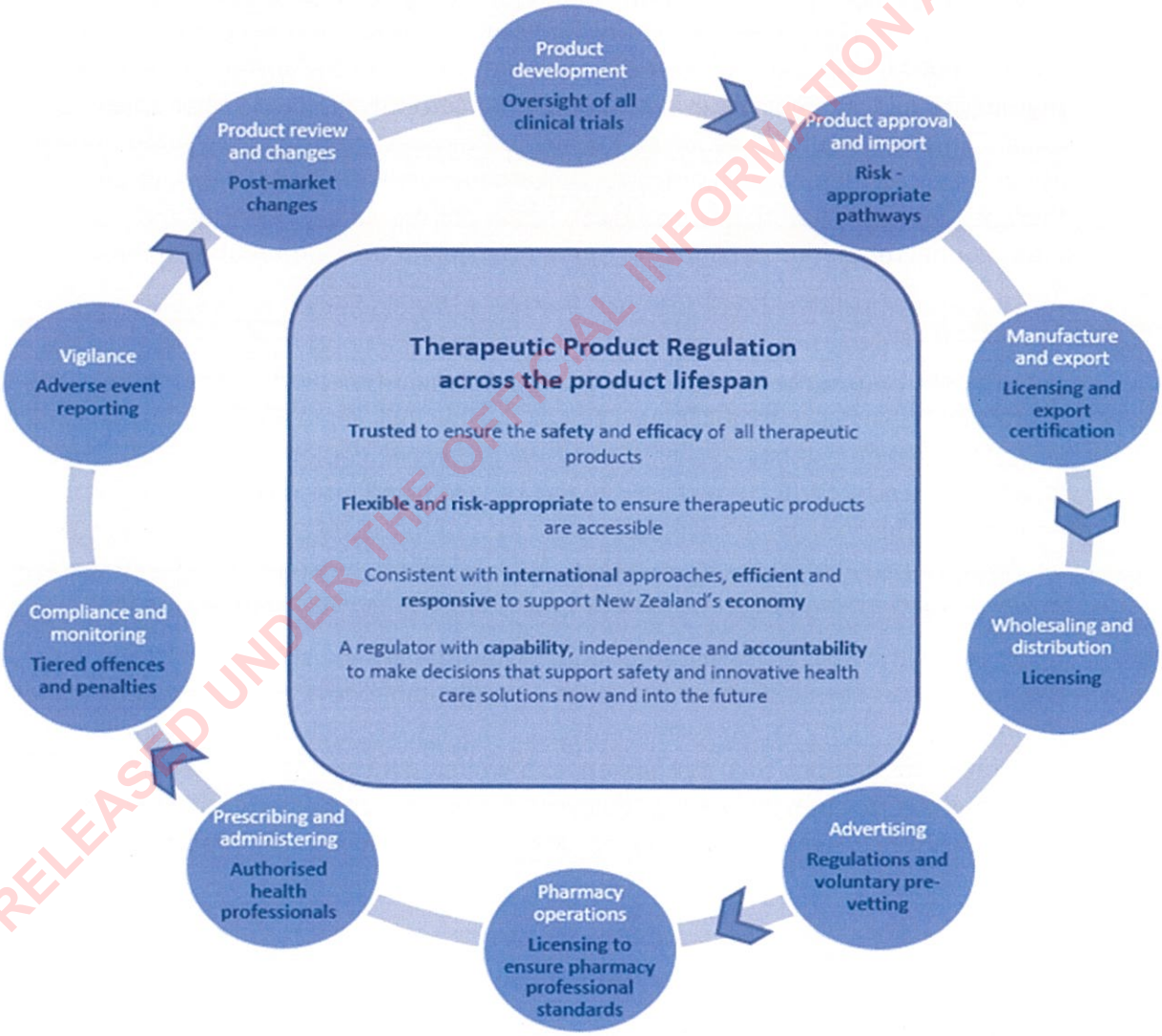
ability to make further progress in other important programmes such as the response to surgical mesh[6]

A Therapeutic Products Bill will replace the Medicines Act

16. The Bill will repeal and replace the Medicines Act. The purpose of the new legislation is to ensure acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare.

17. The new Bill will be aligned with recognised international practice and takes a proportionate approach to managing the risks of different products across their life span. The life cycle includes premarket, in market and post market controls (see Diagram 1).

Diagram 1: Regulation of activities across the therapeutic product lifecycle



[6] A Therapeutic Products Bill would further support ongoing work to respond to surgical mesh by; 1) introducing pre-market approval of mesh products as medical devices; 2) providing the ability to impose restrictions on who could use particularly high risk products, for example only by surgeons who had competed recognised training, and 3) a more efficient and effective processes for managing post-market safety issues.

18. The regulatory scheme comprises the Bill, regulations and other subordinate instruments:

    a. The Bill provides a principles-based legislative framework which is a critical part of ensuring the scheme is future proofed

    b. The technical and detailed requirements for medicines, biologics and medical devices would be provided in regulations and regulator-made instruments, such as rules and notices.

19. Cabinet agreed [refer to SOC-15-MIN-0049, SOC-15-MIN-0050, SOC-16-MIN-0025, SWC-18-MIN-0176] that the objectives of the regime will be best met by:

    a. an enabling legislative framework that can be readily maintained and updated

    b. regulatory requirements that are consistent with international approaches and effectively administered

    c. a regulator that can exercise regulatory powers effectively and independently, is accountable, and can engage internationally and recognise work done by trusted overseas regulators.

20. The Bill will:

    a. provide comprehensive coverage of all therapeutic products and key activities to provide assurance of the safety, quality and efficacy or performance of these products

    b. be able to respond rapidly to the emergence of new technologies or therapies that have a therapeutic purpose

    c. provide flexible approval pathways, streamline processes and improve efficiency and cost-effectiveness

    d. enable increased international cooperation and mutual recognition among regulators

    e. support medical product innovation in New Zealand

    f. remove regulatory barriers to service innovation, particularly in relation to primary and community services and prescribing authority for health practitioners

    g. supports consumer access to, and individual responsibility for, care.

Options to regulate natural health products need to be considered

21. Natural health products (NHP) are a diverse group of products that contain substances that are found in nature or are made in a factory to be identical to substances found in nature. Natural health products include remedies from traditional healing systems such as rongoā Māori and traditional Chinese medicine. Other natural health products include dietary supplements, creams, lotions, nasal sprays and ear drops. NHPs tend to be lower risk products than medicines but are not without risk.

22. Internationally it is common for NHPs to be regulated, on a risk proportionate basis, under therapeutics regulation such as in Australia and Canada, although approaches

vary. Some jurisdictions, such as the European Union regulate these products as traditional herbal remedies.

23. Regulation of NHPs is necessary to provide assurance of the safety and quality of NHPs, ensure consumers have suitable information to make informed choices about their health and wellbeing, and to support sector development and export growth.

24. Current regulation of NHPs is provided under general consumer protection legislation[7] and the Dietary Supplements Regulations 1985 (the Regulations), enabled by the Food Act 2014. Dietary supplements are a subset of the wider category of NHPs, and are substances such as vitamin and mineral tablets, that are taken orally in a controlled dose to supplement foods. The Regulations are due to expire on 1 March 2021.

25. On 9 March 2020, Cabinet agreed to amend the Food Act to extend the Regulations by five years to 1 March 2026 [CAB-20-MIN-0081 refers]. The Food (Continuation of Dietary Supplements Regulations) Amendment Bill gives effect to this decision. The Minister for Food Safety is responsible for that Bill. The Bill is currently with the Primary Production Committee, with a report back due on 11 February 2021.

26. Most NHP stakeholders support regulation and are frustrated at the lack of progress[8]. A very small but vocal section of the NHP sector does not support regulation and do not consider it necessary. Of those that support regulation there is a split among those that favour a stand-alone NHP Bill and those that are open to, or support regulation under the Therapeutic Products Bill.

27. In the absence of a separate Bill for NHPs, the new Therapeutic Products Bill would capture these products, as they fall within the definition of therapeutic purpose. One feasible option is to assess the potential for NHPs to be included under the umbrella of Therapeutic Products, with specific NHP regulations developed that recognise the generally lower risk nature of NHPs compared to medicines.

28. The Ministry of Health and the Ministry for Primary Industries (MPI) work closely across policy and regulation of natural health products. We have engaged with MPI regarding the proposal to regulate NHPs under the Therapeutic Products Bill. MPI officials support this approach because it will provide a coherent and risk proportionate approach to regulating these products. However, MPI does not support a transition period that goes past the proposed 2026 expiry date for the Dietary Supplements Regulations. It also notes that a stand-alone NHP Bill could be equally effective and would likely be strongly supported by industry. However, there is a risk that a standalone bill could not be resourced in a timely manner in light of the need to resource a Therapeutic Products Bill and other pressing issues within the health portfolio.

29. If you agree to us including NHPs within the proposed Therapeutic Products Bill, we will provide you and Hon Dr Verrall, Associate Minister of Health with further advice on options to progress this work in early February 2021.

---

[7] Fair Trading Act 1986 and Consumer Guarantees Act 1993.

[8] Particularly since the previous Natural Health and Supplementary Products Bill 2011 was not reinstated to Parliament following the 2017 Election.

MINISTRY OF HEALTH
MANATŪ HAUORA

There is broad support for a modern therapeutic products regulatory scheme among stakeholders

Overview of stakeholder feedback

30. In 2018 Cabinet agreed to release an exposure draft of the Bill and supporting consultation material for public consultation [SWC-18-MIN-0176].

31. Four hundred and forty-two submissions were received from a variety of stakeholders including consumers, health practitioners and their organisations, health sector and academic organisations and therapeutic product suppliers.

32. Most stakeholders expressed general support for the purpose and principles of the Bill and the need for New Zealand to have a modern comprehensive regulatory scheme for therapeutic products that is aligned with international regulatory practice.

33. However, some submitters raised concerns that the new scheme could create an unnecessary regulatory burden, particularly where there has been minimal regulation to date, such as the clinical trials sector.

34. A key concern raised by most submitters was frustration at the time it has taken to develop the Bill. This concern is shared by the medicines and medical devices sector and by health practitioners, academics and members of the public who chose to make submissions.

35. Other common concerns related to the details of the future regulatory scheme including, regulatory burden and costs and application timeframes and processes were raised by industry stakeholders. DHBs, medical practitioners' and some niche health providers, such as the NZ Defence Force, were also concerned that there would be suitably tailored arrangements for handling of medicines in hospitals and clinical settings.

36. Much of the detail will be addressed in regulations yet to be developed, but which will be consistent with international regulatory practice. The Ministry will need to continue to communicate with the sector to address their concerns and inform development of future regulations.

37. We will continue to work with key stakeholders to ensure we understand their issues and concerns, including future implementation issues, so that we can address these in ongoing design of the regulatory scheme.

Outstanding policy decisions

38. There are policy decisions still to be taken on several matters including in three contentious areas:

    a. Direct to consumer advertising of prescription medicines – options are to continue this practice in New Zealand or to prohibit it.

    b. Pharmacy ownership and licensing – options are to retain and strengthen pharmacy ownership restrictions or to remove ownership restrictions and focus on pharmacy licensing as the key control for safety and quality control of pharmacy practice.

    c. Natural health products – options for regulating these products.

39. Stakeholder feedback on each of these areas has been diverse, with strong views supporting one option or its alternative for each matter. We will provide you with specific advice addressing the policy proposals, alternative options for each and the range of stakeholder positions in February 2021.

Some policy decisions still need to be considered by Cabinet.

40. In December 2018 Cabinet [SWC-18-MIN-0176 refers] invited the Minister of Health and the Ministers of Public Services and Food Safety to report back on the following matters:

    a. the Minister of Health (the Minister) and Minister of Public Services to report-back in March 2019 on the recommended institutional form of the therapeutic products regulator and cost recovery policy for the regulatory scheme

    b. the Minister and Minister for Food Safety to report-back in May 2019 on the options for the regulation of natural health products

    c. the Minister to report-back within four months following the close of consultation on the exposure draft of the Therapeutic Products Bill on: the overall outcomes of consultation, whether increased regulation of direct-to-consumer advertising of named prescription medicines is warranted, and a recommended approach to pharmacy licensing criteria.

41. These report backs were extended several times by the Chair of the Cabinet Social Well-being Committee [SWC-19-MIN-0088 refers]. In February 2020 the Minister of Health at the time (Minister Clark) agreed that these matters be considered by Cabinet between April and July 2020.

42. This did not happen due to the national response to the Covid-19 pandemic from March 2020. We recommend that the report backs on options to regulate natural health products, the overall outcomes of consultation on the Bill and other outstanding policy decisions including for direct to consumer advertising and pharmacy ownership and licensing are consolidated and considered by Cabinet in early 2021.

43. We recommend that the report back on the institutional form of the therapeutic products regulator and cost recovery policy for the regulatory scheme be postponed, until at least mid-2021.

There are options for progressing therapeutic products reform

44. We consider it is feasible for a Bill to be ready for introduction to Parliament by late 2021 or early 2022, subject to Cabinet decisions and PCO drafting time and noting that the drafting time needed for PCO to finalise the Bill is hard to predict. These timeframes do not account for any significant resurgence of COVID-19.

45. We have also identified a slower timeframe for progressing the Therapeutic Products Bill, given the significant focus in 2021 with the ongoing response to COVID-19, significant immunisation programmes, including for COVID-19 and implementation of the health system transformation. The slower option would seek to introduce the Bill to Parliament later in 2022 or early 2023.

46. The following table shows a potential pathway for the Bill under option 1 and option 2:

Key Milestones	Option 1	Option 2
Several Health Reports to you on a range of technical policy issues which address matters raised in consultation. Most are likely to be within existing policy decisions from 2015, 2016 and 2018.	February - April 2021	February - June 2021
Remaining policy decisions including on pharmacy licensing, direct-to-consumer advertising of prescription medicines, options to regulate natural health products, offence and penalty provisions.	May 2021	July 2021
Cabinet decisions for drafting instructions for the final Bill	May 2021	August 2021
PCO drafting of the final draft Bill (estimated)	May-October 2021	Sept 2021-June 2022
Cabinet approval to introduce the Bill	Oct/Nov 2021 or early 2022	June 2022/early 2023
Royal Assent - subject to government legislative programme and Parliamentary time.	2023	2024
Commencement of a new Therapeutic Products Regulatory scheme - 2 years between Royal Assent and commencement provides for consultation on regulations.	By 2025	2026
Transition period varies depending on whether the product or activity has previously been regulated under the current Act.	1-3 years to 2028	1-3 years to 2029

Key risks and mitigation

47. We have identified the following high-level risks and propose mitigations below:

    a. Ongoing risks to the health and safety of patients and consumers arising from the current gaps in the Medicines Act coverage of therapeutic products including medical devices and advanced therapy medicinal products.

        i. Mitigation- continue with steady progress of the Therapeutic Products Bill.

        ii. Continue to respond to issues that pose significant and immediate risk in a bespoke way through non-regulatory approaches or targeted regulatory change.

    b. Ongoing uncertainty for the sector, health practitioners and patients.

        i. Mitigation – officials will continue to engage with key sectors and stakeholders and provide regular updates on progress.

    c. Programme delays due to a possible resurgence of COVID-19

i. Impact or mitigation – subject to the scale of any outbreak and the response required, it may be necessary to redeploy Ministry policy staff to the COVID-19 response. Timeframes indicated in this paper would be impacted and would need to be revised accordingly.

Equity

48. Historically, Māori and Pacific populations have experienced poorer health outcomes than other population groups through multiple shortcomings within the health system settings. Officials have developed a treaty and equity framework to consider these matters in relation to the availability of, and access to, medicines and devices. Opportunities to remove regulatory barriers to enable service innovation (eg, primary and community care, provision of pharmacy services and prescribing authorities for health practitioners) have been identified. Opportunities are expected to provide better choice and improved access that will benefit vulnerable populations in particular. There are also opportunities to ensure Māori and other vulnerable groups have equitable access to, and are protected where they participate in, clinical trials. Officials will continue to apply a robust equity framework to future policy decisions and to the design of the regulatory scheme and its implementation.

Next steps

49. We will provide you with regular updates on the progress of the work programme through our weekly report and detailed briefings on key policy issues in coming months.

ENDS.

Cabinet Social Wellbeing Committee

Summary

Pharmacy Ownership and Licensing: Report Back

Portfolio	**Health**
Purpose	This paper seeks agreement to continue with the current pharmacy ownership and licensing requirements in the Medicines Act 1981(the Act).
Previous Decisions	In December 2018, SWC agreed that the consultation document on a therapeutic products regulatory regime include two options for pharmacy licensing and invited the Minister of Health (the Minister) to report back on a recommended approach to pharmacy ownership and licensing criteria [SWC-18-MIN-0176].
Proposal	The Medicines Act 1981 (the Medicines Act) sets pharmacy ownership requirements as a criterion for gaining a pharmacy licence that are no longer fit for purpose. Consultation feedback in 2019 supported the option of strengthened accountability through pharmacist ownership and effective control. However, given the ongoing impact of COVID-19 and health reforms, the Minister considers that introducing significant change to the pharmacy ownership model in the short-term would create additional uncertainty for the sector. Agreement is therefore sought to retain the current criteria in the Act.
Impact Analysis	The **attached** regulatory impact statement (RIS) is deemed to meet quality assurance criteria. While the RIS supports open pharmacy ownership, the Minister has also considered the cumulative system and regulatory impact of the implementation of the health system reforms which supports retaining the status quo for now.
Financial Implications	None from this paper.
Legislative Implications	The Parliamentary Counsel Office will be directed to revise the Therapeutic Products Bill (the Bill) to reflect retention of the current pharmacy ownership provisions and the current exemption provision in the Medicines Act 1981, including renaming the latter Act if necessary.
Timing Matters	The Bill holds a category 4 priority on the 2022 Legislation Programme (to be referred to a select committee in 2022).

Communications A public announcement will be made.

Consultation Paper prepared by MoH. MBIE (Commerce and Consumer Affairs), and Treasury were consulted. DPMC (Prime Minister) was informed. Te Whatu Ora - Health New Zealand, Te Aka Whai Ora - Māori Health Authority, and the Commerce Commission were also consulted.

The Minister indicates that SWC Ministers were consulted and that discussion will occur with the government caucus.

The Minister of Health recommends that the Committee:

1 note that in December 2018, SWC agreed that the consultation document on a therapeutic products regulatory regime include two options for pharmacy licensing and invited the Minister of Health to report back on a recommended approach to pharmacy ownership and licensing criteria [SWC-18-MIN-0176];

2 note that the paper attached under SWC-22-SUB-0156 is part of work to modernise New Zealand's therapeutics regulatory scheme, central to which is repealing the Medicines Act 1981, including pharmacy ownership and licensing criteria, and replacing it with the Therapeutic Products Bill;

3 note that while the removal of restrictions on pharmacy ownership in the medium to long term would enable innovation in delivery of services, in the short-term, it would create additional uncertainty for the sector while the new health entities and processes are embedded, working relationships are formed with the primary and community care sector and the response to COVID-19 is further managed;

4 agree that the current pharmacy ownership provisions and related exemption provisions in the Medicines Act 1981 be retained, by saving those provisions and repealing all other parts of the Act once the Therapeutic Products Bill is enacted, to allow time for pharmacies to embed changes under the new health system and continue addressing the ongoing impacts of COVID-19;

5 invite the Minister of Health to instruct the Parliamentary Counsel Office to revise the Therapeutic Products Bill to reflect retention of the current pharmacy ownership provisions and the current exemption provision in the Medicines Act 1981 (including renaming the latter Act if necessary).

Rachel Clarke
Committee Secretary

Hard-copy distribution:
Cabinet Social Wellbeing Committee

15 September 2022

1.3 Therapeutic Products Bill: update

This item updates you on progress towards introduction of the Therapeutic Products Bill (the Bill).

Progressing the Bill

Manatū Hauora and the PCO met with your office on 8 September 2022 to discuss the timing of critical steps for introduction of the Bill. We are continuing to engage with your office on this matter.

There are two outstanding policy issues:

1. Embedding the principles of Te Tiriti - you and Minister Henare will receive a joint briefing from us and Te Aka Whai Ora on 19 September 2022 about embedding the principles of Te Tiriti, and provision for the recognition and protection of rongoā.
2. Controls on prescribing authority - Cabinet decided in 2016 to use the Bill to place controls on prescribing authority under the Health Practitioners Competence Assurance Act 2003 [SOC-16-MIN-0025]. A review of the health workforce legislation is underway which requires the approach in the Bill to be reviewed. We will provide you with advice on this in the week commencing 19 September 2022.

We continue to work well with the PCO. Substantial written feedback on the draft Bill has been provided. This Bill is large and highly complex and has significantly increased in size compared to the 2018 exposure draft. We have also provided final instructions to PCO on pharmacy ownership, following Cabinet's decision on 5 September 2022.

Stakeholder engagement on natural health products

Planning is underway on a targeted stakeholder hui on natural health products (NHPs) in early October 2022. The purpose will be to inform stakeholders on how NHPs will be included in the Bill, and to provide an opportunity for the sector to ask questions and share their initial views. We will update you further on this over the coming weeks.

Next steps

In addition to the two briefings that you will receive in week starting 19 September on Te Tiriti and controls on prescribing authority, you will also receive a briefing on implementing the Bill in late September/October 2022.

Deputy Director-General	Maree Roberts, Deputy Director-General, Strategy, Policy, and Legislation, S9(2)(a)

Document 3

22 September 2022

1.4 Therapeutic Products Bill: update

This item updates you on progress towards introduction of the Therapeutic Products Bill (the Bill).

Progressing the Bill

There are two outstanding policy issues:

1. Te Tiriti - you and Minister Henare received a joint briefing on 19 September 2022 from Manatū Hauora and Te Aka Whai Ora on reflecting the principles of Te Tiriti and providing for the recognition and protection of rongoā [HR20220828 refers]. Since this item was drafted, you have provided your response to the Ministry.
2. Controls on prescribing authority – you will receive a briefing in the week of 26 September. Cabinet decided in 2016 to use the Bill to place controls on prescribing authority under the Health Practitioners Competence Assurance Act 2003 [SOC-16-MIN-0025]. Since then, a review of the health workforce legislation has been underway, which requires the approach in the Bill to be reviewed.

The Ministry continues to work well with the Parliamentary Counsel Office (PCO). We have provided written feedback on about half of the draft Bill (v36.19) and will respond to approximately half of the outstanding queries in the next week. There will likely need to be at least a further three rounds of drafts and comments to make sure that the Bill is workable and gives effect to the policy intent.

This Bill is large and highly complex and has significantly increased in size compared to the 2018 exposure draft. We have briefed your office on the need for additional time to revise the Bill to reflect recent and substantial decisions on rongoā, Te Tiriti, and pharmacy ownership.

There is also a need to allow sufficient time to engage with core Crown agencies on the Bill. This includes the Ministry of Primary Industry (MPI) (exports); the Ministry of Business, Innovation and Employment (MBIE) (clinical trials, innovation, and competition); Te Puni Kōkiri (rongoā and Māori development); and Ministry for the Environment (MfE) (biologics and GMOs). We will work with PCO to develop a timeline that will support the introduction of the Bill and provide you with further advice next week on risks and quality implications for progressing the Bill at pace.

Stakeholder engagement

Manatū Hauora met with representatives from Baxter Healthcare on 21 September 2022 to discuss compounding, and the mechanism of supply of compounded products, following your recent visit to their premises. This meeting was an opportunity to hear from those 'on the ground' affected by proposals in the Bill. Outcomes from the meeting will be reported in next week's Weekly Report.

The Ministry me with Pharmac on 21 September 2022 to discuss their current work on a medical device strategy programme and future regulation of medical devices under the Bill. This is part of regular engagement with Pharmac. Outcomes from the meeting will be reported in next week's Weekly Report.

Planning is underway on a targeted stakeholder hui on natural health products (NHPs) in early October 2022. The purpose will be to inform stakeholders on how NHPs will be included in the Bill and to provide an opportunity for the sector to ask questions and share their initial views. There are diverse and strongly held views across this sector. We will update you further on this over the coming weeks.

Next steps

You will receive a briefing on implementing the Bill in late September/early October 2022.

Deputy Director-General	Maree Roberts, Deputy Director-General, Strategy, Policy, and Legislation, S9(2)(a)

Document 3

6 October 2022

1.3 Therapeutic Products Bill: update

This item updates you on progress towards introduction of the Therapeutic Products Bill (the Bill).

Progressing the Bill

Manatū Hauora update

We began a fast-track process of consultation with government agencies on 30 September 2022. To meet the deadline of the introduction of the Bill by the end of November 2022, agencies have unt l close of business on 7 October 2022 to provide feedback. We have already proactively engaged with agencies to give them some notice of the circulation and provided some guidance to support their review.

We are consulting on an updated version of the draft Bill (v37) prepared by the PCO which has been revised in line with the extensive feedback provided by Manatū Hauora. We provided this version of the Bill to your office on 30 September 2022.

PCO update

PCO received the third and final tranche of general feedback on v36 of the Bill on 28 September 2022. The version being used for agency consultation responds to the first of the three tranches of feedback and recent area-specific instructions on medical devices.

PCO is preparing a further draft of the Bill responding to the second and third tranches of comments and instructions on consequential amendments and pharmacy ownership received on 30 September 2022. PCO is expecting further instructions on natural health products and off-label medicine use and aims to address them as well. Manatū Hauora will have a limited opportunity to comment on this further draft before introduction.

PCO has started peer review of v37, which is expected to take at least two weeks. PCO will work with Manatū Hauora to address any significant issues it raises.

Policy issues

You received a briefing on 28 September 2022 related to controls on prescribing authority [HR20221422 refers]. This briefing seeks your decision on how to progress the Bill, and its provisions on prescribing authorities, while the concurrent Health Workforce Legislation review is underway. Our recommended option would support a November 2022 introduction of the Bill.

This briefing also:

- informs you about the work Manatū Hauora and the Ministry for the Environment have underway to ensure alignment between the Bill and the proposed reforms to the Hazardous Substances and New Organisms Act 1996
- notifies you of our intent to consult with you in mid-October 2022 on the proactive release of two Cabinet Papers as part of a general communications approach to support the introduction of the Bill.

Last week, broadcasters from The Hui on channel Three approached both Manatū Hauora and your office separately for comment and interview regarding the Bill and community concerns that it will seek to regulate rongoā. You have previously made decisions in relation to rongoā, and it would be timely to agree a communication strategy with Manatū Hauora on what information can be released on rongoā (and the Bill generally), prior to the introduction of the Bill.

Finally, we are working as directed with Te Aka Whai Ora on advice to Minister Henare on next steps for rongoā and will update you on this work programme in future reports.

Next steps

We have advised your office of a natural health products sector stakeholder hui that is being planned by Manatū Hauora. This is currently planned for the week commencing 31 October 2022. We will shortly send out invitations to the hui.

Deputy Director-General	Maree Roberts, Deputy Director-General, Strategy, Policy and Legislation, S9(2)(a)

13 October 2022

1.4 Therapeutic Products Bill: update

This item updates you on progress towards the introduction of the Therapeutic Products Bill (the Bill).

Progressing the Bill

Manatū Hauora update

We have begun assessing the responses from agency consultation on the Bill that concluded on 7 October 2022, to identify any significant issues that require immediate attention from the Parliamentary Counsel Office (PCO). Based on our review to date, we anticipate that most issues raised have already been addressed in the Bill or will be achievable via the planned secondary legislation. Several issues may still need to be addressed during Select Committee and prior to the Committee of the Whole House.

The general nature of feedback (particularly from clinicians) does highlight that the Bill represents a significant change to the sector, and the Ministry is working to develop simple and clear communication material to support the Bill's introduction. Relatedly, we are working with the Ministry's Disinformation Assessment and Response Team to develop a plan for responding to mis- and disinformation about the Bill.

The Ministry of Justice's (MoJ) offence and penalty vetting team has signed off on the offence and penalty regime in the Bill. This is a positive step, and we are working with MoJ's Bill of Rights Act vetting team to resolve any outstanding queries in relation to the Bill.

We have also begun drafting the supporting material required to facilitate the introduction of the Bill to the House, including a draft Cabinet paper seeking approval from the Legislation Committee of Cabinet to introduce the Bill to Parliament this year (the LEG paper). Agency consultation on the draft LEG paper commenced on 10 October 2022, with feedback due midday 12 October 2022. You will receive the draft LEG paper by midday 21 October 2022, to commence ministerial consultation.

Parliamentary Counsel Office update

PCO continues to progress a further draft of the Bill that responds to the instructions received on and after
30 September 2022. PCO will progress amendments to the Human Tissue Act 2008 and Human Assisted Reproductive Technology Act 2004 when instructions arrive (as the Bill needs to address these to avoid scope issues arising while the Bill is in the House).

Peer review is underway and is due to be completed to the extent possible by 27 October 2022. Proofreading continues and will be taken as far as possible by 8 November 2022.

Policy issues

Rongoā

On 12 October 2022, Te Aka Whai Ora and Manatū Hauora officials met to progress advice to you and the Hon Minister Henare on rongoā. Te Aka Whai Ora and the Ministry's Māori Health directorate will lead this work, with updates provided in reports you receive from Te Aka Whai Ora.

Next steps

In order to provide early comments, your office will receive an early draft of the LEG paper on the afternoon of 17 October 2022. The final draft for ministerial consultation will be provided to your office on 21 October 2022.

The Ministry has invited selected stakeholders from the natural health product sector to attend an in-person hui in Wellington on 1 November 2022. A virtual hui will be held on 3 November 2022 for those who cannot attend in-person. We will brief your Office on any issues arising and any relevant outcomes in advance of the hui.

Deputy Director-General	Maree Roberts, Deputy Director-General, Strategy, Policy and Legislation, S9(2)(a)