Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

Associate Minister of Health

Modernising the Regulation of Medicines and Medical Devices

11 October 2024

These documents have been proactively released by the Ministry of Health on behalf of the Associate Minister of Health, Hon Casey Costello.

Title of Cabinet paper:

- Modernising regulation of medicines and medical devices

Titles of minutes:

- Report of the Cabinet Social Outcomes Committee: Period Ended 27 September 2024 (CAB-24-MIN-0380)
- Modernising the Regulation of Medicines and Medical Devices (SOU-24-MIN-0115)

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Key to redaction codes:

- Out of scope.
- S 9(2)(f)(ii) to maintain the constitutional conventions that protect collective and individual ministerial responsibility.
- S 9(2)(f)(iv) to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials.

CAB-24-MIN-0380

Cabinet

Minute of Decision

Report of the Cabinet Social Outcomes Committee: Period Ended 27 September 2024

On 30 September 2024, Cabinet made the following decisions on the work of the Cabinet Social Outcomes Committee for the period ended 27 September 2024:

Out of scope

SOU-24-MIN-0115 **Modernising the Regulation of Medicines and Medical Devices** CONFIRMED
Portfolio: Associate Health (Hon Casey Costello)

Out of scope

Rachel Hayward
Secretary of the Cabinet

SOU-24-MIN-0115

Cabinet Social Outcomes Committee

Minute of Decision

Modernising the Regulation of Medicines and Medical Devices

Portfolio **Associate Health (Hon Casey Costello)**

On 25 September 2024, the Cabinet Social Outcomes Committee (SOU):

Background

1 **noted** that in May 2024, SOU invited the Associate Minister of Health (Hon Casey Costello) (the Associate Minister), in consultation with the Associate Minister of Health (Hon David Seymour) to report back on proposals for the future direction of the regulation of medicines, medical devices, and natural health products [SOU-24-MIN-0032];

Proposed work programme and legislative framework

2 **agreed** that the Medicines Act 1981 should be replaced with modern regulation of medicines and medical devices under a Medical Products Bill (the Bill);

3 **agreed** that natural health products will be regulated under a standalone bill, to be developed following engagement with the natural health products sector;

Settings for a Medical Products Bill

4 **authorised** the Associate Minister to issue a first tranche of drafting instructions for the Bill that includes the following settings:

Scope

4.1 the Bill should cover medicines;

4.2 the Bill should cover medical devices in a manner and form that recognises the regulatory differences between medical devices and medicines;

4.3 the Bill should include provisions enabling the exclusion of specific product types via secondary legislation;

Purpose and principles

4.4 that the purpose of the Bill should express that legislation is to:

4.4.1 support improved health outcomes for all New Zealanders by enabling timely access to safe, high quality, and effective medical products;

4.4.2 and to do this by providing cost-effective assurance that medical products meet acceptable standards of safety, quality, and efficacy or performance;

4.5 that the overarching principles of the Bill should express the ideas that:

4.5.1 regulation should be proportionate to benefits and risks, and support timely access to medical products;

4.5.2 the likely benefits of medical products should outweigh their likely risks;

4.5.3 regulation should recognise differences between product types, including the differences between medicines and medical devices;

4.5.4 regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators;

4.5.5 the regulatory system should support innovation, competition, economic growth, and exports in a way that maintains New Zealand's reputation as a producer of high-quality products;

Regulation of products

4.6 that the Bill should enable approval pathways for medicines, including:

4.6.1 a verification pathway, discussed further in *Introducing a Verification Pathway for Medicines Approvals* [SOU-24-SUB-0114];

4.6.2 an abbreviated assessment pathway, where a medicine has been approved by one trusted overseas regulator;

4.6.3 a full assessment pathway;

4.6.4 an expedited assessment pathway for use in response to public health emergencies;

4.7 that the Bill should enable approval pathways for medical devices, similar to those listed in paragraph 4.6, but suited to the nature and risk profile of each type of medical device, and providing:

4.7.1 a self-declaration pathway for low-risk devices;

4.7.2 verification pathways for products already approved by trusted overseas regulators;

4.7.3 appropriate pathways for innovative devices and locally manufactured devices;

4.8 that the Bill will enable new approval pathways to be created via secondary legislation, and enable exemptions from product approval and registration;

4.9 that the Bill will enable the appropriate regulation of blood, blood products and (excepted as provided below) other substances of human origin and biological materials derived from non-human sources including viruses, bacteria, and animal cells, and tissues;

4.10 that the Bill will not require human organs and tissues intended for immediate donation to obtain any form of prior approval, and will regulate activities with those products;

4.11 that the Bill will enable appropriate pathways to regulate patient-matched and custom-made medical devices, and patient-matched medical treatments, such as gene therapies and autologous treatments;

4.12 that the Bill will not include any system of mandatory approval for medical products intended for export only;

4.13 that the Bill will enable medicines and medical devices to be classified according to risk;

4.14 that the Bill should provide for a product to be supplied to a patient without a product approval that would otherwise be required, if an appropriately qualified health practitioner considers this to be appropriate;

4.15 that the Bill should allow individuals to continue to import medicines and medical devices for themselves or a person they are a caregiver for, with a requirement that import of prescription medicines requires a New Zealand prescription, and that they comply with any other restrictions;

Regulated activities

4.16 that the Bill should provide for the regulation of some activities with medicines and medical devices, including manufacture, distribution, prescribing, and some types of supply, where regulation of the activity is necessary to protect consumer safety or public health;

4.17 that the Bill amend the Healthcare Practitioners Competency and Assurance Act 2003 to enable Responsible Authorities to alter prescribing authority for a profession by modifying the scopes of practice;

4.18 that any significant expansion of a profession's powers should require the consent of the Minister of Health;

Drawing on the Therapeutic Products Act

4.19 that the following uncontentious provisions of the Therapeutic Products Act 2023 be drawn upon for the Bill, except in relation to natural health products:

4.19.1 part 7 on 'other regulatory matters';

4.19.2 part 8 on enforcement, except for sections relating to advertising, and subject to a review of penalty provisions;

4.19.3 part 10 on administrative matters;

Next steps

5 s 9(2)(f)(ii) [redacted]

6 s 9(2)(f)(iv) [redacted]

7 **invited** the Associate Minister of Health to report back to SOU by the end of the first quarter of 2025 on further policy proposals, including on clinical trials, regulating pharmacies, supporting exporters, statutory timeframes, advertising, offences and penalties, and a separate regulatory system for natural health products.

Jenny Vickers
Committee Secretary

Present:
Rt Hon Christopher Luxon
Hon David Seymour
Hon Nicola Willis (Chair)
Hon Erica Stanford
Hon Louise Upston
Hon Tama Potaka
Hon Matt Doocey
Hon Nicole McKee
Hon Casey Costello
Hon Melissa Lee
Hon Nicola Grigg
Hon Karen Chhour

Officials present from:
Office of the Prime Minister
Officials Committee for SOU
Office of the Associate Minister of Health (Hon David Seymour)
Office of the Minister of Education

In Confidence

Office of the Associate Minister of Health

Cabinet Social Outcomes Committee

Modernising regulation of medicines and medical devices

Proposal

1 This paper seeks agreement to core policy elements of a Medical Products Bill to replace the Medicines Act 1981, and agreement to issue initial drafting instructions for a modern, risk-proportionate law to regulate medicines and medical devices (medical products).

Relation to government priorities

2 This proposal supports the priorities set out in the Government Policy Statement on Health 2024-27, in particular access, timeliness, quality, and supporting the health workforce.

Executive Summary

3 This paper seeks Cabinet agreement to draft a new Medical Products Bill (the Bill) to replace the Medicines Act with modern legislation to regulate medical products.

4 In this paper I am seeking agreement to core policy elements of the Bill, including purpose and principles, scope, and tools to empower our health workforce and enable timely access to quality medical products, including unapproved products.

5 Regulation will be risk proportionate; and medicines and medical devices will be regulated in a way that recognises the differences between those products. Under the Bill, products will generally be registered with, or approved by, a medical products regulator before they are supplied in New Zealand. The process for obtaining approval will vary according to the nature and risk of the product. The lowest risk products, including many medical devices, will either be exempt from the approval requirement, or approved following registration and a declaration that the product meets relevant standards. The Bill will be flexible so that innovative products can be assessed appropriately over time without primary legislation needing to be amended. This approach is consistent with comparable countries and industry's advice on what works.

6 The Bill will improve our approach to higher risk activities involving medicines. Prescribing will remain limited to appropriately qualified practitioners, and manufacturing and other activities (eg, clinical trials) with medicines will still require a licence. However, the Bill will introduce pathways for professions to gain or expand prescribing and other powers in relation to medicines. Overall, the public will be better protected through stronger provisions relating to the manufacture, use, and post-market surveillance of medical devices, while domestic manufacturers will be able to leverage local approvals to take their products to the world.

Background

7 Cabinet noted in May 2024 that the current legislation for medicines and medical devices is outdated and does not meet the needs of industry, consumers, or practitioners. Cabinet invited me, in consultation with Hon David Seymour, Associate Minister of Health, to report back on proposals for the future direction of the regulation of medicines, medical devices, and for natural health products, including the financial implications of proposals. [SOU-24-MIN-0032].

8 This government is implementing a range of interim improvements to the Medicines Act, such as a verification pathway for rapid approval of medicines that have been approved by two trusted overseas regulators [SOU-24-MIN-0055]. However, there is only so much that can be done with legislation which is fundamentally not fit for purpose.

Analysis

9 I propose a new Medical Products Bill (the Bill). It will regulate medicines and medical devices (medical products) in a way which addresses issues with both the Medicines Act and the Therapeutic Products Act 2023.

10 The Bill will ensure that medical products are regulated in a common-sense and risk-proportionate way. This is laid out in paragraph 25. Products which pose very little risk, such as low risk medical devices (eg, surgical masks and handheld surgical instruments), will have minimal regulation. For instance, these products could go through a declaration and notification pathway. Cutting-edge technologies such as gene therapy and medical device software (where treated as a medical product) will be regulated in a way which makes sense for those technologies, not in a way designed for conventional pharmaceutical medicines. Where regulation is required for innovative medical products, it will enable innovation and exports.

11 The medicine and medical device industries have been clear that international harmonisation is essential to supporting New Zealand manufacturers and exporters, and for timely access to products made overseas. For this reason, the proposed regulatory system will align with international systems wherever possible. For example, there are internationally agreed risk classifications that are used for medical devices. By harmonising with these classifications, industry will know how their product will be treated under the new regime.

12 Further, where a product has been approved by trusted overseas regulators, that product will not need to undergo a local evaluation. This will particularly benefit the medical device sector, and reduce the need for a duplicate, local assessment of the device. Finally, the Bill will recognise international conformity assessments, and the fact that domestic manufacturers and exporters often hold international licences and credentials for their activities.

13 Natural health products will also be regulated appropriately, under their own regime. Under the Therapeutic Products Act, natural health products were to be regulated under the same legislation as medical devices and pharmaceuticals. Industry, practitioners and consumers strongly objected to this, and this Government has listened. There will be a separate legislation tailored to natural health products, which

will be developed through engagement with the natural health products sector over the next 12 months.

Purpose and principles of the Medical Products Bill

14 I propose that the purpose clause of the Bill express that the legislation will:

14.1 support improved health outcomes for all New Zealanders by enabling timely access to safe, high quality and effective medical products, and to do this by:

14.2 providing cost-effective assurance that medical products meet acceptable standards of safety, quality, and efficacy or performance.

15 The principles set out how decisions will be made under the Bill. I propose that the principles for the Bill be along the following lines:

15.1 regulation should be proportionate to benefits and risks of the product, and support timely access to medical products

15.2 the likely benefits of medical products should outweigh their likely risks

15.3 regulation should, where possible, harmonise with international good practice and enable reliance on assessments and decisions by trusted overseas regulators

15.4 regulation should support innovation, competition, economic growth, and exports in a way that maintains New Zealand's reputation as a producer of high-quality products.

Products will be regulated in a risk-proportionate way

16 I propose that the Bill cover medicines and medical devices; and enable risk-proportionate controls to be applied across a product's lifecycle. This approach is consistent with international comparators, such as Australia, the United Kingdom, Japan, Singapore, Canada and the United States of America.

17 It is important to note that medical devices are already subject to some regulation under the Medicines Act 1981, primarily an obligation to be notified to the medicines and medical device regulator, Medsafe. However, our regulation of medical devices carries a level of risk where devices can be imported and supplied in New Zealand, even if they have not been approved elsewhere, or if they do not meet appropriate quality standards.

18 This has economic and public health implications. Precious public funding for our health system may be wasted on reactive medical interventions to remedy patient harms caused by substandard or outright non-compliant products. With a limited ability to use the tort system to recover damages from manufactures or practitioners, the costs for addressing injuries arising from defective devices are met by individual patients or the public (via ACC levies or the public health system). Responsible manufacturers may also suffer reputationally, through the parallel importation of devices that may be outdated or substandard. Domestic manufacturers also have no

pathway to obtain a local market authorisation for their medical device that enables them to access faster approval pathways overseas.

19 The public health impacts of defective medical devices are well known. As one example, our current regulation of medical devices has significant gaps that mean that most point of care tests are essentially unregulated. This has led to clinically worthless tests being sold to patients at chemists, including tests for sexually transmitted diseases. I note that this issue has been raised with other Health Ministers and it raises significant risks for people making lifestyle, family and health decisions. The proposals in this paper would improve our knowledge about these products, including who is responsible for their supply in New Zealand, and take action quick for products on the market.

20 Industry is aware of these issues and their peak bodies – such as the Medical Technology Association of New Zealand – support appropriate regulation of medical devices. Industry has told us of the need for risk proportionate regulation that is consistent with international good practice, and which minimises unnecessary duplication in approvals. I have listened to this advice, and the feedback from patient groups and practitioners – who also want to know devices are safe and effective.

21 Consistent with the goal of international harmonisation, I propose that the definition of medicine and medical device be developed by drawing on the terminology used in these comparator countries. New Zealand will retain the ability to modify terms to account for local drafting practices and decisions over specific products (such as artificial intelligence, and human and non-human cells and tissues).

22 The above approach responds to industry concerns over the Therapeutic Products Act, and will better support reliance pathways and joint assessments. Harmonisation with good international practice can be furthered by adopting common standards (eg, classification rules of medical devices according to risk) and processes for evaluating medicines and medical devices. Reflecting industry's advice on what works overseas, I recommend that the Bill have separate sections for medicines and medical devices, to ensure devices are not inappropriately regulated under a medicines-model.

23 Some products that might technically be captured by the Bill (eg, toothpastes), should be exempt from some or all of its provisions, because they are already regulated under other legislation or do not need to be regulated. The new Bill will enable regulations to exclude medical products from the Bill's requirements, with or without conditions.

Product approval

24 Under the Bill, some medical products (mostly medicines) will require approval before being supplied within New Zealand. How this approval would be granted will depend on the nature and risk profile of the product.

25 Specifically, the Bill will:

25.1 continue to require a domestic approval for new medicines, but would incorporate the proposed international verification pathway for Medsafe [SOU-24-MIN-0055]. Provisions in the Bill will enable a range of entities, including the Crown, to act as the 'sponsor' for a medicine.

25.2 enable low-risk medical devices to be approved based on a sponsor's declaration of compliance with applicable standards, and acceptance of their responsibilities as sponsor. Local requirements would be limited to matters such as conformity with New Zealand labelling requirements.

25.3 enable medium- and high-risk medical devices to be approved based on approval by trusted overseas regulators

25.4 enable medium- and high-risk medical devices which have *not* been approved by trusted overseas regulators (eg, locally manufactured devices) to be assessed based on the nature and risk profile of the device. Our current regulation of medical devices does not support local manufacturers to work with a domestic regulator to obtain a medical device approval that is recognised in major overseas markets (ie, to enable an innovative product to enter that market)

25.5 create a mechanism to add new pathways for innovative types of products, so that these products can be assessed appropriately.

26 The Bill would explicitly exempt certain medical products from product approval requirements. For example, substances of human origin will be regulated under provisions tailored to the special characteristics of human blood, tissues and organs.

27 To accommodate advances in manufacturing processes and medical technologies, the Bill would include flexible provisions enabling the approval of processes rather than products. This would include approval of the machines that manufacture patient-matched devices (eg, dental crowns), and of the process for gene therapies that are designed for a specific patient (eg, CAR-T therapies).

Access to unapproved products will still be needed

28 The proposed system outlined above, along with the interim changes this Government is already making (such as streamlining Medsafe's processes) will see medicines approved more quickly. However, there will still be situations when the best product for a specific patient is one that does not have approval. For example, a promising new treatment for a life-threatening illness may become available, or a substitute may be urgently needed if an existing approved product becomes unavailable.

29 The Medicines Act's provisions for the supply of unapproved medicines are overly prescriptive and inflexible, contributing to barriers to access for rural and other communities. They also lack the safeguards necessary to reduce risks of counterfeit, contaminated and ineffective medicines. The Therapeutic Products Act provided new pathways for access to unapproved medicines. Parliament and the public spent a lot of time working on a solution to this issue, and I propose that we do not waste this effort.

30 The Bill will enable suitably qualified health practitioners to supply unapproved medicines when there is no suitable approved medicine available to meet the clinical needs of a patient (affordability may be relevant to a practitioner's determination of suitability). Safeguards on sourcing quality medicines will be set at the importer and distributor level. Patients and their carers will also be able to personally import most prescription medicines, provided they have a prescription from a New Zealand

practitioner. Finally, the Bill will clearly enable post-clinical trial continuity of treatment.

31 Fewer controls will apply to importing medical devices, and the proposed approval pathways will mean there will be few barriers to bringing a new device to New Zealand. As with medicines, the Bill will ensure New Zealanders can access unapproved medical devices that they need.

Policy on export authorisations is being developed with industry

32 One of the major concerns that industry had about the Therapeutic Products Act was that it required products intended solely for export to have a product approval. I agree with industry that this was overreach, and I do not intend to require export-only products to obtain an approval. However, some exporters will need or want an export certificate, as this is an import requirement in some countries. We also want to maintain confidence in the quality of New Zealand-made products. Officials are working with industry on how exports can best be supported, and I will seek Cabinet's agreement to an approach by March 2025.

Higher risk activities with medical products will continue to be regulated

33 There are also activities with medical products which should only be done by properly trained professionals, or with regulatory oversight. Under the Medicines Act, activities such as manufacture, supply and prescribing of medicines require a licence, professional registration, or another mechanism to enable the activity.

34 I propose that the Bill likewise control certain activities involving medical products, and require professional registration, or a licence, permit or other authorisation to undertake them. For medicines, this would include manufacturing, prescribing, and wholesale and some non-wholesale supply activities. Routine healthcare activities by health practitioners (such as administration of prescription medicines) will be enabled via the Bill directly or through regulations.

35 The medicines industry has told us that continuity is important, and the proposed approach does not represent a major change to the regulation of activities with medicines. Businesses and practitioners operating under Medicines Act licences or professional regulation will not see any significant changes, except where they are better supported and enabled to deliver quality products and services.

36 Under the Medicines Act, manufacture and other activities with medical devices are essentially unregulated, even for high-risk devices. This is out of step with comparable countries and creates a high level of risk for the public and healthcare providers. It also makes it difficult to respond promptly when problems with devices are detected. However, I consider that the Therapeutic Products Act went too far in regulating the medical device industry. I propose a risk-proportionate registration and notification system for medical device activities (manufacture, import and distribution). This will enhance visibility over the supply chain in New Zealand.

37 Where industry participates in globally recognised quality assurance programmes for certain activities (eg, manufacture), I also propose that these can be recognised as

satisfying local requirements. This would be a significant improvement on the approach proposed in the Therapeutic Products Act.

38 The approach to some activities requires further engagement with stakeholders. I will report back to Cabinet before March 2025 on proposals for regulating pharmacies and clinical trials under the Bill. Pharmacies and clinical trials involving medicines are currently regulated under the Medicines Act.

The expertise of our health workforce will be better recognised

39 The Medicines Act fails to fully recognise the expertise of many health practitioners, and places inflexible and unnecessary limits on what some professions can do with medicines. The impacts of this inflexibility are disproportionately felt by those living in rural areas, and other populations with limited access to general practitioners.

40 As with the Therapeutic Products Act, I propose that this Bill amend the Health Practitioners Competence Assurance Act 2003 (the HPCA Act) to create a straightforward pathway to expand prescribing rights, via scopes of practice. Using this Bill as the mechanism to amend the HPCA Act is the most pragmatic way to progress this change. This work will be co-ordinated with broader work to review and potentially update the HPCA Act.

41 Health professions are best placed to say what their members can do with medicines and medical devices. Nonetheless, where a profession is gaining significant new or expanded powers, a safeguard is needed. I propose that the Minister of Health's approval be required when a profession is gaining powers which currently require legislative change, such as a profession gaining the right to prescribe medicines. Less significant changes can continue to be made by the relevant body without Ministerial oversight.

The proposed system will include best practice modern regulation

42 Most of the routine, administrative and regulatory provisions, essential to a future regulatory regime for medical products, were uncontroversial in the Therapeutic Products Act. Many are common across modern regulatory legislation, including the powers a regulator will need to collect and share information with other regulators, remove unsafe products, direct regulated parties to take or not take specific actions, and to undertake compliance and enforcement activities. This will enable an effective and proportionate response to dangerous or substandard products.

43 I propose to reuse those provisions from the Therapeutic Products Act. I will return to Cabinet in March 2025 with specific proposals for penalty provisions following consultation with the Attorney-General.

Process for further policy development and drafting

44 By the end of March 2025, I will seek further approvals relating to:

44.1 advertising, exports, post-market controls, statutory timeframes for decision-makers, clinical trials, regulation of pharmacies, and regulation of software as a medical device, including artificial intelligence

44.2 an offence and penalty framework for the Bill, including the extent to which the Crown should be liable for contraventions of the Bill

44.3 a separate regulatory system for natural health products.

Implementation

45 s 9(2)(f)(iv) [redacted]

Cost-of-living Implications

46 The proposals in this paper are unlikely to have significant cost-of-living implications.

Financial Implications

47 s 9(2)(f)(iv) [redacted]

Legislative Implications

48 This paper proposes a new Government bill, the Medical Products Bill, to repeal the Medicines Act 1981 and replace it with modern and risk-proportionate legislation to regulate medicines and medical devices.

49 s 9(2)(f)(ii) [redacted]

Impact Analysis

Regulatory Impact Statements

50 Two Regulatory Impact Statements have been prepared and attached to this Cabinet paper. One covers regulation of medicines, and the other covers regulation of medical devices.

51 The Ministry of Health QA panel has reviewed the Impact Statement titled *"Medicines regulation"*, produced by the Ministry of Health and dated August 2024. The panel considers that the Impact Statement Meets the quality assurance criteria. The Impact Statement is clear, concise, complete, consulted and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

52 The Ministry of Health QA panel has reviewed the Impact Statement titled *"Product and activity controls for medical devices"*, produced by the Ministry of Health and dated August 2024. The panel considers that the Impact Statement Meets the quality assurance criteria. The Impact Statement is clear, concise, complete, consulted and

convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

Climate Implications of Policy Assessment

53 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal, as the threshold for significance is not met.

Population Implications

54 Groups which need to use medical products more often are affected more strongly by unsafe, inaccessible or unaffordable products. These groups include older people, Māori and Pacific people (due to higher rates of poor health), disabled people, and people with chronic or rare health conditions. These groups also tend to have lower average incomes, and this further increases the impact of any higher costs.

55 Groups with limited access to health services, such as rural communities, are disproportionately affected when medical products are difficult to access. Women experience higher rates of harm from unsafe or low-quality medical products, including products which are also used by men.

International obligations

56 The proposals in this paper will be notified under the World Trade Organisation's Technical Barriers to Trade (TBT) Agreement and to New Zealand's Free Trade Agreement partners for transparency and compliance with international obligations. Detailed Bill provisions and associated policy will be notified as appropriate, with due consideration of New Zealand's TBT obligations under the World Trade Organisation Agreement and other trade agreements.

Human Rights

57 The proposals in this paper are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Use of external Resources

58 No external resources were used to produce this paper.

Consultation

59 The Ministry of Health consulted the following agencies on this paper: Whaikaha | Ministry of Disabled People; the Ministry of Business, Innovation and Employment; Te Arawhiti; the Commerce Commission; the Privacy Commissioner; ACC; Health New Zealand; Pharmac; the Public Service Commission; Te Puni Kōkiri; the New Zealand Blood Service; the New Zealand Customs Service; and the Ministry for Regulation. The Department of the Prime Minister and Cabinet was informed.

Communications

60 There will be ongoing consultation by Health Ministers and officials on the proposals in this paper and future papers. I do not intend to publish an exposure draft Bill.

Proactive Release

61 This paper will be proactively released within 30 days of being considered by Cabinet, with redactions as appropriate under the Official Information Act 1982. The associated Regulatory Impact Statements will be published on the websites of the Ministry of Health and the Treasury.

Recommendations

The Associate Minister of Health recommends that the Committee:

1 note that on 6 May 2024, Cabinet invited the Associate Minister of Health (Hon Casey Costello), in consultation with the Associate Minister of Health (Hon David Seymour) to report back to Cabinet on proposals for future direction for regulation of medicines and medical devices, and for natural health products [CAB-24-MIN-0154];

Proposed work programme and legislative framework

2 agree that the Medicines Act should be replaced with modern regulation of medicines and medical devices under a Medical Products Bill (the Bill);

3 agree that natural health products will be regulated under a standalone bill, to be developed following engagement with the natural health products sector;

Settings for a Medical Products Bill

4 authorise the Associate Minister of Health to issue a first tranche of drafting instructions for the Bill that includes the following settings:

Scope

4.1 that the Bill should cover medicines

4.2 that the Bill should cover medical devices in a manner and form that recognises the regulatory differences between medical devices and medicines

4.3 that the Bill include provisions enabling the exclusion of specific product types via secondary legislation

Purpose and principles

4.4 that the purpose of the Bill should express that legislation is to:

4.4.1 support improved health outcomes for all New Zealanders by enabling timely access to safe, high quality and effective medical products, and to do this by:

4.4.2 providing cost-effective assurance that medical products meet acceptable standards of safety, quality, and efficacy or performance.

4.5 that the overarching principles of the Bill should express the ideas that:

4.5.1 regulation should be proportionate to benefits and risks, and support timely access to medical products

4.5.2 the likely benefits of medical products should outweigh their likely risks

4.5.3 that regulation should recognise differences between product types, including the differences between medicines and medical devices

4.5.4 regulation should, where possible, be harmonised with international good practice, enabling reliance on assessments and decisions by trusted overseas regulators

4.5.5 the regulatory system should support innovation, competition, economic growth and exports in a way that maintains New Zealand's reputation as a producer of high-quality products.

Regulation of products

4.6 that the Bill should enable approval pathways for medicines, including:

4.6.1 a verification pathway along the lines agreed by Cabinet in June 2024 [SOU-24-MIN-0055]

4.6.2 an abbreviated assessment pathway, where a medicine has been approved by one trusted overseas regulator

4.6.3 a full assessment pathway

4.6.4 an expedited assessment pathway for use in response to public health emergencies

4.7 that the Bill should enable approval pathways for medical devices, similar to those listed in recommendation 4.6, but suited to the nature and risk profile of each type of medical device, and providing:

4.7.1 a self-declaration pathway for low-risk devices

4.7.2 verification pathways for products already approved by trusted overseas regulators

4.7.3 appropriate pathways for innovative devices and locally manufactured devices

4.8 that the Bill will enable new approval pathways to be created via secondary legislation, and enable exemptions from product approval and registration

4.9 that the Bill will enable appropriate regulation of blood, blood products and – excepted as provided below – other substances of human origin and biological materials derived from non-human sources including viruses, bacteria and animal cells and tissues

4.10 that the Bill will not require human organs and tissues intended for immediate donation to obtain any form of prior approval, and will regulate activities with those products

4.11 that the Bill will enable appropriate pathways to regulate patient-matched and custom-made medical devices, and patient-matched medical treatments, such as gene therapies and autologous treatments

4.12 that the Bill will not include any system of mandatory approval for medical products intended for export only

4.13 that the Bill will enable medicines and medical devices to be classified according to risk

4.14 that the Bill should provide for a product to be supplied to a patient without a product approval that would otherwise be required, if an appropriately qualified health practitioner considers this to be appropriate

4.15 that the Bill should allow individuals to continue to import medicines and medical devices for themselves or a person they are a caregiver for, with a requirement that import of prescription medicines requires a New Zealand prescription, and that they comply with any other restrictions

Regulated activities

4.16 that the Bill should provide for the regulation of some activities with medicines and medical devices, including manufacture, distribution, prescribing, and some types of supply, where regulation of the activity is necessary to protect consumer safety or public health

4.17 that the Bill amend the Healthcare Practitioners Competency and Assurance Act 2003 to enable Responsible Authorities to alter prescribing authority for a profession by modifying the scopes of practice

4.18 that any significant expansion of a profession's powers should require the consent of the Minister of Health

Drawing on the Therapeutic Products Act

4.19 that the following uncontentious provisions of the Therapeutic Products Act 2023 be drawn upon for the Bill, except in relation to natural health products:

4.19.1 part 7 on 'other regulatory matters'

4.19.2 part 8 on enforcement, except for sections relating to advertising, and subject to a review of penalty provisions

4.19.3 part 10 on administrative matters

Next steps

5 s 9(2)(f)(ii) [redacted]

6 s 9(2)(f)(iv) [redacted]

7 invite the Associate Minister of Health to report back to Cabinet by the end of the first quarter of 2025 on further policy proposals, including on clinical trials, regulating pharmacies, supporting exporters, statutory timeframes, advertising, offences and penalties, and a separate regulatory system for natural health products.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health