

In Confidence

Office of the Associate Minister of Health

Cabinet Social Outcomes Committee

Modernising regulation of medicines and medical devices: high-level regulator settings

Proposal

- 1 This paper seeks agreement in principle to high-level regulator settings for a medical products regulator for medicines and medical devices under the Medical Products Bill. These decisions will help inform costings work for a report back in December 2024 and a potential Budget 25 bid.

Relation to government priorities

- 2 This proposal supports priorities in the Government Policy Statement on Health 2024–2027, particularly access, timeliness, quality and supporting the health workforce.

Executive Summary

- 3 This paper is part of a report back, requested by Cabinet in May 2024, 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]. The proposals in this paper relate to medicines and medical devices only.
- 4 This paper sets out options for both the form of a medical products regulator and funding for a future regime. Initial analysis supports:
 - 4.1 expanding the existing regulator, Medsafe, so it can perform new functions relating to medical devices and post-market safety activities, and appointing an independent statutory officer to the regulator
 - 4.2 funding for the future ongoing operation of any regulator being a mixture of fees, levies, and Crown funding (similar to Medsafe’s current funding but with the addition of levies).
- 5 Building up the existing regulator is less expensive and less risky than establishing a new entity. An independent statutory officer is expected to deliver an appropriate level of independence and transparency into the regulatory design. A mixed funding model is most likely to support a well-functioning and sustainable regulatory system.
- 6 The future regulator’s core functions relate to product approvals, licenses for controlled higher-risk activities involving medical products, post-market surveillance, and compliance activities [SOU-24-MIN-0115]. As the new system will appropriately regulate medical devices and advanced cell and gene therapies, the future regulator would have a wider scope and bigger workload than Medsafe.

- 7 The Ministry of Health continues to develop policy for regulating medical products under a new Medical Products Bill. New funding is required to implement that Bill. This funding would support the delivery of highly technical secondary legislation, a regulator, and the development of a required digital platform, in anticipation of ‘going live’ by the end of 2028.
- 8 Cabinet in-principle decisions on regulator form and funding settings will assist the Ministry to develop costings for delivering secondary legislation, the regulator and specialist advice to source and identify an appropriate digital solution. With these costings I will seek final Cabinet agreement to form and funding settings in December 2024 and submit a Budget 25 bid, should I be invited to. In order to meet an anticipated 2028 ‘go live’ date, work needs to begin on delivering secondary legislation, the regulator and a technology solution from 1 July 2025.
- 9 section 9(2)(f)(iv)

Background

Report back on proposals for future direction

- 10 In May 2024, Cabinet invited me [SOU-24-MIN-0032], 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. I have consulted with Hon David Seymour on this paper.
- 11 Medsafe, the current regulator, is an effective regulator with specialist expertise but it is bound by the Medicines Act 1981 regulations and a digital platform which are not fit-for-purpose. As you are aware, Hon David Seymour is leading work to streamline Medsafe’s approval processes, including amending the Medicines Act to implement a verification pathway for medicines that have been approved by two trusted overseas regulators [SOU-24-MIN-0114]. However, there is only so much that can be done with legislation which is overly prescriptive and not fit-for-purpose; and with a digital platform that does not meet the needs of Medsafe or industry.
- 12 On 25 September 2024, Cabinet Social Outcomes Committee agreed 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 medical products [SOU-24-MIN-0115]. New legislation will create new possibilities for enhancing the performance of Medsafe as a regulator of medicines and medical devices.

Analysis

- 13 The Medical Products Bill will provide a modern regulatory regime, underpinned by internationally aligned secondary legislation and a contemporary digital platform that will reduce administrative overheads for industry, and improve the productivity of the

regulator. Overall, the new regime will provide for timely, transparent, flexible, and risk-proportionate regulation of medical products.

High-level settings for the form of the regulator – form follows objectives and functions

The medical products regulator will have a wider scope and range of functions than existing Medsafe

- 14 On 25 September 2024, Cabinet Social Outcomes Committee agreed that the medical product regulator’s core functions will relate to product approvals, licenses for controlled higher-risk activities, post-market surveillance, and compliance activities [SOU-24-MIN-0115].
- 15 The future regulator will have a wider scope, and therefore bigger workload, than the existing Medsafe. The Medical Products Bill may also give the regulator better tools to appropriately regulate innovative and emerging health-technologies (eg, gene therapies and software as a medical device), which the current Medicines Act 1981 is not capable of regulating. These additional tools will enable alignment with the new gene technology legislation currently being developed. Regulating these products will require specialist expertise which Medsafe does not currently have.
- 16 Consistent with Cabinet’s decision on the policy settings for the new Medical Products Bill [SOU-24-MIN-0115], the majority of medical devices are likely to have light-touch regulation (eg, approval following notification to the regulator). Nonetheless, the future regulator will still have a regulatory role involving these products, including managing their notification and auditing information. Industry, patients and practitioners also support an enhanced role in undertaking post-market surveillance and product safety activities for medicines and medical devices, which will result in a bigger workload for the new regulator.

Objectives

- 17 I consider that a successful medical products regulator will need to be:
 - 17.1 trusted by industry, consumers, health professionals and international regulators
 - 17.2 accountable for the performance of New Zealand’s medical products regulatory system
 - 17.3 appropriately resourced to build and sustain its regulatory capabilities and capacity
 - 17.4 empowered to work cooperatively with other health entities, domestic regulators and international medical products regulators.

Options for the form of the regulator

- 18 There will be high expectations from industry, health professionals and consumers for the regulator. In considering the form of the regulator, I considered independence,

cost effectiveness, transparency, accountability, responsiveness and flexibility (see assessment in the attached Regulatory Impact Statement).

- 19 I considered the following options for the form of the new regulator:
- 19.1 a branded business unit within the Ministry of Health (this is expanding Medsafe's current form)
 - 19.2 an independent statutory officer supported by a branded business unit within the Ministry of Health (expanding Medsafe and adding an independent statutory officer)
 - 19.3 a new Departmental Agency with an independent statutory officer
 - 19.4 a new Crown Entity.
- 20 While it is too early to determine exact costs for each option, it is clear that establishing a new entity, as per the third and fourth options, will cost more than the other options. Initial assessment of the options does not show sufficient benefits to justify this additional spending. For example sharing corporate activities such as IT support with the Ministry of Health will reduce costs to the Crown and industry. However, the regulator will still need to pay its share of those costs.
- 21 A branded business unit will also have lower implementation risks and faster establishment, especially if the form is effectively expanding Medsafe and adding an independent statutory officer to cover a broader range of regulatory functions. Medsafe's valuable intellectual property, technical medicines regulation expertise, institutional and process knowledge and stakeholder relationships can help build the regime.
- 22 An independent statutory officer can exercise, and is accountable for, their specific functions and powers under a Medical Products Act independently of the Director-General of Health and Minister of Health. This role will deliver a high degree of specialist oversight, transparency and regulatory independence than a branded business unit without an independent statutory officer.
- 23 The independent statutory officer option is consistent with industry feedback on the need for the regulator to have clear performance expectations and transparent reporting, particularly in relation to product approval timeframes. It is therefore my preferred option, subject to costings being developed for the December Cabinet paper and a potential Budget 25 bid. Given the above factors, the Ministry's significant experience in standing up regulatory regimes and regulators, and the Government's priority of reducing Crown spending, I propose that the December Cabinet paper focuses on only the two options to expand Medsafe.

Proposed High-level settings for the future funding of the regulator

- 24 Currently, most of Medsafe's costs are covered by user fees and charges (cost recovery). Cost recovery is consistent with international best practice. For a sense of scale, Medsafe's annual budget is \$17.198 million for 2024/25. Given the wider remit

proposed for the new regulatory regime, it is anticipated that any regulator would have a larger staff complement and budget when it goes operationally “live”.

25 I have considered three options for the future ongoing funding of the regulator:

25.1 the status quo of the regulator charging fees to mostly cost recover its operations, with Crown funding providing the balance of operating costs

25.2 full cost recovery from industry, with no Crown funding

25.3 extending the status quo mixed funding model (first option) to include levies for different sectors and actors within the medical products supply chain.

26 My initial analysis of these options supports retaining cost recovery and Crown funding, with an added power to set levies (third option). Fees and levies are expected to recover the costs of approvals, accreditation and certification activities, audits, official assurances and export certificates, international engagement and cooperation and monitoring and testing compliance. The Crown would fund other operating costs, such as enforcement activities. This option is consistent with Treasury guidelines. The Ministry will work with Treasury on these proposals as part of developing the December Cabinet paper, including the financial implications of each option in paragraph 25. All final proposals for fees and levies will be developed in consultation with industry during the development of secondary legislation.

Implementation

27 It is anticipated that the Medical Products Bill will be introduced to Parliament in late 2025. Crown establishment funding is required to deliver highly technical secondary legislation, a regulator and a digital platform in time for ‘go live’ by the end of 2028, noting that transitional periods will apply for products to become compliant.

Subject to new funding, work to implement the Bill will start on 1 July 2025

28 Developing secondary legislation will require significant technical support from Medsafe and external expertise, as well as ongoing engagement with industry. This work will need to be carefully managed to ensure the day-to-day work of Medsafe continues efficiently and is resourced effectively. Given the scale of secondary legislation required, the work will take about 24 months from 1 July 2025, before allowing for Cabinet approval and industry transition arrangements.

29 The regulator will utilise existing international and national standards to ensure effective regulatory functioning and alignment with counterparts. Medsafe’s close relationships with other medical products regulators will be leveraged in drafting of secondary legislation and in designing pathways for approving medical products. This will reduce the time and cost of developing secondary legislation, and uncertainty for industry.

Subject to new funding, a new digital platform is a significant enabler of the Bill

30 The new regime cannot go live without a new digital platform. The current Medsafe data platform dates back to 1996 and cannot be reconfigured. Costings for specialist

expertise to support identifying and sourcing an appropriate digital platform will be considered in the December Cabinet paper and a potential Budget 25 bid.section 9(2)(f)(iv)

- 31 Industry has long called for a new digital platform. Market authorisation applicants and licensees do not have a clear view of the progress of market authorisation, and license and approval applications. Manual activity and paper handling causes delays in identifying information gaps and is time consuming and cumbersome. Industry cannot upload applications seeking pre-market approval for medicines to the data platform or pay fees online. This can cause delays in approval and increased administration costs to both Medsafe and industry.

Next steps and timeframes

- 32 The Ministry will engage and work with industry peak bodies on implementation of the new regulatory regime. The required transition process will involve significant interaction with stakeholders to ensure that services are maintained and enhanced.

Milestone/Activity	Timeframe
Cabinet paper with a proposed way forward, including costings	December 2024
Budget 2025 bid submission (TBC)	December 2024
Second Cabinet paper on Medical Products Bill content, RIS, approval to draft Bill	Quarter One 2025
Medical Products Bill introduced to Parliament	Late 2025 (TBC)
section 9(2)(f)(iv)	
Medical Products Bill enacted	2026
Cabinet approval of regulations	2028
New regulator and medicines regulation regime goes live in tranches	From end of 2028
Sector transition over 5 years	End of 2028 to 2033

Cost-of-living Implications

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

Financial Implications

- 34 Implementation of the Medical Products Bill is dependent on new Crown funding. In particular, operational funding is needed to:

- 34.1 employ specialist and technical expertise for the development of secondary legislation, including back filling Medsafe staff where they are utilised
- 34.2 employ specialist expertise to transition the regulator to the future state
- 34.3 design and build a new digital platform for the regulator, as the existing Medsafe platform is not fit for purpose and cannot be reconfigured.

- 35 Development of secondary legislation is a core part of the Ministry's role. However, some of the new secondary legislation will be highly technical and require specialist expertise to ensure that it meets the needs of industry and the regulator. External expertise will also be required for the organisational design and delivery of the new regulator and digital platform.
- 36 As noted in paragraph 15 the regulator will have a wider scope than the current Medsafe. Future funding of the regulator will need to reflect its new roles and functions so it can be financially sustainable. Although some costs will be covered by fees and levies, some additional and ongoing Crown funding will be required.
- 37 To support informed Cabinet decision making, I propose to develop a December Cabinet paper, which will include:
- 37.1 the financial details and costs for the development of secondary legislation, the regulator build and identification of the digital platform solution to implement the Medical Products Bill
 - 37.2 seeking final Cabinet agreement to the regulator form and funding arrangements, noting functions and costs, and
 - 37.3 setting out in detail the implementation pathway with a focus on the legislative, transition and digital work programmes, governance arrangements, and key decision points over the next few years.
- 38 If a bid in Budget 2025 is unsuccessful, I will re-assess implementation plans with other Health Ministers and come back to Cabinet. Deferring this work would mean there is a risk to the Government of a Bill/Act with no implementation resources and therefore a commencement date that cannot be met.

Legislative Implications

- 39 On 25 September, Cabinet agreed to core policy elements of a new Government bill, the Medical Products Bill. This bill will need to include the form of the regulator and how the regime will be funded.

Impact Analysis

Regulatory Impact Statement

- 40 A Regulatory Impact Statement has been prepared and attached to this Cabinet paper. It covers the form of the regulator and funding settings. The Ministry of Health QA panel has reviewed the Impact Statement titled "*Entity form and cost-recovery settings for a medical products regulator*", 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

- 41 The Climate Implications of Policy Assessment (CIPA) team confirms that CIPA requirements do not apply to this proposal as it not expected to result in any significant, direct emissions impacts.

Population Implications

- 42 Appropriate regulation of medical products is important for all New Zealanders. Almost everyone will use medical products at some point in their lives, so it is vital for everyone that these products do what they claim, are of high-quality, and that product approval pathways do not create unnecessary barriers to timely access.
- 43 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.
- 44 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.

Human Rights

- 45 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

- 46 No external resources were used to produce this paper.

Consultation

- 47 The following agencies have been consulted on this paper: The Treasury; Public Service Commission; the Ministry for Regulation; the Ministry of Business, Innovation and Employment; Office for Māori Crown Relations; Health New Zealand; ACC; Pharmac and the Commerce Commission. The Department of the Prime Minister and Cabinet was informed.
- 48 The Public Service Commission support the regulator being established as an independent statutory officer supported by a branded business unit in the Ministry of Health and the December Cabinet paper being focussed on how to deliver the regulatory functions under this model.
- 49 The Ministry will provide further advice to Treasury on the build of the digital platform and submit a risk-profile assessment in 2025. If Treasury determines the digital build is high-risk, a Gateway review will be completed before a business case goes to Cabinet.

50 On 23 September 2024, my office met with the Prime Minister's Office where it was agreed to revise this Cabinet paper to clarify that the initial preferred options involve Medsafe continuing as a branded business unit (with or without an independent statutory officer), rather than creating new entities.

Communications

51 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

52 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 Statement will be published on the websites of the Ministry of Health and Ministry for Regulation.

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]
- 2 note Cabinet Social Outcomes Committee agreed to core policy elements of a Medical Products Bill to replace the Medicines Act 1981 and for me to issue initial drafting instructions for a modern, risk-proportionate law to regulate medicines and medical devices (medical products) [SOU-24-MIN-0115]

Form and functions of the Regulator

- 3 note the core functions of the regulator will relate to product approvals, licences for controlled higher-risk activities, post-market surveillance and compliance activities [SOU-24-MIN-0115]
- 4 note that I have considered four options for the form of the medical products regulator:
 - 4.1 a branded business unit within the Ministry of Health
 - 4.2 an independent statutory officer supported by a branded business unit within the Ministry of Health (my preferred option)
 - 4.3 a new Departmental Agency with an independent statutory officer
 - 4.4 a new Crown Entity
- 5 agree in-principle to the form of the medical products regulator being an independent statutory officer supported by a branded business unit within the Ministry of Health, subject to costings being presented to Cabinet in December 2024

High-level settings for the funding of the regulator

- 6 note that I have considered three options for funding the medical products regulatory regime:
 - 6.1 the status quo of the regulator charging fees to mostly cost recover its operations, with Crown funding providing the balance of operating costs
 - 6.2 full cost-recovery from industry, with no Crown funding
 - 6.3 extending the status quo mixed funding model (first option) to include levies for different sectors and actors within the medical products supply chain (my preferred option)
- 7 agree in-principle to the medical products regulatory regime being funded by extending the status quo under the Medicines Act 1981 to include levies for different sectors and actors within the medical products supply chain, subject to costings being presented to Cabinet in December 2024
- 8 note that to implement the Medical Products Bill the following is required:
 - 8.1 development of highly technical secondary legislation
 - 8.2 development of and transition to a medical products regulator
 - 8.3 development of a digital platform to enable the new regime
- 9 9(2)(f)(iv)
- 10 agree that the December Cabinet paper will either
 - 10.1 only consider the first two options for the entity form of the regulator in recommendation 4, reflecting the higher costs and risks of establishing a new entity compared to a branded business unit within the Ministry of Health (recommended), *or*
 - 10.2 consider all four options in recommendation 4
- 11 invite the Associate Minister of Health (Hon Casey Costello), in consultation with the Associate Minister of Health (Hon David Seymour) to report back to Cabinet in December 2024 on the preferred way forward, including costings.

Authorised for lodgement

Hon Casey Costello

Associate Minister of Health