Briefing

High level settings for a medical products regulator

Date due to MO:	16 August 2024	**Action required by:**	21 August 2024
Security level:	SENSITIVE-BUDGET	**Health Report number:**	H2024046953
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health Hon David Seymour, Associate Minister of Health and Minister of Regulation		
Consulted:	Health New Zealand: ☒		

Contact for telephone discussion

Name	Position	Telephone
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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

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Purpose of report

1. This briefing seeks your decisions on high level settings for a future medical products regulator, and on a Budget 2025 bid to support implementation.

Summary

2. In May 2024, Cabinet invited you, in consultation with the Hon David Seymour, Associate Minister of Health, to report back before the end of November 2024 on proposals for the future regulation of medicines and medical devices, including financial implications [CAB-24-MIN-0154].

3. You have agreed to high-level policy settings for a Medical Products Bill to regulate medicines and medical devices, and discussed these settings with Minister Seymour [H2024045831]. Based on your decisions, we now seek your agreement, in consultation with Minister Seymour, on high-level settings for a medical products regulator and on a Budget 2025 bid to support implementation.

4. Based on your earlier decisions, the future regulator's core functions will relate to product approvals, licenses for controlled higher-risk activities, post-market surveillance, and compliance activities. As the new system will appropriately regulate medical devices and innovative products (eg, gene therapies and software as a medical device), the future regulator will have a larger workload than Medsafe.

5. We considered the following four options for the regulator's form:

    a. a branded business unit (BBU) model (similar to Medsafe)

    b. an independent statutory officer (ISO) supported by a BBU within the Ministry of Health (our recommended form based on cost-effectiveness and stronger form of regulatory and financial independency than option a)

    c. a new departmental agency with an ISO

    d. a Crown entity.

6. An independent statutory officer, supported by a branded business unit would have stronger form of regulatory independency while being accountable to the Director-General of Health for their general performance and subject to general government policy. The Minister of Health or Director-General of Health would not have a role in decisions on specific products or licence applications.

7. Currently, most of Medsafe's costs are covered by user fees and charges (cost-recovery). We recommend retaining cost-recovery as the primary basis for funding the new

regulator and regime, including through levies. We also recommend that the regulator receive some Crown funding to provide the balance of operating costs and to enable mechanisms such as fee waivers for non-commercial activities.

8. We recommend that you discuss the matters covered in this paper with Minister Seymour, Hon Dr Shane Reti, Minister of Health, and Hon Nicola Willis, Minister of Finance. Implementation of this work programme depends on a successful Budget 2025 bid. A paper to Cabinet in September 2024 will seek Cabinet approval for the form of the regulator, cost recovery options and the development of a Detailed Business Case to support a Budget 25 bid.

Recommendations

We recommend that you:

a)	**Note** that Cabinet invited you, in consultation with the Hon David Seymour, Associate Minister of Health, to report back before the end of November 2024 on proposals for the future regulation of medicines and medical devices, including financial implications [CAB-24-MIN-0154]	**Noted**
b)	**Note** that you have agreed to high-level policy settings for a Medical Products Bill to regulate medicines and medical devices, and discussed these settings with Minister Seymour [H2024045831]	**Noted**
c)	**Agree** that the medical products regulator should be an independent statutory officer, supported by a branded business unit within the Ministry of Health	**Yes / No**
d)	**Agree** that the regulator will be accountable to the Director-General of Health for their general performance and subject to general government policy, but make independent decisions on specific products or licence applicants	**Yes / No**
e)	**Agree** to the funding settings in this paper, including a mix of cost-recovery (including levies) and Crown funding	**Yes / No**
f)	**Note** that implementation of this work programme depends on a successful Budget 25 bid	**Noted**
g)	**Agree** to seek Cabinet agreement to the form of the regulator, cost recovery options and to develop a Detailed Business Case to support a budget bid, before the end of September 2024	**Yes / No**
h)	**Discuss** the matters in this paper with Minister Seymour, Hon Dr Shane Reti, Minister of Health, and Hon Nicola Willis, Minister of Finance	**Yes / No**

Maree Roberts

Deputy Director-General

Strategy, Policy and Legislation

Date: 16 August 2024

Hon Casey Costello

Associate Minister of Health

Date:

High level settings for a medical products regulator

Background

9. In May 2024, Cabinet invited you, in consultation with Associate Minister of Health, Hon David Seymour, to report back before the end of November 2024 on proposals for the future regulation of medicines and medical devices (medical products), including financial implications [CAB-24-MIN-0154]. The financial implications will depend on decisions on the regulator and regulatory regime.

Policy decisions on a new Medical Products Bill

10. You discussed future legislation with officials over May and June 2024. You agreed that:

    a. there will be a Medical Products Bill to regulate medicines and medical devices, and a separate bill to regulate natural health products

    b. the Medical Products Bill will be enacted in this term of parliament

    c. regulation will cover products and some activities, and that the degree of regulation (for example product approval pathways) will be proportionate to risk

    d. there will be appropriate regulatory mechanisms for innovative and non-standard products and treatments, including products which may be invented in the future

    e. some products will be exempt from any requirement to have product approval

    f. elements of the TPA that were consistent with modern drafting practice for regulatory bills will be carried over.

11. section 9(2)(g)(i)

Current regulation of medicines and medical devices

12. The Medicines Act 1981 (the Medicines Act) places many core regulatory powers with the Minister of Health, which are exercised by Medsafe under delegation. This model does not enable an easy separation of performance and monitoring. It also makes the Minister responsible for technical decisions that have significant impacts on private interests, and which ought to be directly conferred on a more appropriate entity.

13. Medsafe is a branded business unit in the Ministry of Health. It functions on a cost-recovered basis, with fees and charges covering around 90% of its costs. Medsafe is budgeted for 83.86 FTE in the 2024/2025 financial year. This is relatively small by international standards; less than 10% of the size of equivalent regulators in Australia and Singapore. This difference is partly due to medical devices being essentially unregulated.

14. Medsafe does not have operational or budgetary independence, nor does the Medicines Act set out specific accountability arrangements for its performance. section 9(2)(g)(i)

High level policy settings for a future medical products regulator

15. This section presents advice on a future regulator, specifically:

a. objectives
b. functions
c. options for the form of the regulator
d. accountabilities
e. funding settings.

Objectives for the new regulator

16. We consider that a successful medical products regulator will need to be:
    a. trusted by industry, consumers and international regulators
    b. accountable to the Minister of Health and other parts of the health system for the performance of New Zealand's medical products regulatory system
    c. appropriately resourced to build and sustain its regulatory capabilities and capacity
    d. empowered to work cooperatively with other health entities, domestic regulators, and international medical products regulators.

Functions of the future regulator

17. Appendix 1 lists the indicative functions of a medical products regulator under the Medical Products Bill, based on your policy decisions. Its core functions relate to product approvals, licenses for controlled higher-risk activities, post-market surveillance, and compliance activities.

18. The future regulator will also be regulating innovative and unusual products (eg, gene therapies and software as a medical device), which the Medicines Act is not capable of regulating. Regulating these products will involve specialist expertise which Medsafe does not currently have. While the majority of medical products are likely to have light touch regulation, the future regulator will still have a regulatory role involving these products, which is likely to incur a bigger workload for the new regulator than Medsafe.

Options for the form of the medical products regulator

19. We considered the following options for the form of the new regulator:
    a. a branded business unit (BBU) within the Ministry of Health (similar to Medsafe)
    b. an independent statutory officer (ISO) supported by a BBU within the Ministry of Health (provides more protection of regulatory and financial independence than option a)
    c. a new Departmental Agency with an ISO (operationally autonomous agency hosted by and legally considered part of the Ministry of Health, established under the Public Service Act 2020; this option requires the disestablishment of Medsafe and setting up a new entity)
    d. a new Crown Entity (governed by a board and accountable to the Minister via letter of expectations; this option requires the disestablishment of Medsafe and setting up a new entity).

20. A detailed description and analysis of these options are set out below.

Regulator Entity Form Options and Analysis

Option and description	Analysis	Implementation option
Option a Branded business unit (BBU) within the Ministry of Health. **Description of option** This option is similar to the status quo, as Medsafe is a BBU within the Ministry. Under this option, Medsafe/the regulator would have a wider role and responsibilities as provided by a new Medical Products Bill and proportionately more resources (eg, pre-market assessment of high-risk medical devices). The statutory powers of the regulator would be vested in the Director-General and be delegated to appropriate staff within the Ministry.	**Pros:** • Cost-effective to implement • Timely to implement • Least new funding required for establishment • Existing technical knowledge is retained (for medicines) • Least potential of disruption to Medsafe's current work pre-commencement of a new Medical Products Bill. **Cons:** • Weaker regulatory and financial independence than other options • Less clarity over decision-making than other options (eg, between the regulator and Director-General; and the regulator and the Minister) • Does not address potential conflict of interest where regulator needs to engage with Director-General or Ministry of Health as a regulated party (eg, where the Ministry or a Health entity purchases medicines or medical devices).	The BBU within the Ministry of Health option can be done by expanding/adapting/rebranding the current organisational and operational structures/functions of Medsafe.

Option b [recommended option] A BBU, headed by an independent statutory officer (BBU + ISO). **Description of option** A BBU within the Ministry headed by an ISO. In this option, the statutory powers of the regulator would be vested in the ISO who would: • be appointed by the Director-General and accountable to the Director-General for the performance of their functions and duties, and the exercise of their powers • be a person who the Director-General is satisfied has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the regulator • exercise their functions and powers as regulator independently of the Director-General and Minister • operate within the Government's and Ministry's strategic and policy framework • be supported by protected funding within the overall Vote Health. Examples of an ISO are the Director of Radiation Safety under the Radiation Safety Act 2016, and the Standards Executive under the Standards and Accreditation Act 2015.	This option is similar in practice to the status quo but would represent an enhancement on option a in several important ways. This option was adopted for the TPA. **Pros:** • Cost-effective to implement • Timely to implement • Less new funding required for establishment than options c and d • Existing technical knowledge can be retained (for medicines) • More protection for regulatory independence than option a as decision-making functions of ISO are specified in legislation • More clarity around accountability than option a as relationship with the Director-General and Minister of Health specified in legislation **Cons:** • Slightly longer establishment time than option a, due to need to recruit and appoint ISO • Less strong form of regulatory and financial independence than options c and d	This option can be implemented by either of the following approaches: • expanding/adapting Medsafe, or • standing up a new organisational structure (ie, disestablish Medsafe). Both models of transformation of Medsafe would require a certain degree of change management, data transfer, training and other operational transitions prior to the implementation of a new Medical Products regime. While further work is needed to advise on the exact costing of each approach, adopting the first approach (expanding/adapting) to implementation would likely reduce the costs of establishing a new regulator, and disruption to the current work of Medsafe.

Option and description	Analysis	Implementation option
Option c Departmental agency with an independent statutory officer (ISO). **Description of option** An operationally autonomous agency hosted by, and legally considered part of, the Ministry, established under the *Public Service Act 2020*. The Departmental Agency (DA) would: • be headed by its own chief executive, who would be directly responsible to the Minister of Health • contain an ISO, who may or may not be the chief executive, who would exercise the statutory powers of the regulator • receive corporate services from the Ministry, unless other arrangements were agreed by both chief executives. The DA could operate within the Government's and Ministry's overall strategic and policy framework.	**Pros:** • Faster and cheaper to implement than option d • Stronger form of regulatory independence than options a and b (ie, the regulator's day-to-day operations as well as decision-making are at arm's length from the Director-General and health entities) • Financial independence that could enable the regulator to set up systems that enables it to discharge its responsibilities well (as it is stated as a con above in options a and b) • Stronger transparency and accountability than options a and b **Cons:** • More establishment costs than options a and b, especially if a new chief executive is required in addition to the ISO • Higher operating costs than options a and b • Longer establishment time than options a and b (eg, appointment of a chief executive and an ISO)	This option requires disestablishment of Medsafe and standing up a new agency Existing Medsafe staff can remain employed by the Ministry of Health but will work for the DA.

Option and description	Analysis	Implementation option
Option d Crown entity A separate Crown entity. **Description of option** The regulator is established as a Crown Entity that exercises power under a new Medical Products Bill. The entity would be governed by a board and accountable to the Minister in relation to the letter of expectations. Government could still issue letters of expectation to set broad policy parameters and to require the entity to act consistently with whole-of-health system Government policy. Note: Cabinet rejected the Crown entity option in 2018 and confirmed this decision in 2021.	**Pros:** • Strongest form of statutory independence to exercise regulatory powers (ie, the regulator's operations are at arm's length from Ministers.) • Financial independence that could enable the regulator to set up systems that enables it to discharge its responsibilities well. **Cons:** • Most expensive option to implement (eg, longest and most complex establishment process and additional operational costs due to a need to maintain separate board and corporate functions). • Note: These additional costs could be borne by the sector due to cost-recovery framework. • Harder to keep the regulator connected with the wider Ministry and other health entities, and position it close to Ministers in support of international co-operation with other regulators. • Option unlikely to be supported by the PSC, Treasury or Department of Prime Minister and Cabinet.	This option requires disestablishment of Medsafe and standing up a new entity. A chief executive and board would need to be appointed. Existing Medsafe staff would need to be transferred to the new agency.

21. We **recommend option b**, for three key reasons:

    a. a BBU is more cost-effective and quicker to establish than the new entities under options c and d

    b. an ISO can exercise their powers independently of the Director-General of Health and Minister of Health, delivering a higher degree of regulatory, operational and financial independence than a BBU without an ISO

    c. keeping the regulator within the Ministry of Health will enable a more seamless transition from the existing regime, including retaining existing technical knowledge for medicines.

22. Option b is consistent with industry feedback on the exposure draft of the Therapeutic Products Bill (TPB), in which they called for the regulator to have clear performance expectations and transparent reporting, particularly in relation to product approval timeframes.

23. Option b is broadly the same as the entity form proposed under the Therapeutic Products Act (TPA). Objections to the Therapeutic Products Regulator mostly concerned regulation of natural health products, or were based on the misunderstanding that the regulator would be an individual. Concerns that products would be regulated inappropriately are addressed via policy on the regulatory system.

Accountabilities of the regulator

24. We propose that a new Medical Products Bill clearly set out the regulator's relationship and accountabilities to the Minister of Health and Director-General of Health.

25. The Minister of Health should be specifically enabled to issue a general policy direction to the regulator. A direction could deal with matters such as how the regulator applies its risk framework to certain classes of products, development of approval pathways for innovative products, and timeliness and transparency in decision making.

26. The regulator should be accountable to the Director-General for the general performance of their functions. They should also be required to publish a Regulatory Strategy. This will enhance transparency over the approach the regulator intends to adopt to classes and types of products, its approach to risk, and how it will approach its compliance and enforcement powers.

27. We do not recommend that the Minister of Health or Director-General have a direct role in individual product approval or licensing decisions. Independence on these matters will support regulatory certainty.

28. Industry stakeholders have requested that future legislation include statutory timeframes for decisions such as product approvals. We will provide you with advice on statutory timeframes by the end of 2024.

Funding settings of proposed regulator

29. In line with Treasury guidelines, the Ministry proposes a funding regime that:

    a. reduces reliance on funding from general taxation

    b. places costs on regulated parties singly (either by group or generally)

    c. recognises the public and merit goods from effective regulation of medical products.

30. Currently, most of Medsafe's costs are covered by user fees and charges (cost-recovery). We propose to retain cost-recovery as the primary basis for funding the new regulatory and regime, including through industry levies.

31. We also propose that the regulator receive some Crown funding to provide the balance of operating costs and enable mechanisms such as fee waivers and exemptions. These could incentivise the transition of products to the new regime earlier; support non-commercial clinical trials, or aid approval pathways for domestically produced innovative products.

32. The table below shows the activities needed for the effective administration of a medical products regulatory scheme and our recommended funding settings for each activity.

Proposed funding mechanisms for regulator's activities

Activity	Fees	Levies	Crown funding
Approval, accreditation, and certification activities	✓		
Monitoring and testing compliance		✓	
Audits of individual businesses	✓		
Investigations and enforcement action, including prosecutions			✓
Policy advice and legislative change *[note: under options a and b, this cost would be undertaken by the Ministry and met through Ministry baselines]*			✓
Guidance			✓
Development of regulations, rules and notices			✓
International engagement and cooperation through work-sharing, joint assessments and standard setting		✓	
Official assurances and export certificates	✓		
Medicine misuse containment			✓
Enablers (one-off)			
Regulator (establishment or redevelopment)			✓
Digital platform (Implementation and training)			✓
Optional activities (depending on future Government decisions)			
Developing export standards			✓
Developing and maintaining market access		✓	

33. The proposed model is consistent with industry feedback on the exposure draft of the TPB, where submitters stated that industry should not be charged for policy development, or the costs of establishing the new regime.

34. Further analysis is required to inform the exact split of fees/levies and Crown funding, as well as overall funding. This will be covered in a high-level model for cost recovery the Ministry of Health is developing, and a Detailed Business Case discussed below. All final proposals for fees, charges and levies will be developed in consultation with industry during the development of secondary legislation.

Financial implications

35. Implementation of this work programme is dependent on a successful Budget 25 bid. In particular, funding is needed to:

    a. procure and build a new digital platform for the regulator (the existing Medsafe platform is not fit for purpose for the regulatory regime)

    b. employ specialist and technical expertise for the development of secondary legislation

    c. employ specialist expertise to establish the regulator.

36. 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 in order to ensure that it meets the needs of industry and the regulator. It is important that this work start as soon as possible to allow engagement with industry and ensure regulatory certainty before the new regime takes effect. External expertise will also be required for the development of the IT Platform and the organisational design of the new regulator.

37. The Budget bid will require a Detailed Business Case, which requires Cabinet agreement before the end of November 2024. If you agree, we will prepare a paper seeking Cabinet agreement to the Detailed Business Case.

38. If a bid to Budget 25 is unsuccessful, we will re-assess the approach to delivering the programme of work and provide you with advice on how to proceed at that point.

Equity

39. 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, which further increases the impact of higher costs.

Next steps

40. If you agree to the recommendations in this paper, we will develop a paper for you to take to Cabinet in September 2024, alongside a parallel paper on policy settings for a new Medical Products Bill. This paper will also seek Cabinet's agreement to develop a Detailed Business Case, which will be submitted to Cabinet in November 2024.

41. We recommend that you discuss this paper with your colleagues, the Minister of Health, Hon Dr Shane Reti and the Associate Minister of Health and Minister for Regulation, Hon David Seymour, and the Minister of Finance and Minister for Public Service, Hon Nicola Willis.

ENDS.

Minister's Notes

Appendix 1 – Indicative functions for a medical products regulator

Regulating medical products

(a) to regulate the availability and use of medical products, including by—
    i. issuing product approvals, including following a verification of decisions and assessments by designated approval bodies
    ii. developing systems to enable registration of low-risk medical devices, approved by designated approval bodies
    iii. granting licences and permits
    iv. regulating the carrying on of controlled activities and other supply chain activities
(b) to carry out post-market surveillance
(c) to take action to address issues relating to—
    i. the safety, quality, and efficacy of medicines and APIs
    ii. the safety, quality, and performance of medical devices
(d) to monitor and enforce compliance with this Act.

Engagement with other entities

(e) to foster co-operative and consultative relationships with—
    i. other health entities under the Pae Ora (Healthy Futures) Act 2022; and
    ii. regulators or administering agencies for relevant laws (eg, the proposed new Gene Tech Regulator)
(f) to engage and co-operate with relevant government, local government, and non-government entities (including regulators), including by sharing information
(g) to engage and co-operate with overseas regulators and overseas organisations, including—
    i. by sharing information; and
    ii. by providing assistance to, and seeking assistance from, those organisations; and
    iii. to facilitate the Regulator being able to rely on their reports, assessments, or decisions, or information received from them
(h) to ensure that New Zealand participates in overseas organisations and forums relating to the regulation of therapeutic products.

Information

(i) to collect, analyse, and make available (including to the public) information relating to—
    i. the safety, quality, and efficacy or performance of medical products
    ii. the performance of the regulator of their functions (including matters relating to the timeliness of decision-making by the regulator)
    iii. any other matters relating to medical products
(j) to provide guidance, advice, and information about medical products to—
    i. persons to whom this Act applies (including sponsors, licensees, permit holders, and persons in the supply chain)
    ii. other persons and entities who are concerned with medical products (including, but not limited to the Director-General of Health, the Chief Executive of a Health Entity, and the Minister of Health)
    iii. the public
(k) to issue official statements.

Engagement with users of medical products and the activities of the regulator

(l) to engage with individuals and population groups, including Māori, in a manner that reflects their needs and aspirations in relation to medical products.

Advice to chief executive and Minister

(m) to monitor the adequacy and performance of, and funding for, the regulatory system for medical products, and to provide advice about those matters to the Director-General of Health and the Minister

(n) to provide any other relevant information and advice about medical products to the chief executive of the Ministry of Health and the Minister of Health, on request.

Other functions

(o) to perform any other functions conferred on the Regulator under this or any other Act.