Regulatory Impact Statement: Entity form and cost-recovery settings for a medical products regulator

Coversheet

Purpose of Document	
Decision sought:	Analysis produced for the purpose of informing initial Cabinet decisions on the entity form and cost-recovery settings for a medical products (medicines and medical devices) regulator.
Advising agencies:	Ministry of Health | Manatū Hauora
Proposing Ministers:	Hon Casey Costello, Associate Minister of Health
Date finalised:	29 August 2024

Problem Definition

Consumers and medical professionals usually cannot establish the safety, quality or efficacy of a medicine for themselves; and unsafe, low quality and/or ineffective medicines can cause death and other serious harm. The Medicines Act 1981 (Medicines Act) is the primary legislation that enables evaluation of the safety, quality and efficacy of medicines before they are available for public use.

The Medicines Act places many core regulatory powers with the Minister of Health, which are exercised by Medsafe (a branded business unit within the Ministry of Health) 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.

Medsafe 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 in New Zealand.

Medsafe does not have operational or budgetary independence, nor does the Medicines Act set out specific accountability arrangements. These gaps present challenges to Medsafe's financial sustainability. Its current funding basis means that it cannot adequately support all its necessary activities.

Executive Summary

Medicines are currently regulated under the Medicines Act. The Medicines Act is outdated, inflexible and no longer fit for purpose, particularly in relation to innovative treatments such as gene therapies. It also fails to recognise the expertise of many health practitioners and provide meaningful safeguards around the supply of unapproved medicines. It also creates barriers to timely access to essential and novel products due to a lack of statutory powers to rely on other trusted international regulators of medical products.

The future regulator for medical products (medicines and medical devices) will be regulating innovative and unusual products (eg, gene therapies and software as a medical device). Regulating these products will involve specialist expertise which Medsafe does not currently have. The future regulator will have a regulatory role involving these products, which is likely to incur a bigger workload for the new regulator than that currently of Medsafe.

Entity form

The Ministry of Health's preferred option for the entity form of a new medical products regulator is an independent statutory officer supported by a branded business unit for the following three reasons:

- an independent statutory officer can exercise, and is accountable for, their specific functions and powers under a Medical Products Bill independently of the Director-General of Health and Minister of Health; delivering a higher degree of specialist oversight, transparency and regulatory, operational and financial independence than a branded business unit without an independent statutory officer
- 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
- a branded business unit is more cost-effective and quicker to establish than new entities such as a Departmental Agency or a Crown Entity.

The Ministry's proposed option is consistent with industry feedback received during the development of the Therapeutic Products Bill during 2018/2019 and 2022 public consultations. Industry called for the regulator to have clear performance expectations and transparent reporting, particularly in relation to product approval timeframes.

Cost-recovery settings

Currently, most of Medsafe's costs are covered by user fees and charges (cost-recovery). The Ministry proposes to retain this approach as the primary basis for funding the new regulatory regime under a Medical Products Bill (the Bill), including through industry levies. The Ministry also proposes 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 early transition of products to the new regime; support non-commercial clinical trials, or aid approval pathways for domestically produced innovative products.

Limitations and Constraints on Analysis

The Associate Minister of Health, Hon Casey Costello wishes to have new legislation enacted within this term of Parliament. This involves short timeframes for policy development, relative to the number and complexity of decisions needing to be made. There has been extensive prior policy development and stakeholder engagement, including on development of the Therapeutic Products Act. However, there has been limited time to assess new evidence or test policies which differ significantly from both the status quo and the Therapeutic Products Act.

Improving access to medicines is a Government priority, as is reducing regulation and government spending. This has limited the scope of potential policies, as we have assumed that options involving more regulation will not be considered unless there is compelling rationale.

We have treated policies agreed by Cabinet in 2024 but not yet implemented, such as the verification pathway for medicines approval, as part of the status quo.

Under the Medicines Act and the proposed future regulatory system, the funding of medicines and approval process for medicines are separate, and carried out by different entities. This RIS therefore does not address funding issues. Where it refers to access, this does not include issues of funding or affordability of medicines.

Implementation of the new medical products work programme is dependent on successful Budget 2025 and 2026 bids. In particular, funding is needed to:

- procure and build a new digital platform for the regulator (the existing Medsafe platform is not fit for purpose for the regulatory regime)
- employ specialist and technical expertise for the development of secondary legislation
- employ the specialist skills required to design and establish the regulator.

Responsible Manager(s) (completed by relevant manager)

John McGrath

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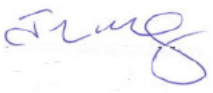

26 August 2024

Quality Assurance (completed by QA panel)

Reviewing Agency:	Ministry of Health internal QA panel
Panel Assessment & Comment:	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.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo and context expected to develop?

1. In recent decades the regulation of medicines has increasingly become internationalised. Various international bodies, including the World Health Organization and harmonisation groups, have established common regulatory norms, benchmarks and minimum requirements for the manufacture of medicines and the processes by which medicines are evaluated (e.g., for quality, safety and efficacy) and approved. Efficiencies in regulation can be achieved through engagement in joint assessments and work-sharing programmes. However, participation in these programmes requires local regulation to meet international norms.
2. Medicines are currently regulated under the Medicines Act 1981 (Medicines Act) and the Medicines Regulations 1984, which control how medicines can be manufactured, prescribed and supplied in New Zealand. The Medicines Act imposes some post-market obligations on product sponsors and grants the Crown limited post-market powers.
3. Currently, the Medicines Act is administered by Medsafe as a branded business unit in the Ministry of Health. Medsafe also houses the Psychoactive Substances Regulator and has responsibilities under the Misuse of Drugs Act 1975 and the Smokefree Environments and Regulated Products Act 1990. Regulation of medicines is currently undertaken on a cost-recovered basis, with Medsafe reporting that fees and charges cover approximately 90% of Medsafe's costs.
4. The Medicines Act places many core regulatory powers with the Minister of Health. In practice, the power held by the Minister of Health to approve medicines is exercised by the Group Manager of Medsafe under delegation from the Minister. This is a dated practice. Modern regulatory schemes clearly place these substantive regulatory powers at arm's length from the Director-General of the Ministry of Health and Ministers to ensure independence in decision-making, particularly where there are vested interests and highly technical subject matter. Such a scheme is exemplified by the Director for Radiation Safety appointed as an independent statutory officer under the Radiation Safety Act.
5. While part of the Ministry, Medsafe has a separate identity in the sector. Previous consultation with the sector shows that Medsafe is generally seen as a trusted regulator and administrator of the Medicines Act. However, from a technical perspective it does not have operational or budgetary independence, or specific accountability arrangements. These gaps present challenges for Medsafe and mean that in its current form it cannot adequately support all its necessary activities.

The entity form and its funding need to support the wider functions of the new regulator and future trends

6. The new regulatory regime under the Bill will provide more clarity around functions and accountability than the status quo as the relationship with the Director-General and Minister of Health will be specified in legislation. For example, the new regulator will be the point where regulatory powers are vested in ensuring the safety, quality and efficacy or performance of regulated products across their lifecycle. It will:
    a. design and implement risk-proportionate market authorisation pathways to support the timely availability of safe, effective and high-quality medical products
    b. engage with international counterparts, industry sectors, and across government (eg, with Health New Zealand, Pharmac and other health entities specified in the Pae Ora (Healthy Futures) Act 2022).
7. The new regulatory regime for medical products will also differ from the status quo in a number of respects. Notably it will:

a. be more comprehensive and have greater reach, covering considerably more products (particularly medical devices and gene therapies) and regulatory responsibilities in relation to activities such as for pre-market application processes, audits, inspections and compliance monitoring

b. have greater regulatory independence and commensurately greater accountability.

8. To be effective in delivering these functions, the regulator will need to be resourced and empowered to deal with new, complex and specialised treatments and products coming on the market[1]. This will require specialist staff.

9. The new regulator will be larger than Medsafe and require additional revenue to meet its costs and deliver a sustainable regulatory regime. 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 new regulator would have a larger staff complement and budget.

What is the policy problem or opportunity?

10. The Medicines Act has been considered out of date since the 1990s. This view has been shared by successive governments, practitioners, industry and the public. The Therapeutic Products Act 2023 (Therapeutic Products Act) was enacted in 2023 and was intended to replace the Medicines Act with modern legislation which would appropriately regulate medical devices and innovative medicines such as biologics. It would also have regulated natural health products.

11. There were concerns from industry and other stakeholders that the Therapeutic Products Act) would have made product approvals too difficult, expensive and/or time-consuming to obtain, particularly for natural health products and lower-risk medical devices. As a result, a bill to repeal the Therapeutic Products Act is currently before the Health Committee. Instead, the Government has decided to develop a modern, risk proportionate regulatory regime for medicines and medical devices, and a separate modernised regime for natural health products [CAB-24-MIN-0154]. Repeal of the Therapeutic Products Act means status quo regulation under the Medicines Act will continue.

Entity form of the future regulator

12. Selecting an appropriate entity form of the regulator is critical to the success of the regulatory regime. It must support operational independence and clear accountability, sustain capacity and capability, provide a positive regulatory culture, be organisationally effective, and have enough flexibility to adapt to changing and new expectations.

13. In addition to achieving the objectives of the proposed Medical Products Bill, the form of the regulator also needs to work as an integral part of the wider health and disability system and contribute to achieving a vision of pae ora/healthy futures for all New Zealanders.

14. To ensure the regime is effectively and sustainably delivered, consistent with its agreed objectives and legislative principles, the regulator will need a level of independence. Independence includes regulatory, operational, institutional and budgetary independence. Operational independence allows a regulator to make decisions without undue industry or political interference, and in a manner independent from other actors within the health system such as the Director-General of Health, or Health New Zealand.

[1] Including advanced cell therapies, gene therapies, nano-therapeutics, hybrid technologies (with biological and mechanical components), and artificial intelligence and medical software.

Funding the regulator – cost-recovery

15. The options considered included:

    a. continuing with the status quo of the regulator charging fees to mostly cost-recover its operations, with Crown funding providing the balance of operating costs. Most fees and charges are applied to transactions (eg, processing applications)

    b. full cost-recovery (ie, all operating costs from industry with no Crown funding)

    c. extending the regulator's cost-recovery powers to include setting levies for different sectors and actors within the medical products supply chain.

16. Many submitters on the Therapeutic Products Bill indicated that they intended to comment (or comment further) once specific cost-recovery proposals were provided. Several submitters considered that industry should not pay fees, while many were broadly supportive, with the following points:

    a. the need for the regulator to have clear performance expectations and transparent reporting, particularly in relation to product approval timeframes, which many submitters considered should be prescribed in regulations

    b. the need for waivers or reduced fees in situations (eg, rare disease medicines and 'non-commercial clinical trials'), with appropriate safeguards to minimise the risk of 'gaming' the system

    c. that industry should not be charged for policy development, the costs of establishing the new regime or the initial costs during the transition period.

17. Not recovering costs from industry is not considered as an acceptable option as it would deviate from the current status quo, result in the public covering transaction costs for private parties who stand to financially benefit from having their products and activities licensed and approved and would be inconsistent with international practice. As such, it is not considered as an option in this analysis.

18. While levies and fees can be a tool to build sector capacity and support economic development through the pooling of resources, there is an attendant risk of unintended inequities resulting from raising barriers to entry and ensuring traditional (and previously unregulated) practices are not unjustifiably limited.

What objectives are sought in relation to the policy problem?

19. We propose the following high-level objectives for the new medical products regulatory system:

    a. safe - meets expectations of risk-management and assurance of safety
    b. efficient - results in efficient and cost-effective regulation
    c. flexible - be flexible, durable, up-to-date and easy to use
    d. quality decisions - ensure high-quality, robust and accountable decision-making
    e. capacity - fosters sustainable regulatory capacity
    f. economy - supports New Zealand trade and economic objectives
    g. trust - be trusted and respected
    h. access - supports consumer access and individual responsibility for care.

20. These objectives are to be realised through:

    a. an enabling legislative framework

b. regulatory requirements that reflect international norms, standards and frameworks

c. a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable and able to engage internationally.

21. We have also considered the context of the health and disability system reforms under the Pae Ora (Healthy Futures) Act 2022 and the recent publication of the Government Policy Statement on Health 2024-2027 to ensure coherence with the objectives for the wider health system.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

22. The following criteria have been applied to compare different options for the entity form models. These principles are derived from objectives for the regime discussed above.

23. Proposals for the entity form of the regulator were assessed against criteria of:

a. **independence** – the regulator has regulatory, budgetary, operational and institutional independence

b. **cost effectiveness** – the regulator's size and scale is proportionate to its scope, and is cost-effective in its ongoing operation through attracting, training and retaining staff, engaging international expertise (eg, on committees) and participation in international fora (eg, standards setting)

c. **transparency** – decision-making and processes are clear and communicated effectively

d. **accountability** – ability of the institutional form to give effect to accountability arrangements for the regulator (eg, review by Regulations Review Committee, engagement with industry and consumers, and reporting requirements)

e. **responsiveness and flexibility** – the regulator can align with Government priorities for the health system by minimising any structural impediments to the regulator working collaboratively with other health entities, incorporate other functions, administer other related regulatory regimes, or change over time, including its institutional form if the Government decides to in future.

24. The new regulator will establish trustworthiness and respectability with the medical products sector through the outcomes of good regulatory design and operation. In particular, a regulator will be trusted and respected if it is seen as independent, transparent and accountable.

25. The cost-recovery model was developed with regard to Treasury's cost recovery guidelines[2] and the following principles:

a. **effectiveness** – the level of funding should be fit for purpose and support a sustainable regulator

b. **efficiency** – decisions to recover costs should be consistent with efficient allocation of resources

[2] See the Guidelines for Setting Charges in the Public Sector [2017]

c. **transparency** – information on cost-drivers and components of charges should be available to stakeholders

d. **consultation** – engagement in meaningful consultation and opportunities made available for stakeholders to contribute to the policy and design of the cost recovery activity

e. **equity** – stakeholders should be treated equitably and impacts over time should be identified

f. **simplicity** – the cost-recovery regime should be straightforward and understandable.

26. These criteria were applied in an unweighted manner.

What scope will options be considered within?

27. The scope of options has been influenced by a range of factors:

a. functions of the regulator - the exact form of the regulator will be contingent on the functions of the regulator and its objectives, as well as Cabinet's decisions on the high-level policy settings for a new Medical Products Bill (Appendix One). However, we propose to carry over elements of the functions set out in the Therapeutic Products Act, where these were uncontroversial (except in relation to natural health products and rongoā) and are consistent with modern drafting practice for regulatory bills. The development of detailed functions and objectives of the regulator will be guided by the health sector principles set out in the Pae Ora (Healthy Futures) Act 2022 and advice from the Ministry's regulatory stewardship subcommittee

b. timing – the Minister wishes to have new legislation enacted within this term of Parliament. This involves short timeframes for policy development, relative to the number and complexity of decisions needing to be made. There has been extensive prior policy development and stakeholder engagement, including on development of the Therapeutic Products Act. However, there has been limited time to assess new evidence or test policies which differ significantly from both the status quo and the Therapeutic Products Act

c. financial implications – current financial constraints on the health system may limit the Ministry's ability to fully implement the new regulatory framework. For example, successful and sufficient Budget 25 and 26 bids are required to start procurement and development of a significant amount of secondary legislation, a regulator under a new Bill and a digital platform to enable the new regulatory regime.

28. Options for cost-recovery have considered past New Zealand experience under the Medicines Act and similar regulatory regimes, international practice for comparable medical products regulators and stakeholder feedback received during the development and passage of the Therapeutic Products Bill in 2021/2022.

What options are being considered?

Entity form of the future medical products regulator

Option one – Status quo – Branded business unit within the Ministry of Health, with an employee of the Ministry of Health exercising powers delegated by the Minister

29. This option is the status quo but (as described above) the regulator would have a wider role and responsibilities and proportionately more resources.

30. In this option, statutory regulatory powers are vested in the Minister and delegated to appropriate staff within the Ministry.

31. An enhancement on the current status quo would be the establishment of a separate budgetary appropriation to provide for and signal greater budgetary independence of the regulator.

Option Two – Branded business unit within the Ministry of Health, with an independent statutory officer exercising the powers and functions of the 'regulator'

32. This option builds on option one by the addition of an independent statutory officer operating independently of the Minister. The officer would be responsible for exercising the powers of the regulator set out in the new legislation and would:
    a. 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
    b. 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
    c. exercise their functions and powers as regulator independently of the Director-General and Minister
    d. operate within the Government's and Ministry's strategic and policy framework
    e. be supported by protected funding within Vote Health.
33. Examples of an independent statutory officer are the Director for Radiation Safety under the Radiation Safety Act 2016, and the Standards Executive under the Standards and Accreditation Act 2015.

Option three – Departmental agency with an independent statutory officer

34. An operationally autonomous agency hosted by, and legally considered part of, the Ministry of Health, established under the Public Service Act 2020.
35. The departmental agency would:
    a. be headed by its own chief executive, who would be directly responsible to the Minister of Health
    b. contain an independent statutory officer, who may or may not be the chief executive, who would exercise the statutory powers of the regulator
    c. obtain corporate services from the Ministry of Health, unless other arrangements were agreed by both chief executives.
36. The agency would operate within the Government's and Ministry of Health's overall strategic and policy framework (eg, Government Policy Statement on Health 2024-2027), as medical products are central to all aspects of the health system. This option would require the disestablishment of Medsafe.

Option four – Crown entity

37. A separate Crown entity would be directly accountable and governed by a board, and accountable to the Minister through a letter of expectations. It will also be accountable to Parliament and the public through statutory requirements, including an annual report.
38. As a cost-recovered entity, the costs would be borne by the sector, including board member fees and administrative support for the board. This option would require the disestablishment of Medsafe.

How do the options for the form of the regulator compare to the status quo?

	1 – Status quo: branded business unit (BBU) headed by MOH employee	2 – Branded business unit with independent statutory officer (ISO)	3 - Departmental agency with ISO, hosted by the Ministry of Health	4 - Crown entity
Independence	0 Power is formally held by the Minister and delegated to an employee of the Ministry of Health – no statutory independence	+ The powers of the ISO are exercised independently of the Director-General of Health and Minister of Health The ISO is appointed by the Director-General of Health	++ The powers of the ISO are exercised independently of the Director-General of Health and Minister of Health The Chief Executive of the departmental agency is directly responsible to the Minister The agency is legally part of the Ministry of Health	+++ Governed by a board and accountable to the Minister of Health through letters of expectation Completely separate from the Ministry of Health
Cost effectiveness This row compares costs of different regulator forms and does not include costs of new regulatory activities (eg regulating medical devices)	0 The Regulator is a unit within the Ministry of Health and uses the Ministry's corporate services such as IT support, security and office space	0 Cost of this form should be little more than the status quo, as the only change is to the appointment of the ISO and business unit establishment and branding	- There is significant cost to establishing a new departmental agency Corporate services shared with the Ministry of Health, so operationally streamlined	- - - Significant costs to establishing a new Crown entity, including Board appointments, branding and other establishment costs No shared corporate services, so operational costs are likely to be less cost-effective on a per-employee basis
Transparency	0 Current legislation does not set out how delegated powers are exercised	+ Clearer transparency mechanisms between the ISO, the Director-General and Minister of Health will be included in primary legislation	++ The regulator's functions are clearer as a separate departmental agency from the Ministry	+++ A board provides governance functions for the regulator, and the Minister's expectations are set out in letters of expectation
Accountability	0 No formal accountability in legislation	+ Statutory decision-making powers of the ISO and accountability lines will be more clearly defined in legislation than the status quo	++ Agency Chief Executive would be directly accountable to the Minister, and ISO accountable for the exercise of independent functions	++ Statutory accountability arrangements are as contained in the Crown Entities Act 2004. The entity is accountable to the Board, the Minister, and to Parliament

	1 – Status quo: branded business unit (BBU) headed by MOH employee	2 – Branded business unit with independent statutory officer (ISO)	3 - Departmental agency with ISO, hosted by the Ministry of Health	4 - Crown entity
Responsive-ness and flexibility	0 The regulator is exercising power delegated from the Minister, so can be highly responsive	- Formal independence limits responsiveness. Changes to form or functions can be delegated within the Ministry and incorporated through legislation, and the regulator would be operating within the Ministry's strategic and policy priorities and frameworks	- - Regulatory powers for other regimes would be delegated to the Chief Executive. However, this is offset by the separate reporting relationship between the Chief Executive of a departmental agency and the Minister, which risks reducing collaboration with the Ministry	- - - Other functions can be incorporated through delegation, contract or legislation. However, this is offset by the distance from the Ministry, which could reduce collaboration and alignment with Government priorities
Overall	0	+	+	**0**

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

39. The four options above sit on a scale of independence, with the status quo (option 1) being least independent and option 4 being most independent. This has flow-on effects into the other criteria: more independent entities are less cost-effective, and less responsive to the Minister and Government. Overall, options 2 and 3 both strike a good balance between independence on the one hand and cost-effectiveness and responsiveness on the other. We consider that option 2 is marginally preferable, as it is more cost-effective than option 3 and only slightly less independent.

Key:

++	much better than the status quo
+	better than the status quo
0	about the same as the status quo
-	worse than the status quo
- -	much worse than the status quo

Cost-recovery settings

40. 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.
41. 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.
42. 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, and/or aid approval pathways for domestically produced innovative products.
43. Table 1 below shows the activities needed for the effective administration of a medical products regulatory scheme and our recommended funding settings for each activity undertaken by the new regulator.

Table 1. 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			√

Activity	Fees	Levies	Crown funding
Developing and maintaining market access		√	

Option one – *Status quo* – (Mixed model without levies)

44. Under the status quo, approximately 90% of regulatory activities undertaken by Medsafe are cost-recovered from industry. In addition to fees and charges (applied to transactions such as processing applications), Medsafe is funded by the Crown for the balance of operating costs.
45. The current cost-recovery funding model also aligns with the international norm. All comparable overseas regulators apply some measure of cost-recovery, ranging from the Australian Therapeutic Goods Administration, which is 100% cost-recovered, to the US Food and Drug Administration which is 50–60% cost-recovered across a more restricted set of activities.
46. The usual international practice is for fees to be applied to pre-market application processes, audits and inspections; and levies to cover other elements of post-market surveillance and monitoring. There are also variations in approach between medicines and medical devices.
47. Under this option, all costs will be recovered from industry except for defined public good activities. Public good activities might be defined as certain kinds of policy-related activities and/or enforcement activities (eg, investigations and enforcement action including prosecutions and drug abuse containment). Government would determine the level of public good activity from time to time.

Option two – Full cost-recovery model with the ability to set levies

48. All activities undertaken by the regulator in Table 1 above would be cost-recovered via fees and levies[3] including public good activities.

Option three – A mixed funding model, (with levies and protected Crown funding for public good activities)

49. This option would see the regulator funded through a mix of Crown funding, fees and levies.
50. The new regulatory scheme would be funded through Crown funding and cost-recovery as follows:
    a. fees will be charged for approvals, accreditation and certification activities, audits, official assurances and export certificates
    b. levies will recover the costs of international engagement and cooperation, and monitoring and testing compliance
    c. Crown funding will be applied to policy development, guidance, enforcement, and containment activities, the development of regulations, rules and notices, and establishment costs of the regulator and digital platform.
51. To further secure the independence of the regulator, as well as ensure its ability to sustain and build regulatory capacity and capabilities, the regulator will need a degree of budgetary independence from the Ministry of Health. This could be achieved by Cabinet

[3] Treasury guidelines for setting charges in the public sector 2017 defines a fee as a defined payment from a specified party to another in return for the provision of a good or service. A levy will also be charged to a particular party or group, for a specified purpose, but not necessarily for a specific good or service

agreeing to a sustainable funding basis for the regulator. For example, ‘ring-fenced’ funding for its activities through the maintenance of a specific budgetary appropriation and memorandum account (for fees and levies).

How do the cost recovery options compare to the status quo?

	1 – *Status Quo* (Mixed model without levies)	2 – Recover all costs from industry with the ability to set levies	3 - Recover all costs from industry except defined public good activities and ensure budgetary independence (Option 2 plus protected Crown funding)
Effectiveness and efficiency	0	- Higher risk to the regulator if industry is the only source of funding; risk that the regulator will need to prioritise activities which directly gather revenue	++ The regulator will have additional Crown funding to cover public good activities and its ability to undertake these activities will not be reliant on non-government revenue
Transparency	0	- Costs of compliance and other public goods will need to be built into fees and levies, reducing clarity on what funds go where	+ Clear differentiation between different activities and income sources
Consultation	0	- Submitters commented that the cost-recovery model should not cover the policy and establishment of the new regulator	+ Aligns more with the view of submitters by including Crown funding for regulatory policy activities as a public good
Equity	0	- - Compliant parties will bear the cost of non-compliance, as cost of enforcement and related activities is built into fees and levies	+ Fees and levies will be based on the benefits each industry receives. Crown funding will cover public good activities so fees will not be disproportionate to their benefit
Simplicity	0	- Fees and levies will need to pay for all regulator costs, including public goods which may not be predictable	++ More clarity on what fees and levies will fund
Overall assessment	0	- -	+

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

52. The analysis supports option 3, recovering all costs from industry except defined public good activities while ensuring budgetary independence over the status quo and full cost-recovery.

53. The proposed model is consistent with industry feedback on the Therapeutic Products Act, where submitters stated that industry should not be charged for policy development or the costs of establishing the new regime.

54. 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. All final proposals for fees, charges and levies will be developed in consultation with industry during the development of secondary legislation. Outcomes of this work will inform the development of a stage 2 Cost Recovery Impact Statement (CRIS).

Key:	
++	much better than the status quo
+	better than the status quo
0	about the same as the status quo
-	worse than the status quo
- -	much worse than the status quo

What are the marginal costs and benefits of the option?

This section analyses the marginal costs and benefits of the preferred form of the regulator (option 2). The costs and benefits of the preferred cost-recovery option are more complex to calculate.

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the preferred option compared to taking no action			
Regulated groups	<u>Costs</u> Compliance costs (one-off and ongoing fees and levies)	Low	High *Compliance costs will increase for some regulated parties under the new Medical Products Bill as more activities and parties are regulated. However, an increase in compliance costs (fees and levies) will not result from the choice of the regulator entity form.*
	Compliance requirements/ administrative burden (ongoing)	Low	High *Compliance requirements will increase for some regulated parties under a new Medical Products Bill as more activities and parties are regulated. However, an increase in compliance requirements will not result from the choice of the regulator entity form.*
	Compliance rate (ongoing)	Low	Low-Medium *Option 2 will strengthen regulator's ability to undertake compliance activities (eg, audits and investigations). Based on an assumption that more visible compliance activities result in higher compliance overall, these reforms will likely lead to an increase in the compliance rate. The extent to which the entity form contributes directly to this increase is unquantifiable.*

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the preferred option compared to taking no action			
Regulator	Not applicable as this option relates to the regulator	Not applicable as option relates to regulator	N/A
Public	<u>Costs</u> Establishment – one-off Operational – ongoing	Low	High *The choice to establish the regulator as an independent statutory officer plus branded business unit is unlikely to impose material costs over the status quo as the branded business unit is already headed by a senior public servant. There should be negligible establishment costs related to the role of the independent statutory officer.* *Some additional ongoing costs to the public are expected, as the regulator (and branded business unit) will have an expanded remit and accordingly be larger than the status quo – however, this is independent of the decision over entity form of the regulator.*
Total monetised costs		N/A	
Non-monetised costs		*Low*	
Additional benefits of the preferred option compared to taking no action			
Regulated groups	Familiarity with process and regulator (including its host agency – the Ministry of Health)	Medium	High *As this option represents an enhancement of the status quo, there will be an increase in benefit to regulated parties. This will mitigate any increase in compliance costs and requirements.*
Regulator	Greater institutional resilience, effectiveness and sustainability	Medium	Low-moderate *This benefit is largely dependent on third parties and the performance of the regulator once operating.*
Total monetised benefits		N/A	
Non-monetised benefits		*Low*	

Section 3: Delivering an option

How will the new arrangements be implemented?

55. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.

56. Regardless of the entity form adopted, the new regulator will be responsible for a much greater range of medical products and have a more tailored suite of regulatory controls applied across the entire lifecycle of regulated products.

57. The new regulator will operate a medical products regulatory regime on behalf of the Crown, and the Ministry of Health will retain a stewardship and oversight role to be consistent with the Pae Ora (Healthy Futures) Act 2022. Detailed analysis on the medicines and medical devices framework is discussed in two separate RIS' *Medicines regulation* and *Product* and *activity controls for medical devices.*

58. The form of the entity and cost-recovery settings will need to be reflected in legislation. Prior to determining fees and levies, a stage 2 Cost Recovery Impact Statement will be developed in consultation with the public and relevant stakeholders. Fees and levies will be implemented by the regulations and other secondary legislation and reviewed every three years.

59. Mechanisms for determining levy rates will need to be set up; it will be vital that regulated parties know well in advance how much they will need to pay. Processes for payment will also need to be user-friendly, especially if regulation extends to smaller businesses such as some custom medical device manufacturers.

60. The cost-recovery model selected will ultimately determine the success of the new regulator in implementing the new regime and this will remain an ongoing regulatory activity for government.

61. It is anticipated that the Medical Products Bill will be introduced to Parliament in late 2025. To implement the Bill by the end of 2028 (for medicines regulation), Crown funding is required. Implementation is expected to take three-four years. This includes the delivery of highly technical secondary legislation, a regulator and a digital platform.

62. Developing secondary legislation will require significant technical support from Medsafe and external expertise. 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.

63. Depending on the form of the regulator and funding, initial work can commence on establishing a regulator from 1 July 2025. The regulator will utilise international and national standards to ensure effective functioning and alignment with counterparts, and effective data sharing in the health ecosystem.

64. A major issue for the successful implementation of the new legislation is having well designed digital systems in place by the end of 2028. The new regime cannot go live without a new digital platform. The current Medsafe data platform dates back to 1996 and cannot be reconfigured.

65. 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 are time consuming and cumbersome. Industry cannot upload applications seeking pre-market approval for medicines to the data platform, and/or pay fees and levies online etc. This can cause delays in approval and increased administration costs to both Medsafe and industry.

66. The Ministry has significant experience in standing up new regulatory systems, for example, assisted dying. However, as with all new systems, there is a risk of time and cost over-runs. There are lessons New Zealand can learn from its existing regime for

medicines and medical devices. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for product approval, including those involving reliance and notification.

How will the new arrangements be monitored, evaluated, and reviewed?

67. The new medical products regulatory regime will not be fully operational until the end of 2028. This reflects the current timetable for further policy development, the legislative process and the proposed implementation and transitional arrangements.

68. There may be a requirement for the Minister of Health to review the policy and operation of the new system within five years after it comes into force.

69. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:

    a. time taken to approve medicines via the various pathways

    b. time taken to issue licences for controlled activities

    c. compliance and enforcement action taken.

70. The medicines industry and the healthcare sector have productive relationships with the Ministry and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.

Stewardship expectations

71. The Government has signalled its core expectations for regulatory stewardship[4] to agencies involved in designing and administering regulation. As the regulator sits within the Ministry of Health – and the regulator will be accountable for their performance to the Director-General of Health – the regulatory regime will be subject to the Ministry of Health's ongoing responsibility to:

    a. actively monitor and periodically assess the performance and condition of the regulatory regimes it administers, and to use that information to advise or act on problems, vulnerabilities and opportunities for improvement

    b. adopt best practice compliance strategies, as part of a cross-government forum designed to share experiences and promote greater consistency between regulators

    c. report publicly on its regulatory management strategy, the state of the regulatory stock, and plans for improvement, including engaging actively with stakeholders and other regulatory agencies, and undertaking rigorous organisational self-review.

72. These requirements will influence the development of the new regime (ie, the design will need to enable and be compatible with effective stewardship).

[4] As of 1 May 2024, the Treasury's regulatory functions, including responsibility for the public service regulatory management system, have transferred to the new Ministry for Regulation. Information relating to these functions will continue to be available on the Treasury website while the transition occurs.

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 active pharmaceutical ingredients
   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
   ii. by providing assistance to, and seeking assistance from, those organisations
   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 medical 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 Director-General 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.