Regulatory Impact Statement: Therapeutic and Natural Health Products Regulation – Supplementary Analysis 2022 No. 2

Coversheet

Purpose of Document	
Decision sought:	Supplementary analysis produced to support Cabinet's decision to introduce the Therapeutic Products Bill to Parliament in 2022
Advising agencies:	Ministry of Health
Proposing Ministers:	Ministry of Health
Date finalised:	4/11/2022

Problem Definition

The Therapeutic Products Bill (the Bill) will replace the current Medicines Act 1981 (Medicines Act) and the Dietary Supplements Regulations 1985 (DSR) under the Food Act 2014, to provide for the comprehensive regulation of therapeutic products (medicines, medical devices and natural health products). It will also control a range of activities, including pharmacy businesses, manufacturing, and clinical trials.

The problems with the current Medicines Act are longstanding and have been examined in a previous regulatory impact statements (RIS) prepared in 2015 and 2016.[1] The DSR also have longstanding issues and were examined in a RIS in 2021.[2]

Since the 2016 RIS was undertaken, reforms to the Public Service Act 2020 and the anticipated Pae Ora (Healthy Futures) Act 2022 necessitate a reassessment of previous options for the entity form of the regulator. This also includes reconsidering how the regulator is to be funded, in the context of optimising outcomes for the new therapeutic product regulatory regime.

Executive Summary

Therapeutic products, which are medicines, medical devices and natural health products are used by all New Zealanders in their everyday lives and in all parts of the health system. Because of the potential for serious harm from the use (and misuse) of therapeutic products and inequalities of power and information between all actors in the system, strict government oversight and regulation is appropriate.

Currently medicines are regulated under the Medicines Act, which has not kept pace with rapid advances in health technologies or developments in best practice regulation. For example, that Act provides little oversight of the increasing medical device and biologic medicines sectors.

[1] Available on the Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

[2] Available on the Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

In 2015 Cabinet agreed to repeal and replace the Medicines Act with a new Therapeutic Products Bill (the Bill) [SOC-15-MIN-0049] and regulatory regime. An exposure draft of the Bill was prepared in 2018 and underwent public consultation. In July 2021, Cabinet agreed to include natural health products in the Bill [SWC-21-MIN-0109].

This supplementary RIS considers an additional option over those previously considered for the entity form of the regulator: namely, a branded business unit within the Ministry of Health with an independent statutory officer exercising the powers and functions of the regulator.

While the 2016 RIS included an analysis of the appropriateness of maintaining a cost-recovery basis for many of the regulator's functions (and that analysis remains current), an updated analysis is included as to which form of the regulator which would best support its future functions.

Limitations and Constraints on Analysis

The options considered in this supplementary RIS build on policy decisions taken to date. The options also build on wider decisions around the health and disability system reforms under the Pae Ora (Healthy Futures) Act. The criteria by which proposals and options were presented to Cabinet in October 2021 is replicated in this RIS in an expanded form.

Policy constraints

This supplementary analysis is limited in scope to new policy decisions and choices for the Bill's content, and it builds upon previous work and Cabinet decisions. Relevant Cabinet decisions include:

- Cabinet's 2015 agreement to repeal and replace the Medicines Act with a new Therapeutic Products Bill (the Bill) [SOC-15-MIN-0049] and regulatory regime, with the following objectives:
    - [Safe] – meet expectations of risk management and assurance of safety
    - [Efficient] – result in efficient and cost-effective regulation
    - [Flexible] – be flexible, durable, up-to-date, and easy to use
    - [Quality decisions] – ensure high-quality, robust and accountable decision-making
    - [Capacity] – foster sustainable regulatory capacity
    - [Economy] – support New Zealand trade and economic objectives
    - [Trust] – be trusted and respected
    - [Access] – support consumer access and individual responsibility for care.
- Cabinet's 2015 agreement that the objectives for the regulatory regime be best met by (SOC-15-MIN-0050 and SOC-15-MIN-0049):
    - an enabling legislative framework
    - regulatory requirements that reflect international norms, standards and frameworks
    - a regulator that can exercise regulatory powers and associated administrative powers effectively and independently, is accountable, and able to engage internationally.
- Cabinet's decision in July 2021 to include regulation of natural health products as part of the Bill [SWC-21-MIN-0109].

The analysis has also been conducted in the context of the 2018 exposure draft Bill.

Prior public consultation

Public consultation on an exposure draft of the Bill and a consultation document was undertaken between December 2018 and April 2019, with 442 submissions received by way of feedback. A summary of that feedback is available on the Ministry's website: https://www.health.govt.nz/system/files/documents/publications/submissions_on_the_therapeuticproducts_bill-keythemes_0.docx.

The consultation document signposted the Ministry's intention to retain a cost-recovery model for the new regulator; although the document only referred to the regulator's ability to 'charge fees to cover any costs not covered by government funding'. While 'fees' could also by implication include levies, we are now proposing that the cost-recovery model for the regulator explicitly include both fees and levies.

The public were not consulted on the specific entity form of the future regulator. This was due, in part, to time constraints. We note that previous decisions of Cabinet had ruled out some forms of regulator (e.g., a non-government regulator and a Crown Entity). We also note a preference for an entity form with low operating costs could be inferred from industry's feedback on the cost-recovery proposals in the consultation paper.

The public will not be directly affected by the entity form of the regulator, other than indirectly through its public funding requirements.

Importantly, the Bill provides only a framework for much more detailed secondary legislation that will establish most of the new therapeutic products regulatory regime. The development of this secondary legislation (including the specific cost-recovery model and resultant regulations setting the level of fees and levies) over a period of two to three years after Parliament's consideration of the Bill will afford significant opportunity for industry and public input.

Timing

The Government has expressed its intention to table the Bill in Parliament in late 2022.

Responsible Manager(s) (completed by relevant manager)
Tim Vines Manager, Therapeutics Strategy, Policy and Legislation Ministry of Health 4 November 2022

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health, Papers and Regulatory Committee
Panel Assessment & Comment:	The Committee has reviewed the supplementary analysis on the form of the regulator and cost-recovery options and advised that it partially meets the quality assurance criteria. While the paper meets most of the criteria, the Committee considered that there there could have been further clarification to make the analysis and scoring of the options more robust.

Entity form

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. Currently, the Medicines Act is administered by Medsafe as a branded business unit (BBU) in the Ministry of Health. Medsafe also houses the Psychoactive Substances Regulator and has responsibilities under the Misuse of Drugs Act and Smoke Free Act. 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.
2. While part of the Ministry, Medsafe has a separate identity in the sector. Previous consultation with the sector indicates that Medsafe is generally seen as a trusted regulator and administrator of the Medicines Act. However, as a matter of form, it does not have operational or budgetary independence, nor specific accountability arrangements. These gaps present challenges to the sustainability and integrity of the regulator. In its current form it cannot adequately support all of its necessary activities.
3. In 2015 Cabinet agreed to repeal and replace the Medicines Act with the Bill. This would involve the establishment of a new therapeutic products regulator. An analysis of entity forms was undertaken in the regulatory impact statements that were prepared in 2015 and 2016.[3] The decision to repeal and replace the Medicines Act is an assumed part of the status quo.
4. In 2021 Cabinet agreed to include natural health products in the Bill. Natural health products include dietary supplements, preparations used in complementary and traditional medicines such as rongoā Māori, long-established practices such as Chinese medicine, and western practices such as aromatherapy and homeopathy.

<u>The entity form and its funding need to support the wider remit of the new regulator and future trends</u>

5. As part of the status quo (replacement of the Medicines Act with the Therapeutic Products Bill), the new regulator will assume responsibility for 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, quality, and effective medicines and medical devices, and safe, quality natural health products.
    b. engage with international counterparts, industry sectors, and across government (e.g., with Pharmac and new health entities proposed in the Pae Ora Bill).
6. However, the new regulatory regime will differ substantially from the status quo in a number of respects. Notably it will:
    a. be more comprehensive, covering considerably more products (particularly medical devices and natural health products) and will have a more comprehensive set of regulatory responsibilities in relation to activities such as exports, clinical trials and pharmacy licensing
    b. have greater regulatory independence and thus greater accountability.
7. To be effective in delivering these functions it is vital that the regulator have credibility as an independent regulator that can be effective in a dynamic and changing health environment. The regulator will need to have a clear mandate and meaningful resourcing

[3] Available on the Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

in order to regulate appropriately the new complex and specialised treatments and products coming on the market[4]. This will require specialist staff.

8. The regulator will be larger than Medsafe and require additional revenue to meet its costs and deliver a sustainable regulatory regime. The Ministry's working assumption is that the regulator will have in the region of 120 – 150 staff (equivalent to the current FTE allocations for the administration of the Medicines Act, the Psychoactive Substances Act, and the Misuse of Drugs Act, with additional capacity for the administration of additional functions). The Medsafe operating budget (which includes these other functions) is currently $12.2m, of which $10m is from third party revenue. These budgets are expected to increase in the new regulatory regime. By way of comparison, Pharmac has approximately 100 FTEs, an operating budget of about $24m and is a Crown Entity (Crown Agent).

9. Cabinet has previously agreed that the regulator should recover its costs through fees and levies where these costs are not met by Crown funding [SOC-15-MIN-0050]. Cabinet has also agreed settings that ensure there is no inappropriate pressure on the regulator created by funding arrangements.

What is the policy problem or opportunity?

10. Since the 2015 and 2016 assessments, there have been significant reforms to machinery of government options (e.g., the *Public Service Act 2020*) and anticipated changes arising from the Pae Ora (Healthy Futures) Bill 2022. Cabinet has also agreed that natural health products will be regulated under the Bill. These changes support a reassessment of entity form options for the regulator and the related issue of cost-recovery. Consequently, this analysis focuses on:

    a. A new entity form option: a branded business unit within the Ministry of Health, with an independent statutory officer exercising the powers of the regulator

    b. Cost-recovery settings (including levies) for the regulator in the context of this new option.

<u>Entity form of the future regulator</u>

11. Selecting an appropriate entity form of 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.

12. In addition to achieving the objectives of the 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.

13. In order that the regime is effectively and sustainably delivered consistent with its agreed objectives and legislative principles the regulator will need a level of independence. In its 2014 report *Regulatory Institutions and Practices* the New Zealand Productivity Commission[5] identifies the following four dimensions of independence:

    a. *regulatory independence* - the degree to which the regulator can set and adjust regulatory requirements. Regulatory independence has been agreed by Cabinet and the regulator will have the ability to set and adjust detailed regulatory requirements

    b. *budgetary independence* - the degree to which the regulator is protected from political or sector pressure through funding arrangements. Cabinet has agreed that

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

[5] See *Regulatory Institutions and Practices* 2014

legislation will enable both cost recovery and Crown funding. Exactly how costs will fall is yet to be determined. Cabinet has also agreed settings that aim to ensure there is no inappropriate pressure on the regulator through funding arrangements (e.g., fees will be set by regulations, accountability arrangements promote transparency in respect of financial reporting, and legislation requires independent assessment of benefits and harms). Operational independence (discussed below) is a key factor in ensuring budgetary independence in practice

c. *operational independence* - the degree to which the regulator has operational independence or a broad discretion to exercise a range of powers. Cabinet has agreed that the regulator will exercise regulatory powers and associated administrative powers independently; and that it needs to be able to do so effectively. To fulfil this obligation, it needs the operational independence to deploy resources as it sees fit to meet its obligations and responsibilities

d. *institutional independence* - the degree of distance in the regulator's relationship with Government and the rules governing the appointment and dismissal of governors or senior staff.

14. The central policy problem to resolve is which entity form satisfies these matters, while meeting administrative demands and efficiencies.

Funding the regulator – cost recovery

15. An analysis of cost recovery and funding models was undertaken in the previous RIS and is not repeated here.

16. Since that analysis was undertaken, the exposure draft of the Bill and a consultation document were released for public comment (December 2018-April 2019).

17. In brief, the options considered included:

    a. Continuing with the status quo of the regulator charging fees to partially cost recovery its operations, with Crown funding providing the balance of operating costs. Most fees and charges are applied to transactions (e.g., processing applications)

    b. Full cost-recovery (i.e., 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 therapeutic products supply chain.

18. Note, the option of not recovering costs from industry was not considered as a viable option or analysed (inconsistent with international practice and would create significant compliance burdens for the public).

Submitters views

19. Many submitters on the draft 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 (e.g., rare diseases 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.

20. We note with the inclusion of natural health products under the Therapeutic Products Bill, there will be a need to ensure equity and that cost recovery does not disproportionately affect traditional practices.

What objectives are sought in relation to the policy problem?

21. Cabinet has previously agreed [SOC-15-MIN-0049 & SOC-15-MIN-0050] to the high-level objectives for the new therapeutic 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.
22. Cabinet also agreed that 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.
23. We have also considered the context of the health and disability system reforms to ensure coherence with the objectives.

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

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

24. The following criteria have been applied to compare different options for the entity form and cost recovery models. These principles are derived from Cabinet's objectives for the regime (see discussion above).

25. Proposals for the entity form of the regulator are assessed against criteria of:

    a. **Independence** – that the regulator has regulatory, budgetary, operational, and institutional independence as identified by the Productivity Commission

    b. **Cost-effective** – the regulator's size and scale is proportionate to its scope and is cost-effective in its ongoing operation. This includes the costs associated with the regulator's establishment.

    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 e.g., review by Regulations Review Committee, engagement with industry and consumers, reporting requirements

    e. **Sustaining regulatory capability, capacity and flexibility** – the regulator form supports the attraction and retention of specialist staff and the wider functions of the regulator (e.g., engaging international expertise)**.** The regulator form support flexibility in changing roles over time.

    f. **Coherence within health system** – the degree to which the regulator will need to be aligned with the government priorities for the health system and minimising any structural impediments to the regulator working collaboratively with other health entities

26. These qualitative criteria were applied through an unweighted quantitative Multi-Criteria Analysis.

27. The cost recovery model was developed with regard to Treasury's cost recovery guidelines[6] 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 the efficient allocation of resources

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

    d. **Consultation** – engagement in meaningful consultation and opportunity should be 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.

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

28. These criteria were applied in an unweighted manner.

What scope will options be considered within?

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

    a. Timing – the Government has indicated that the Bill will be introduced to Parliament in 2022, leaving little time to update the existing exposure draft Bill and to explore additional options to those considered in the more detailed 2016 Regulatory Impact Statements.

    b. Previous policy decisions –

        i. Cabinet has already set the high-level objectives for the new therapeutic products regulatory regime

        ii. Cabinet decided in 2016 that the regulator should not be a Crown entity, and that further consideration be given to establishing it as a departmental agency or within the Ministry of Health [SOC-16-MIN-0025]. Cabinet agreed that this issue warranted further review in 2018 [SWC-18-MIN-0176]. In October 2021, Cabinet agreed to establish the regulator as a branded business unit within the Ministry of Health, with the functions of the regulator to be exercised by an independent statutory officer [CBC-21-MIN-0117].

        iii. Cabinet has already agreed that the regulator will recover its costs through fees and levies where those costs are not met through Crown funding, and that these fees and levies will be reviewed within three years of first being set [SOC-15-MIN-0049]. This decision was reflected in the exposure draft of the Bill, released for consultation in late 2018. The consultation document noted that the split between industry and Crown funding had not yet been decided, but that a significant proportion was likely to be recovered from industry.

        iv. Cabinet has also agreed to the funding model set out in paragraph 59 [CBC-21-MIN-0117]. This decision was also made on an assessment of the criteria set out at paragraph 25 above.

30. Options for cost recovery have considered past New Zealand experience under the Medicines Act and similar regulatory regimes, international practice for comparable therapeutics regulators and stakeholder feedback from December 2018-April 2019.

31. Further discussion of the scope of options on other aspects of the proposed regime are set out in the 2015 and 2016 regulatory impact statements available on Ministry's website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

What options are being considered?

Entity form of the future therapeutic products and natural health products regulator

Option One – Status quo – Branded business unit within the Ministry of Health, with powers formally vested in the Director-General

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

33. Under the exposure draft Bill (i.e., future status quo) the statutory powers of the regulator would be vested in the chief executive of the Ministry of Health (i.e., the Director-General of Health), and be delegated to appropriate staff within the Ministry.

34. 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'

35. This option builds on Option One by the addition of an independent statutory officer (ISO). The ISO, rather than the Director-General of Health (DG) would be responsible for exercising the powers of the regulator set out in the Bill.

36. The ISO would:

    a. be appointed by the DG Health

    b. be a person who the DG Health is satisfied has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the regulator

    c. be an employee of the Ministry of Health (or be appointed as an employee of the Ministry)

    d. exercise their functions and powers as regulator independently of the DG Health and Minister

    e. be subject to general policy directions given by the Minister of Health that are not inconsistent with the Bill, regulations, or other legislative instruments

    f. be accountable to the DG Health for the performance of their functions and duties and the exercise of their powers

    g. have arrangements in place to avoid or manage any conflicts of interest that may arise in the performance of functions and duties and the exercise of powers

    h. operate within the Government's and Ministry's strategic and policy framework

    i. be supported by protected funding within the overall Vote Health.

37. Examples of an ISO 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

38. An operationally autonomous agency hosted by, and legally considered part of, the Ministry of Health, established under the Public Service Act 2020.

39. 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.

40. The agency would operate within the Government's and Ministry of Health's overall strategic and policy framework (e.g., Government policy statement), as therapeutic products are central to all aspects of the health system.

Option Four – Crown entity

41. A separate Crown entity that gives effect to Government policy (i.e., Crown agency). The entity would be directly accountable and governed by a board, and accountable to the Minister in relation to a letter of expectations and accountable to Parliament and the public through statutory requirements, including an annual report.

42. As a cost-recovered entity, the costs would be borne by the sector including board member fees and administrative support for the board.

Cost-recovery

43. The options below are guided by the Treasury Guidelines for Setting Charges in the Public Sector, and use the terminology of that guidance accordingly, e.g., 'club good'.

44. The table below sets out the activities of the regulator in that context.

Table 1. Regulator Activities

Activity	Private goods	Club goods	Public goods
Approval, accreditation and certification activities	✓		
Monitoring and testing compliance		✓	
Audits of individual businesses	✓		
Investigations and enforcement action including prosecutions			✓
Policy advice and legislative change			✓
Guidance			✓
Development of regulations, rules and notices			✓
International engagement and cooperation			✓
Export facilitation: - Developing export standards - Developing and maintaining market access - Export certification	✓	✓	✓
Drug abuse containment			✓

Option One – *Status quo* – Mixed model (currently ~90% cost-recovery from industry)

45. Under the status quo, the regulator would continue to recover the bulk of its costs from industry and be funded by the Crown for the balance of operating costs. Most fees and charges are applied to transactions (e.g., processing applications).

46. Approximately 95 percent of regulatory activities undertaken by Medsafe are cost-recovered from industry. All comparable overseas regulators apply some measure of cost recovery, ranging from the Australian Therapeutic Goods Administration, which is 100 percent cost recovered, to the US Food and Drug Administration which is 50–60 percent cost recovered across a more restricted set of activities.

47. The usual 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. Natural health products will also need specific consideration.

48. Under this option, all costs will be recovered from industry except defined public good activities:

    a. Fees for private goods but no ability to institute levies for club goods. There will be the power to set industry fees and charges in Regulations.

    b. Public good activities might be defined as certain kinds of policy-related activities and/or enforcement activities. 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

49. All activities undertaken by the regulator in Table 1 above would be cost recovered, including public goods.

Option Three – A mixed funding model, with levies and some Crown funding for public goods

50. This option would see the regulator funded through a mix of Crown funding, fees and levies.

51. The new regulatory scheme would be funded through Crown funding and cost-recovery as follows:

    a. fees will be charged for approval, accreditation and certification activities, export facilitation and audits of individual businesses

    b. levies will be charged for sector development activities, developing and maintaining market access, monitoring and testing compliance

    c. Crown funding will be applied to policy advice, legislative development, international engagement and cooperation, guidance, development of export standards, investigations and enforcement action including prosecutions, and drug abuse containment

52. 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 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 options compare to the status quo?

0/neutral = no change; + = improvement; - = less than status quo

Entity form

	1 - BBU (*status quo*)	2 – Branded business unit with ISO	3 - Departmental agency with ISO	4 - Crown entity
Independence[7]	0	++ The powers of the ISO are exercised independently of the Director-General of Health and Minister 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	+++ Strongest signal of independence of institutional forms as a separate entity to the Ministry
Cost-effective	0	- Unlikely to impose material costs over the status quo as the branded business unit is already headed by a senior public servant	--- Additional costs involved in establishing a departmental agency	--- Due to board fees and separate corporate functions, and costs that would be borne by the sector as a cost-recovered entity
Transparency	0	+ Boundaries between the BBU, ISO and wider Ministry may not be clear, however transparency mechanisms are 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 in addition
Accountability	0	+ Statutory decision-making powers of the ISO and accountability lines more clearly defined 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

[7] Four aspects drawn from the Productivity Commission report *Regulatory Institutions and Practices* 2014.

Sustaining regulatory capability, capacity and flexibility	0	+ More attractive to staff and internationally due to additional independence arrangements with an ISO, with technical capability	++ Additional independence from separate appointment of the chief executive	++ A Crown entity's independence is likely to make it easier to develop systems to support recruitment and retention of specialist and technical staff than a BBU or a Departmental agency. However this is offset by limited opportunities for staff advancement within a Crown entity
Coherence within health system	0	++ The regulator would be operating within the Ministry's strategic and policy priorities and frameworks	- The separate reporting relationship between the chief executive of a departmental agency and the Minister risks reducing collaboration with the Ministry	--- Distance from the Ministry could reduce collaboration and alignment with government priorities
Overall (unweighted)		**6**	**5**	**2**

Cost-recovery

	1 – *Status Quo* (Mixed model without levies and less Crown funding)	2 – Recover all costs from industry	3 - Recover all costs from industry except defined public good activities and ensure budgetary independence
Effectiveness	- Medsafe report that current funding arrangements are insufficient for existing activities so effectiveness is likely to decline under the status quo	- The regulator may not be sustainable if not enough revenue is brought in to cover the cost of providing regulatory activities	++ The regulator will have additional Crown funding to cover public good activities and its ability to do so will not be reliant on non-government revenue
Efficiency	0	- The regulator may not be sustainable if not enough revenue is brought in to cover the cost of providing regulatory activities	+ The regulator will have additional Crown funding to cover public good activities and its ability to do so will not be reliant on non-government revenue
Transparency	0	+	+
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	- There is the potential for the increase in costs on industry that can further impact the public	+ Fees will be distributed equitably with fees and levies set 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	+	+
Overall assessment	-1	-2	7

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

Entity form

53. The 2016 regulatory impact statement recommended the regulator not be a Crown entity. In light of the transformation taking place in the health system, we endorse this position.

54. Unweighted, option 2 (a branded business unit with an ISO) and option 3 (departmental agency with an ISO) score closely.

55. Option 2 is recommended due to the weighting given to the criteria of regulatory coherence in the health system. A branded business unit in the Ministry with an ISO is the most likely regulator form to meet the transformed health and disability system's vision of pae ora (healthy futures for all New Zealanders), given the centrality of therapeutic products to the health of New Zealanders.

56. Establishing the regulator as a branded business unit with an ISO is also likely to result in less disruption to the work of the current regulator in supporting New Zealand's response to COVID-19 and in its delivery of its other regulatory functions, for example those under the *Misuse of Drugs Act 1975.*

Cost Recovery

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

58. The funding framework will:

    a. Ensure the efficiency and effectiveness of that regulator through reducing the regulators reliance on fees and levies.

    b. Fees and levies will also be equitably redistributed and ensures that the cost paid by industry is relative to the benefit they receive. As well as services that have previously been free will now be appropriately charged for by those who receive the service.

59. A Stage 2 Cost Recovery Impact Statement (CRIS) will be developed once the cost-recovery model has been developed further. In the interim, the proposed model for cost recovery is:

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			✓
Guidance			✓
Development of regulations, rules and notices			✓
International engagement and cooperation			✓
Export facilitation: - Developing export standards - Developing and maintaining market access - Export certification	✓	✓	✓
Drug abuse containment			✓

What are the marginal costs and benefits of the option?

Entity form

Preferred option: Branded business unit within the Ministry of Health, with functions of regulator exercised by an independent statutory officer (BBU+ISO)

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the preferred option compared to taking no action			
Regulated groups	Costs Compliance costs (one-off and on-going fees and levies)	Low	High *Compliance costs will increase for regulated parties under the new Therapeutics 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 (on-going)	Low	High *Compliance requirements will increase for regulated parties under the new Therapeutics 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 (on-going)	Low	Low-Medium *Option will strengthen regulator's ability to undertake compliance activities (e.g., 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.*

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. Assuming that no additional position is created (i.e., the current position responsible for Medsafe will become the independent statutory officer) 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 as 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)	Low	High *As this option represents only a minor enhancement of the status quo the increase in benefit to regulated parties is low. However, it will mitigate any increase in compliance costs and requirements.*
Regulator	Greater institutional resilience, effectiveness and sustainability	Low	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?

60. Implementation of the proposals in this supplementary analysis is tied to the development and implementation of the new Bill, which will replace the current Medicines Act and its regulations. The Ministry of Health (including staff from Medsafe) will be responsible for leading the implementation of the Bill.

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

62. Regardless of the entity form adopted, the new regulator will be responsible for a much greater range of products and have a more tailored suite of regulatory controls applied across the entire lifecycle of products. We estimate that this will require around 120 - 150 staff to administer the therapeutic products regulatory scheme.

63. 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 the government.

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

Formal review of Bill and regulatory regime

64. The regulatory regime will not be fully operational until 2026. This reflects the current timetable for further policy development, the legislative process, and the proposed transitional arrangements.

65. The Bill requires the Minister of Health to review the policy and operation of the Therapeutic Products Act five years after it comes into force, and every five years thereafter. The Minister of Health must report on each review within 12 months and present the report to the House of Representatives as soon as practicable after it is completed.

Opportunities for review and evaluation during the design of the regulatory regime

66. Following the passage of the Bill, substantial work will be required to prepare the necessary secondary legislation – regulations, rules and regulator's notices – to support the therapeutic products and natural health products regulatory regime. This work will be led by the Ministry of Health, including staff from Medsafe and – eventually – the new regulator. The development of the regime will provide significant opportunities to review and evaluate different options, and to engage with stakeholders within and outside government.

67. Consultation is further protected in the Bill, which imposes a duty on the Minister of Health administering the Act and the regulator to consult persons and organisations that the Minister or regulator considers appropriate, having regard to the subject matter of the proposed secondary legislation. This consultation must occur prior to making the secondary legislation.

68. Legislated consultation requirements will be supported by formal parliamentary accountability mechanisms and health system performance oversight provided by the Ministry of Health and the proposed Māori Health Authority. Stakeholders will be able to contribute to the development of the Bill during the Select Committee stage.

Stewardship expectations

69. The Government has signalled its core expectations for regulatory stewardship 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.

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