Regulatory Impact Statement:

The regulation of rongoā and small-scale producers of natural health products under the Therapeutic Products Bill

Coversheet

Purpose of Document	
Decision sought:	Regulation of rongoā and small-scale producers of natural health products under the Therapeutic Products Bill.
Advising agencies:	Manatū Hauora Ministry of Health
Proposing Ministers:	Minister of Health, Hon Dr Ayesha Verrall Associate Minister of Health (Māori Health), Hon Peeni Henare
Date finalised:	10 May 2023

Problem Definition

Rongoā

Rongoā is held as a taonga by Māori, with rights under Article 2 of Te Tiriti o Waitangi | the Treaty of Waitangi (Te Tiriti).

Feedback from our engagement tells us that Māori strongly oppose the inclusion and regulation of rongoā under the Therapeutic Products Bill (the Bill). Rongoā is primarily included in the Bill by implication and as a consequence of the Bill's regulation of natural health products (NHPs) and medical devices.

Inclusion of rongoā in a regulatory regime is potentially contrary to the right of undisturbed possession of a taonga guaranteed under Article 2 of Te Tiriti.

Small-scale NHP producers

The Bill, as introduced to Parliament requires small-scale New Zealand NHP producers to seek authorisation for each NHP to be supplied (e.g., sold) and to be licensed to manufacture those NHPs. This may not be proportionate to the risks and benefits, and the associated fees may be unduly costly, which could potentially result in the loss of some small-scale New Zealand producers.

Executive Summary

Rongoā

Under the current version of the Bill, rongoā and rongoā practitioners will be subject to controlled activities, licenses, permits, health benefit claims, advertising, manufacturing, supply and supply chain activities, surveillance and monitoring, and search and entry related to specific places.

Māori have strongly expressed that rongoā and its practices should be excluded from the Bill through submissions to the Health Committee, a petition to Parliament and engagement with the Ministry of Health's rongoā workstream.

Two options are considered:

- option 1 is the status quo
- option 2 is amending the Bill to create an explicit exclusion of rongoā and establishing a process to determine the scope of the exclusion. For this option, this entails the establishment of an advisory committee that will advise the proposed Therapeutic Products Regulator (the Regulator) on the scope and nature of rongoā and matters pertaining to rongoā for the purpose of excluding rongoā from the Bill.

The Ministry of Health's preferred option is option 2. Option 2 acknowledges the rangatiratanga and mana of Māori over rongoā. Costs will be incurred in the establishment and ongoing operation of the Rongoā Advisory Committee; however, the Regulator would benefit from the ongoing expert advice on rongoā.

Small-scale NHP producers

Many (more than a quarter but less than half) of the 16,586 written submissions to the Health Committee stated that the proposed regulatory scheme would adversely affect small-scale NHP producers, who may not be able to afford market authorisation fees, licence fees, and other compliance costs. Submitters said that some producers would likely be driven out of business despite considering their products have little or no risk to the public.

Given the degree of concern, it is necessary to consider options for small-scale New Zealand NHP producers who supply small volumes of products directly in New Zealand. This would help ensure regulation is proportionate to the risks associated with small-scale distribution.

Three options are considered:

- Option 1 – status quo where all NHP producers would be required to have a manufacturing licence, and every product made would need a market authorisation before it could be supplied in New Zealand or exported (unless the Regulator considers there are grounds to issue a single licence). Fees could also be reduced or waived.

- Option 2 – a general exemption in the Bill from requirements for market authorisation and/or manufacturing licences for all New Zealand NHP producers below a certain volume or turnover, when they directly and solely supply within New Zealand.

- Option 3 – an exemption power in the Bill for the Minister of Health to exempt classes of small-scale NHP producers from requirements for market authorisation and/or a manufacturing license, when they directly supply within New Zealand. The

volume or turnover level below which an exemption would apply would be set in regulations rather than the Bill itself.

Manatū Hauora's analysis of options shows that Option 1 is the recommended option, particularly if greater weight is given to addressing indirect risks associated with NHPs (such as misinformation and missed opportunities to access mainstream health services in a timely way), and accounting for an expected underreporting of harm from NHPs.

Option 1 best protects the public from a wider range of harms associated with NHPs, because it imposes stronger controls on the manufacturing and supply of products. Option 1 can support small businesses through applications made to the Therapeutic Products Regulator using current provisions in the Bill. This includes using licensing and enabling provisions to allow businesses to apply for a single licence to cover all their manufacturing and supply activities, rather than needing individual product authorisation; or implementing fee reductions or waivers for individual market authorisation.

It can also support good regulatory practice, including equal compliance costs for all therapeutic product producers. Option 1 is easy to implement because no changes are required to the Bill, and therefore, can be implemented before the general election.

If a greater weight were given to mitigating realised and proven harms from the use of NHPs, and avoiding potentially disproportionate compliance costs on small businesses, then option 3 would be ranked more highly. It is also, therefore, a recommended option.

Limitations and Constraints on Analysis

Previous policy work limits and constrains options and analysis. Constraints include that the Bill is very large, complex and contains many interdependencies. This makes it difficult to make major changes to the Bill quickly, without potentially significant flow-on impacts on different parts of the Bill (given the many internal linkages) and the potential for unintended consequences and delays to its passage if significant changes are made.

Further, the current status of the Bill (as of 2 May 2023, the Bill is before Parliament's Health Committee). A consequence of this constraint is that the Bill as introduced is the status quo and there are limits to the scope and scale of changes feasible while still enabling the Bill to be passed within the timeframe specified by its category rating.

Another limitation is the previous policy work on the Bill which has flow-on impacts on rongoā, including the work undertaken as part of the 'rongoā workstream' discussed below.

Rongoā

Legislative considerations

The health sector principles in section 7 of the Pae Ora (Healthy Futures) Act 2022 guide the health system to provide opportunities for Māori to exercise decision-making authority on matters of importance to Māori. This is relevant to whether rongoā should be excluded from the Bill and also the manner in which any exemption is operationalised, which is of high importance to Māori.

Evidence of the problem

Rongoā was indirectly captured for regulation under the Bill as a consequence of certain ingredients used in rongoā falling under the Bill's definition of 'NHP ingredient'. While

government made no explicit decision to capture rongoā under the Bill, this raised the need for the government to address the question of what to do regarding this situation.

Through the engagements of the rongoā workstream and submissions made to the Health Committee on the Bill, Māori have clearly articulated that rongoā is considered a taonga and that, since Māori possess the undisturbed possession of all taonga under Article 2 of Te Tiriti or Waitangi, they should also possess undisturbed possession of rongoā. This conclusion is also supported by the findings of the Waitangi Tribunal in their report for Wai 262 *Ko Aotearoa Tēnei*. This is contrary to the current approach of the Bill.

Policy constraints

The rongoā workstream was established on 30 November 2022, alongside the Bill's introduction to the House of Representatives, on the request of the Minister of Health. The rongoā workstream explored gaps and opportunities in the Bill for rongoā, and provided advice about the protection of rongoā, assurance of patient safety and protecting export market access (alongside those providing therapeutics and products with health benefit claims).

The rongoā workstream held 2 online hui, 2 in-person hui and ran an online survey, engaging with approximately 300 Māori, in the development of its advice to Ministers.

The options discussed in this RIS are informed by the consultation and timeframes to hand.

Small-scale NHP producers

Evidence of the problem

The Bill was designed to provide for a risk-proportionate and consistent regulatory regime for NHPs. In this context, no distinction was made between small and large-scale NHP suppliers in the Bill, although it was intended that further consideration would be needed in secondary legislation. Once the Bill was presented before the Health Committee, many NHP suppliers commented on the possible compliance burden associated with the new regime. In particular, some commented that the likely compliance burden on small-scale suppliers was disproportionate, particularly given the absence of evidence that the regulatory approach preceding the Bill has created any harm.

During Health Committee's consideration of the Bill, Manatū Hauora commissioned a literature review on the evidence of harm from using NHPs. From the identified studies, none of them examined the severity or frequency of harm from using NHPs supplied by small-scale producers (i.e., through overuse, interactions with other products or medicines, use of unsafe products, and/or use of NHPs for a condition that requires clinical care and prescription medicine). Many people do not report or link the use of NHPs with adverse outcomes. There are, however, known risks for NHPs, such as herb-induced liver injury.

There is also a paucity of available data on how many small-scale New Zealand NHP producers are operating within New Zealand. This paper does not provide a definition for small-scale New Zealand NHP producers because it does not sufficiently know the size of operations across the entire NHP industry. Consultation on regulations under a lapsed

Natural Health Products Bill in 2015 assumed 40 annual applications for a licence to manufacture.[1]

Ministerial constraint

A government constraint is that a Cabinet decision is made in time to introduce a Government Supplementary Order Bill for consideration by the Committee of the whole House and enactment of the Bill before the 2023 general election.

Public consultation on the proposed options

The Health Committee consulted on the Bill from 15 December to 5 March 2023 and received over 16,500 submissions, many of which commented on regulation for small-scale NHP producers. There has been no subsequent consultation on options to exempt small-scale NHP producers from requirements for market authorisation and manufacturing licences.

Overall impact

The overall impact of these limitations and constraints is likely to be low given the careful consideration of the matters above and the long gestation time of the Bill more broadly overall. In short, Ministers can be reasonably confident when using the analysis in this RIS to inform their decisions.

Submissions to the Health Committee strongly indicated an issue for small-scale NHP producers and a need to examine an exemption (which this Regulatory Impact Statement examines). While there is no recorded evidence of significant public harm in New Zealand due to small-scale NHP producers, the known risks associated with NHPs and unknown number of small-scale NHP producers still pose some risk as one batch of unsafe NHPs could cause serious harm (even if the extent of the harm in terms of numbers of likely people impacted is limited in scope by the design of the proposed exemption).

Responsible Manager(s) (completed by relevant manager)	
Tim Vines Manager Therapeutics Policy Manatū Hauora | the Ministry of Health 10 May 2023	
Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health, Papers and Regulatory Committee
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled “The regulation of rongoā and small-scale producers of natural health products under the Therapeutic Products Bill”, produced by the Ministry of Health and dated May 2023.

[1] Ministry of Health (2015). The Regulation of Natural Health Products: Consultation document https://www.health.govt.nz/publication/regulation-natural-health-products-consultation

	The panel considers that the Impact Statement Partially Meets the quality assurance criteria. The Impact Statement is concise, complete and consulted. The analysis is clear and convincing with respect to small-scale NHP manufacturers but the panel considered that the RIS would benefit further clarity and information on the rongoa proposals to be fully clear and convincing, such as further detail on the precise nature of the Rongoā Advisory Committee and to what extent Māori will influence appointments.

Section 1: Diagnosing the policy problem

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

The Therapeutic Products Bill (the Bill) and regulation of natural health products

1. The Bill passed its first reading on 14 December 2022. Its purpose is to protect, promote, and improve the health of all New Zealanders by providing for the –

    a. Acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their life cycle; and

    b. Acceptable safety and quality of natural health products across their life cycle.

2. Natural health products (NHPs) are a broad group of products intended to support health and wellbeing. Examples include rongoā products, vitamin and mineral tablets, garlic capsules, omega-3 and glucosamine capsules, and herbal products such as echinacea tablets and herbal teas.

3. Whether a particular product is an NHP under the Bill depends if the ingredients in the product are also on a list of recognised 'NHP ingredients' (clauses 29 and 30). This list would be determined in secondary legislation following enactment of the Bill and with public consultation, including consultation with Māori (clause 380).

4. Under the Bill, nearly all therapeutic products, including NHPs, will require market authorisation from the Therapeutic Products Regulator (the Regulator). Manufacturers of NHPs and other therapeutics will also generally require a manufacturing licence. The purpose of market authorisations and licences is to ensure that products are safe to use; for example, that they are made in hygienic conditions and do not contain any ingredients which may endanger the product user.

5. Therapeutic products can only make certain authorised claims about what the product can do/achieve. The approved claims that a specific medicine and medical device can make will be set out in its market authorisation. The Bill enables the Regulator to make (via secondary legislation) a list of approved 'health benefit claims' that can be made in relation to a NHP. The Regulator will not approve all health benefit claims, although any such claim will need to be substantiated by scientific or traditional evidence.

The natural health products market and New Zealand consumers

6. Natural Health Products NZ, a national industry group, estimated that the sector was worth approximately $2.3b per annum to the New Zealand economy in 2019, growing at an estimated 10 percent per annum since 2014.[2] Exports were valued at $642 million, with significant potential for export growth. The global market for complementary and alternative medicines was estimated at USD$192 billion in 2018 and is expected to reach USD$271.8 billion by 2024.[3]

[2] Natural Health Products NZ (2019). Natural Health Products NZ Industry Survey 2019. https://www.survey.naturalhealthproducts.nz/

[3] Global Complementary and Alternative Medicines Market: Analysis and Forecast to 2024. https://www.businesswire.com/news/home/20200204005716/en/Global-Complementary-Alternative-Medicines-Market---Analysis-Forecast-to-2024---ResearchAndMarkets.com

7. Nielson IQ scan data in 2022 revealed that New Zealanders spent $135 million on vitamins, minerals and herbal extracts at the supermarket.[4] A survey of 1001 nationally representative New Zealanders aged 18 years and over that was carried out by Consumer NZ in November 2022, found that 55 percent and 54 percent of people had taken a multivitamin or vitamin respectively in the past 12 months. Other types of NHPs had also been consumed.[5]

Rongoā

8. Rongoā is a way of being (knowing and doing) to preserve and heal te taiao (nature), including tāngata (people), to achieve balance and sustain mauri (life-force) and wairua (spirit). Rongoā is not just knowledge and practice for the physical. The term rongoā is knowledge and practice that spans across cultivation, harvest, preparation, manufacture, production, aetiology, diagnosis, prognosis, and treatment/therapy – all according to mātauranga, tikanga and kawa. Every aspect of rongoā includes wairua or spiritual elements that is usually expressed through karakia.

9. Māori hold rongoā to be a taonga tuku iho (a treasure that is handed down from tūpuna or ancestors). In submissions on the Bill and through the rongoā workstream Māori have argued that inclusion of rongoā in the Bill is contrary to Te Tiriti o Waitangi. They argue that is a problem as it continues to undermine the rangatiratanga and mana of Māori, and the mātauranga possessed by Māori.

10. It was strongly asserted by many submitters on the Bill that Māori already regulate the practice of rongoā sufficiently well. It is regulated by Māori through specific practices, tikanga and kawa that have developed over centuries. Furthermore, there is no available evidence that the practice and regulation of rongoā to date has created significant risks to the health of the public. A literature review conducted in March 2023 examined reported harms from the use of NHPs that also included a section on rongoā.

11. The current version of the Bill does not specifically refer to rongoā. However, some products used in the practice of rongoā or made by rongoā practitioners may be captured under the Bill as NHPs or in rare cases medicines or medical devices.

Small-scale NHP producers

12. A Natural Health Products New Zealand survey of its members in 2019 found that about 51 percent were small to medium sized enterprises (SMEs) (5-49 SMEs)[6]. The Ministry of Business, Innovation and Employment defines small businesses as smaller than 20 employees, and reports that they account for 29.3 percent of employment and contribute over a quarter of New Zealand's gross domestic product (GDP).[7]

13. Only 5 percent of respondents from a Consumer NZ survey carried out in November 2022 said they bought their products from a natural health practitioner such as a

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[4] Consumer (2023). 'Pill popping'. Issue 619, Autumn 2023. consumer.org.nz

[5] Consumer (2023). 'Pill popping'. Issue 619, Autumn 2023. consumer.org.nz

[6] Natural Health Products NZ (2019). Natural Health Products NZ Industry Survey 2019. https://www.survey.naturalhealthproducts.nz/

[7] Ministry for Business, Innovation and Employment. Small business. https://www.mbie.govt.nz/business-and-employment/business/support-for-business/small-business/#:~:text=More%20information-,Small%20business%20in%20New%20Zealand,representing%2097%25%20of%20all%20firms.

naturopath or rongoā practitioner.[8] Another 6 percent of respondents said they bought products from their GP; 8 percent from large chain stores such as The Warehouse; 15 percent from health food stores; 18 percent from retailers such as online stores and 49 percent from the supermarket.

What is the policy problem or opportunity?

Regulation of rongoā

14. There is likely to be a material overlap between small-scale NHP producers and rongoā practitioners who supply their products outside a patient consultation. As such, the above discussion also applies to rongoā practitioners.

15. However, there are specific Te Tiriti considerations that apply in relation to the inclusion of rongoā in the Bill (even if its inclusion is indirect).

16. Through submissions on the Bill and the rongoā workstream, Māori have strongly expressed their dissatisfaction with the inclusion of rongoā and have requested that rongoā is excluded from the Bill. This request is based on Te Tiriti grounds (including the status of rongoā under Te Tiriti), acknowledging the role of tikanga and kawa in providing the safety of rongoā for Māori and ongoing concerns from Māori about Crown interference with the practice of rongoā.

17. Under the current regulatory regime of the Medicines Act 1981, the practice of rongoā is already regulated to some extent because rongoā practitioners cannot currently make 'therapeutic claims' about their products unless they are approved medicines. The new Bill provides an opportunity to properly engage with considerations under Te Tiriti, including the Crown's duty of active protection.

Regulation of small-scale NHP producers

18. The majority of submitters on the Bill (54 percent) opposed the regulation of NHPs, with many (more than a quarter but less than half) arguing that the proposed regulation was out of proportion to risk from NHPs. There were concerns about impacts on small-scale producers, including the possibility that regulatory costs would drive small producers out of business.

19. Fees for market authorisations and manufacturing licences have not yet been set. However, fees could make some small-scale New Zealand NHP producers who supply within New Zealand unprofitable. This might not, therefore, support an open and well-functioning market, or choice and equity of access to products.

What objectives are sought in relation to the policy problem?

20. The objectives sought in relation to the policy problem are to:

    a. ensure that regulation of NHPs is proportionate to risk

    b. ensure that small-scale producers and Māori are not excluded from the market and business opportunities

[8] Consumer (2023). 'Pill popping'. Issue 619, Autumn 2023. consumer.org.nz

c. provide clarity to regulated parties (or those who would *not* be regulated under the Bill), especially those who lack access to the resources of larger companies

d. identify a workable and implementable solution that does not undermine the overall integrity of the proposed Therapeutic Products Bill.

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

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

21. Different selection criteria are used for the two proposals in this document.

Rongoā

22. The following selection criteria are based on the ability of the options to meet the Crown's obligations under Te Tiriti according to the principles of Te Tiriti:

    a. **Tino rangatiratanga** – denotes Māori authority to govern themselves and determine their own destinies, to participate in Crown governance, law, and policy, and to have their rights protected. Māori possess centuries of mātauranga, kawa and tikanga for rongoā and has been passed down for numerous generations.

    b. Tino rangatiratanga does not detract from the Crown's duties to respect and protect the rights of all individuals, including Māori. It is a model inspired by an understanding of equity that means all peoples and individuals should be able to realise their potential, but that this might only be possible if different approaches are taken for different peoples and individuals. It does not mean that all individuals must be treated the same.

    c. **Active protection** – the Crown has the obligation of actively protecting rongoā. This protection is in both the benefit and enjoyment of rongoā, as well as the protection of mana (authority) to exercise control over it. The degree of protection is dependent on the nature and value of the rongoā to Māori. The value placed on rongoā is a matter for Māori to determine. Additionally, such value is not confined to, or restricted by, traditional uses of rongoā. It includes present day usage, and such potential usage as may be thought appropriate by those having rangatiratanga over rongoā. The rongoā workstream has heard through engagement, and previous Waitangi Tribunal reports, that rongoā is a highly valued taonga tuku iho to Māori.

    d. **Partnership** – The Crown must work in partnership with Māori in the governance, design, delivery, and monitoring of health services. Māori must be co-designers, with the Crown, of the health system for Māori. In the context of rongoā, this mean forming genuine relationships with rongoā practitioners and groups, built on mutual trust and under pinned by Te Tiriti.

    e. **Equity** – In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes. For rongoā, equity ensures that rongoā should be available to meet the health needs of people, should they choose to access it.

    f. **Options** – There must be provision for and proper resourcing of kaupapa Māori health services, including rongoā. Furthermore, the Crown is obliged to ensure that all health and disability services are provided in a culturally appropriate way that recognises and supports the expression of mātauranga, including rongoā, at every facet of the health system.

23. The following selection criteria are generic considerations:

    a. **Time required for implementation** – time to implement the preferred option is restricted to the legislative timeline for the Bill.

    b. **Difficulty of implementation** – additional resource, expertise of rongoā and the support of Māori will be required for implementation of the preferred option.

Small-scale producers

24. The selection criteria for regulation of small-scale NHP producers reflect the purpose of the Bill in clause 3, the principles set out in clause 4, and general principles of good regulatory practice. The criteria are:

    a. **Protection of the public:** As per the purpose of the Bill, the health of all New Zealanders should be protected by providing for the acceptable safety and quality of NHPs. This means that any significant risks from NHPs should be addressed through regulation. This principle should be weighted more strongly than the other principles, reflecting the relative importance of the purpose and principles in the Bill;

    b. **Support for small business:** principles guiding exercise of powers under the Bill are to support:

        i. timely availability of therapeutic products (including NHPs)

        ii. open and well-functioning markets for those products

        iii. innovation, including opportunities for Māori

        iv. choice of, and equity of access to, products for Māori and other population groups;

    c. **Good regulatory practice:** Regulation should follow the government expectations for the design of regulatory systems, including clarity, flexibility, fairness, and meeting objectives with the least cost;[9]

    d. **Time required for implementation:** time to implement the preferred option is restricted to the legislative timeline for the Bill;

    e. **Difficulty of implementation**: ability to draft requirements that give effect to the desired outcome.

25. Taken together, these criteria require regulation, and especially regulatory cost, to be proportionate to risk. Proportionate regulation will protect the public from higher risk NHPs while supporting small-scale producers of low risk NHPs.

What scope will options be considered within?

26. The Bill is currently before the Health Select Committee. While there is scope to adjust elements of the regulatory framework within the Bill, the overall framework will not change. The options for both rongoā and small-scale NHP producers are therefore

[9] https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

limited to the status quo in the Bill as introduced, or full or partial exemption from regulation under the Bill.

27. The scope of options presented reflects the commissioning of establishing the rongoā workstream and decisions made by the Minister of Health and Associate Minister of Health (Māori Health) based on the advice of the rongoā workstream where other options were considered but ruled out (partial exclusion, partial inclusion, and a strengthened approach of the status quo).

28. Engagement with Māori through the rongoā workstream has also significantly influenced the development of these options.

What options are being considered?

Rongoā

Option 1 – leave the Bill unamended (Status Quo)

29. The current version of the Bill does not specifically refer to rongoā. However, some products used in the practice of rongoā or made by rongoā practitioners may be captured under the Bill as NHPs, medical devices or, in rare cases, medicines.

30. Whether a particular rongoā product is an NHP under the Bill depends if the ingredients in the product are also on a list of recognised NHP ingredients. This list would be determined in secondary legislation following enactment of the Bill and with public consultation, including consultation with Māori (clause 380).

31. Under the version of the Bill introduced to Parliament, rongoā and rongoā practitioners will be subject to provisions in the Bill controlling certain activities (such as manufacturing NHPs) and imposing an obligation to obtain market authorisations before importing, supplying and exporting products. Other provisions relating to what health benefit claims can be made in relation to NHPs and rules governing advertising, manufacturing, supply and supply chain activities would also apply.

Option 2 – Expressly disapply provisions of the Bill from applying to rongoā and establishing a process to determine the scope of the exclusion

32. Under this option, the Bill would be amended to disapply many of the provisions of the Bill in their application to rongoā practitioners and to establish a process of informing the scope of the exemption, to be given effect via secondary legislation.

33. Specifically, the Bill would be amended to remove obligations currently in the Bill requiring rongoā practitioners to:

    a. apply for a NHP manufacturing licence for making NHPs if the product is intended to be used in a rongoā service or activity

    b. obtain a market authorisation for NHPs prior to supplying those products in New Zealand if the product is intended for use in a rongoā activity or service (including limited wholesale supply)

    c. obtain a market authorisation for NHPs exported to patients of the rongoā practitioner or at the request of another rongoā practitioner.

34. Excluding devices made and used by rongoā practitioners would be achieved via regulations made under existing provisions in the Bill.

35. Rongoā will remain subject to clauses of the Bill relevant to wholesale supply, in particular large-scale wholesale supply (such as pharmacies and supermarkets) and wholesale supply via exports. This is to ensure that high-quality products are made

available on the domestic market and that products meet export standards and official Government endorsement of rongoā products is obtained through export certificates issued by the Ministry of Primary Industries.

36. Due to the rongoā being held as a taonga by Māori and the expertise of rongoā laying with Māori, only a minimal definition would be included in the Bill and, to enable an ongoing discussion between Māori and the Regulator, a statutory Rongoā Advisory Committee (the Committee) would be established.

37. The role of the Committee would be to provide advice to the responsible Minister on the nature and scope of rongoā and rongoā practitioner for the purpose of exemption and any other advice on rongoā requested by the Minister or Regulator.

38. The Committee would also provide advice to the Minister on excluding devices used in rongoā via regulations made under clause 16(3) and 19(2). Building off the proposal to create an exemption power in relation to small-scale NHP producers, the Committee would also advise on the use of this power in relation to rongoā. The Committee would provide advice in relation to a proposal to prohibit a product under clause 33.

39. In its undertakings, the Committee would need to ensure it took account of local variation and evolution in the understanding and practice of rongoā, and ensure its advice reflects and accommodates local mātauranga as it applies to rongoā.

40. Appointment to the Committee would need to be done in a manner that supported Māori leadership in the operationalisation of the exemption provision. Different methods of appointment are possible, including appointment by the Minister of Health after consulting with the Minister of Māori Development and any other persons the Minister believes to have the appropriate mātauranga or knowledge of rongoā and the delivery of rongoā services. This may include Te Aka Whai Ora, ACC, Ara Poutama Aotearoa Department of Corrections, iwi, hapū, marae, rongoā practitioners or rongoā collectives. It is important for the Minister of Māori Development to be consulted to ensure that the wider impacts for rongoā, especially in the Government's response to Wai 262, is considered by the Minister of Health.

41. The Minister will be required to consider the advice provided by the Committee and to the extent and in the form the Minister considers desirable, give effect to that advice. This could be via regulations made under the Bill or a direction to the Regulator under clause 333 of the Bill. If the Minister disagrees with the advice (in whole or in part), the Minister would be required to table a statement in the House of Representatives explaining why they did not accept the advice.

42. This option does not seek the exclusion of rongoā from the regulations for wholesale exports of rongoā. This is due to access to the wholesale export market requiring Government imprimatur or official endorsement for exporting certificates to be granted by the Ministry for Primary Industries and to ensure the export of rongoā meets the standards of the importing country.

Small-scale producers

Option 1 – leave the Bill unamended (Status quo)

43. The Bill regulates small-scale NHP producers in the same way as larger producers, with requirements to be licensed to manufacture and for every product to be authorised. Fees for licences and authorisations would be set in regulations on a cost-recovery basis.

44. The Bill provides flexibility that includes potential consideration of low production volumes or turnover. Applications could be made to the Therapeutic Products Regulator (the Regulator) for a single licence to cover all manufacturing and supply activities, rather than needing individual product authorisation. However, this would rely on the Regulator implementing such a licensing regime.

45. Fee reductions or waivers for individual market authorisation could also be considered.

Option 2 – Exemption in the Bill for small-scale NHPs

46. Under this option, all New Zealand NHP producers below a certain volume or turnover would be specifically exempt in the Bill from requirements for market authorisation and manufacturing licences when supply was within New Zealand.

Option 3 – Enable an exemption scheme for small-scale NHP producers

47. Under option 3, the Bill would be amended to enable regulations to exempt classes of New Zealand NHP producers below a certain volume or turnover. The level below which an exemption would apply would be set in regulations rather than the Bill itself. This would enable the level to be adjusted without amending primary legislation, should monitoring show that it is too high or too low.

48. In determining the scope of the exemption in secondary legislation, the following matters would be taken into account:

    a. any inherent risks associated with the ingredients used in specific NHPs, safe manufacturing and handling requirements and other factors that are relevant in providing for acceptable safety and quality of NHPs

    b. the potential impact on consumers, including those related to risk, access and choice of products

    c. the frequency and scale of operation, including whether supply is via online. Online sales pose a greater risk because a purchaser has less ability to ask questions from the manufacture or to follow up on an issue if there is no contact provided other than the webpage.

    d. the appropriateness of regulatory control in comparison with controls specified for other NHPs or therapeutic products, or types or descriptions of producers.

49. The exemption would not apply to small-scale importers, even though they may have a large range of products that they supply in small amounts. This is because the Regulator would not be able to ensure that the imported products met any risk proportionate manufacture standards that might be set.

50. The exemption would also not apply to small-scale retailers, other than when they are small-scale NHP producers. Generally, the NHPs sold by retailers will have market authorisation from the importer or wholesaler that they obtain their goods from.

51. Examples of activities that may be covered by an exemption include where NHPs are supplied at a physical event a certain number of times a year (e.g., a farmers' market or school fete), or limited numbers or volume are made in the home and supplied in-person to someone. A condition would be that the products supplied under this exemption are intended for the use of the purchaser or their family (i.e., they are not intended for resale). Additional labelling requirements would be applied to indicate a product has been exempt from most requirements of the regulatory regime and cannot be resold.

52. These approaches allow a purchaser to ask questions about how the ingredients are sourced and manufactured, and how claims are substantiated. Claims that have been pre-approved by the Regulator would be the only claims that would be able to be made.

53. A similar approach is adopted in section 33 of the Food Act, which enables activities such as sausage sizzles, food supply by small scale accommodation providers, and selling home-grown produce at a farmers' market, to be exempt from the general requirement to operate under a food control plan or national programme.

54. Any exemption could be amended or revoked, and conditions could apply to the exemption (e.g., information must be available on request from the Regulator).

How do the options compare to the status quo?

Rongoā

	Option 1 – Status Quo	Option 2 – Expressly excluding rongoā and establish a statutory Rongoā Advisory Committee
Tino rangatiratanga	0 Does not enable Maori decision making or authority as to their control of their taonga	++ Rangatiratanga and mana of Māori is recognised by disapplying many of the provisions on the Bill in relation to rongoā. Rangatiratanga and mana of Māori is recognised through the recognition of Māori expertise, inclusion of Māori in the nomination process and establishment of the Rongoā Advisory Committee. Māori can also provide evidence of who are rongoā practitioners for the purpose of exclusion.
Active protection	0 Is not active, it is passive and silent as to the status of Rongoa or how it is protected	++ Achieves the exclusion of rongoā and protects rongoā from interference where there is no evidence of harm. The regulator is also advised by experts on rongoā through the establishment of the Rongoā Advisory Committee.
Partnership	0 There is no explicit partnership between Māori and the Crown on this matter. Past conduct whereby the Crown has conducted itself in these matters (e.g., Tohunga Suppression Act 1907) create considerable mistrust and fear.	++ Partnership between Māori and the Crown is enabled through the process and establishment of the Rongoā Advisory Committee.
Equity	0 The issue of equity and Rongoa is not explicitly addressed	+ Māori expertise on rongoā is enabled and prioritised through the establishment of the Rongoā Advisory Committee and requirements for the Minister and Regulator to seek and take account of the advice.
Options	0	+

	No real options for explicit exclusion of Rongoa from Crown interference	The exemption would still enable Māori, including rongoā practitioners, to continue to practice rongoā as they previously have and also access the new therapeutic products regime.
Time for implementation	0 The status quo requires no time to implement	- There is limited time to establish the Committee and for the Committee's advice to be provided to the Regulator and inform secondary legislation.
Difficulty of implementation	0 Does not require additional amendments to the Bill and no further resource for implementation. But could lead to unintended negative consequences in the implementation phase.	0 Exclusion can be achieved through a Supplementary Order Paper but the establishment of the Rongoā Advisory Committee may require additional funding and resource to implement.
Overall assessment	0	7

Small-scale NHP producers

	Option 1 – Status Quo	Option 2 – Exemption in the Bill for small-scale NHPs	Option 3 – Exemption scheme
Protection of the public	0 Regulatory oversight would apply to all NHPs, irrespective of the scale of operation	- - No regulatory oversight of, or protection from, unsafe products, either pre- or post-marketing.	- Risks may arise, although post-marketing controls could be put in place. Also, parts of the Bill will still apply to small-scale NHP producers (e.g., NHPs could not be administered by injection or parenteral infusion).
Support for small business	0 Existing tools within the Bill provide for discretionary decisions (e.g., licenses and permits)	+ Small-scale NHP producers would have reduced regulatory costs (time and money) for products supplied within New Zealand for a while. Over time, however, it would be less clear because of the potential for unintended consequences (e.g., if safety issues arose that may have otherwise been prevented by regulatory oversight, it could result in reputational damage and loss of business). Products that were exported would need export authorisation and certification to meet importing requirements.	+ Small-scale NHP producers would have reduced regulatory costs (time and money) for products supplied within New Zealand for a while, noting the scope of the exemption would not be clear until regulations are developed once the Bill is enacted. Products that were exported would need export authorisation and certification to meet importing requirements. Over time, however, it would be less clear because of the potential for unintended consequences (e.g., if safety issues arose that may have otherwise been prevented by regulatory oversight, it could result in reputational damage and loss of business).
Good regulatory practice	0 Could provide for a stream of benefits or positive outcomes in excess of its costs or negative outcomes through flexible tools in the Bill	- - Would be simple, transparent, and cost effective for the Regulator and small-scale NHP producers. However, it would be inflexible, and likely negative outcomes and/or unfairness (e.g., with small-scale importers or retailers) would arise that would not be	- Could be proportionate to the risks and benefits, transparent and cost effective for the Regulator and small-scale NHP producers. However, exempting groups of NHP producers via regulations risks unintended consequences and/or unfairness (e.g., with small-scale importers or retailers).

		able to be resolved without amending the Therapeutic Products Act.	
Time to implement	0 The status quo requires no time to implement as no change would be required to the Bill.	- - The Bill would not be able to be implemented before the general election as developing a threshold for the exemption would take significant analysis and consultation.	**0** Change could be implemented before the general election, by introducing a Supplementary Order Paper. However, there would be insufficient time to engage on affected parties.
Difficulty of implementation	0 Issuing a single licence to a business for all NHPs and manufacture could undermine the NHP regulatory system as all businesses might argue for such an approach. Developing fee reductions and waivers will likely be difficult.	- - Setting a threshold in the Bill based on a volume or unit number of NHPs, an annual turnover (i.e., business income) or profit would be difficult. Business may seek ways to be exempt, although they would not be able to supply NHPs by wholesale or export products.	- Setting a threshold in regulations, based on a volume or unit number of NHPs, an annual turnover (i.e., business income) or profit would be difficult. Business may seek ways to be exempt, although they would not be able to supply NHPs by wholesale.
Overall assessment	0	**-7**	**-3**

Key for qualitative judgements:

++	much better than doing nothing/the status quo
+	better than doing nothing/the status quo
0	about the same as doing nothing/the status quo
-	worse than doing nothing/the status quo
- -	much worse than doing nothing/the status quo

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

Rongoā

55. Option 2 has advantages relative to the status quo, and is most likely to address the problem, achieve the policy objectives and deliver the highest net benefits.

56. Benefits of option 2 include:

    a. the recognition of the role and leadership of Māori in the practice and evolution of rongoā

    b. genuine partnership between Māori and the Crown is embedded in legislation

    c. the ability for Māori to determine outcomes for rongoā in the development of secondary legislation,

    d. ability for the rongoā sector to grow more than it would under the status quo,

    e. the Regulator is supported with expert rongoā advice, and

    f. Māori expertise of rongoā is enabled and prioritised within the regulatory regime.

Small-scale NHP producers

57. The analysis for small-scale NHP producers is based on greater weight being given to addressing non-direct risks associated with NHPs (such as misinformation and 'loss of chance' to access mainstream health services), and accounting for an expected underreporting of harm from NHPs

58. Option 1 (status quo) carries the least risk to the public from using unsafe NHPs. Options 2 (exemption in the Bill for small-scale NHPs) and 3 (exemption scheme) carry some risk because there is no regulatory oversight other than through post-marketing monitoring of NHPs. Option 2 provides greater risk than option 3. As discussed above, there is evidence of harm from using NHPs, but no recorded evidence of significant harm from using NHPs produced by small-scale NHP producers (noting there is little if any data available). There is always the potential for harm that might not otherwise occur with regulatory oversight.

59. Options 2 and 3 better support small businesses than the status quo, with a general exemption being more supportive than an exemption scheme. It is unclear whether both options would continue to support small business over time because of the potential for unintended consequences (e.g., if safety issues arose that may have otherwise been prevented by regulatory oversight, it could result in reputational damage and loss of business).

60. Option 1, when implemented with single licencing for market authorisation and manufacture, as well as fee reductions or waivers, would likely be proportionate, fair and equitable for small-scale producers. Option 2 would be simple and transparent, but over time is unlikely to be proportionate, fair and equitable given its inflexibility. Option 3 provides better regulation than option 2 but exempting groups of NHP producers via regulations also risks unintended consequences and/or unfairness.

61. Option 1 would be easy to implement and would be achieved before the general elections as no changes would be required. Option 3 could be achieved within the timeframe, although determining a particular threshold would be difficult to justify.

Option 2 would not be able to be implemented within the required timeframe as it would be difficult to determine the threshold with justification.

62. Overall, given the greater weightings, option 1 (status quo) is recommended. It best reflects protecting the public, providing risk proportionate regulation, and providing measures that assist small-scale NHP producers from being excluded from the market unnecessarily (e.g., the Regulator could reduce or waiver fees). Option 1 would also be able to be implemented before the general elections as no changes would be required.

63. There is, however, some risk that the costs cannot be easily reduced or waived (e.g., if larger businesses were not prepared to cross-subsidise them). This could result in the costs being prohibitive for some producers. Protecting the public means that certain standards must be met, and this can best be met by meeting certain standards.

64. The analysis could have given a greater weight to mitigating realised and proven harms from the use of NHPs, and supporting small businesses. If this were the case, then option 3 would be ranked more highly, and could also be a recommended option.

What are the marginal costs and benefits of the options?

Rongoā

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the preferred option compared to taking no action			
Crown (Ministry of Health)	Costs for establishment and ongoing role of the Rongoā Advisory Committee and the exemption scheme	Low – costs estimated to be $600,000.00 (fees and expenses for Committee). There may be costs for engagements with Māori to establish the Committee.	Low .
Total monetised costs		Estimated $600,000.00	
Non-monetised costs			
Additional benefits of the preferred option compared to taking no action			
Regulator	Ongoing expert advice on rongoā.	Medium	High – the Regulator does not possess the required expertise of rongoā.
Māori / rongoā practitioners	Can see the immediate impacts of the Bill on rongoā. Confidence in the regulatory regime and not being subject to unjustified interference of the Regulator.	High	High – feedback through engagement highlights Māori wanting rongoā to be excluded from the Bill.
Consumers of rongoā and other NHPs	Greater selection of NHPs, especially rongoā, on the market; potentially lower prices due to lower regulatory costs to producers	Medium	Medium
Non-monetised benefits		High	High

Small-scale NHP producers

The preferred option is status quo (ie, as applied in the Bill that is being considered by Parliament). There is therefore no need to consider marginalised costs and benefits of the

preferred option compared to taking no action because it would be comparing the same things.

The analysis indicated that if a greater weight was given to mitigating realised and proven harms from the use of NHPs, and supporting small businesses, then option 3 would be ranked more highly, and could also be a recommended option. Option 3 is the Minister of Health's preferred option. The following table, therefore, considers the marginalised costs and benefits of option 3.

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of option 3 compared to taking no action			
Small-scale NHP producers	Ongoing lower regulatory costs for low risk NHPs, assuming there is no harm to the public from using exempt NHPs, and small-scale NHP producers comply with any requirements (e.g., minimal product standards and labelling requirements).	Low	Medium. There is limited evidence other than via submissions to Health Committee that taking no action would be cost prohibitive. There is limited evidence on how large this group is. There will be cost savings though.
Regulator	Ongoing lower post-market surveillance costs, except when a review was being undertaken that targeted small-scale NHP producers. This is based on there being no public harm from using exempt NHPs. Authorisations and licencing are cost recovered activities so this would not affect costs for the Regulator.	Medium	Medium. There is limited evidence on how frequently reviews will be needed for this sector compared to taking no action. The costs of a review will be high, given it will be hard to reach this sector. It is likely there will be some cost savings.
Consumers of NHPs	Ongoing lower costs, provided small-scale NHP producers do not include the compliance costs that they would otherwise include if the exemption did not apply.	Medium	Medium. There is little evidence to indicate the extent to which small-scale NHP producers would price their products according to their costs rather than their competitor's pricings who do not have an exemption.
Total monetised costs		-	-
Non-monetised costs		Medium	Medium

Additional benefits of option 3 compared to taking no action			
Small-scale NHP producers	Time and money are saved that can be spent elsewhere, and the business can continue to operate, assuming it would otherwise be viable	High	Medium. Small-scale NHP producers will clearly benefit but the benefited amount is not yet known.
Regulator	No requirement to authorise NHPs and grant manufacturing licences for small-scale NHP producers. This is based on there being no public harm from exempt products.	Low	Medium. Although there is a benefit, that will be diminished if exempt products are unsafe and cause public harm, in which case the Regulator will have to review the exemption/s given.
Consumers of NHPs	For consumers who purchase from small-scale NHP producers, there would be a continued ability to purchase from them.	Medium	Low. It is not known how many consumers need/want to purchase NHPs from small-scale NHP producers as opposed to other producers.
Total monetised benefits		-	-
Non-monetised benefits		Medium	Medium

Section 3: Delivering an option

How will the new arrangements be implemented?

Rongoā

65. As outlined in Option 2 above, implementing this option will require amendments to the Bill through a supplementary order paper:

    a. to exclude rongoā from the Bill (noting that exclusion does not apply to wholesale supply),

    b. provide a legislative basis for the establishment of the Rongoā Advisory Committee,

    c. description of the Rongoā Advisory Committee's role and functions,

    d. an appointment process for the Rongoā Advisory Committee, and

    e. a compulsory requirement for the Minister to implement the advice of the Rongoā Advisory Committee, including the development of an assessment of rongoā for wholesale export.

66. Implementation will also require establishing the Rongoā Advisory Committee and adequate funding and resource.

67. The Rongoā Advisory Committee will need to be established in the early stage of implementing the Bill to ensure the Regulator is well-supported in enacting its functions and development of secondary legislation.

68. The secondary legislation of the regulatory regime will need to be completed and ready for enactment by 1 September 2026 as indicated in the Bill. Failing to have a comprehensive regulatory regime in place will mean that rongoā will be subject to the default approach of the Bill.

69. Māori will need to be engaged in the appointment process to ensure the selection criteria of candidates reflects the aspirations, rangatiratanga and mana of Māori for rongoā. This will require strategic engagement and communications plans to ensure a robust and fair process is implemented. Additionally, the engagement and communications plan will need to ensure Māori are aware and well-informed of the implications of the Bill for rongoā.

70. Through the engagement of the rongoā workstream, Māori strongly expressed their mistrust of Crown and its Government. This may pose a risk of Māori not engaging with or supporting the implementation of this option. The engagement and communications plans will need to address this matter and strengthen the relationship between Māori and the Crown. This process can be supported by Te Aka Whai Ora.

Small-scale NHP producers

71. The scheme will be developed as part of general work on secondary legislation and in the implementation of the regulatory regime for NHPs. There will be extensive engagement with NHP producers, particularly small-scale producers.

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

Rongoā

72. Concerns regarding rongoā may be raised directly with the Rongoā Advisory Committee and addressed accordingly. A system issues log or equivalent will be established for the Rongoā Advisory Committee to support their processes of recording and responding to issues.

73. As part of their stewardship role, Manatū Hauora will monitor the Rongoā Advisory Committee to ensure they are fulfilling their legislative role and functions. Māori will be able to raise concerns of the Rongoā Advisory Committee with Manatū Hauora and the Minister of Health.

74. If the Rongoā Advisory Committee fails to deliver on its legislative role and functions, that would compromise the implementation of the regulatory regime. By 1 September 2026 Manatū Hauora will advise the Minister of Health on any applicable circumstances and provide advice to the Minister of Health of the available options to remedy matters.

75. If the Rongoā Advisory Committee fails to deliver on its statutory function, Manatū Hauora will advise the Minister of Health of these circumstances and provide advice to the Minister of Health of the available options to remedy matters.

76. As part of their monitoring role, Te Aka Whai Ora and Te Whatu Ora may monitor the delivery of rongoā services and provide public reports on the results.

Small-scale NHP producers

77. The Regulator would review small-scale NHP producers through auditing individual operations that have obtained single licensing at regular intervals. The frequency of auditing would be prescribed in rules under the Bill. Where audits identify ongoing compliance issues with a producer, one or more NHPs, or the licence to manufacture may be suspended or cancelled.

78. Additionally, post-marketing surveillance of the entire sector of small-scale NHP producers would occur to assist in a five-year review. This would help ensure they comply with any requirements that apply to them, including manufacturing standards. It may include examining any suspected adverse reactions and investigations, as well as random and/or targeted post-marketing reviews.