Coversheet: Regulating natural health products

Advising agencies	Ministry of Health; Ministry for Primary Industries
Decision sought	Regulation of natural health products under the Therapeutic Products Bill
Proposing Ministers	Minister of Health, Associate Minister of Health with responsibility for natural health products; Minister for Food Safety.

Summary: Problem and Proposed Approach

Problem Definition

What problem or opportunity does this proposal seek to address? Why is Government intervention required?

Natural health products include dietary supplements, preparations used in traditional practices such as rongoā Māori, long-established practices including Chinese medicine, and western practices such as aromatherapy and homeopathy. Natural health products are not risk-free – generally speaking they are higher risk than foods, and lower risk than medicines.

The current approach to regulation of natural health products is not fit for purpose. Efforts to improve the situation have been ongoing for more than a decade.

The main areas of concern with the status quo are:

- Consumer safety and information: limited ability to ensure consumers are using products that are safe, are what they say they are, and that the information provided about them is accurate, complete, and helps consumers make informed choices about their health and wellbeing.
- Barriers to growth and innovation: there is no ability for a regulator to certify that New Zealand-made natural health products have been produced under a recognised regulatory scheme. This reduces market access and stifles innovation and industry development. New Zealand is demonstrably out of step with international norms in this area.
- Piecemeal regulation of natural health products: there is no comprehensive scheme for natural health products, resulting in a complex and incomplete regulatory landscape.
- No ability to recognise or actively protect rongoā Māori or to recognise traditional evidence of use and effects.

Summary of Preferred Option or Conclusion (if no preferred option)

How will the agency's preferred approach work to bring about the desired change? Why is this the preferred option? Why is it feasible? Is the preferred approach likely to be reflected in the Cabinet paper?

In July 2019 the Minister of Health agreed to a new regulatory scheme for natural health products, with two main objectives (HR20191339 refers):

a. Support **consumer safety** – by providing assurance of product quality and reliable information including labelling, health claims[1], advertising, marketing, and promotion) to encourage consumers to make informed choices about their health and wellbeing; and

b. Support **industry development and growth** – by establishing a well-functioning, cost effective regulatory scheme that provides greater clarity and certainty to the sector on their obligations and the pathways to follow; and to create an internationally-recognised regulatory scheme providing export certification and improve market access.

We considered three options for regulating natural health products:

Option 1: status quo: passive inclusion in the Therapeutic Products Bill. Natural health products that are captured by the Bill would be regulated as medicines.

Option 2: regulation under a stand-alone Natural Health Products Bill

Option 3: regulation of natural health products under the Therapeutic Products Bill.

We recommend **Option 3**. We consider this option provides the most timely and efficient means of achieving the policy objectives. The principles and purpose of the Bill provide for a risk-based, proportionate approach to regulation that minimises regulatory cost and burden while maintaining appropriate oversight, and an approach tailored to the risk profile of natural health products. Option 3 also provides for recognition and protection of rongoā Māori.

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

The main expected beneficiaries are consumers, the natural health products industry (suppliers, importers, exporters manufacturers and retailers), and regulators. There are specific benefits for Māori in relation to recognition and active protection of rongoā Māori.

A comprehensive, tailored regulatory scheme would benefit consumers by providing greater assurance that products are safe, made to a good quality, contain what they claim, and are accompanied by accurate, complete information to inform consumer choices about their health and wellbeing.

All parts of the industry would have certainty about the requirements that apply the manufacture, provision and/or sale of their products. A comprehensive scheme would clarify product and process approval processes, and set clear expectations at all parts of the supply chain. A single regulatory scheme and a single regulator will be more efficient for the sector, and support compliance and consistent, proportionate enforcement.

Exporters will benefit from a robust scheme that other jurisdictions can recognised as providing safety and quality assurances. The scheme will provide for the regulator to issue export certification, opening new export markets and provide a solid platform for industry development and innovation. There will be greater incentives to conduct research and develop new products

[1] Health benefits claims refer to products that support health and wellbeing, distinct from therapeutic claims for products proven effective (usually through clinical trials) in the treatment of named conditions. Therapeutic claims cannot be made for natural health products; any product for which therapeutic claims are made will, as is the case now, be regulated as a medicine.

Where do the costs fall?

This proposal is for a new comprehensive and consistent regulatory scheme. It is likely to include producers who have not previously been subject to regulation and may involve additional costs to those currently regulated under other schemes, for example food or cosmetics. A key component of the design of the scheme is that regulatory controls and costs will be proportionate. Higher risk products will generally require greater oversight and incur a higher regulatory cost burden than lower risk products.

Consumers may bear some costs where producers pass on increased compliance costs. There is the potential for some products to be removed from sale if the compliance cost and/or regulatory burden makes them uneconomic. (In the case of products where the risk profile triggers safety and/or quality assurance controls that the producer cannot afford to meet, then withdrawal from the market may in fact protect consumer safety.)

The Crown may incur additional costs associated with establishing the regulatory agency proposed by the Therapeutic Products Bill; however, we anticipate that these will be marginal and related to securing the skills and knowledge specific to natural health products, and sector-specific work such as tailored guidance, engagement and consultation, and international engagement on natural health product regulation (if required).

There will be costs associated with establishing processes to regulate natural health products, and guidance to support the industry's transition to and sustained participation in the regulatory scheme. Compliance and enforcement activities will result in costs to the regulator.

What are the likely risks and unintended impacts? How significant are they and how will they be minimised or mitigated?

Costs of the scheme

There is a risk that the new scheme may introduce compliance costs that are too high. This would result in a disproportionate burden on businesses: some may exit the market, or increase the price of their products. Both outcomes would reduce consumer access to natural health products. There are two mitigations available: targeted engagement with the sector to inform the setting of oversight costs as part of the cost recovery scheme development; and a transition period. This will give the industry time to plan for and adjust to the new scheme.

The Bill provides that the regulator must review the methods and levels of cost recovery at least once every three years (s256(2)).

Sector perspectives and concerns

While most of the natural health products sector is cautiously supportive of regulation, there is a small group who oppose regulation of these products, and in particular regulation under the same scheme as medicines. There is a risk that if this group's view gain traction, it could delay the passage of the Therapeutic Products Bill, and introduce uncertainty about the benefits of the proposal to regulate natural health products.

We anticipate a period of vocal opposition from opponents of natural health products regulation. Early and open engagement with the sector, and delivery of consistent, factual,

and open communication will help minimise the risk of a minority view delaying the benefits of a robust regulatory scheme.

Treaty of Waitangi implications

The Ministry of Health's Te Tiriti o Waitangi Framework and Whakamaua: Māori Health Action plan includes goals and principles expressed in terms of mana. The application of these principles and goals, informed by engagement with rongoā Māori practitioners, will minimise risks and unintended impacts of regulation of natural health products.

Those risks relate to reduced access to rongoā Māori through increased compliance costs and/or controls on ingredients and finished products. This would be a barrier to achieving the goals of mana motuhake – the right to make choices that reflect Māori values and practices; and mana Māori - enabling Ritenga Māori (customary rituals) that support wellbeing and are encapsulated in mātauranga Māori (Māori knowledge).

Recognition and active protection would contribute to achieving a balance between growth and protection of mātauranga Māori in a time of commercialisation, and sector and export market expansion.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?

Our assessment of the evidence strength is moderate.

Consumer safety

Natural health products are not risk-free. As there is no framework for post-market monitoring of natural health products in New Zealand, it is not possible to determine how many people may have been harmed by natural health products. Based on adverse reactions data from Australia and other international recall data, it is reasonable to assume that natural health products do result in harm in New Zealand.

Many larger manufacturers voluntarily apply recognised standards; however, these are not audited or independently checked by a regulatory agency. Choosing to apply those standards represents a willingness to demonstrate good practice, while at the same time highlights the lack of a level playing field for manufacturers and an inconsistent approach to product quality which can impact consumer safety.

Producers want to (and do) make claims about their products; however, there is inadequate oversight and control over the validity of the claims.

The Dietary Supplements Regulations 1985, which specify, for example, allowable levels of minerals and vitamins are prescriptive and outdated, and do not cover products that are intended for therapeutic, not food uses. The Medicines Act 1981, which does cover therapeutic products, has no suitable pathway for approving supplements and similar products.

Evidence for market growth opportunities

Anecdotal evidence indicates that there is significant opportunity for export market growth; and that benefits unrealised due to limitations on export market access has not been quantified; however, we are confident that it is significant.

International good practice

New Zealand is unusual in not having a regulatory scheme for natural health products. The World Health Organization conducted a survey in 2018 which asked if Member States had laws or regulations on traditional and complementary medicines. Of the 170 states that

responded, 65 percent had a legislative framework for natural health products. New Zealand is in the minority generally, and certainly among our major trading partners. Comparable jurisdictions including Australia, the UK, China, and the EU have comprehensive regulations. China and Canada are strengthening their schemes to improve product quality standards and improve the standard of information available to consumers.

To be completed by quality assurers:

Quality Assurance Reviewing Agency:
Ministry of Health
Quality Assurance Assessment:
The Ministry QA panel has reviewed the Impact Statement titled "*Regulating Natural Health Products*", produced by the Ministry of Health and dated 20 May 2021. The panel considers that the Impact Statement **meets** the quality assurance criteria.
Reviewer Comments and Recommendations:
The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed.

Impact Statement: Regulating natural health products

Section 1: General information

1.1 Purpose

The Ministry of Health is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing key policy decisions to be taken by Cabinet.

1.2 Key Limitations or Constraints on Analysis

Evidence of the problem

As noted in section C, there is limited quantitative evidence on the negative impact of the status quo on the New Zealand natural health product industry. There is also limited evidence on the actual harm to consumers from the use of natural health products through overuse, interactions with other products or medicines, use of unsafe products, and/or use of natural health products for a condition that requires clinical care and prescription medicines.

Previous decisions on natural health product regulation

The option of regulating under the Therapeutic Products Bill (the preferred option) has not been publicly consulted and has not been explicitly tested with the sector. In consultation to date, the majority of the sector has been generally supportive of regulation provided it is fit for purpose, proportionate, risk-based, and supports industry growth.

1.3 Responsible Manager (signature and date):

Fiona Ryan

Manager, Therapeutics

System Strategy and Policy

Ministry of Health

20 May 2021

Section 2: Problem definition and objectives

2.1 What is the current state within which action is proposed?

This proposal is part of a wider suite of work to develop a modern and comprehensive regulatory scheme for therapeutic products, enabled by the replacement of the Medicines Act 1981 by a new Therapeutic Products Act, currently being developed by the Ministry of Health. This proposal is one of several policy and design issues for the scheme that will be considered by Cabinet over the next few months.

About natural health products

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. They can be mass-produced in manufacturing plants or made by individuals in a cottage industry setting. The products are made for commercial sale and/or use in treatment by natural health practitioners or integrative providers (doctors or other clinical practitioners who integrate natural health products and complementary therapies into their practice).

Natural health products can be regulated differently depending on their preparation and intended use. For example, mānuka honey is regulated as a food if sold without health claims and for human consumption, a cosmetic ingredient if it is included in a moisturiser, a natural health product if contained in throat lozenges or balms which 'support wellness' or 'treat dry skin', or a therapeutic product if incorporated in a wound dressing to control infection and support healing.

Use of natural health products

There are limited data on the prevalence of natural health product use in New Zealand.

Based on the results of a 2015 survey of 1,650 people on dietary supplement use, the Southern Cross Healthcare Group estimated that 1.56 million New Zealanders regularly took natural health products, and about 750,000 people (about 35 percent of the population) had done so for at least five years. Forty-two percent of women use them frequently compared with 27 percent of men. Fish and plant oils, multivitamins, and vitamin C were the most used products.

A 2019 Nielson research estimated that New Zealanders spent approximately $116 million on vitamins, minerals, and supplements at supermarkets alone. Improvements in regulation will ensure the safety and quality of products used by a large part of the population. These figures are similar to use patterns found in Australian research.

The natural health products market

The natural health products industry estimates that the sector is worth approximately $2.3b per annum to the New Zealand economy, growing at an estimated 10 percent per annum.[2] 2019 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 $271.8 billion by 2024[3].

[2] 2019 estimate by Natural Health Products New Zealand: https://www.naturalhealthproducts.nz/about-natural-health-products-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

The New Zealand industry

Natural Health Products New Zealand (NHPNZ) reported at its 2020 annual summit that in 2019 about 51 percent of natural health product companies were small to medium sized enterprises. The industry traded export products worth NZD$642 million, up 125 percent on five years previous. China, the US, Australia, and Canada are the major markets.

In 2019 the Ministry of Health and the Ministry for Primary Industries surveyed the natural health products sector. While the response rate was low (about 12 percent of companies) it identified that New Zealand firms are involved across the full range of natural health product types and at all parts of the supply chain. Some are also involved in producing, importing, and/or selling foods, medicines, and/or cosmetics. Approximately half the respondents are involved in export in some way.

Rongoā Māori and Treaty of Waitangi obligations

Rongoā Māori is a wellbeing-oriented practice, formulated in a Māori cultural context and the accumulated knowledge of tipuna Māori. It includes culturally determined responses in the form of karakia (prayer), mirimiri (massage), and rongoā rākau (preparations made from native flora).

Under Article 2 of the Treaty of Waitangi the Crown has a particular obligation to actively protect rongoā Māori, and to recognise and support the role it plays in improving the wellbeing of Māori.

The Wai 262 Tribunal report, Ko Aotearoa Tēnei, and the current Wai 2575 Health Services and Outcomes Inquiry, include consideration of rongoā Māori. Both Inquiries are relevant to and will inform the approach to regulating natural health products.

The Therapeutic Products Bill

The Bill will repeal and replace the Medicines Act 1981, and will establish a modern, comprehensive regulatory scheme that aligns with international practice and provides assurance of the safety, quality, and efficacy of therapeutic products.

Similar outcomes would be highly desirable for natural health products, to provide assurance of their safety and quality.

Previous work on regulation of natural health products

Efforts to comprehensively regulate natural health products have been underway for more than a decade. A stand-alone Natural Health and Supplementary Products Bill was introduced in 2011; however, was not reinstated by the 52nd parliament in November 2017. In 2018 Cabinet noted that not reinstating the stand-alone Natural Health Products Bill would have the unintended consequence of bringing natural health products within the ambit of the Therapeutic Products Bill unless steps were taken to mitigate this risk.

Cabinet agreed that natural health products should, as far as possible, be excluded from the Therapeutic Products Bill. Key concerns at the time were avoiding delay to the progress of the Therapeutic Products Bill, and to provide time for officials to analyse options for regulation of natural health products [SWC-MIN-18-0176 refers]. This has been perceived by some stakeholders as meaning that natural health products would not be regulated under the Bill, which was not the intent.

In 2019 the Ministry of Health and the Ministry for Primary Industries began developing a new regulatory scheme for natural health products separate from the Therapeutic Products Bill. This work was placed on hold during the response to COVID-19.

In the interim, Ministry officials have further considered options for regulation of natural health products. As the Therapeutic Products Bill is now progressing well, the issue of natural health products delaying the Bill is significantly reduced and in fact, a stand-alone Bill would almost certainly take longer to implement.

As noted in section 1.2, the preferred option has not been publicly consulted.

2.2 What regulatory system(s) are already in place?

The current regulatory framework is both complex and incomplete. All the instruments applicable to natural health products were designed and implemented with the objective of providing for quality and safety of other types of products.

Currently natural health products must comply with the relevant parts of the following: the Food Act 2014 and the Dietary Supplements Regulations 1985, the Hazardous Substances and New Organisms Act 1996 and the Cosmetic Group Standard 2017, the Medicines Act 1981, and/or the Animal Products Act 1999. Enforcement primarily relies on the Fair Trading Act 1986 and the Consumer Guarantees Act 1993 [HR 20210678 and HR 20191586 refer]. This situation creates problems and incurs cost for the industry, determining what scheme(s) apply to their products, and managing relationships with multiple government agencies.

2.3 What is the policy problem or opportunity?

The existing regulation of natural health products is not fit for purpose. There is no comprehensive scheme: natural health products that are regulated sit awkwardly across several regulatory schemes. No one agency has the mandate, tools, depth of knowledge, and capacity to effectively regulate natural health products.

There is opportunity to protect consumers' safety and support industry development and growth through a comprehensive, proportionate, risk-based and tailored approach to natural health product regulation.

Consumer safety

Natural products are not risk-free: they are generally higher risk than foods and lower risk than medicines. Consumers can be affected by taking more than a safe dose of a vitamin or mineral, interaction with prescribed medicines, and/or relying on natural health products and delaying seeking clinical care. The risks range from, for example, mild skin irritation from a balm or cream, to severe organ toxicity and even death.

As there is no post-market monitoring of natural health products in New Zealand, it is not possible to accurately determine how many people may have been harmed by natural health products. Based on adverse reactions data from Australia and other international recall data, it is reasonable to assume that natural health products do result in harm in New Zealand.

Piecemeal regulation of natural health products

The status quo comprises multiple schemes that were not designed to provide a scheme for natural health products. The interfaces between the schemes are unclear,

difficult to navigate, and do not fully address the risks posed by natural health products.

Some natural health products that are taken orally are regulated under the Dietary Supplements Regulations 1985. The regulations were recently extended to February 2026 to provide time for development of a comprehensive scheme to regulate natural health products. There are no credible grounds for further extension of the regulations.

Without the regulations, most dietary supplement products would have to comply with strict food requirements to be sold legally – most would be unable to meet these requirements. Business would have to decide to re-formulate or re-label their products to comply with the Food Act 2014 or the Medicines Act 1981; however, this option would not be suitable for many products for reasons including:

- The doses in vitamins and mineral supplements exceed those allowed in food.
- Many ingredients in natural health products would be considered 'novel ingredients' under the Food Standards Code and may need to apply for approval to market the products as food, noting that the Code and the Food Act 2014 do not envisage foods being presented in controlled dose forms like capsules or tables.
- The cost of complying with the Medicines Act, particularly with respect to manufacturing products, would be disproportionately high and the controls would be disproportionate to the risks posed by most natural health products.

Barriers to industry development and growth

The status quo – a lack of a comprehensive regulatory scheme – means that New Zealand cannot certify that natural health products made here meet legal requirements for product safety and quality. As a result, New Zealand products are not accepted for sale in some jurisdictions.

The problem is clear; however, there is limited evidence of the size of the impact. We are not aware of independent analysis of the size of the New Zealand natural health products industry, or independent research to quantify the potential benefits of export market expansion enabled by export certification. The loss of income related to barriers to export growth has not been quantified; however, we are confident it is significant.

Rongoā Māori and Treaty of Waitangi obligations

The status quo does not provide for the recognition or protection of rongoā Māori, and therefore does not contribute to delivering the Crown's obligations under the Treaty of Waitangi. There is no ability to include consideration of traditional evidence for natural health product use.

2.4 What do stakeholders think about the problem?

The stakeholders include consumers; manufacturers, importers, sellers of the products; other regulators in particular Ministry for Primary Industries and the Environmental Protection Agency; rongoā Māori practitioners, and practitioners of other traditional and complementary practices (e.g., Chinese traditional medicine and Ayurveda).

In the past decade there have been several formal consultation and engagement processes with the natural health products sector, consumers, and other interested stakeholders. These took place in 2010, 2012, 2015, and 2019.

The feedback from the natural health products sector has been consistent: most support regulation as long as it is practical, proportionate to risk, minimises compliance costs, and can be scaled to the size and complexity of the production process. There is wide

agreement that the current system is not fit-for-purpose, and particular concern about the inability of the Government to issue export certification.

Those who support regulation want it in place as soon as possible, and certainly well before the Dietary Supplements Regulations expire in 2026.

Some industry stakeholders and consumers oppose any regulation of natural health products from an ideological perspective. They have consistently opposed attempts to regulate the sector and are particularly trenchant in their opposition to regulating natural health products in the same scheme as medicines.

Respondents highlighted the importance of recognising and protecting rongoā Māori[4]. Te Kāhui Rongoā – a national body that protects, nurtures and promotes tradition healing systems, neither supports or opposes including rongoā Māori in the proposed Bill so long as the legislation permits the current practice of rongoā Māori in its many forms, and without significant compliance costs.

Consumers who commented support the availability of safe products and information that helps them make informed choices. Concerns relate to additional controls, cost increases, or prohibitions on products that are already available.

Medical professional representative organisations responded to the 2019 consultation on the Bill, supporting the regulation of natural health products for safety and quality reasons, and to enable the identification and management of risks associated with these products.

Other government agencies

We have undertaken initial discussions with the Ministry for Primary Industries, the Ministry for Business, Innovation & Employment, and the Ministry for Foreign Affairs and Trade. They have indicated general support and an interest in more detailed discussion after the Ministers' decisions on a preferred option.

2.5 What are the objectives sought in relation to the identified problem?

In July 2019 the Minister of Health agreed to a new regulatory scheme having two main objectives (HR20191339 refers):

a. Support **consumer safety** – by providing assurance of product quality and reliable information including labelling, health claims[5], advertising, marketing, and promotion) to encourage consumers to make informed choices about their health and wellbeing; and

b. Support **industry development and growth** – by establishing a well-functioning, cost effective regulatory scheme that provides greater clarity and certainty to the sector on their obligations and the pathways to follow; and to create an internationally-recognised regulatory scheme providing export certification and improve market access.

The key design principles proposed to underpin a new regulatory scheme are:

a. regulation will be fit for purpose

[4] Rongoā Māori is a wellbeing-oriented practice, formulated in a Māori cultural context and the accumulated knowledge of tipuna Māori. It includes culturally determined responses in the form of karakia (prayer), mirimiri (massage), and rongoā rākau (native flora herbal preparations)

[5] Health benefits claims refer to products that support health and wellbeing, distinct from therapeutic claims for products proven effective (usually through clinical trials) in the treatment of named conditions. Therapeutic claims cannot be made for natural health products; any product for which therapeutic claims are made will, as is the case now, be regulated as a medicine.

b. regulation will be proportionate to the risks associated with natural health products

c. natural health products will be accompanied by accurate and comprehensive information, with any claims made being support by scientific or traditional evidence

d. compliance costs will be minimised, equitable and fair

e. consistency with Treaty of Waitangi principles

f. coherence with international standards and recognition by other jurisdictions.

Annex one sets out the principles and purpose of the Bill alongside the agreed policy objectives and design principles for the natural health products scheme. ill

Section 3: Option identification

3.1 What options are available to address the problem?

Option 1: Continuing with the **status quo** would result in eventual passive inclusion in the Therapeutic Products Bill. This approach is not consistent with the design principles, would not achieve the policy objectives, and would perpetuate the current risks and limitations.

Products not captured by the Therapeutic Products scheme would be un- or under-regulated; many captured by the scheme would be over-regulated and compliance costs would be disproportionately high as the scheme will not provide proportionate controls on products that are lower risk than medicines.

When the Dietary Supplements Regulations expire in 2026, the sale of those products would be covered by other regulation not designed for natural health products, primarily the Food Act and the Medicines Act, or left unregulated.

Option 2: Development of a **stand-alone Bill** for natural health products would achieve the policy objectives and be consistent with the design principles. It would be based on previous work pre-2017, though would require extensive updating. It could provide for protecting and recognition of rongoā Māori.

It is likely to be more palatable to stakeholders who are wary of regulating natural health products under the same regime as medicines.

A separate bill would create new boundaries with other legislation including the Therapeutic Products Bill. It would ideally pass before or at the same time as the Therapeutic Products Bill to ensure that products are regulated appropriately and under the right scheme, and could delay the introduction of the Therapeutic Products Bill, current planned for early 2022.

Much of the work required for a stand-alone bill would duplicate work already underway on the regulatory scheme for therapeutic products.

Option 3 – preferred option: Inclusion in the **Therapeutic Products Bill** would have natural health products defined and recognised as a product category, distinct from medicines.

The Bill would include provisions for measures specific to natural health products (for example, recognition of traditional evidence and sustained use), and tailored risk classification settings with product and manufacturing standards to ensure a proportionate regulatory framework. Options 3 would also provide for recognition and protection of rongoā Māori.

The Bill is well advanced and has good support and momentum. This option reduces the risk that regulation of natural health products will be delayed again.

This option would deliver the policy objectives and align with the design principles. A small section of the sector will be vocally opposed to this option.

Non-regulatory interventions

A non-regulatory option would not meet international expectations, for example, address the issue that lack of regulation currently means New Zealand cannot issue export certification.

Guidance and information for the industry would be an essential component for implementation and transition to a new scheme, and to support and encourage compliance in the long term.

International experiences

As noted above, most other States – including our main trading partners – have comprehensive regulatory schemes for natural health products. We are well-placed to learn from and where appropriate align with other states.

3.2 What criteria, in addition to monetary costs and benefits have been used to assess the likely impacts of the options under consideration?

The objectives set out in section 2.5 establish the policy criteria used to assess the options.

In addition, we considered how options align with the Cabinet-approved objectives for a therapeutic products scheme (SOC-15-MIN-0049):

a) meets expectations of risk management and assurance of acceptable safety;
b) results in efficient and cost-effective regulation;
c) is flexible, durable, up-to-date, and easy to use;
d) ensures high-quality, robust and accountable decision-making;
e) is able to sustain capable regulatory capacity;
f) supports New Zealand's trade and economic objectives;
g) is trusted and respected;
h) supports consumer access and individual responsibility for care.

3.3 What other options have been ruled out of scope, or not considered, and why?

As noted above, these products are nor risk-free, and products with similar risk profiles are actively and comprehensively regulated. The status quo – effectively a piecemeal approach – is resulting in demonstrably negative effects for consumers and industry. Therefore, this analysis does not include consideration of not regulating natural health products.

Section 4: Impact Analysis

Marginal impact: How does each of the options identified in section 3.1 compare with taking no action under each of the criteria set out in section 3.2?

Key:

++ 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

	Option 1: Status quo	Option 2: Stand-alone Bill	Option 3: Regulation under the Therapeutic Products Bill
Consumer safety	**0** Extant issues continue. Could be exacerbated if new, higher risk products enter the market	++ Tailored approach to risk profiles of products; proportionate controls	++ Bill has focus on safety and risk-proportionate controls, application through regulatory instruments
Industry growth	**0** Lack of progress will have increasingly negative effect on industry from benefits not realised	+ Slower realisation of benefits	++ Faster resolution of trade barriers. Greater certainty for industry
Alignment with objectives for the therapeutic products scheme	- - Is a barrier to achieving these objectives for natural health products. Negative impacts increase over time.	++ Significant improvement on the status quo	++ Significant improvement on the status quo
Recognition of rongoā Māori	**0** No means of recognition or protection	++ Included in drafting	++ Bill can be amended to provide explicit recognition
Fit for purpose	**0**	++ Provides comprehensive scheme	++

	Option 1: Status quo	Option 2: Stand-alone Bill	Option 3: Regulation under the Therapeutic Products Bill
	Does not impose any additional costs or burdens; does not apply fair proportionate controls		Tailor instruments provided in the Bill to provide for natural health product characteristics
Timely implementation	**0**	**+** Time to draft new Bill. Will duplicate work on the Therapeutic Products Bill	**++** Bill is well advanced. Option reduces the risk of regulation being delayed again
Complexity: drafting / amendments required	**0** Introduction of the Therapeutic Product Bill without provision for natural health products will require amendment to other legislation	**+** Revision of previous Bill; more complex alignment, including with Therapeutic Products Bill to 'carve out' natural health products	**+** Amendments to include natural health products. Provisions and instruments in the Bill can give effect to therapeutic scheme objectives and design principles (see annex 1)
Legislative and regulatory coherence	**0**	**++** Can be drafted to align with other legislation	**++** Can be amended to align with relevant legislation
Overall assessment	**Not recommended**	**Not recommended**	**Preferred option**

Section 5: Conclusions

5.1 What option, or combination of options is likely to best address the problem, meet the policy objectives and deliver the highest net benefits?

Preferred option

On balance, we recommend option three. Both options two and option three would deliver on the consumer safety and industry growth objectives and can provide for a proportionate and practical regulatory scheme.

Both would be equally supported by stakeholders who favour regulation; option three will be less palatable to those who oppose regulation under the same legislation as medicines.

Option three provides the timeliest pathway to natural health product regulation. The Therapeutic Products Bill provides a framework that is fit for purpose for natural health products without the duplication of work required under option two.

The export-led benefits of option two partially depend on timely enactment of the Therapeutic Products Bill. The Bill is now well-advanced and is a priority for the Government, for the Ministry, and for most of the sector. A high level of confidence is reasonable.

Te Tiriti o Waitangi

The interests of Māori and Tiriti o Waitangi implications are included at section 2.1.

Sector perspectives

Section 2.4 summarises stakeholders' views. These have remained consistent over the decade of discussion on this issue. Any of the options is likely to be controversial: the difference is the source and reason for that controversy.

The majority of the sector generally supports regulation and is likely to oppose the status quo as it does not address any of their concerns. This group is likely to be generally supportive of options one and three; however, the likelihood of faster implementation is a favourable characteristic of option three.

Those who oppose any regulation would likely be more comfortable with the status quo, opposed to option one, and strongly opposed to option three as it would have natural health products under the same legislation as medicines. The views of this group cannot be fully met without compromising the agreed policy objectives for natural health product regulation.

5.2 Summary table of costs and benefits of the preferred approach

Affected parties	Comment	Impact	Evidence certainty
Additional costs of proposed approach compared to taking no action			
Regulated parties	Initial transition costs and increased regulatory oversight	Medium / high	Low/ medium
Regulators	Increased costs of oversight and enforcement	Low / medium	Medium

Wider government	MFAT and MBIE: Ensuring compliance with trade agreements	Low	Medium
Other parties	Product costs may increase; some may leave the market	Medium	Medium
Total Monetised Cost		To be confirmed	
Non-monetised costs		Medium	Medium

Expected benefits of proposed approach compared to taking no action			
Regulated parties	Ongoing reduced burden through a one-stop-shop for all products rather than working with multiple regulators Ongoing benefits of increased export market access	Medium/high	Medium
Regulators	Improved alignment increases certainty reduces duplication Clearer definition of regulatory roles and responsibilities increases certainty and efficiency	Medium	High
Wider government	Clearer definition of agency roles and responsibilities increases certainty and efficiency	Medium	High
Other parties	Consumers: improved safety and information, assurance of product quality and safety.	Medium	Medium
Total Monetised Benefit		To be confirmed	
Non-monetised benefits		Medium	Medium

5.3 What other impacts is this approach likely to have?
This approach will bring New Zealand into line with comparable states. It will enhance our reputation as a credible regulator of natural health products within the wider scope of a modern, fit-for-purpose approach to therapeutic product regulation.

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

The details of the scheme will be developed, tested, and finalised as part of the development and implementation of the Bill. At a high level, the approach to natural health products would include the following:

- Defining natural health products for the purpose of the Bill
- Standards for manufacture and product safety
- Consumer information
- Export provisions
- Post-market monitoring and compliance

The Bill already provides for regulation, rules, and notices which will set out the details of the scheme. Alignment with other legislation would be provided in the Bill to clarify the scope of the Bill, and the respective roles of regulators.

The Bill provides for a transition period; we anticipate a period of three years which would be tested with the sector. Targeted consultation and engagement with affected parties would inform the amendments to the Bill before its introduction, and in the development of the specific regulatory mechanisms for natural health products.

Once the Bill is enacted, the Dietary Supplements Regulations 1985 would be repealed and necessary amendments made to other legislation.

6.2 What are the implementation risks?

There is a risk that including natural health products in the Therapeutic Products Bill will slow the progress of the Bill. That could result in continuation of the extant safety issues for longer than expected, delay realisation of benefits such as export market growth, and increase sector opposition to the approach. Less likely but of greater impact would be a significant delay to the implementation of the Bill, slowing progress of the modernisation of legislation of therapeutic goods generally.

The Therapeutic Products Bill is well-advanced and is a priority for the Ministry. Including natural health products is a more efficient approach than a stand-alone Bill – that option is not as simple as restarting work on the Bill that was not reinstated in 2017.

Progressing both options at the same time would place additional call on resources and add complexity to drafting. Our analysis indicates that a stand-alone Bill would not improve the outcomes and could delay benefit realisation. Coordinated planning and strong cross-agency and sector engagement, coupled with frequent communication on progress will mitigate this risk.

There is an assumption that compliance costs are inevitable as this is an area that has not previously been comprehensively regulated. The policy intent, as set out in the design principles and reflecting the Expectations for Good Regulatory Practice, is that costs are

outweighed by the benefits of regulation in terms of increased safety and quality of natural health products and the potential for industry development, growth and innovation.

The cost recovery framework that will be developed will attempt to ensure compliance costs are fair and equitable. As noted above, the Bill requires regular reviews of the costs to ensure they are not under or over recovered.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

Under the Bill, the regulator has the responsibility to monitor safety. Specifically it must have a system in place to continuously monitor product safety with the details to be set in regulations. The regulator also has recall powers, product prohibition powers, and the ability to make directions.

These responsibilities and powers provide for systems that will provide data on sector regulatory performance.

As this is a sector that has not previously been comprehensively regulated, there will be the need to establish a base line of system-level impacts specific to natural health products. Methods such as cross-sector (e.g., comparison with the food sector) and international benchmarking may prove useful in the short to medium term, and in the longer term as a comparison of regulatory effectiveness.

Adverse events and product quality monitoring

A benefit of the proposed approach is that it would enable monitoring of adverse events related to natural health products. Medsafe currently provides pharmacovigilance initiatives such as a spontaneous reporting scheme for adverse events, an early warning scheme and a publicly accessible database of suspected adverse reactions. These initiatives would be continued, and potentially enhanced, under the new therapeutic products scheme, and would include natural health products as appropriate.

The Bill provides to investigate quality issues and complaints, noting that these would be conducted in a risk-proportionate manner.

Industry outcomes

The regulator will monitor the capability development and growth of the natural health products industry through monitoring the number of product notifications made and approvals and licences issued. This will provide data on the size of the industry, and the range and volume of natural health products being sold or manufactured in New Zealand. We anticipate working with the Ministry for Business, Innovation & Employment and the Ministry of Foreign Affairs and Trade for additional information on domestic and international market growth as required.

7.2 When and how will the new arrangements be reviewed?

Section 268 of the Therapeutic Products Bill requires the Minister to review the policy and operation of the Therapeutic Products Act five years after it comes into force, and every five years after that. The Minister must report on each review within 12 months and present the report to the House once it is completed.

The regulator will have ongoing contact with the sector and as per the Expectations for Good Regulatory Practice, will provide simple, accessible ways for regulated parties and consumers to put forward their views, and for the regulator to respond.

Annex one: Alignment of the Therapeutic Products Bill framework with the design principles for natural health product regulation (existing policy work)

<table>
<tr><th colspan="2">Therapeutic Products Bill</th></tr>
<tr><td colspan="2">Purpose:

To protect personal and community health by—
(a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and
(b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products</td></tr>
<tr><th>Objectives for the therapeutic products scheme (SOC-15-MIN-0049)</th><th>Natural health products regulation: design principles (existing policy work)</th></tr>
<tr><td>a) meets expectations of risk management and assurance of acceptable safety;
b) results in efficient and cost-effective regulation;
c) is flexible, durable, up-to-date, and easy to use;
d) ensures high-quality, robust and accountable decision-making;
e) is able to sustain capable regulatory capacity;
f) supports New Zealand’s trade and economic objectives;
g) is trusted and respected;
h) supports consumer access and individual responsibility for care.</td><td>• Regulation is proportionate to risk
• Regulation is fit for purpose
• Compliance costs are fair, equitable, and minimised as far as possible
• Consistent with the principles of Te Titiriti o Waitangi
• Coherence with international standards; recognised by other jurisdictions</td></tr>
<tr><th colspan="2">Core components for natural health products regulation (existing policy work)</th></tr>
<tr><td colspan="2">• Defines natural health products and differentiates these from foods, medicines, and cosmetics
• Provides for regulation of ingredients and finished products
• Provides for manufacturing standards
• Provides for health claims provided they can be substantiated, with standards set for acceptable evidence (scientific and traditional)
• Enables export certification
• Recognition and active protection of rongoā Māori
• Post market controls: monitoring quality and safety</td></tr>
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