In Confidence

Office of the Minister Health

Office of the Associate Minister of Health

Office of the Minister for Food Safety

Cabinet Social Wellbeing Committee

Regulating natural health products

Proposal

1 We propose that regulation of natural health products be included under the Therapeutic Products Bill.

Relation to government priorities

2 This proposal is part of the Government's plan to develop a modern and comprehensive regulatory scheme for therapeutic products such as medicines and medical devices. It aligns with the delivery objectives for the reform of the health system, because ensuring equitable access to safe, and high-quality products and enabling innovation will contribute to the goal of Pae Ora: healthy futures for all. The 2021 Speech from the Throne committed to fostering innovation as part of the COVID recovery.

Executive summary

3 The current arrangements for regulating natural health products are not fit for purpose. A new regulatory scheme for natural health products is needed to achieve two main objectives:

3.1 Support **consumer safety** – by providing assurance of product quality and safety, and access to reliable information (including labelling, permissible claims about the benefits of the product, and marketing), to encourage consumers to make informed choices about their health and wellbeing;

3.2 Support **industry development and growth** – by establishing a well-functioning, cost-effective regulatory scheme that provides clarity and certainty to the sector, and opens new market opportunities through establishing an internationally-recognised regulatory scheme to enable export certification of New Zealand-made products.

4 We are seeking agreement to regulate natural health products under the Therapeutic Products Bill (the Bill). This will provide for timely implementation of a comprehensive and credible scheme for regulation of natural health products.

5 Should you agree, officials will:

5.1 Undertake further policy work on specific aspects of the scheme;

5.2 undertake targeted engagement with consumer and industry representatives, and other stakeholders, to inform the drafting that will include natural health products in the Bill;

5.3 engage with practitioners of rongoā Māori (a traditional wellbeing practice that includes use of rongoā rākau – native flora preparations) to ensure active protection and recognition;

5.4 prepare drafting instructions reflecting Cabinet's decision and revise the current version of the Bill before it is introduced to Parliament.

6 This paper fulfils the requirement to report back to Cabinet on options for developing a new regulatory scheme for natural health products [SWC-18-MIN-0176].

7 This proposal is part of work to modernise the regulation of therapeutic products in New Zealand, centred on repealing the Medicines Act 1981 and replacing it with the Therapeutic Products Bill.

Background

What are natural health products?

8 Natural health products are a broad group of products that are made and sold to support health and wellbeing, including vitamin and mineral supplements, herbal remedies, animal extracts, probiotics, enzymes and essential fatty acids. Natural health products include preparations made for and used in rongoā Māori, and the preparations used in in traditional healing systems such as traditional Chinese medicine and Ayurveda.

9 The difference between natural health products and medicines is not as clear-cut as dividing between naturally derived and chemically synthesised products. Many pharmaceuticals are derived from or contain ingredients from natural sources, and some natural ingredients and products pose risks to consumers.

Natural health products are not risk-free

10 Natural health products generally pose higher risks than most foods, and lower risk than most medicines.

11 Examples of the potential risks related to natural health products include:

11.1 products that contain ingredients that are unsafe for consumption, or at a dose that could be harmful;

11.2 poor manufacturing practices leading to spoiled or adulterated products;

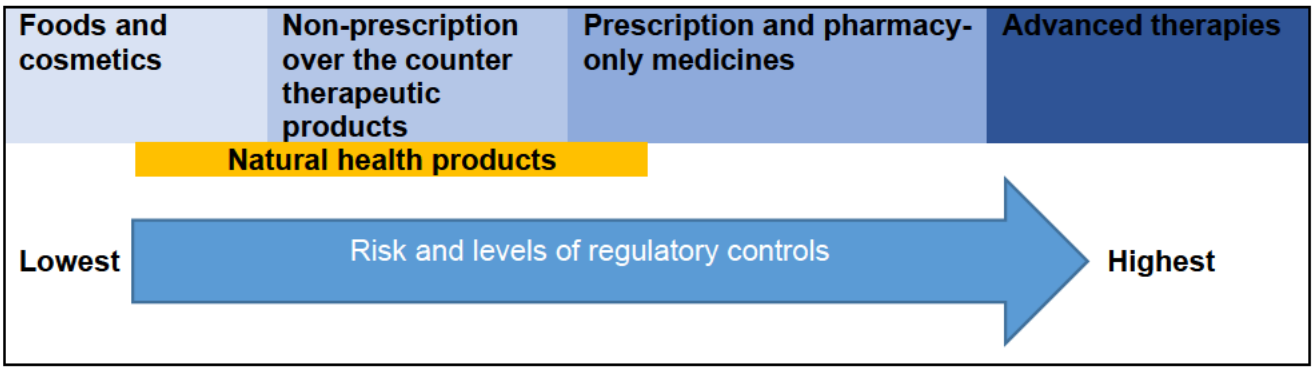
11.3 improper use (e.g., consumers take more than the recommended dose);

11.4 harmful interactions between natural health products and prescription medicines.

12 Possible harm from natural health products ranges from mild discomfort to severe adverse reactions, even death. Some consumers may use natural health products to treat serious illness rather than seek clinical diagnosis, advice and treatment.

13 Appropriate regulation may result in natural health products and medicines with the same level of risk being addressed through proportionate controls that both ensure consumer safety while recognising the difference between the intended purpose of those products.

Figure 1: relationship of natural health products to other related regulated products



Existing regulation of natural health products is not fit for purpose

14 New Zealand lacks a comprehensive approach to regulating these products. No single agency has a mandate to develop and apply controls. Enforcement primarily relies on the Fair Trading Act 1986 and the Consumer Guarantees Act 1993, which do not provide a full suite of measures to ensure the safety and quality of natural health products.

15 Natural health products that are taken orally, such as vitamin and mineral supplements, are currently regulated under the Dietary Supplements Regulations 1985. The Regulations were due to be repealed after the commencement of the Food Act 2014. They have been extended several times in anticipation of full regulation of natural health products. The most recent extension was made earlier this year and goes through until February 2026.

16 The Regulations have been extended; however, in anticipation of a new regulatory scheme they have not been updated. They have not kept pace with advances in clinical knowledge (for example, upper dose limits for vitamins), the introduction of new products, or been adapted to consumers' rights for information (for example, requiring allergen warnings).

17 New Zealand cannot certify that natural health products meet legal requirements for product safety and quality, meaning that New Zealand-made products are not accepted for sale in some jurisdictions. Anecdotal evidence indicates there is significant opportunity for export market growth and while the

scale of unrealised benefits due to the lack of adequate regulation has not been quantified, we are confident it is significant.

18 The goals of the World Health Organization (WHO) Traditional Medicine Strategy 2014-2023 include supporting member states to harness the potential of traditional medicines and promote their safe and effective use through regulation, research, and integration with clinical medicine where appropriate. Unlike New Zealand, 65 percent of WHO member states including Australia, the EU, Canada, China, Singapore, Malaysia and the UK have comprehensive regulatory schemes for traditional and herbal medicines.

Health benefit claims

19 The status quo does not support consumer access to accurate, substantiated information to help them make informed decisions about the natural health products they use, and relies on general consumer protection legislation to respond to advertising and consumer information issues.

20 The Medicines Act 1981 provides for therapeutic claims for products with a therapeutic purpose, for example, preventing, alleviating, or treating a named condition. These claims must be backed up with scientific evidence. It is an offence to make a therapeutic claim for a product that cannot be regulated as a medicine.

21 The Dietary Supplements Regulations provide that dietary supplements cannot be labelled or advertised with statements relating to therapeutic claims or misleading claims; however, they are silent on what statements can be made about these products.

Nutrition, health, and related claims for foods

22 Standard 1.2.7 of The Food Standards Australia and New Zealand (adopted under the Food Act 2014) sets out the claims that can be made on labels, or advertisements about the nutritional content of food; claims about the health effects of a food and the requirements for making those claims.

23 The Standard stipulates that the claims cannot be therapeutic in nature – they cannot refer to prevention, diagnosis, cure or alleviation of a disease or condition.

24 Claims must be substantiated: food suppliers must ensure that the claims are truthful and supported by adequate scientific evidence, and the level of that evidence is relative to the claim being made. For example, health claims that involve a food-health relationship must undergo pre-market assessment and approval by FSANZ.

International models

25 In other jurisdictions including Australia, Canada, the EU, and the UK, manufacturers can make health claims about natural health products provided they can be substantiated through scientific evidence, and/or the recognition of traditional evidence as provided in regulation. This approach means consumers can have confidence that the product information is accurate and the nature of the health claims are substantiated and inform consumers'

purchasing decisions. The applicants are clear on requirements for substantiation of health claims for natural health products in a risk-proportionate way, and the regulators have the means to deal with non-compliance.

26 Care is needed to clarify the interface between the regulatory schemes for foods, medicines, cosmetics, and dietary supplements, including the approach to substantiating health benefit claims for of different products.

Previous work on regulation of natural health products

27 Consideration of options for regulation of natural health products is not new. A stand-alone Natural Health and Supplementary Products Bill was introduced in 2011, considered by Select Committee and reported back to the House, but not reinstated by the 52nd Parliament in November 2017.

28 In 2018 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 Bill, and to provide time for officials to analyse options for regulating natural health products [SWC-MIN-18-0176].

29 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 Bill. This work was placed on hold during the response to COVID-19.

30 In the interim, officials have further considered options for regulation of natural health products. The Therapeutic Products Bill is now well advanced, while separate legislation for natural health products has not progressed. Officials have taken the opportunity to consider the options including whether - and if so how - the Bill could provide for appropriate regulation of natural health products in a timely and efficient way.

Sector perspectives

31 Previous work on natural health product regulation has included four rounds of consultation between 2010 and 2019. The sector has provided consistent feedback: the majority supports regulation, provided it is practical, proportionate and risk based. Annex one provides a summary of that feedback by stakeholder group.

32 Supporters of regulation would like the scheme to begin as soon as possible, particularly to foster export growth, and to provide certainty well before the Dietary Supplements Regulations expire in 2026.

33 There is a group in the natural health products sector that has been and is likely to continue to be vocal in its opposition to any regulation, and especially regulation under legislation that also covers medicines.

Regulating natural health products

Analysis

34 In addition to achieving the consumer safety and industry development policy objectives, officials developed the following design principles for the previously proposed stand-alone Bill for natural health products:

34.1 Regulation will be fit for purpose.

34.2 Regulation will be proportionate to the risks posed.

34.3 Compliance costs will be minimised and will be fair and equitable.

34.4 The scheme will be consistent with the principles of the Treaty of Waitangi.

34.5 The scheme will be consistent with international standards and be recognised by other jurisdictions.

35 These principles are consistent with the objectives for the therapeutic products scheme, approved by Cabinet in 2015 (SOC-15-MIN-0049):

35.1 meets expectations of risk management and assurance of acceptable safety;

35.2 results in efficient and cost-effective regulation;

35.3 is flexible, durable, up-to-date, and easy to use;

35.4 ensures high-quality, robust and accountable decision-making;

35.5 is able to sustain capable regulatory capacity;

35.6 supports New Zealand's trade and economic objectives;

35.7 is trusted and respected;

35.8 supports consumer access and individual responsibility for care.

Options for regulation

*Option one: **Status quo** and enactment of the Therapeutic Products Bill*

36 This option assumes that the status quo remains for natural health products, i.e., limited regulation, while the Therapeutic Products Bill progresses and is enacted with provisions that exclude natural health products as a product class.

37 In the short term, the safety and quality of natural health products would be largely unregulated, and industry and export development would not be supported. There would be no improvement on the ability to, or clarity around, making health benefit claims for natural health products.

38 The Dietary Supplements Regulations will expire in 2026. At that point, dietary supplements would have to comply with strict food requirements to be sold legally. Most would be unable to meet those requirements. Businesses would have to decide to re-formulate or re-label their products to comply with the Food Act 2014 or the Therapeutic Products Act (when enacted). These options would not be suitable for many products as:

38.1 the doses in vitamins and mineral supplements exceed those allowed in food;

38.2 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;

38.3 the costs of complying with the medicines provisions of the Therapeutic Products Bill would be high, and the controls would be disproportionate to the risks posed by most natural health products.

39 Consumer choice would be limited by manufacturers withdrawing products and/or passing on increased compliance costs in the form of price increases. The quality of information available to consumers would not improve.

40 This option would not deliver the policy objectives of consumer safety and industry development, is not consistent with the design principles or good regulatory practice, and would perpetuate the current risks and limitations of inadequate and outdated requirements.

*Option two: Development of a **stand-alone Bill** for natural health products.*

41 This option would deliver the policy and design criteria and deliver a fit-for-purpose scheme. It is likely to be more palatable to stakeholders who are wary of regulating natural health products under the same regime as medicines. This option can provide for protection and recognition of rongoā Māori. It would also provide for substantiated health benefit claims.

42 The drawbacks to this option relate to timing and complexity. A separate Bill would create a new boundary with the Therapeutic Products Bill, in addition to those with the Food Act and other existing legislation. Rather than consolidating legislation and regulation, this option introduces new law and a separate regulatory scheme. Analysis does not indicate that the benefits would justify this approach.

43 While a new Natural Health Products Bill could be based on the work done pre-2017, work would be required to align it with the Therapeutic Products Bill. Progressing both the Therapeutic Products Bill and a Natural Health Products Bill concurrently would ensure consistency, but would create duplication of work as the purposes, principles, and instruments are closely aligned.

44 A new Bill 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. This could delay the introduction of the Therapeutic Products

Bill, currently planned for early 2022. If the Bill regulating natural health products was delayed, the current risk and issues would remain in place in the interim.

*Option 3: Inclusion in the **Therapeutic Products Bill** (preferred option)*

45 Under this option, natural health products would be defined and actively regulated as a product category distinct from medicines. The mechanisms already in the Bill would be tailored to provide for measures specific to natural health products, and tailored risk classification to ensure a proportionate regulatory framework. The Bill would define health benefit claims for natural health products, and regulatory instruments would provide for substantiation by scientific and/or traditional evidence.

46 Like option two, option three would deliver the policy objectives, and meet the other criteria. And, like option two, there would be additional drafting as this approach would require amendments to the Therapeutic Products Bill, though option three would not include the duplication that would occur under option two.

47 Administrative simplicity and efficiency would be a benefit of establishing one regulator using tailored, risk-proportionate regulations for natural health products. Option three is likely to best support the objectives of ensuring consumer safety and supporting industry development. It would also realise the benefits of modern regulation in a timelier way than option two.

48 This option would be supported by the majority of the natural health product sector that has consistently signalled support for regulation as long as it is proportionate and practicable. However, we expect this option would spark opposition from stakeholders who do not support regulation. Clear communication on the benefits of regulation would mitigate the risk of a minority view affecting the progress of the Bill.

49 This option would require revisions to the draft Therapeutic Products Bill. This work would be done in conjunction with general refinements to the Bill before it is introduced to Parliament. These revisions would include active protection and recognition of rongoā Māori.

Treaty of Waitangi

50 The Wai 262 tribunal report, Ko Aotearoa Tēnei, and the current Wai 2575 Health Services and Outcomes Inquiry are relevant to and will inform consideration of how regulation of natural health products would affect rongoā Māori, equitable access to safe products and accurate and accessible information, and considerations of industry growth and development in the context of recognition and protection.

51 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.

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

Implementation

53 We envisage that the Bill would be revised to enable relevant controls to be applied to natural health products in a proportionate and risk-based way. These would include:

53.1 Standards for manufacture and product safety

53.2 Consumer information, including health benefit claims

53.3 Export provisions

53.4 Post-market monitoring and compliance

54 The details of how natural health products would be regulated would be developed, tested, and finalised as part of the development and implementation of the Bill. Details of the scheme would be contained in the regulations, rules and regulator's notices provided for in the Bill.

55 The Bill would provide for alignment with other legislation to clarify the scope of the Bill and the respective roles of other domestic regulators, for example the Ministry for Primary Industries as the food regulator.

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

Further policy work

57 Further policy work would also be undertaken to inform the detailed work to ensure that natural health products are appropriately regulated under the Bill and regulatory scheme. This work would include (but not be limited to) the following:

57.1 defining natural health products in terms of form and function for the purposes of the Bill, clarifying the scope of the scheme and ensuring it aligns with schemes for foods, cosmetics, medicines, and other products;

57.2 coherence with international trade obligations and ensuring the scheme aligns with trade-related requirements such as technical barriers to trade;

57.3 appropriate recognition and protection of rongoā Māori under the Bill;

57.4 providing for substantiated health benefit claims for natural health products, including recognition of scientific and traditional evidence.

58 With specific reference to the interface between the regulatory schemes for foods and natural health products, officials would undertake further analysis of the consistency, proportionality and coherence of the regulatory schemes in the following areas:

58.1 Ensuring that quality control methods are appropriate and proportionate to the risks associated with natural health products and foods and that the approach is coherent;

58.2 The nature and level of evidence to support health benefit claims;

58.3 Export assurance requirements for natural health products and foods, including protection of New Zealand's trading reputation;

58.4 Defining natural health products' form and function so as not to inadvertently capture foods, particularly supplemented foods, medicinal foods, foods for special purpose or personalised nutrition, and to preserve policy space for the development and appropriate regulation of high-value foods to support health and wellbeing in the context of Fit for a Better World.

59 We are confident that the proposed regulatory approach would address these issues. Primary Industries and Health officials will work closely on policy issues through the finalisation of the Bill and the development of the regulatory scheme.

Financial Implications

60 The Bill provides that all costs of the therapeutic products regulatory scheme are recovered through fees or charges, and this would apply to natural health products. The Bill provides that the regulator must review the methods and levels of cost recovery at least once every three years to ensure they remain set at the right level.

61 A report back on the recommended institutional form for the therapeutic products regulator and the cost recovery policy for the regulatory scheme is was due to the Social Wellbeing Committee in March 2019 (SWC-18-MIN-0176). That report will be provided to SWC in the next few months.

Legislative Implications

62 s 9(2)(f)(iv) [redacted] The option recommended in this paper would be given effect through revisions to the existing draft of the Therapeutic Products Bill. Officials expect to instruct the Parliamentary Counsel Office this year.

63 The development of a single comprehensive regulatory scheme for natural health products would require the revocation of the Dietary Supplements Regulations 1985, and any consequential amendments to the Food Act 2014, the Animal Products Act 1999, and other legislation as necessary.

Impact Analysis

Regulatory Impact Statement

64 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.

65 The panel considers that the Impact Statement meets the quality assurance criteria.

66 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.

67 The Impact Statement is attached at annex two.

Climate Implications of Policy Assessment

68 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

Population Implications

Implications for Māori

69 Rongoā Māori is a taonga under the Treaty of Waitangi. The Crown has an obligation to ensure rongoā Māori is recognised and protected. This would be considered in further policy work.

70 The application of the Treaty principles and Whakamaua goals 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. The regulatory scheme for natural health products can address the goals of mana motuhake – the right to make choices that reflect Māori values and practices; and mana Māori, enabling Ritenga Māori (customary rituals) framed by te ao Māori, and encapsulated in mātauranga Māori (Māori knowledge) which is the foundation of rongoā Māori.

71 Meaningful engagement with rongoā Māori practitioners and representatives would be required throughout the development of a regulatory scheme that protects the practice, recognises oral traditions as evidence, and ensures the safety of products used within rongoā Māori practice.

Implications for women

72 International studies indicate that the majority of natural health product users are women.[1] Women are more likely to bear any cost increases resulting from

[1] Roy Morgan Research (2019) *Women more likely to buy vitamins than men*. This survey of 50,000 Australians indicated that 47% of women buy vitamins, minerals, and other supplements compared with 35% of men.

natural health product regulation, and this could limit women's choices and access to products that could support their wellbeing.

73 Measures to improve safety, quality, and consumer information about natural health products could inform women's decisions about their health and increase health literacy and agency.

Human Rights

74 Nothing in this proposal is inconsistent with the New Zealand Bill of Rights Act 1990 and or Human Rights Act 1993.

Consultation

75 The Ministry of Health has consulted with the following agencies on the development of this paper: the Environmental Protection Authority, the Ministry for Business, Innovation and Employment, Te Puni Kōkiri, were consulted and the Ministry of Foreign Affairs and Trade, and the Department of the Prime Minister and Cabinet. All support the proposal.

Comments

76 The Ministry for Business, Innovation and Employment and the Ministry for Foreign Affairs and Trade both indicated interest in the further policy work on alignment with international standards, trade-related requirements, and matters relevant to export opportunities.

77 The Ministry for Primary Industries is leading the development of the Government's Food and Beverage Industry Transformation Plan. They note alignment between the Plan and the policy objectives for regulation of natural health products, as both seek mechanisms to support industry growth and increased export potential. The development of a clear interface between natural health products and foods is an important consideration, noting that the scope of the Plan has not been finalised.

78 The Environmental Protection Authority note the importance of a definition that provides for clear delineation between the scopes of regulatory schemes, in this case between the Cosmetic Product Group Standards covering cosmetics that include natural ingredients, and natural health products intended to support wellbeing, which would be regulated under the Therapeutic Products Bill.

79 Treasury was informed and noted the proposal.

Communications

80 The natural health products sector is keenly interested in this issue. We intend to communicate the decision to the natural health products sector and other relevant stakeholders as soon as practicable. This would be the first step of a wider programme of communication to actively engage the natural health products sector during the revision and progression of the Bill.

81 As previously noted, there is a small group within the natural health products industry that is likely to be opposed to regulation of natural health products,

and regulation under the Therapeutic Products Bill in particular. We will work with officials to respond appropriately.

Proactive Release

82 We intend to release this paper in accordance with the guidance in Cabinet Office Circular CO (18) 4.

Recommendations

The Minister of Health, and the Associate Minister of Health and Minister for Food Safety, recommend that the Committee:

1 **note** that this paper fulfils the requirement to report to Cabinet on options for the regulation of natural health products [SWC-18-MIN-0176];

2 **note** that there is no coherent regulatory framework for natural health products, and current arrangements for their regulation are not fit for purpose because they do not ensure consumer safety or support development and growth of New Zealand's natural health product industry;

3 **note** that the Government is developing a modern, comprehensive and risk-based regulatory scheme for therapeutic products, through repealing the Medicines Act 1981 and replacing it with the Therapeutic Products Bill;

4 **agree** that natural health products will be regulated under the Therapeutic Products Bill;

5 **agree** that the objectives for the natural health product regulatory scheme are aligned with those for the therapeutic products regulatory scheme, which are that it:

5.1 meets expectations of risk management and assurance of acceptable safety;

5.2 results in efficient and cost-effective regulation;

5.3 is flexible, durable, up-to-date, and easy to use;

5.4 ensures high-quality, robust and accountable decision-making;

5.5 is able to sustain capable regulatory capacity;

5.6 supports New Zealand's trade and economic objectives;

5.7 is trusted and respected;

5.8 supports consumer access and individual responsibility for care;

6 **agree** that the draft Therapeutic Products Bill be revised to:

6.1 include a definition of natural health products for the purpose of the Bill;

6.2 apply the regulatory mechanisms in the Bill as appropriate to natural health products, and in a way that is relevant to the risk/benefit profile of natural health products;

6.3 provide for the protection and recognition of rongoā Māori;

6.4 providing for substantiated health benefit claims for natural health products, including recognition of scientific and traditional evidence;

6.5 provide for product certification that can be recognised by other jurisdictions.

7 **note** that officials from the Ministries of Health and Primary Industries will undertake further policy work on specific aspects of the regulatory scheme for natural health products, consistent with the objectives in Recommendation 5 above and the interface with other legislation and regulatory schemes;

8 **agree** that drafting instructions be provided to the Parliamentary Counsel Office for a including in the Therapeutic Products Bill a regulatory scheme for natural health products that is in accordance with Cabinet's decisions.

Authorised for lodgement

Hon Andrew Little

Minister of Health

Hon Dr Ayesha Verrall

Associate Minister of Health

Minister for Food Safety

s 9(2)(g)(i)