MANATŪ HAUORA
MINISTRY OF HEALTH

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3 March 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023019574

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 25 January 2023 for information regarding rongoā Māori and the Therapeutic Products Bill. Each part of your request is responded to below.

> *Provide information that shows the promotion or invitation to consult on the Therapeutic Product Bill to*
> *a) Tangata Whenua as Treaty Partner*
> *b) Rongoā Māori Practitioners and nation-wide Rongoā Māori roopu*
>
> *Please provide evidence of how the TP team publicly promoted the 'opening' date of the consultation process to engage with the tangata whenua (Treaty partner) about the inclusion of Rongoā Māori in the Therapeutic Product bill.*
>
> *Please provide evidence of how the TP team notified individual Rongoā Māori roopu NZ wide informing of the 'opening' date of the consultation process to engage with the tangata whenua (Treaty partner) about the inclusion of Rongoā Māori in the Therapeutic Product bill.*
>
> *Please provide evidence of the public announcement and the individual notification to Rongoā Māori roopu NZ wide of the 'closing' date for the consultation process of the TP bill.*

On 30 November 2022, the Associate Minister of Health, the Hon. Penni Henare announced a new rongoā workstream alongside the Therapeutic Products Bill (the Bill) to assess the interface between rongoā Māori and the Bill. The announcement is publicly available at: www.beehive.govt.nz/release/new-rongo%C4%81-workstream-announced-alongside-therapeutic-products-bill. The public consultation following the announcement included targeted engagement with key stakeholders, Māori, and expert groups. Consultation was structured around different sections of the Bill, such as forums on medical devices, medical trials, and natural health products (NHPs).

The consultation process included up to eight sector forums (cells and tissue, Christchurch, consumer forum, health practitioners, medical device forum, pharmacy forum, research forum.) For Tangata Whenua and Rongoā Practitioners the consultation process was limited to 1 or 2 individuals from one crown-funded organisation. Why were there no forums held for Māori to consult?

a) What was the rationale for inequitable consultation with Tangata Whenua as treaty partner?

b) What was the rationale for inequitable consultation with Rongoā practitioners?

c) Provide all meeting minutes, written documents, memos, letters, notes, emails

Manatū Hauora has identified two emails from 2019 in scope of this part of your request, itemised in Appendix 1 as Document 1, along with a series of decision documents itemised in Appendix 1 as Document 2. Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

The forums were open forums held in 2019 based on specific sectors relevant to the Bill and Māori Roopu. The emails in Document 1 outline the schedule for each forum. Māori organisations were contacted to partake in these forums. As NHPs were not yet included in the draft Bill at the time, no specific forum was held regarding NHPs with Māori stakeholders in 2019. Therapeutic products Cabinet papers, meeting minutes and documents are publicly available here: www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

Early drafts of the Therapeutic Products Bill show in 2019 that Natural Products nor Rongoā Māori were excluded in the bill. I request that the TP team please provide all meeting minutes, written documents, reports, memos, letters, notes, emails and draft documents where all Rongoā Māori products or Rongoā Māori practices were discussed in relation to the Therapeutic Products Bill between [2019 - Present}

I have interpreted this part of your request as seeking documents that led to a formal decision for the inclusion of NHPs and rongoā Māori in the Bill. A series of decision documents are attached to this letter under the heading “Document 2” and are also attached at Appendix 1 as an itemised list. These include Ministerial briefings, health reports, and memos regarding the inclusion of NHPs and rongoā Māori in the Bill.

The 2021 Cabinet Paper decision about regulating NHPs is publicly available at: www.health.govt.nz/system/files/documents/pages/regulating_natural_health_products_cab_paper_redacted_redacted.pdf. The associated NHP Regulatory Impact Statement can be found at: www.health.govt.nz/system/files/documents/pages/regulatory_impact_statement_-_regulating_natural_health_products.pdf.

Provide all meeting minutes where a representative or spokesperson of Te Kahui Rongoā was in attendance in person or virtually during the consultation process.

The information you have requested is attached to this letter as Document 3 and is itemised below in Appendix 1. This includes the meeting minutes, notes, and summaries for every hui and wānanga held with Te Kāhui Rongoā.

Provide all emails received from [specific email address, or Donna Kerridge or Te Kahui Rongoā] during the consultation process to date.
Provide all emails sent to Donna Kerridge or Te Kahui Rongoā about the TP bill from 2019 to date.

Information in scope of this part of your request is attached to this letter as Document 4 and is itemised below in Appendix 1.

> *In 2022 Te Kahui Rongoā received government funding;*
> *a) Provide the funding application*
> *b) Provide the terms of reference for this funding*
> *c) Provide a breakdown of how these funds have been agreed to be used*
> *Please provide evidence of the Crown signing an agreement with Te Kahui Rongoā Trust in January 2022.*
> *Please provide a copy of the above agreement between the crown and Te Kahui Rongoā Trust.*

Please refer to the relational agreement between Manatū Hauora and Te Kāhui Rongoā, which is publicly available here: www.health.govt.nz/system/files/documents/information-release/h2023019049_response.pdf.

> *Please provide evidence to acknowledge that Donna Kerridge and Te Kahui Rongoā Trust had the mandate from myself, of the tangata whenua, whānau, hapu, iwi Māori and/or any Rongoā Māori rooopu throughout New Zealand to be their leading advocate and speak on our/their behalf.*
>
> *Please provide evidence and an explanation of who made the decision of how Donna Kerridge and Te Kahui Rongoā Trust could legally speak on my behalf without my knowledge nor without any of my input, information and contribution to the korero. I did not consent to this!*

Manatū Hauora understand that Donna Kerridge was the appointed māngai (spokesperson) for Te Kāhui Rongoā Trustees at the time the relational agreement was signed. Te Kāhui Rongoā has consistently stated and maintained that they represent many, but not all, rongoā practitioners. They have a mandate to speak on behalf of their membership.

Not all rongoā practitioners are members of Te Kāhui Rongoā, and Te Kāhui Rongoā have never represented themselves as the representative body for all rongoā practitioners or Māori. We acknowledge that matters related to rongoā are important for all Māori and, while it was not possible for Manatū Hauora to engage with all interested tangata whenua in the development of the Bill, Parliament's consideration of the Bill and the Select Committee process provide everyone with the opportunity to have their say.

> *Please provide evidence of the invite issued to Te Kahui Rongoā Trust to be part of this consultation process in support of the inclusion of Rongoā Māori in the TP bill.*

Document 5 appended to this letter shows an email from Manatū Hauora to Te Kāhui Rongoā, seeking their expertise as part of the work undertaken in the Bill and regulation of NHPs. This is itemised below in Appendix 1. Manatū Hauora has never asked Te Kāhui Rongoā to speak in support of the inclusion of rongoā Māori in the Bill.

> *Please provide evidence of the $300k funding that was given to Te Kahui Rongoā Trust in January 2022 and explain specifically what this funding was for.*
>
> *Please provide evidence and an explanation to show why Te Kahui Rongoā Trust was paid $300,000 to support the bill right throughout the consultation process until it was closed."*

In May 2022, $300,000 of funding was provided to Te Kāhui Rongoā by the interim Māori Health Authority. This was to facilitate the reinstatement of Te Kāhui Rongoā on the Charities Register as a charitable organisation, and to support Te Kāhui Rongoā to become fully operational. Manatū Hauora has not provided any funding to Te Kāhui Rongoā to support the Therapeutic Products Bill throughout the consultation process.

> *Please provide evidence that Te Kahui Rongoā Trust is the legal advocate for my whānau, my hapu and my iwi Māori or the Rongoā Māori sector for that matter.*

This part of your request is refused under section 18(e) of the Act, as the information requested does not exist. As previously mentioned, Te Kāhui Rongoā have maintained they only have the mandate to speak on behalf of their membership and that not all rongoā practitioners are members of Te Kāhui Rongoā.

> *Please provide evidence that I/myself, whānau, hapu and iwi Māori from all rohe and regions in New Zealand, gave up or handed over our/their own rights under the Treaty - regarding Tino Rangatiratanga, Mana Motuhake, Autonomy and Sovereignty of our/their own Taonga and Matauranga a Rongoā Māori specific to our/their own respective rohe and Mahi a Rongoā Māori - to be governed by Te Kahui Rongoā Trust.*

This part of your request is declined as the information requested does not exist. As stated above, Manatū Hauora sought the expertise of Te Kāhui Rongoā as part of the work undertaken in the Therapeutic Products Bill. This included a wānanga hosted by Te Kāhui Rongoā to build the understanding and awareness of rongoā with the Therapeutic Products team. The minutes and meeting summary are provided in Document 1 and are itemised below in Appendix 1.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Steve Waldegrave
Associate Deputy Director General
Te Pou Rautaki | Strategy, Policy & Legislation

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	13 -21 February 2019	Email Correspondence: Consultation on the Therapeutic Products Bill	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons.
2	December 2017 August 2019 August 2019 October 2019 September 2022	Ministerial Briefing: Natural health products Health Report: New Natural Health Product Regulations: core components Memorandum: Regulating Natural Health Products: legislative vehicle options Health Report: Overview of proposed natural health products regulatory scheme	Some information withheld under the following sections of the Act: • Section 9(2)(a); • section 9(2)(f)(iv) to maintain the constitutional conventions that protect the confidentiality of advice tendered by Ministers and officials; • Section 9(2)(g)(ii) to maintain the effective conduct of public affairs through the protection of Ministers, members of organisations, officers, and employees from improper pressure or harassment; and • Section 9(2)(h) to maintain legal professional privilege. Some information deemed out of scope of your request.
3	May to July 2022	Te Kāhui Rongoā hui and wānanga meeting minutes, notes and summary	Some information withheld under the following sections of the Act: • Section 9(2)(a); and • Section 9(2)(g)(ii).
4	August 2021 – November 2022	Emails Correspondence: Donna and Te Kāhui Rongoā	Some information withheld under the following sections of the Act: • Section 9(2)(a); and • Section 9(2)(g)(ii). Some information deemed out of scope of your request.

#	Date	Document details	Decision on release
5	17 August 2021	Email: Request for hui with Te Kāhui Rongoā	Some information withheld under section 9(g)(ii) of the Act.

Document 1

Document Profile

Therapeutics Domestic Regulatory Scheme

Status:	Final
Date:	13/02/2019
Title:	Consultation schedule for the draft Therapeutic Products Bill
Author:	Hannah Adams
Document Type:	Email
Summary:	
Knowledge Content:	Med

Drawer:	2. Stakeholder Engagement and Communications
Folder:	2. Stakeholder Engagement\Correspondence\2019
File Location:	
Unit:	Ministry of Health System Strategy and Policy Regulatory Policy\Safety and Access
Maintainer(s):	Alison Cossar Andi Shirtcliffe Andrea Eng Jane Hubbard Michael Haynes Patricia Farrelly Saerom Shin Sue Scott Hannah Adams Strategy and Policy System Strategy and Policy Michael Roberts

Hi Megan and Fiona

It was nice to meet with you this morning.

Here is our schedule for the sector forums on the draft Therapeutic Products Bill. We have also just started discussion whether we should hold a general forum in Christchurch, as we aren't holding any forums in the south island.

Sector	Date	Location
Medicines	Afternoon, Monday 18 March	Auckland
Medical devices	Morning, Tuesday 19 March	Auckland
Cell & Tissue	Afternoon, Tuesday 19 March	Auckland
Research	Morning, Wednesday 20 March	Auckland
Pharmacy	Morning, Thursday 21 March (TBC – this is a change from the originally proposed time of morning Friday 22 March)	Wellington
General / Consumer	Afternoon, Thursday 21 March	Wellington
Health Practitioners	Afternoon, Friday 22 March	Wellington
Research	TBC	Due to the low number of registrations we intend to

		video conference with those stakeholders

I have added Fiona to the list of attendees for the medical device forum on 19 March. If you decide you would like additional people to attend that forum or would like to attend another forum please let me know.

Kind regards,
Hannah

Hannah Adams
Senior Policy Analyst (Part time: Monday - Wednesday 9.30am to 2.30pm & Thursday 9.30am to 6pm)
Regulatory Policy
System Strategy and Policy
Ministry of Health
DDI: 04 816 3922
Fax: 04 4692191

http://www.health.govt.nz
mailto:Hannah_Adams@moh.govt.nz

Document 1

Document Profile

Therapeutics Domestic Regulatory Scheme

Status:	Final
Date:	21/02/2019
Title:	Consultation on the Therapeutic Products Bill
Author:	Hannah Adams
Document Type:	Email
Summary:	
Knowledge Content:	Med

Drawer:	Consultation
Folder:	2019\Consultation Process
File Location:	
Unit:	Ministry of Health System Strategy and Policy Regulatory Policy\Safety and Access
Maintainer(s):	Alison Cossar Andi Shirtcliffe Andrea Eng Jane Hubbard Michael Haynes Patricia Farrelly Saerom Shin Sue Scott Hannah Adams Strategy and Policy System Strategy and Policy Michael Roberts

Kia ora Ana

I wanted to provide you with an update on our approach for engaging with Māori as part of the consultation on the draft Therapeutic Products Bill. Karen (a contractor who was helping us at the end of last year) had engaged with Anna-Lee about this previously.

The draft Therapeutic Products Bill and consultation document were released for public consultation on 14 December, with the consultation closing 18 April. Details of the consultation were sent to a number of Māori organisations, which I think Anna-Lee provided to Karen,

As part of the consultation process we are holding the following sector forums: Medicines, Medical Devices, Cell & Tissue, Research, Pharmacy, Consumer, Health Practitioner.

We also asked for registrations of interest for a Hui and Pasifika fono in Auckland. There were only two registrations for the hui, which were from industry stakeholders, who had also signed up for a number of other forums. There were no registrations for the proposed fono. Therefore, we are not intended to hold a hui and fono. There was one late registration request for the Hui from the Māori Pharmacist Association.

We consider the low of registration reflects the high level and technical nature of the Bill. At this stage in the process, the Bill is of most relevance to those that are developing and supplying therapeutic products and will be regulated under the scheme established under the Bill.

It is the requirements within the regulatory scheme, which will be set in regulations and rules, that will be of more relevance from a consumer, Māori, and Pasifika perspective. When the Ministry is developing the regulations (which will be at a later stage, probably next year), we will identify the aspects of the scheme that will be particularly relevant from a Māori and Pasifika perspective and engage with relevant representative groups on those aspects.

In saying that, there are some aspects in the Bill that we consider are relevant for Māori organisations that have a consumer, health practitioner, pharmacy, or research focus. Therefore, I am going to email the relevant Māori organisations (based on the lists provided to Karen) to encourage them to attend those forums. As the Māori Pharmacist Association requested to attend the hui, we had also offered to arrange a video conference or teleconference if they would like a separate discussion.

I have attached a table of the organisations I will be contacting below.

We would welcome any advice on any other organisations you think we should invite to those forums; in particular any Māori organisations with a consumer or disability focus.

Let me know if you would like to discuss any aspects of our approach.

Kind regards,
Hannah

Hannah Adams
Senior Policy Analyst (Part time: Monday - Wednesday 9.30am to 2.30pm & Thursday 9.30am to 6pm)
Regulatory Policy
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Health Practitioner Forum	Nga Kaitiaki o Te Puna Rongoa O Aotearoa (Māori Pharmacists Association)
Health Practitioner Forum	Nga Maia O Aotearoa - Maori Midwivies
Health Practitioner Forum	Nga Pou Mana Maori Allied Health Professionals of Aotearoa Inc
Health Practitioner Forum	Te Hotu Manawa / Toi Tangata
Health Practitioner Forum	National Council of Māori Nurses Incorp: Te Kaunihera O Nga Neehi
Health Practitioner Forum	Te Ohu Rata O Aotearoa
Health Practitioner Forum	Te Ao Marama Maori Dental Association
Health Practitioner Forum	Nga Manukura o Apopo - Māori Nursing & Midwifery
Pharmacy	Nga Kaitiaki o Te Puna Rongoa O Aotearoa (Māori Pharmacists Association)
Pharmacy	Tū Ora Compass Health
Pharmacy	Leanne Te Karu, Pharmacist prescriber
Consumer / disability	Kapo Māori o Aotearoa - Maori Disability Provider
Research	

Document 1

	s 9(2)(a) [redacted]

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report number: 20171555

Security classification: In-Confidence

File number: AD62-14-2017
Action required by: N/A

Natural health products

To: Hon Dr David Clark, Minister of Health

Purpose

Following correspondence from Natural Health Products New Zealand you have requested a briefing on the regulation of natural health products. This briefing provides an introductory overview of natural health products and the related issues and considerations in respect of regulation. It recommends that the Ministry meet with you early in the New Year to discuss the issues and next steps.

Key points

- Natural health products (NHPs) are a broad group of products that aim to assist with poor health. They are generally low-risk and sit above foods and below medicines on the continuum of products from food to prescription medicines. While generally low-risk, poor quality products, misleading claims, and inappropriate use can lead to negative health impacts. A lack of regulation also hampers health benefits being realised.
- Regulation of NHPs in New Zealand is patchy, compliance is poor, and most products are on the market in breach of current requirements.
- The regulation of natural health products is increasing internationally, and is a prerequisite for export to many markets. Risk-calibrated regulation of NHPs will lead to gains in safety and trade.
- The Therapeutic Products Bill is being developed to comprehensively regulate therapeutic products in New Zealand using modern, risk-appropriate regulatory requirements. NHPs were to be excluded from the Therapeutic Products Bill. However since the NHP Bill has been discontinued it would be possible for NHPs to be regulated under the Therapeutic Products Bill as a sub-category of product where the generally low-risk nature of these products would be recognised. It would also be possible to develop a new standalone regulatory scheme for NHPs.
- Sector views are mixed. Most are in favour of regulation of NHPs but there is a small, very vocal, minority against it or against aspects of previous regulatory proposals.
- It would be beneficial to discuss the issues with you early in 2018, including whether you wish to continue the Dietary Supplements Regulations as an interim measure (these are due to expire on 1 March 2019). If you wish to do so it will be necessary to make a relatively straightforward amendment to the Food Act 2014.
- A draft response to the letter from Natural Health Products New Zealand is attached for your consideration.

Contacts:	Sheila Swan, Chief Advisor, Regulatory Policy, Strategy and Policy	s 9(2)(a) [redacted]
	Hannah Cameron, Deputy Chief Policy Officer, Strategy and Policy	

Health Report number: 20171555

Recommendations

The Ministry recommends that you:

a)	**agree** to meet with Ministry of Health officials in early 2018 to discuss the issues in respect of natural health products and their regulation	**Yes/No**
b)	**sign** the draft letter to Natural Health Products New Zealand	

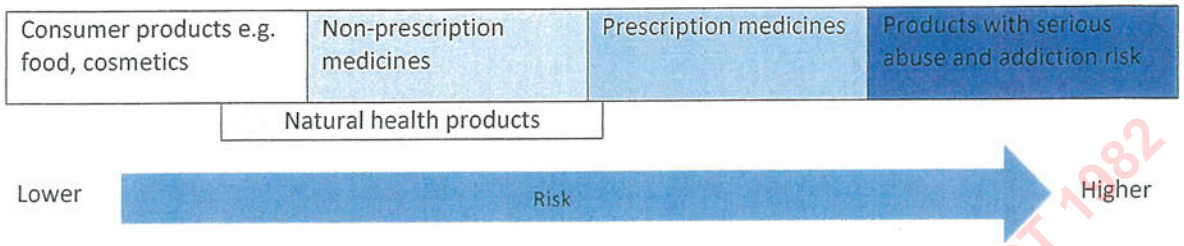
Hannah Cameron
Deputy Chief Policy Officer
Strategy and Policy

Minister's signature:

Date:

Natural health products

1. Natural health products (NHPs) are generally low-risk therapeutic products that sit on the product continuum as shown below.



2. NHPs include dietary supplements, and complementary and traditional medicines. They contain vitamins, herbs, amino acids or animal products and come in a variety of dose forms such as tablets, capsules, solutions, creams, drops, and injections. They are generally aimed at treating or alleviating illness/symptoms and maintaining health. That said, they also give rise to safety risks. Risks are often poorly understood by consumers (for example, modern extraction techniques can change the safety profile of traditional products by concentrating ingredients, or as a result of using solvents). Regulation is the norm in comparator jurisdictions and is recommended by the World Health Organization.

3. NHPs are also a valuable market commodity. In recent years there has been a marked increase in the volume of NHPs marketed alongside over the counter medicines through pharmacies; and in the number of pharmaceutical companies marketing these products. Trade is also expanding and regulation for safety reasons is inextricably linked to industry and export growth.

Regulation: current situation

4. There is a complex and overlapping web of regulation covering the product continuum including, the Misuse of Drugs, Medicines, Food, Hazardous Substances and New Organisms, and Psychoactive Substances Acts. Beyond general consumer law (eg. the Fair Trading Act) NHPs are regulated patchily at the moment by:

    a. The Medicines Act 1981 which regulates products used for therapeutic purposes and associated activities. Many NHPs are on the market in breach of the Medicines Act (because, for example, they are unapproved or make unverified therapeutic claims). Breaches have largely been tolerated by the Ministry of Health because it accepts that the Medicines Act is unsuitable for the generally low-risk nature of NHPs. It is designed for medicines and sets standards higher than those required for NHPs.

    b. The Dietary Supplements Regulations 1985 (under the Food Act) which cover products taken orally that are intended to supplement the amount of a substance normally derived from food (eg. zinc to supplement that normally obtained from grains or meat). The regulations set maximum daily doses for nutrients, limit the content of some vitamins and minerals, restrict some ingredients, and prevent therapeutic/health claims being made. They are lacking in many respects, are largely unenforced, and many products are on the market in breach of the regulations. The regulations do not:

        i. allow claims to be made and these would be reasonable for some products;

        ii. adequately manage the risks posed by the wide range of ingredients found in supplements; and

iii. contain up to date quantities of allowable substances.

The 1985 regulations were carried into the Food Act 2014 without being updated and they expire on 1 March 2019. (It was anticipated that a separate regulatory scheme for NHPs would be in place by that time).

5. The NHP Bill aimed to regulate NHPs through a standalone regulatory scheme. In general, other jurisdictions regulate NHPs under medicines and/or food legislation. Some, eg. Canada, have standalone legislation. The history in respect of the regulation of therapeutic products and NHPs is a long, complex, and at times contentious (refer Appendix one).

Therapeutic Products Bill

6. There is an important interface between NHPs and the Therapeutic Products Bill that is intended to repeal and replace the Medicines Act 1981. The Medicines Act needs replacement and, since the late 1980s, there have been a number of attempts to do so (refer Appendix one). The need is increasingly pressing in order to manage the risks associated with products using advanced technology, or to enable the full benefits of these products, and new ways to deliver services to be realised. A new act is sought by stakeholders across the sector. The Bill will:

    a. Cover the safety of all therapeutic products used in New Zealand (medicines, medical devices, cell and tissue therapeutic products, and hybrid products) from clinical trials to disposal. The Medicines Act has significant gaps in its coverage.

    b. Enable modern, efficient, regulatory practice. The Medicines Act prevents new practices (e.g. recognition of overseas approvals, electronic systems) being put in place.

    c. Enable the regulatory scheme to be kept up to date by having detail in regulations. The Medicines Act contains a lot of prescriptive and dated detail.

    d. Align New Zealand with international norms enabling the regulator to be more efficient and for benefits to flow to industry, consumers, and the health and disability sector.

7. The Bill aims to control products and key points in the supply chain. It would enable products to be approved and related activities to be licensed (eg. manufacture, wholesale, pharmacy). Controls would be placed on prescribing and systems required for in-market safety monitoring.

8. It is a complex and technical Bill and is currently being drafted. Officials are intending to consult on an exposure draft before the Bill is introduced to the House. This would enable the many stakeholders affected to comment and technical issues to be resolved before the parliamentary process. In the New Year it would be beneficial to discuss your preferences for this work.

NHP – Therapeutic Products Bill interface

9. The Therapeutic Products Bill would regulate all products intended for a *therapeutic purpose*. This internationally-defined term means, in short, the prevention, diagnosis, monitoring and treatment of ill health, testing for diseases, or pregnancy, and supporting or sustaining life.

10. NHPs fall within this definition. If it had been passed products regulated by the NHP Bill would have been carved out from the Therapeutic Products Bill. In the absence of the NHP Bill, these products are under the Therapeutic Products Bill unless specifically excluded. It would be possible, though not simple, to do this, likewise it would be possible to develop a risk-appropriate regulatory arrangement for NHPs under the Therapeutic Products Bill (refer later discussion).

Regulation of NHPs into the future

11. The Ministry's view is that product specific regulation of NHPs is necessary and desirable to promote consumer safety, choice, and health gain; and to support trade and industry growth.

Consumer safety, consumer choice and health gain

12. Regulation supports consumers having the choice to use NHPs to support their health in the knowledge that the products are safe, claims can be made and they are accurate, and products are true to label. The benefits of products can be maximised by avoiding known harms such as:

    a. Those arising from a lack of manufacturing controls eg. pesticide contamination, under- or over-potent ingredients

    b. Use of unsafe or poorly understood ingredients

    c. Unsubstantiated claims about the health benefits of products and uninformed consumer decisions, eg. to stop taking a prescription medicine

    d. Interactions: in particular circumstances (eg. pregnancy), pharmaceuticals, or other NHPs

13. Clinical literature describes potential and actual safety concerns about NHPs as well as where they can be used safety and efficaciously. Risks range from the serious – death, interactions with other medicines (eg. anti-coagulants, contraceptives, those for mental illness) – to the very mild (albeit inconvenient). Safe use is documented in respect of particular ingredients, patient groups, interactions to avoid etc.

14. To not regulate would result in the unusual situation where lower risk products (food and cosmetics) have to meet higher quality standards than NHPs. For example, while a novel ingredient would need to be assessed for safety before inclusion in a food, there would be no such assessment of the safety of ingredients used in dietary supplements which consumers take in medicinal dose forms. Similarly, manufacturing standards would be higher for food.

Trade and industry growth

15. NHPs are a growth market domestically and internationally. In 2014 industry estimated that NHPs contributed $1.4 billion per annum to the New Zealand economy and that there is sizeable export growth potential. The lack of a credible regulatory framework is identified by industry as a barrier to growth and a lost opportunity to capitalise on New Zealand's positive 'clean, green' image. Exporters see that domestic growth will be driven by increasing exports.

16. Export markets seek assurance that imported products contain safe ingredients, make truthful claims about efficacy and use, and have been manufactured to minimise contamination and adulteration risks. Increasingly our products may be shut out of overseas markets (eg. China) without regulation consistent with international norms for traceability, quality, safety and efficacy.

Regulatory options

17. In general, NHP regulation should involve putting risk-appropriate controls on ingredients, manufacturing processes, and claims. There are two options for product specific regulation:

    a. Therapeutic Products Bill. Appropriate arrangements would be made for NHPs under the Bill. Careful thought and consultation would be needed on the types of controls, costs, and other matters. NHPs could be made a *sub-category* of therapeutic products to

recognise that they should not be treated in the same way as pharmaceuticals. This option recognises that NHPs are part of the product continuum and aligns internationally.

b. New NHP legislation separate from the Therapeutic Products Bill. Consideration would be given to the matters that led to the NHP Bill not being reinstated. This option would align internationally and, as did the NHP Bill, give rise to boundary issues with the Therapeutic Products Bill that would need managing.

18. The following approaches meet neither trade nor safety objectives and are not recommended:

a. Regulation under general consumer law only. The Dietary Supplements Regulations would expire and NHPs would be carved out of the Therapeutic Products Bill. This approach would only provide an avenue for a remedy if consumers became aware of a faulty product, but by then, the damage is often already done and the consumer may not be aware. Pre-market controls on ingredients, manufacture, and claims require a specific regulatory scheme. The approach would not support trade and export.

b. Continue the Dietary Supplements Regulations only. Products not taken orally would be subject only to general consumer law.

Stakeholder perspectives are mixed

Those supportive of regulation …

19. include manufacturers looking to grow and export, consumers seeking assurance of safety and efficacy, sceptics of non-conventional treatments concerned about the claims made for some products, and health professionals concerned about negative health impacts and who want to normalise discussion about NHPs to improve clinical care (eg. so that interactions with pharmaceuticals can be considered).

Those opposed to regulation …

20. include some smaller manufacturers who believe NHPs are insufficiently risky to warrant it, consumers concerned that NHPs they value will become unavailable, importers of products that may not meet New Zealand standards, importers/producers of small amounts but wide ranges of products (these businesses are negatively impacted by per-product fee models), and some advocates opposed to Government intervention in personal health matters. Those that are opposed to regulation are a small but very vocal minority which have been very active to date.

Industry

21. Generally speaking, the industry comprises two groups. A large proportion of NHPs, about 80%, are produced by 20% of the industry. The remaining 20% are produced by an estimated 80% of manufacturers. Views on the costs and benefits of regulation diverge accordingly. For larger manufacturers regulatory costs are justified by export benefits and the Export Institute of New Zealand and Natural Health Products New Zealand have written in support of regulation. For small non-exporting manufacturers, the cost of regulation is more difficult to meet.

Ministry view

22. In supporting regulation, the Ministry also considers that there should be diligent attention to ensuring that controls and costs are risk-proportionate, to processes to transition industry into regulation, and to communication and sector engagement. It is worth noting that all jurisdictions have experienced controversy when they have tightened regulation of NHPs. The Ministry also notes that over the long period of attempted regulatory reform there has been considerable growth and maturity within the industry and in consumer expectations of government regulation.

Timing matters

23. Industry interest in the Government's plans for NHPs is likely to grow. In terms of progressing regulation the key decision in the short term is whether the expiry of the Dietary Supplements Regulations should be delayed as it is unlikely that either of the two regulatory approaches proposed above could be developed and operationalised before 1 March 2019. If you wish to regulate it would be prudent to continue the Dietary Supplements Regulations as an interim measure. This would require a Bill to amend the Food Act. Ideally (but not essentially) a bid would be made for the 2018 Legislation Programme. Bids are due from Ministers in late January 2018 and this bid would need discussion with the Minister, and Ministry, of Primary Industries as they are responsible for the Food Act 2014.

Correspondence from Natural Health Products New Zealand and next steps

24. Established in 2002 with support from New Zealand Trade & Enterprise, Natural Health Products New Zealand is the main industry organisation for dietary supplements companies and it has been closely involved with the NHP Bill. Natural Health Products New Zealand has written seeking to understand why the NHP Bill was not reinstated and your future plans for NHPs (refer Appendix two). A draft response is attached for your consideration – Appendix three.

25. The Ministry recommends meeting early in 2018 to discuss the issues in this briefing.

END .

Appendix One – Background information on the regulation of therapeutic products including natural health products

Efforts to bring in comprehensive regulation of all therapeutic products (natural health products, medicines, medical devices) began in the late 1980s when it was identified that the Medicines Act 1981 was no longer fit-for-purpose. Drafting instructions were issued but did not result in a Bill being introduced.

A further attempt was made in 1993. This was relatively quickly overtaken by the late 1990s work to establish a joint arrangement with Australia. By the later 1990s it was becoming increasingly evident that New Zealand would find it difficult to staff a full service regulator for all products over time and particularly for those using new, complex technology. In addition the Trans-Tasman Mutual Recognition Arrangement required both countries to examine how regulatory barriers between their markets could be removed. Combined with the need to replace the Medicines Act 1981, these factors lead to New Zealand's regulatory reform efforts being deployed on establishing a joint regulatory scheme and regulator with Australia.

In the period from the late 1990s until 2007 New Zealand and Australia developed and agreed an establishing Treaty, enabling Bills in both countries (the New Zealand Bill progressed through Select Committee and was reported back to the House), and a comprehensive regulatory scheme to sit under the Treaty and legislation. By this stage it was also clear that the range of products needing regulation also included cell and tissue based therapeutic products and these were included within the scope of the regulatory scheme.

The Australia New Zealand Therapeutic Products Agency (ANZTPA) was a sophisticated approach to meeting New Zealand's objectives for therapeutic products safety and greater trans-Tasman harmonisation (the model could have been applied in other areas). That said, it was also challenging for many in Government and industry, the natural health products industry in particular. The key concerns were New Zealand sovereignty and whether the regulatory model, costs, and regulatory practice would be suitably tailored to the generally low-risk nature of NHPs. There was also concern – which has continued – about regulation of NHPs at all. The inclusion of NHPs in the ANZTPA scheme was non-negotiable for Australia and ultimately these concerns caused efforts to establish ANZTPA to be put on hold in 2007 as there was insufficient support within the House to pass the New Zealand Bill.

In 2009 New Zealand began work on the Natural Products Bill to regulate NHPs consistent with an agreement between the then National-led Government and the Green Party. This work resulted in the Bill being introduced and progressing through the parliamentary process as far as the Committee of the Whole by early 2013. The Bill remained at this stage until it was not reinstated in November this year.

Alongside the NHP Bill development, in 2011 efforts recommenced to establish ANZTPA. The Australian Government led by Julia Gillard agreed that NHPs on the New Zealand market could be carved out of the joint regulatory scheme. This work continued until 2014 when a joint review by the departments of prime minister and cabinet in both countries concluded that work should cease.

At that time the Minister of Health requested that the Ministry commence work on a new Therapeutic Products Bill to repeal and replace the Medicines Act and address the issues identified in the late 1980s and since.

Appendix Two - Correspondence from Natural Health Products New Zealand

NATURAL HEALTH PRODUCTS NZ

9 November 2017

The Hon. Dr David Clark
Minister for Health
Parliament Buildings
Wellington

Dear Minister

Natural Health Products Bill – Withdrawn

Natural Health Products is the industry organisation for dietary supplements companies and with over 140 members we represent 85% of the industry which is a significant and growing contributor to New Zealand's economy with an estimated $1.4 billion per annum value to the economy in 2014.

The NHP Bill has been part of our remit for many years now and in its present state would ensure further success in our export sector and would allow consumers to retain access and choice for the vast majority of products as well as give them increased transparency regarding our products. We note that yesterday it was withdrawn from parliament.

We ask if you can provide us with some background as to its withdrawal and to give us a plan for the future of this important Bill which is vital to the growth of our sector, in particular in export.

Yours sincerely
Natural Health Products NZ

AQuesnel

Alison Quesnel
Corporate Affairs Director

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BRIEFING PAPER
Natural Health Products Bill

NATURAL HEALTH PRODUCTS NZ

THE PROPOSED LEGISLATION

New Zealand is the only first-world country without a modern regulatory system for natural health products. The Natural Health Products (NHP) Bill proposed regulating the manufacturing and selling of natural health products in this country by strengthening regulation around:

- which ingredients and health benefit claims will be permitted / not permitted
- what product information must be provided
- how products are manufactured
- manufacturing and export documentation (that is respected internationally)

THE CURRENT SITUATION

The Bill, which was awaiting its third reading, has been withdrawn from the Coalition Government's legislative Order Paper. Furthermore, the current regulations for our industry (The Dietary Supplements Act 1985) expire in March 2019. This expiry, combined with the withdrawal of the NHP Bill from the Order Paper, could result in there being no effective regulation for dietary supplements except the Fair Trading Act.

DESIRED OUTCOMES

It is vital that there is strong, effective and proportionate regulation governing natural health products sold in New Zealand and internationally. Many years of extensive consultation and work have gone into drafting the Bill. The process has involved respected industry representatives, academic experts and many others working in collaboration with the Ministry of Health. If the Government is unhappy with the Bill in its current form, then we propose using it as a starting point for working with the Government and other stakeholders on drafting a mutually-acceptable alternative.

HOW THE LAW WILL BENEFIT CONSUMERS, THE NATURAL PRODUCTS SECTOR AND NZ INC.

Passing the NHP Bill into law will:

- promote further industry growth by providing local consumers and export markets with a higher level of assurance that products are safe, effective and contain what is stated on the label
- help to remove export market barriers by positioning New Zealand as having world-class regulatory, compliance and audit systems
- enable consumers to find out more about the products they are buying and to therefore become better informed about how best to use them
- facilitate increased industry compliance and make it far more difficult for questionable products to be marketed and sold here
- maintain New Zealand's control over setting the regulatory rules for natural health and dietary supplement products sold here and overseas under Brand NZ

.../2

WHY NATURAL HEALTH PRODUCTS NZ'S VIEW MATTERS

Natural Health Products NZ (NHPNZ) is the national industry body that represents this country's natural health products, functional foods, complementary medicines, cosmeceuticals and nutraceuticals industries within New Zealand and internationally. Members include product manufacturers, suppliers and branded goods companies.

With over 145 members, NHPNZ represents around 85% of the sector by business, 80% by retail market revenue and 60% by export revenue. The industry is a significant and growing contributor to New Zealand's economy, contributing more than $1.4 billion per annum. NHPNZ believes the Bill's passage into law will help to further accelerate this growth.

KEY POINTS

Please be aware that, under the proposed regulations...

- ✓ Having a recognised internationally-aligned regulatory system will enhance the sector's export possibilities
- ✓ Consumers will be able to receive far better information about natural health products
- ✓ Compliance will be fair, reasonable and affordable
- ✓ Prices will not go up
- ✓ Traditional / cultural / ethnic / herbal medicine will still be widely available
- ✓ The vast majority of natural health products will still be widely available
- ✓ It will be affordable for micro-, small and traditional medicine businesses to comply

23 November 2017

Membership List

NATURAL HEALTH PRODUCTS NZ

Full Members
Green Cross Health Ltd
Health 2000
HealthPost Limited
Comvita
Manuka Health NZ Ltd
Vitaco NZ Ltd
GMP Pharmaceuticals Ltd
Go Healthy NZ Ltd
Good Health Products Ltd
New Image Group Ltd
Red Seal Natural Health Ltd (EBOS)
Swisse Wellness PTY Ltd
Alaron Products Ltd
Alpha Group Holdings Ltd
NZ Health Manufacturing
RMF Nutraceuticals
Blackmores Ltd
Health World Ltd
Integria Healthcare
Lifestream Ltd
Natural Health Laboratories (Clinicians)
New Zealand Manuka Group
Phytomed Medicinal Herbs Ltd
SeaDragon Marine Oils Ltd
Xtend-Life Natural Products (Intl) NZ
Hibiscus Solutions
Seperex Nutritionals Ltd
Artemis Ltd
Harker Herbal Products Ltd
Health and Herbs International
Midlands Nutritional Oils
NBTY International
NZ Health Food Company Ltd
PA & SC Steens Ltd
Weleda NZ Ltd
ENZO Nutraceuticals Ltd
Lipa Pharmaceuticals
Naturex Australia
New Zealand Extracts Ltd
RFA Regulatory Affairs
Zealand Health Manufacturing Limited
Absolute Essential Ltd
Anagenix Ltd
ApiHealth NZ Ltd
BioBalance Ltd
Brauer Professional Pty Ltd
Forest Herbs Research Ltd
MitoQ
Mountain Red Ltd
Nelson Honey Ltd
OneOne Health
Promisia Integrative Ltd
Return 2 Health
Supreme Health New Zealand Limited
Tui Balms
Apotex NZ Ltd
FlowMotion Ltd
HCH Formulas
Hubris International Ltd
Maraeroa C Incorporation
Nuzest NZ Limited
Pure Vitality Health Products Ltd (Canaan Farming)
PureLand
SOHO Flordis International Pty Ltd
Sun Life Nutritionals
Wakatu Incorporation
Aotearoa Fisheries Ltd
BioPacific Partners
Ciprian Consulting Ltd
Essentially New Zealand Ltd
Kiwi Herbs Ltd
Merinova Ltd
NZ Glacial Clay
ORA Foods Ltd
Pharmaceutical Technologies Ltd
Quantec Ltd
United Fisheries Ltd

Associate Members
A S Harrison
ADM
Advanced Wellness Regulatory Solutions
AJ Park
Alchemy Agencies
AsureQuality Ltd
Baldwins Intellectual Property
Biopolymer Network Ltd
Brandfolio
Brenntag New Zealand Ltd
Bronson & Jacobs NZ
Callaghan Innovation
Cameron Healthcare Ltd
Capsugel NZ Ltd
Cawthron Institute
Chemplas (NZ) Ltd
Clinical & Regulatory Services (CARSL)
Cospak Ltd
Crowe Horwath
DSM Nutritional Products NZ Ltd
ESR
ESupply Global Ecommerce Tech
GC Rieber Oils AS
Ibis Business Intelligence Solutions
IMS Health Ltd
Ingredients Plus NZ Ltd
Institute for Innovation in Biotechnology
Invita NZ Ltd
IRI (NZ) Ltd
Keene Manufacturing Solutions
Lintbells NZ Ltd
Midwest Pharmaceutical NZ Ltd
Pak World Ltd
NZ Trade & Enterprise
Pacific Flavours & Ingredients Ltd
Pathways
Pharma Pac Ltd
Provelco Co-operative Ltd
Pharmaceutical Solutions Ltd
Plant & Food Research
RDC Global
Rise Creative Ltd
Sensient Technologies
Simpson Grierson
Smart Regulatory Solutions
Sue Akeroyd and Associates
The Cosmetic Company Ltd
Victoria University of Wellington

Partners
Forbes Packaging
IMCD NZ Ltd
James & Wells
New Wave Consulting Ltd
New Zealand Couriers
Scientific & Technical Recruitment Ltd

Industry Associates
ASEAN NZ Business Council
Cadence Communications
CMA
Cosmetics NZ (CTFA)
GOED
Macular Degeneration New Zealand
Medical Technology Association of NZ (MTANZ)
New Zealand China Trade Association (NZCTA)
New Zealand German Business Assn (NZGBA)
NZ Bio
NZ Food Innovation Network Ltd
NZ Self-Medication Industry (NZSMI)
Omega-3 Centre
The Organic Exporters Association of NZ Inc
US China Health Products Association

Appendix three - **Draft letter to Natural Health Products New Zealand**

Ref. C1700

Alison Quesnel
Corporate Affairs Director
Natural Health Products New Zealand
PO Box 9026
Newmarket
Auckland 1149

Dear Alison Quesnel

Natural Health Products Bill

Thank you for your letter dated 9 November 2017 seeking background regarding the withdrawal of the Natural Health Products Bill.

I appreciate the important contribution that risk-appropriate regulation can make to the growth of your sector. I wish to ensure that any new regulation meets the needs of the health and disability support sector now and into the future and is mindful of the global settings for natural health products. It is important to me to ensure that any regulation meets expectations of appropriate risk management, is trusted and respected, and among other things, supports New Zealand trade and economic objectives.

I acknowledge the effort the sector contributed and the challenges that were faced to develop the Bill. However, I believe we could do better. With the Therapeutic Products Bill now under development, I wish to ensure that we have sound and cost effective regulation across all these products. I am aware that under the Food Act 2014, the Dietary Supplements Regulations expire in 2019 and this issue will need to be addressed.

Once I have considered the wider issues I will advise the sector on the proposed next steps.

Yours sincerely

Hon Dr David Clark

Minister of Health

Health Report

New Natural Health Product Regulations: core components

Date due to MO:	30 July 2019	**Action required by:**	15 August 2019
Security level:	IN CONFIDENCE	**Health Report number:**	20191339
To:	Hon Dr David Clark, Minister of Health		
Copy to:	Hon Damien O'Connor, Minister for Food Safety		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Sheila Swan	Chief Advisor, System Strategy and Policy	s 9(2)(a)

Action for Private Secretaries

Forward a copy of this paper to Minister O'Connor's office. **Date dispatched to MO:**

Return the signed report to the Ministry of Health.

Natural Health Product Regulations: core components

Purpose of report

This report seeks your agreement to the high-level approach for regulating natural health products. This builds on previous advice in HR 20190822 and HR 20181894. This report is intended to enable discussion with your colleagues, and to inform further advice for you to take to Cabinet.

Key points

- Consumers expect natural health products to be safe, of acceptable quality, and true-to-label. Equally, the industry wants to meet growing demand by providing products that are valued by consumers. Current regulations do not support these goals.
- Objectives of the proposed regulatory scheme are to **support consumer safety, and in doing so support industry development**. To achieve these objectives, a key design principle is to ensure the regulatory scheme is **risk and cost-proportionate**.
- Together with the Ministry for Primary Industries we propose an approach that is risk-proportionate, aligns with related product regulations in New Zealand (e.g. therapeutic products, food, medicinal cannabis), and with international regulations.
- In order to achieve the objectives, controls are needed in four core areas. Our recommended approach is as follows:
    - **ingredients** – develop an evidence-based list of safe ingredients and amounts
    - **manufacture** – establish risk-proportionate regulation
    - **claims** – establish a list of pre-approved claims, and allow new claims if they can be substantiated
    - **labelling, advertising, marketing, and promotion** – set risk-proportionate standards, some of which can be operationalised through an industry self-regulatory system.
- The proposed approach is largely similar to that of the previous Natural Health Products Bill. This is because the key considerations are largely unchanged. However, to better support low-risk businesses to meet new regulations we propose a different approach in the following areas:
    - **manufacture** – we are exploring a range of manufacturing standards for different risk profiles
    - **industry support package** – we can explore non-regulatory initiatives with industry, with potential to develop a wider industry strategy
    - **other components of a regulatory scheme** (e.g. marketing approval) – we intend to incorporate flexible and risk-proportionate approaches in several areas to reduce the financial and compliance burden on low-risk businesses and products.
- We will provide advice in August 2019 on the legislative vehicle to inform advice for you to take to Cabinet.

Recommendations

The Ministry recommends that you:

a) **Note** that a comprehensive regulatory scheme for natural health products is required to provide safety and quality assurance for consumers, and to support industry growth

b) **Agree** that a new regulatory scheme needs to be risk and cost-proportionate in order to achieve key objectives, which are to: **Yes/No**

   i. **support consumer safety** – by ensuring products contain safe ingredients, are of acceptable quality, and are accompanied by good consumer information (which includes claims, labelling, advertising, marketing, and promotion)

   ii. **support industry development** (in both domestic and international markets) – by establishing a well-functioning, cost-effective regulatory scheme from which industry can build

c) **Agree** to the proposed approach for regulating key components of a natural health products scheme (as outlined on page 8): **Yes/No**

   i. **ingredients** – develop an evidence-based list of safe ingredients and amounts

   ii. **manufacture** – establish risk-proportionate regulation

   iii. **claims** – establish a list of pre-approved claims, and allow new claims if they can be substantiated

   iv. **labelling, advertising, marketing, and promotion** – set clear standards, some of which can be operationalised through an industry self-regulatory system

d) **Note** that officials will provide advice in August 2019 on the recommended legislative vehicle for natural health product regulations

e) **Meet** with officials to discuss the approach outlined in this report and next steps, including the approach to stakeholder engagement and further advice to take to Cabinet. **Yes/No**

Maree Roberts
Deputy Director-General
System Strategy and Policy

Hon Dr David Clark
Minister of Health
Date:

Background

The need to regulate natural health products is a pressing issue with a long history

1. Natural Health Products (NHPs) are a growing range of products that do not fit neatly within current regulations. Efforts to bring in comprehensive regulation of all therapeutic products (NHPs, medicines, medical devices) began in the late 1980s when it was identified that the Medicines Act 1981 had some gaps in regulation (e.g. it does not cover cell and tissue therapies). Several attempts have been made to develop regulation over the years but this has been difficult to complete due to the diversity of consumer and industry views that need to be considered.

2. More recently, in November 2017, the Natural Health and Supplementary Products Bill, which was at Committee of the Whole stage, was not reinstated. In December 2018, the Cabinet Social Wellbeing Committee agreed that options for regulating natural health products should be reconsidered in order to let work continue on the Therapeutic Products Bill, and to allow NHPs to be fairly regulated [SWC-18-MIN-0176 refers].

At least half of New Zealanders use natural health products, and the industry is growing to meet increased demand

3. NHPs encompass a wide range of products, including vitamin and mineral supplements, supplemented foods, topical applications, cosmetics, herbal medicines, and complementary and traditional medicines such as traditional Chinese medicine and rongoa Māori. They come in a variety of dose forms such as tablets, capsules, solutions, creams, drops and injections.

4. Consumers use NHPs to manage, improve, and protect their health according to their beliefs, values, and perceptions of what will be beneficial for them. We estimate that at least half of New Zealanders use NHPs, and that women and older adults are likely to be more frequent users[1].

5. The industry is growing to meet increased demand for NHPs. In 2014 the NHP industry estimated that the industry contributes around $1.4 billion to the New Zealand economy (e.g. market value, employment), and that this was growing[2].

New regulations aim to provide safer and better quality products for consumers, and support a growing domestic and international market

6. Consumers expect NHPs to be safe, of acceptable quality, and true-to-label. In addition, the industry wants to meet growing demand by providing products that are beneficial to, and valued by consumers. However, the current lack of a comprehensive, NHP-specific regulatory scheme does not support these goals.

7. It is important to have a regulatory scheme which proactively and adequately manages risk given the potential for some products to reach a wide audience and have fairly serious adverse effects. In addition, most NHPs are available for consumer self-selection

[1] **Based on the 2008/09 Adult National Nutrition Survey which looked at dietary supplement use.**

[2] **Based on an industry survey conducted by Natural Health Products New Zealand who represent approximately 80% of the industry by product volume.**

(i.e. there is usually no trained person present to assess benefits, risks, and give advice). This increases the risk that products may be used in an unsafe way if the right information is not provided. Below are some examples where NHPs can cause harm if they contain unsafe ingredients, are of poor quality, or are improperly used (see Appendix 1 for more examples):

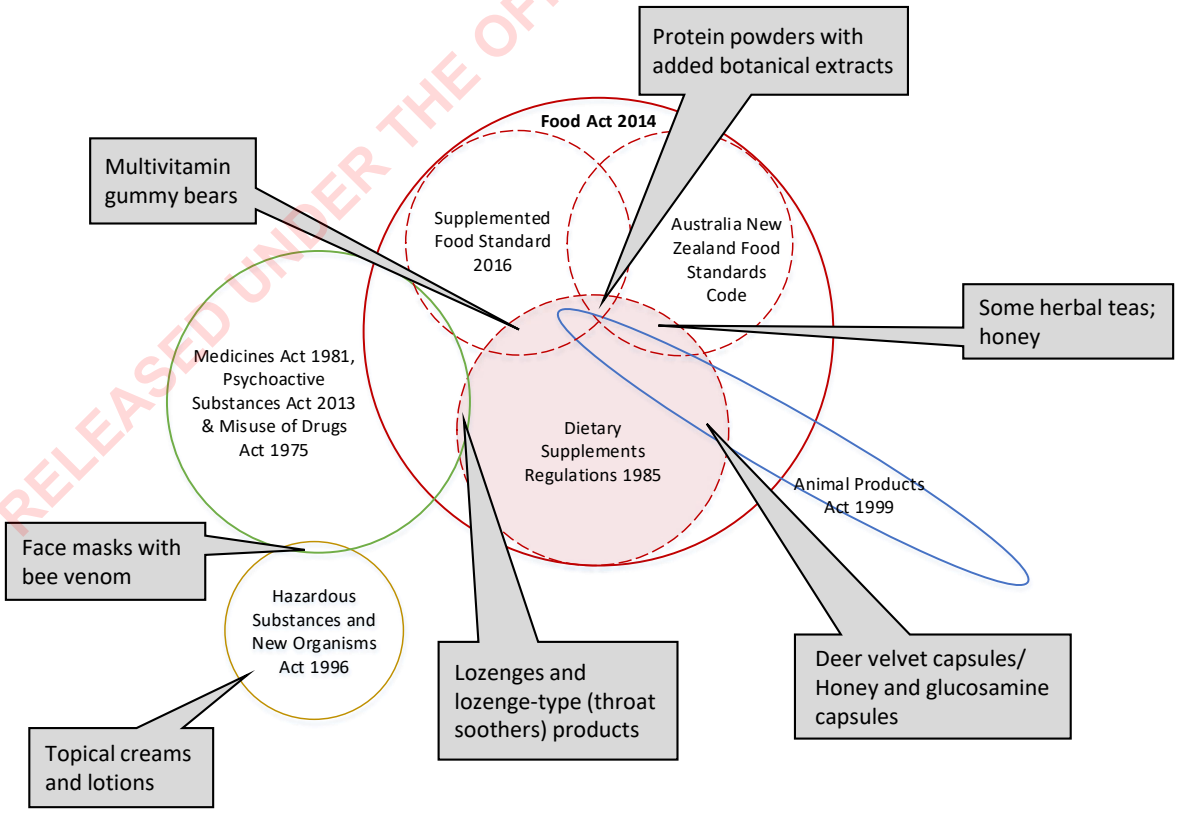
a. some naturally occurring substances are inherently toxic – e.g. ingesting small amounts of the foxglove plant can cause irregular heart function and death

b. a product can interact with medicines to increase toxicity or reduce effectiveness – e.g. the main active ingredient in turmeric can interact with blood thinning medications such as warfarin to increase the risk of serious bleeding.

8. Current regulations are complicated and are spread across several Acts (see Figure 1). Orally consumed NHPs are covered under the **Dietary Supplements Regulations 1985**, which are under the **Food Act 2014.** While these regulations provide some risk mitigating measures, they are out of date. The regulations are not based on risk, do not have an adequate regulatory structure for approving claims, do not clearly define dietary supplements, do not capture other types of NHPs (e.g. herbal balms), and do not provide enforcement options to manage non-compliance.

9. Note that the Dietary Supplement Regulations expire on 1 March 2021 and will need to be extended to prevent dietary supplements becoming non-compliant foods while a new NHP regime is being developed.

Figure 1. Current regulations for natural health products are complicated.



10. Non-oral NHPs are covered under the **Hazardous Substances and New Organisms Act 1986** (e.g. topical creams and lotions) which is administered by the Environmental Protection Authority, and the **Medicines Act 1981** (e.g. nasal sprays and lozenges) which is administered by the Ministry of Health.

11. **The Fair Trading Act 1986** also applies basic safety and consumer information expectations for all consumer products. However, these regulations are insufficient to manage the risk that some NHPs pose because there is no capacity to build in the technical oversight needed (e.g. to assess ingredients, manufacture and claims). Furthermore, it only addresses harm after it has happened.

12. The current system is difficult to enforce due to overlaps in product definitions and inconsistencies in requirements. This means that many products are in breach of regulations (e.g. dietary supplements which make higher-level health claims) and that consumer safety is being compromised (see Appendix 1 for examples). Our approach does not align with our main trading markets which have higher safety and quality standards (e.g. Australia, UK, Canada, and the USA), nor the World Health Organisation which recommends comprehensive regulations for NHPs.

Objectives and core components of the regulatory scheme

13. New regulations need to primarily enable a good standard of consumer safety, and in doing so support industry development. We aim to do this by having robust regulation that instils trust in consumers, and is recognised and respected by our main trading markets. Therefore, the objectives of the new regulatory scheme are to:

    a. **support consumer safety** – by ensuring products contain safe ingredients, are of acceptable quality, and accompanied by good consumer information (which includes claims, labelling, advertising, marketing, and promotion)

    b. **support industry development** (in both domestic and international markets) – by establishing a well-functioning, cost-effective regulatory scheme from which industry can build.

14. In order to achieve these objectives, the regulatory scheme needs to be **risk and cost-proportionate.** These are key principles which will inform the design of regulations as far as possible:

    a. being risk-proportionate means having only as much regulatory oversight as is necessary to manage a product's risk. This principle has largely informed our proposed approach for the regulatory scheme

    b. being cost-proportionate means setting compliance costs in proportion to the work required to assess or approve a product, and minimising costs where possible so they are not a significant barrier to entry. Cost-proportionate measures will be expanded upon in later phases of regulatory development.

15. We have identified four core areas where controls are required in order to achieve our objectives:

    a. **ingredients** – to ensure a product's contents are safe. We recommend developing an evidence-based list of safe ingredients and amounts

    b. **manufacture** – to ensure a product is of acceptable quality and safely processed. We recommend establishing risk-proportionate standards

    c. **claims** – to ensure a product's health benefits are truthful. We recommend having a list of pre-approved claims and allowing new claims if they can be substantiated

    d. **labelling, advertising, marketing, and promotion** – to ensure a product's associated information and promotional material is truthful, not misleading, and in line with regulations. We recommend setting risk-proportionate standards, some of which can be operationalised through an industry self-regulatory system.

16. The table below summarises our proposed approach, rationale, and anticipated impacts for the regulator and the industry. This approach balances consumer and industry interests, is risk-proportionate, aligns with related product regulations in New Zealand (e.g. therapeutic products, food, medicinal cannabis), and with international regulations for NHPs.

How our recommended approach compares to the previous Natural Health Products Bill

17. The proposed approach is largely similar to that of the previous Natural Health Products Bill. This is because the key considerations are largely unchanged. However, to better support low-risk businesses to meet new regulations we propose a different approach in the following areas:

    a. **manufacture** – we are exploring a range of manufacturing standards for different risk profiles

    b. **industry support package** – we can explore non-regulatory initiatives with industry, with potential to develop a wider industry strategy (see paragraphs 37-38)

    c. **other components of a regulatory scheme** (e.g. marketing approval) – we intend to incorporate flexible and risk-proportionate approaches in several areas to reduce the financial and compliance burden on low-risk businesses and products.

18. In addition, the proposed approach is supported by both the Ministry of Health and the Ministry for Primary Industries. The previous Natural Health Products Bill was primarily driven by the Ministry of Health.

	INGREDIENTS	MANUFACTURE	CLAIMS	LABELLING, ADVERTISING, MARKETING, PROMOTION
	Document 2			
	Develop a **list of permitted ingredients and amounts** under defined conditions (i.e. a 'white list').	Establish **risk-proportionate manufacture standards**.	Develop an **evidence-based, risk-proportionate scheme** which allows claims to be made if they are substantiated and within the scope of NHPs.	Set **risk-proportionate** standards, some of which can operationalised through an **industry self-regulatory system**.
PROPOSED APPROACH	Develop a list of **safe ingredients and amounts.** Additional criteria may apply depending on risk (e.g. can only be used under certain conditions). Use **scientific and traditional evidence** to justify approval of an ingredient. Allow companies to **apply for new ingredients to be approved**. Aim to capture an **extensive and diverse range** of ingredients, including indigenous and traditional ingredients.	Consider **recognising or drawing from a range of existing manufacture standards,** for example: - **Good Manufacturing Practice (GMP).** These standards would be relevant to non-food NHPs. There are a range of levels within GMP, and the strength of the quality standards required depend on a product's risk (i.e. lower standards would be required for lower-risk products). - **Food safety measures** (e.g. National Programmes 1-3, Food Control Plan). These standards would be relevant to oral NHPs. - **Other risk-proportionate schemes** if assessed to be appropriate.	Allow health and traditional claims to be made if they are **substantiated by the appropriate level of evidence.** Higher level claims will require a higher standard of evidence. Both scientific and traditional evidence will be recognised. Allow claims which are **appropriate for an NHP**. Claims will mostly be of a 'wellbeing and health maintenance' nature. Products wishing to make therapeutic claims will largely need to follow therapeutic product regulations. Allow a **small selection of therapeutic-level claims** to be made. Additional criteria will apply. **Pre-approve** a range of claims. Allow companies to **apply for new claims to be approved.** Consider allowing health claims that meet criteria in **other risk-proportionate schemes** (e.g. food safety schemes).	Establish **risk-proportionate standards for labelling and promotional material** (e.g. higher-risk products will have greater requirements to state risks and safe uses). Consider an **industry self-regulatory system to oversee promotional material** where media only uses material if it has been checked by a third party such as: - **Therapeutic Advertising Pre-vetting Service (TAPS).** Companies currently use this service to check their promotional material for therapeutic products. Develop **guidelines and criteria** for a third party to enable them to approve NHP promotional material. These would be **consistent with a product's approved claims and required labelling content**.
RATIONALE	A white list provides **greater safety assurance** for both consumers and companies. This is in comparison to regulation that allows all ingredients to be used unless they are proven to be unsafe (i.e. a 'black list'). A white list **aligns with most international jurisdictions** (e.g. Australia, Canada, the EU, China). Wide coverage will be needed to support **industry innovation**.	We are considering existing schemes because they are **well-tested, established, and risk-proportionate.** This will also ensure there is **consistency** between NHPs, foods, therapeutic products, and other related products. Considering other risk-proportionate schemes may help maintain **consistency** between NHPs and related products. Recognising existing risk-proportionate schemes may help **avoid duplication.** This means that if a product already has to comply with recognised manufacture regulations (e.g. under the Animal Products Act) then it wouldn't need to re-meet manufacture requirements under NHP regulations.	Claims should be allowed if they are able to be **substantiated** and a product is **safe and good quality** (i.e. has met ingredient and manufacture standards). Allowing some therapeutic-level claims will ensure a **smooth transition between NHPs and therapeutic products**. However, these will be limited, and additional criteria will apply to maintain the **integrity, clarity, and enforceability of the NHP and therapeutic product schemes**. Pre-approving claims **reduces burden on companies** and provides certainty. Recognising other claims schemes may help **avoid duplication**.	This approach is **consistent with therapeutic product and food regulations, and the Fair Trading Act 1986**, in terms of requiring products' labelling and promotional material to be truthful and non-misleading. The industry self-regulatory approach is **well-tested and effective.** It works because media companies want to ensure their content meets the Advertising Standards Authority's Therapeutic and Health Advertising Code. Having a third party to check this makes it easy for media.
IMPACTS	**Regulator: Medium.** Work will be needed to establish a white list, and ongoing work needed to keep it up to date. An existing draft list can be utilised. **Consumers:** We intend that consumers have more confidence that a product is safe, and experience fewer adverse reactions. **Industry:** We intend that companies have more clarity and confidence that their products are safe. Companies wishing to use ingredients which are untested, in a new application, or in higher amounts will need to apply for approval. It is not intended to affect small businesses which make/sell products containing well-tested ingredients being used in conventional ways.	**Regulator: Low/Medium.** Utilising existing systems would likely mean low costs for the regulator. Further work is required to work out how these would work together. **Consumers:** We intend that consumers have more confidence that a product has been safely and consistently made, and is true-to-label (e.g. products act consistently and as expected). **Industry:** We intend that companies will be better supported to make and sell safe and acceptable quality products. Those operating below an acceptable safety standard and dealing with higher-risk products will require the most work to improve manufacture standards. Some small local businesses may need to meet additional standards, but these will be proportional to the risk of the products they make/sell. Additional non-regulatory support may be available. A regulatory system that supports high manufacture standards will increase export potential for companies wishing to export.	**Regulator: High.** Significant work needed to pre-approve claims, and ongoing work to approve new claims. Recognising relevant approved health claims for food and therapeutics in New Zealand, and reviewing health claims approved internationally may alleviate some regulatory burden. **Consumers:** We intend that consumers are accurately informed about the benefits of a product**.** **Industry:** We expect that most companies will benefit as currently a low level of claims are permitted. Products will be more competitive internationally as this is a key mechanism for companies to promote and add value to products. For companies wishing to make a pre-approved claim, this approach provides certainty and clarity, and is low effort. It would particularly benefit those using well-tested ingredients. Companies wishing to make higher-level or other new claims will require specialist expertise to self-substantiate them. Small businesses may not be able to make their desired claim.	**Regulator: Low/Medium.** Some work needed to develop labelling and promotional material standards. Previous work on labelling requirements can be utilised. A self-regulatory system to oversee promotional material would not require regulator involvement once set up. **Consumers:** We intend that consumers are accurately informed about a products benefits and risks. **Industry:** We intend that companies will be better supported to convey the benefits and risks products accurately, and that all promotional material will truthful and non-misleading. Those operating below an acceptable standard and dealing with higher-risk products will require the most work to improve labelling and promotion standards.

Impacts on industry

20. The proposed regulatory approach is intended to facilitate domestic and international trade while safeguarding public health in New Zealand. We aim to do this by having robust regulation that instils trust in consumers, and is recognised and respected by our main trading markets. However, regulations will differentially impact importers, exporters, and domestic supply-only companies.

21. Importers and domestic supply-only companies benefit from the current low level of regulations, in that they can sell products with low requirements to show they are safe, of acceptable quality, and accompanied by good consumer information. A new regulatory scheme may introduce costs due to the additional work needed to meet the new standards.

22. On the other hand, exporters are limited by the current low level of regulations as our regulatory measures do not assure overseas markets that our products meet their higher levels of safety and quality. A new regulatory scheme would rectify this by providing exporters with export certification which they currently cannot obtain. We believe that current exporters would incur minimal or no costs because stakeholders have told us that many exporters are already meeting higher standards.

23. In addition, all companies currently have very limited ability to make health claims. Therefore, all companies have potential to benefit by being able to draw from a wide range of pre-approved health claims, and make higher-level or new claims if they can be substantiated. Making health claims is an important mechanism for promoting and adding value to products.

24. We have considered setting lower standards for domestic sale to support importers and domestic supply-only companies. However, this is difficult to justify as this would mean New Zealanders receive less safe or lower quality products. Therefore, we instead propose the same standards for products sold domestically and overseas.

25. This may mean some products can no longer be sold, or that companies will require work to meet new standards. However, it is only intended to affect products which contain unsafe ingredients or are manufactured to an unacceptable standard. As we propose a risk-proportionate regulatory scheme, those dealing in lower-risk products will be less affected.

26. Importers and domestic supply-only companies may be supported to adapt to a new regulatory scheme in a number of ways. For example, providing an adequate transition period and sufficient educative resources to ensure the new requirements are understood.

Other components of a regulatory scheme

27. We will provide further advice detailing the other components necessary for a complete regulatory scheme. A few of the key issues are outlined below.

Exemptions

28. Regulating in a risk-proportionate manner will allow some products to be exempt from certain controls if they are low-risk (e.g. low concentration of low-risk active ingredient), or they have other ways to control safety (e.g. administered by a practitioner).

Practitioners

29. We consider that practitioners could have special exemptions as currently all practitioners are covered under the Health and Disability Commissioner Act 1994. This means if someone experiences an adverse effect from a product they can report this to the Health and Disability Commissioner. In addition to this, it is possible to manage risk as a collective profession through a code of ethics or best practice. This is a self-regulatory approach and relies on practitioners belonging to a professional body.

30. Some practitioners have applied to be regulated as a collective profession under the Health Practitioners Competence Assurance Act 2003, such as Traditional Chinese Medicine practitioners, and Western Medical Herbalists. Registration of these professions would contribute to a successful NHP regulatory scheme.

Manufacturing exemptions for low-risk products / businesses

31. In the previous Natural Health Products Bill there were manufacturing exemptions for small-scale manufacture, or low revenue businesses. The intent was to exempt small, low-risk businesses from high manufacture costs (e.g. those selling at local markets).

32. However, we are now considering taking a purely risk-based approach, where every product or business is managed based on risk, no matter the size or revenue. The intent is to ensure that costs are-proportionate to the risk – i.e. lower risk means lower cost.

33. This approach recognises that small businesses have potential to produce high risk products, and is consistent with how therapeutic products and food are regulated. It also addresses concerns under the previous Bill that large businesses may have been incentivised to break their company into smaller companies in order to avoid manufacturing costs and processes.

34. This approach is intended to enable small, local businesses to be eligible for manufacturing exemptions providing their products are low-risk (e.g. low-risk ingredients being used in conventional ways).

Marketing approval

35. Marketing approval is a before-market check issued by the regulator to ensure a product meets all relevant regulations and is fit for sale / use. We are exploring the viability of a triple-tiered, risk-proportionate scheme:

    a. **Individual product approval** – higher-risk products approved on an individual basis. The sponsor (i.e. person or company that puts the product on the market) needs to show that each product meets the standards for ingredients, manufacture, claims, advertising etc.

    b. **Grouped product approval** – similar groups of medium and high-risk products are approved together (e.g. a range of products with similar ingredients). The sponsor needs to show that the group of products meets the standards for ingredients, manufacture, claims, advertising etc.

    c. **Licensing manufacturer to a standard** – a manufacturer is allowed to make a range of products which meet clearly defined standards around ingredients, manufacture, claims, and advertising. This route would only apply to low-risk products and associated claims.

36. A difference in this approach to the previous Natural Health Products Bill is the consideration of grouped product approval, and manufacturer licensing. This provides some flexibility for lower-risk businesses to have lower compliance costs.

Industry support package (non-regulatory initiatives)

37. In addition to a regulatory scheme, there are a number of non-regulatory ways that the government could support industry to meet good standards for safety and quality for NHPs. Supporting initiatives could help address some concerns that industry members have around a new regulatory scheme, such as increased costs. For example, exploring with industry ways to help smaller companies test and validate ingredients.

38. This idea could be explored further with other Ministers and agencies through development of a wider industry strategy with the aim of supporting and growing the industry.

Stakeholders

39. There are a range of stakeholder views which we have been cognisant of during the development of this regulatory approach. It is impractical to develop a scheme that will suit all stakeholders perfectly while also ensuring a level of consumer safety which is consistent with comparable products (e.g. therapeutic products, food, medicinal cannabis) and international jurisdictions (e.g. Australia, UK, USA).

40. Key concerns have been raised around:

    a. **high compliance costs and administrative burden** – these stakeholders are generally those importing a wide range of low-sales volume products, and smaller businesses.

    b. **support for rongoa Māori products and practices** – these stakeholders are generally those making, selling, or providing rongoa Māori products as part of their business or practice.

41. These views are well-understood and we propose addressing as many as possible in more detailed phases of regulation development (e.g. through lower marketing approval costs for low-risk products, and ensuring traditional ingredients are approved). In addition, non-regulatory options may be able to help facilitate and ease the transition for stakeholders who are most affected or have less capacity to meet the new standards.

Next steps

42. We will provide further advice on the legislative vehicle in August 2019.

43. We recommend meeting with officials to discuss the approach outlined in this report and next steps, including the approach to stakeholder engagement and further advice to take to Cabinet.

ENDS.

Appendix 1: How safe are NHPs?

What are NHPs?

44. Natural health products (NHPs) are a broad group of products used for a variety of health purposes including maintaining good health, and preventing or treating an ailment or condition. Their main ingredients must exist in nature.

45. The term NHP includes dietary supplements, complementary and traditional medicines. Examples include:

    a. garlic capsules to support healthy blood pressure and cholesterol

    b. glucosamine capsules for healthy joints

    c. magnesium tablets to assist with sleep

    d. throat sprays for sore throats and mouth ulcers

    e. herbal products (e.g. echinacea, herbal teas) to assist with colds and stress

    f. kawakawa balm for dry skin.

How safe are NHPs?

46. Although evidence on the health benefits of many NHPs is mixed, we view that NHPs can be beneficial to health if they are contain appropriate ingredients, are made to an acceptable quality, and accompanied by good information.

47. However, if NHPs are not made to a good standard, they have potential to cause a level of harm that outweighs the benefit they provide. Some of these harms are comparable to those in medicines and foods – both of which have risk-proportionate regulations to ensure safety and quality.

48. A product that contains substances that are found in nature or are made in a factory to be identical to substances found in nature does not necessarily mean they are safe. The following examples illustrate a number of occasions where natural ingredients can cause harm:

    a. some naturally occurring substances are **inherently toxic** – e.g. ingesting small amounts of the foxglove plant can cause irregular heart function and death

    b. when natural ingredients, including foods and traditional medicines, are used over a **long period of time**, or in a **highly concentrated** form – e.g. long-term use of vitamin A can cause liver damage[3]. Essential oils are highly concentrated and can cause skin reactions if undiluted, and a range of adverse effects if ingested in high quantities (e.g. vomiting, rapid heart rate, seizures).

    c. when a substance is **dangerous in particular groups of people** such as pregnant women, young children or those with certain health problems – e.g. vitamin A can cause fetal deformations if taken in high quantities in pregnant women.

[3] **This is mainly an issue for fat-soluble vitamins (e.g. vitamin A and D) as they accumulate in fatty tissues. There is less risk of chronic toxicity for water-soluble vitamins like vitamin C.**

d. when a product **interacts with medicines** to increase toxicity or reduce effectiveness – e.g. St John's wort is often found in herbal teas and can interact with prescription medicines like Prozac (an anti-depressant) to reduce effectiveness. The main active ingredient in turmeric can interact with blood thinning medications such as warfarin to increase the risk of serious bleeding.

e. when a product **loses stability** – e.g. antioxidants and oils. Rancid fish oils can are ineffective and could induce side effects such as vomiting

f. when a product is used for **a health benefit that is not evidence-based** – e.g. a number of vitamin B capsules (vitamin B3, B5, B12) have been claimed to prevent sunburn. This is misleading and could contribute to health issues such increased risk of sunburn and long-term increased risk of skin cancer due to disuse of better UV protection methods such as sunblock

g. when a product has been **contaminated** due to poor manufacturing processes, or with **illegal use of prescription / over the counter medicines** – e.g. sildenafil (the active in Viagra) is an over the counter medicine often found in "herbal remedies" that claim to improve erectile dysfunction.

Memorandum

Regulating Natural Health Products: legislative vehicle options

Date due to MO:	22 August 2019	**Action required by:**	27 August 2019
Security level:	IN CONFIDENCE	**Health Report number:**	20191586
To:	Hon Dr David Clark, Minister of Health		
Copy to:	Hon Damien O'Connor, Minister for Food Safety		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Fiona Ryan	Principal Policy Analyst, System Strategy and Policy	s 9(2)(a)

Action for Private Secretaries

Forward a copy of this report to Minister O'Connor's office. **Date dispatched to MO:**

Return the signed report to the Ministry of Health.

Regulating Natural Health Products: legislative vehicle options

Purpose of report

1. Following discussions with you on 20 August 2019 on a regulatory scheme for natural health products (NHPs), this report provides advice on options for a legislative vehicle, including:

   a. an **annotated agenda** to support discussions with your cross-government colleagues – **Appendix 1**

   b. a proposed **timeline** to progress a stand-alone bill for NHPs – **Appendix 2.**

Key points

2. New, comprehensive NHP regulation is required to better support consumer safety and industry development, both for exports and locally-sold products. You have indicated that this is a matter of interest to your Ministerial colleagues.

3. In July 2019, you agreed to the high-level approach for regulating NHPs in four core areas: ingredients; manufacture; claims; and labelling, advertising, marketing, and promotion [HR 20191339 refers].

4. The next key step is to determine which legislative vehicle is most appropriate. There are four options for a legislative vehicle to regulate NHPs. The key considerations for each option are outlined in the attached annotated agenda to support discussions with your cross-government colleagues (Appendix 1).

5. On balance, officials recommend the option of a stand-alone bill for NHPs. The reasons for this are outlined in the annotated agenda.

6. In discussions with you on 20 August, you expressed interest in a timeline to progress a stand-alone bill for NHPs. An indicative timeline is attached as Appendix 2. Key milestones are:

   a. a **Cabinet paper** to the Social Wellbeing Cabinet Committee in **November 2019**

   b. **targeted stakeholder engagement** (industry, consumers, Māori, and other interested parties) on the proposed regulatory scheme over 6-8 weeks from **mid-January to February 2020**

   c. **introducing a bill** to Parliament in the **first quarter of 2020** (subject to necessary policy decisions, and confirmation of drafting schedules with PCO).

Maree Roberts
Deputy Director-General
System Strategy and Policy

Appendix 1: Annotated agenda on a NHP regulatory scheme

Agenda

Natural Health Products - Core components of a NHP Regulatory Scheme and options for a legislative vehicle

	AGENDA ITEM
1	**CORE COMPONENTS OF A REGULATORY SCHEME FOR NHPs** • The policy objectives for NHP regulation are to support consumer safety and industry development (including exports), while ensuring the regulatory scheme is risk and cost-proportionate. • The four core components of a NHP scheme and the recommended framework are: ○ **ingredients** – develop an evidence-based list of safe ingredients and amounts, recognising scientific and traditional evidence ○ **manufacture** – establish risk-proportionate regulation, exploring the suitability of a range of existing manufacturing standards ○ **claims** – establish a list of pre-approved claims that businesses can make about their products, and allow new claims if they can be substantiated ○ **labelling, advertising, marketing, and promotion** – set risk-proportionate standards, some of which (such as advertising) can be operationalised through an industry self-regulatory system. • The proposed approach is largely similar to that of the previous Natural Health Products Bill, but with a different approach in some areas to provide flexibility. Further work by officials will explore options to provide different pathways that maintain risk-proportionate regulation while minimising compliance costs further, particularly for small businesses. Examples include further investigating: ○ manufacturing standards – consider a range of standards such as Good Manufacturing Practice (GMP), and Food Control Plans that match products or product categories to the most appropriate requirements. ○ cost allocation (i.e. Crown or sector) and cost recovery options ○ tiered marketing approvals aligned with product risk such as: ○ Individual product approval – higher-risk products approved on an individual basis. E.g. a company needs to show that **each product** meets regulations ○ Grouped product approval – similar groups of medium-risk products are approved together (e.g. a range of products with similar ingredients). The sponsor needs to show that the **group of products** meets regulations

	○ Licensing manufacturer to a standard – a **manufacturer** can make a **range of products** which meet clear standards around ingredients, manufacture, claims, and advertising etc. This would only apply to low-risk products.
2	**OPTIONS FOR A LEGISLATIVE VEHICLE FOR NATURAL HEALTH PRODUCTS** There are three key considerations for the legislative vehicle: 7. **The similarities between NHPs and therapeutic products** – NHPs cover a range of products across the spectrum of foods, herbal remedies, over the counter products (e.g. pharmacy-only medicines), and prescription medicines. 8. **Ability to address policy objectives** – to support consumer safety and industry development, including exports, in a way that is risk and cost-proportionate. 9. **Stakeholder views** – a strong preference across the NHP sector and among some consumers for regulation of NHPs to be separate to therapeutic products and medicines. **THE OPTIONS ARE:** **OPTION 1 - Food Act 2014**. This would not provide a comprehensive approach to NHPs, as it would only cover edible NHPs, and the Food Act is not well suited to addressing the more therapeutic nature of NHPs. Non-edible NHPs would continue under the status quo situation (which is inadequate) and many would be captured by the proposed Therapeutic Products Bill. This means there will be an unclear interface between some non-edible NHPs and therapeutic products. MoH and MPI officials have previously assessed this option and do not consider that fully addresses the policy objectives. **This option is not recommended.** **OPTION 2 - Do the minimum in Therapeutic Products Bill by providing an exclusion for the very lowest risk NHPs (i.e. there would be no new regime for NHPs).** This would mean most NHPs would be captured within the Therapeutic Products Bill, and it would not address all the policy issues relating to NHPs. It would also require the status quo to be extended for NHPs not captured in the Therapeutic Products Bill with significant uncertainty and complexity for industry, consumers and regulators. **This option is not recommended.** **OPTION 3 - Explicitly address NHPs as a category in the Therapeutic Products Bill**. This would enable a risk-proportionate approach to regulation of NHPs and would recognise the generally lower-risk nature of these products in relation to medicines. Due to strong NHP industry preference for stand-alone NHP legislation, there is potential for this option to delay progress of the Therapeutic Products Bill. **This is a feasible option for further discussion.** **OPTION 4 - Stand-alone NHP legislation** separate to the Therapeutic Products Bill and Food Act 2014. This would enable a risk-proportionate approach to regulation of NHPs and would recognise the generally lower-risk nature of these products in relation to medicines. Due to strong NHP industry preference for stand-alone NHP legislation, there is less potential to delay progress on the Therapeutic Products Bill. **This is a feasible option for further discussion. This is officials' preferred option**.

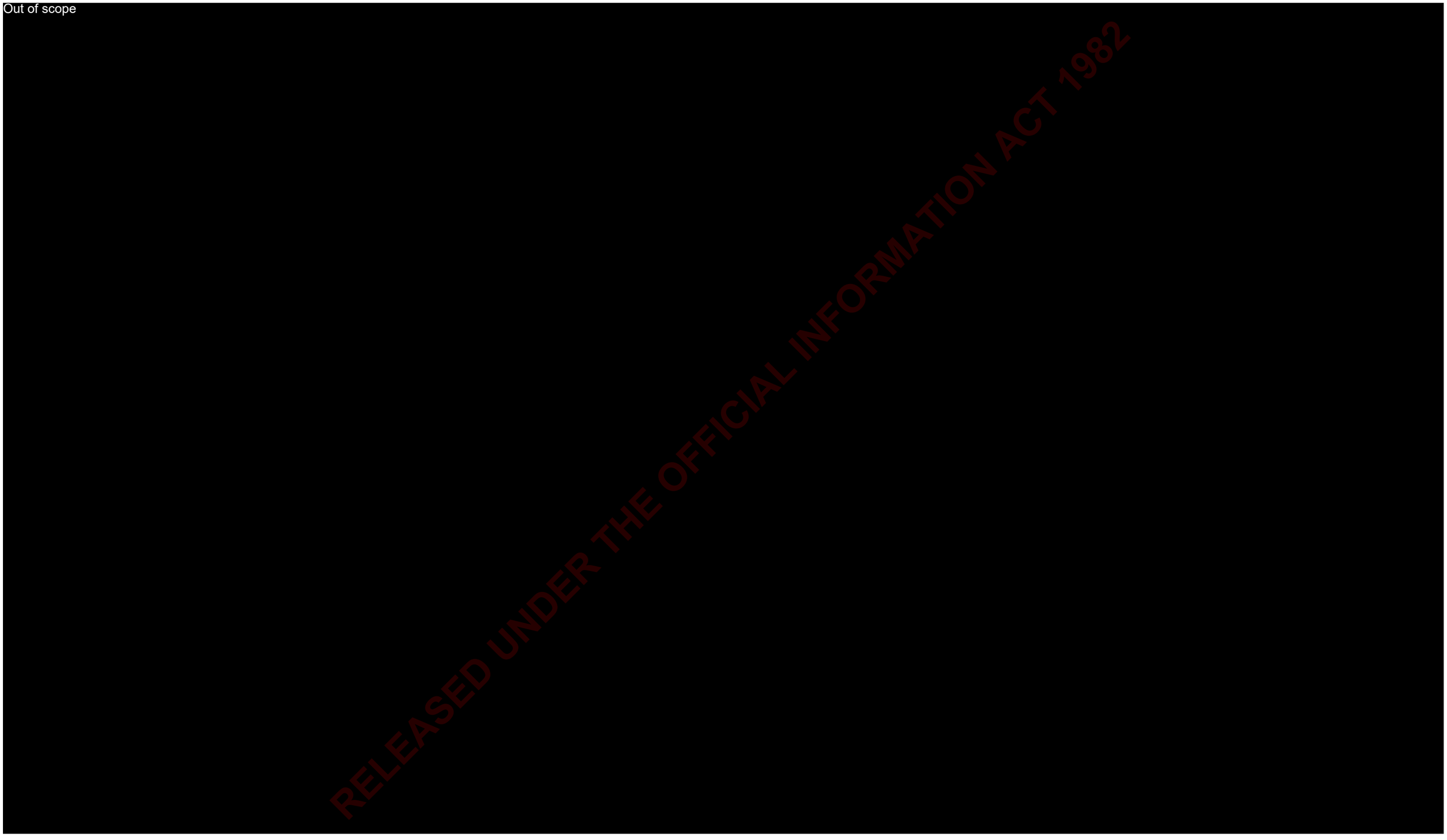
	IN SUMMARY:
	
	• **Options 1** (Food Act) **and 2** (Do the minimum in Therapeutic Products Bill) are **not recommended** as they do not:
	  ○ provide a comprehensive, risk proportionate regulatory scheme for edible and non-edible NHPs
	  ○ address the policy objectives for a regulatory scheme for NHPs, which are to support consumer safety and industry development
	  ○ improve the certainty or clarity for the regulation of NHPs for industry, consumers or regulators
	
	• **Options 3** (NHPs as a category in Therapeutic Products Bill) **and 4** (a standalone bill for NHPs) **are both feasible options** that would provide a comprehensive, risk-proportionate, fit-for-purpose regulatory scheme for NHPs and address the policy objectives. In addition **option 4** will provide clarity and certainty for industry and consumers and has less potential to slow progress on the Therapeutic Products Bill.
	
	• The development of a modern, clear, fit-for-purpose regulatory scheme for NHPs in either Option 3 or 4 would help manage any remaining interfaces with other legislation for food and medicines.

3	**TIMING AND COORDINATION OF LEGISLATION FOR NHPs AND THERAPEUTIC PRODUCTS** • **Expiry of the Dietary Supplements Regulations 1985**- Any new legislation addressing NHPs would ideally be passed before 1 March 2021 to address the expiry of the Dietary Supplements Regulations 1985. If the Dietary Supplements Regulations are allowed to expire, without a new regulatory scheme for NHPs in place (or a bespoke extension of the Dietary Supplements Regulations), there would be a regulatory gap where all products covered under these regulations will become non-compliant foods and will not be able to be sold legally. • **Coordination of NHP and Therapeutic Products Bill** - Any separate NHP legislation would need to be co-ordinated with the Therapeutic Products Bill, and would ideally be passed ahead of the Therapeutic Products Bill. NHPs would be excluded from the Therapeutic Products Bill provided they meet requirements in the NHP scheme. This is the simplest and most effective way to provide clarity for suppliers of NHPs as to their regulatory requirements, and would mean that the Therapeutic Products Bill does not need to contain a complex 'carve-out' for NHPs. If a bill for NHPs does not precede the Therapeutic Products Bill there would need to be a complex 'carve-out' of NHPs from the Therapeutic Products Bill. The 'carve-out' would be needed because it is simply not possible to develop a clean definition between medicines and NHPs (i.e. the definitions of therapeutic product, therapeutic purpose, and medicine in the Therapeutic Products Bill are such that NHPs are caught within them. These definitions are internationally accepted and permeate the Therapeutic Products Bill). This complex carve out would still result in some NHPs being captured by the Therapeutic Products Bill. This would not meet the policy objectives for NHPs and will concern many in the NHP industry.

Document 2

Appendix 2: Indicative Timeline to progress a stand-alone Bill for Natural Health Products

Out of scope



MINISTRY OF HEALTH
MANATŪ HAUORA

Detailed timeline for 2019 for Cabinet consideration

Out of scope

Document 2

MINISTRY OF HEALTH
MANATŪ HAUORA

Health Report

Overview of proposed natural health products regulatory scheme

Date due to MO:	N/A	**Action required by:**	As soon as possible
Security level:	IN CONFIDENCE	**Health Report number:**	20191980
To:	Hon Dr David Clark, Minister of Health		
Copy to:	Hon Damien O'Connor, Minister for Food Safety		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Fiona Ryan	Acting Manager Regulatory Policy, System Strategy and Policy	

Action for Private Secretaries

Forward a copy of this report to Minister O'Connor's office.

Return the signed report to the Ministry of Health.

Date dispatched to MO:

RECEIVED
21 OCT 2019
Office of Hon David Clark

Ministry of Health
20 OCT 2019
DISPATCHED

MINISTRY OF HEALTH
MANATŪ HAUORA

Overview of proposed natural health products regulatory scheme

Purpose of report

You have requested policy work to be undertaken on a new regulatory scheme for natural health products (NHPs), with a view to informing advice to Cabinet by December 2019. This briefing provides you with an overview of the proposed regulatory scheme and seeks your thoughts on the proposed scheme.

Key points

- This paper outlines a regulatory scheme for natural health products (NHPs) that would distinguish NHPs from other products (eg, therapeutic products and food).
- A new standalone bill to regulate NHPs would build on the previous bill and clarify expectations around the sale and manufacture of NHPs, manage risks associated with NHPs and support industry development and growth.
- The new regulatory scheme is proposed to:
  - be fit for purpose and risk-proportionate
  - clarify whether something is an NHP
  - outline a process for gaining permission to sell and market NHPs in New Zealand, facilitated by pre-approved lists of ingredients and health claims
  - specify standards for the manufacture of NHPs in New Zealand
  - specify what types of products are exempt from the scheme.
- To progress the development of the new NHP regulatory scheme, it is proposed that you take a paper to Cabinet Social Wellbeing Committee on 4 December 2019 which:
  - outlines the key elements of the proposed scheme and options for giving effect to them
  - seeks approval to publicly consult on the scheme, either through endorsement of a draft discussion document or endorsement to delegate authority to approve the discussion document to you.

MINISTRY OF HEALTH
MANATŪ HAUORA

Recommendations

The Ministry recommends that you:

a) **note** that policy work is underway to develop a new regulatory scheme for natural health products

b) **indicate** your view on proposals for a new regulatory scheme for natural health products where marked in this paper **Yes/No**

c) **agree** to take a paper on a new regulatory scheme for natural health products to Cabinet Social Wellbeing Committee on 4 December **Yes/No**

d) **note** officials will provide you with a draft Cabinet paper for ministerial consultation in mid-November 2019

e) **indicate** if you would like to discuss any matters in this paper with officials where marked in the body of this paper. **Yes/No**

Maree Roberts
Deputy Director-General
System Strategy and Policy

Hon Dr David Clark
Minister of Health
Date: 13/11/19

MINISTRY OF HEALTH
MANATŪ HAUORA

Context

1. Following recent cross-party discussions on the regulation of natural health products (NHPs), you asked officials to undertake policy work on developing a regulatory scheme for NHPs to inform advice to Cabinet by December 2019 (HR 20191586 refers). This new scheme is proposed to be progressed through a standalone bill rather than through other legislative vehicles.

A new regulatory scheme for natural health products is needed to manage risks to consumers and support sector development and growth

2. NHPs are a broad group of products used for a variety of health purposes, including maintaining or promoting health or wellness, nutritional support, vitamin or mineral supplementation, affecting or maintaining the structure or function of the body and the relief of symptoms. Their main ingredients exist in nature. Although NHPs generally carry lower health risks than medicines, they are not risk free.

3. There are risks associated with the products themselves (eg, adverse effects), as well as risks associated with a lack of clarity about the health benefit claims that can be made (eg, inaccurate or misleading claims can result in people not seeking timely medical attention), and the manufacturing process of NHPs (eg, dosage accuracy and contamination).

4. As outlined previously (HR20191339 refers), current regulation is complicated and spread across several Acts which are implemented by different agencies. There are gaps, overlaps and inconsistencies in requirements which creates confusion for consumers, the NHP sector and regulators. This makes it difficult to adequately manage the risks of NHPs. A new regulatory scheme can help proactively and adequately manage the risks associated with NHPs, whilst also supporting industry development and growth.

Developing a new regulatory scheme for natural health products

We can build on previous attempts to regulate natural health products...

5. In 2017, a previous bill, the Natural Health and Supplementary Products Bill, was not reinstated by the Government.

6. Based on previous feedback received from stakeholders, including the NHP sector and consumers, there is broad support for regulating NHPs, particularly through a standalone scheme that is separate from medicines. Stakeholders however differ in their views on the level of regulation required, and a small number of stakeholders feel there should be no regulation.

7. Many stakeholders viewed the previous bill as being too restrictive, particularly for NHPs they considered to be safe. For example, it limited the ingredients which could be used in NHPs. Stakeholders also raised concerns about the potential for increased compliance costs and reduced availability of NHPs. Recommendations were also made about changes to particular clauses of the previous bill.

8. We intend to build on the lessons from similar jurisdictions such as Australia and Canada, as well as feedback received to date, to ensure a new NHP regulatory scheme is fit for purpose, addresses risk proportionately and minimises compliance costs.

... but we need to look at and consult on what regulation would be appropriate

9. Since work started on the previous Natural Health and Supplementary Products Bill in 2009/10 there have been significant contextual changes to both consumer aspirations and the NHP sector. This means we have an opportunity to re-examine what would constitute appropriate and proportionate regulation for NHPs.

10. Consultation with consumers and the NHP industry is needed to test the feasibility of proposed new options that have not previously been consulted on, re-establish relationships with stakeholders, and reset conversations with stakeholders about the need for and benefits of regulation. Consultation also offers the opportunity to give stakeholders an early signal of proposed changes to address concerns that they have previously raised.

11. As substantial consultation took place as part of work on the previous bill, a brief, four-week period of consultation is proposed to inform the development of a new draft bill. This will include engagement with Māori. This approach to consultation has been tested with Natural Health Products New Zealand (NHPNZ), a national industry organisation. NHPNZ indicated that consultation, even for a short period of time, is imperative.

Changes to consumer aspirations

12. Data from the 2008/09 New Zealand Adult Nutrition Survey suggests that at least half of New Zealanders use NHPs, with more recent anecdotal evidence indicating that consumer demand for NHPs is increasing. This is consistent with demand in other countries such as Canada and Australia.

13. Consumers are increasingly focused on health and wellness and are keen to make proactive and informed choices. They expect NHPs to be high quality, safe and true-to-label.

Changes to the natural health products industry

14. Earlier this year the Ministry of Health and Ministry of Primary Industries surveyed the NHP sector to gain a better understanding of the sector. While only a small number of responses were received (96 responses; 12 percent response rate), the survey indicated that NHP firms:

    a. are involved across the full range of NHP product categories, and some firms are also involved with food and medicines

    b. vary in their operations and may be involved in activities across the supply chain from raw materials supply, manufacturing, wholesale and distribution, marketing and retail, import and export, to practitioners

    c. are largely focused on the domestic market, however over half of the respondents indicated some form of export

d. are diverse in size: compared to the rest of the New Zealand economy there are fewer small firms (firms with fewer than 20 employees), and more medium and large firms (firms with 21–50 employees and more than 50 employees, respectively).

15. The NHP industry has evolved, with new technologies and markets emerging. This is changing market demands. There is also increasing interest in bioactive substances in New Zealand flora and ensuring products with these substances are high quality and true-to-label. NHPNZ advise export growth has been constrained by a lack of fit for purpose regulation despite substantial export growth potential for New Zealand firms.

16. In 2014, the NHP industry estimated the total value of the NHP industry to the New Zealand economy at $1.4 billion per annum, with $285 million per annum in exports and potential for substantial further growth.

The new regulatory scheme will need to ensure consumer safety, industry development and growth, and be fit for purpose

17. In July 2019 (HR20191339 refers), you agreed to the new regulatory scheme having the following key objectives:

a. support consumer safety – by providing assurance of product safety, quality and reliable information (which includes claims, labelling, advertising, marketing and promotion). This would enable consumers to make informed choices about their health and wellbeing

b. support industry development and growth – by establishing a well-functioning, cost-effective regulatory scheme that provides greater clarity and certainty on expectations. This would be export-boosting. A scheme recognised by overseas jurisdictions would support increased exports.

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

a. regulation will be fit for purpose

b. regulation will be proportionate to the risks associated with NHPs

c. compliance costs will be minimised, equitable and fair

d. consistency with Treaty of Waitangi principles

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

19. Following cross-party discussions, you have subsequently indicated a preference to introduce a new standalone NHP bill by mid-2020. To facilitate achieving this timeframe, we suggest you take a paper to Cabinet Social Wellbeing Committee on 4 December 2019. The paper would seek initial policy decisions and permission to undertake public consultation. Further Cabinet decisions and approval to issue drafting instructions would be sought in early 2020.

Do you broadly agree with this proposed approach?	**Yes/No**
Would you like to discuss this proposed approach with officials?	**Yes/No**

20. To address the product and manufacturing risks associated with NHPs, a new NHP bill would focus on regulating the commercial sale and manufacture of NHPs. The new NHP bill would largely be based on the previous bill and would:

    a. define NHPs, and provide mechanisms to clarify whether something is a NHP, as opposed to food, a cosmetic or a medicine, and prevent gaming of the system

    b. provide for risk proportionate manufacturing standards

    c. provide a cost recovery framework

    d. provide for increased health claims to be made in advertising and marketing (provided these claims can be substantiated), and specify the standards of evidence that would be required to support such claims.

21. Further work is required to develop the regulatory scheme and bill in greater detail. This includes the work signalled below, as well as other work to update the previous bill, including reviewing technical details for the bill (eg, appeals, offences and penalties and cost recovery provisions), examining the interface with other legislation and exploring what regulatory mechanisms (eg, rules and notices) would need to sit under the bill. Public consultation on the proposed scheme will facilitate this work.

Do you broadly agree with these proposed features of a new bill to regulate NHPs?	**Yes/No**
Would you like to discuss these proposed features of a new bill to regulate NHPs with officials?	**Yes/No**

How the new regulatory scheme is proposed to work

22. As per the previous bill, it is proposed that the regulatory scheme for NHP be lighter than the product life cycle approach for medicines which includes application, assessment and approval. This proposed approach is justifiable given the generally lower level of risks associated with NHPs when compared to medicines.

23. We propose a new NHP regulatory scheme be largely based on a self-certification product notification system for product ingredients and claims; with manufacturing standards, listed exemptions and a regulator with the ability to verify information and perform audits. Policy work is being conducted in these areas, as outlined below.

Do you broadly agree with this proposed approach to the regulatory scheme?	**Yes/No**
Would you like to discuss this proposed approach to the regulatory scheme with officials?	**Yes/No**

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Product notification system

24. The product notification system would require importers or manufacturers to self-certify their NHPs meet New Zealand regulations prior to marketing or sale by entering product information into an online database. This would enable risk-proportionate monitoring of post-market safety surveillance, which supports consumer safety.

25. The web-based nature of the product notification parts of the scheme would provide a cost-effective and efficient process for both product notifiers and the regulator.

26. The product notification system would include pre-approved lists of permitted ingredients and health claims, as well as guidance on acceptable standards of scientific and traditional evidence required to substantiate a health claim. This would facilitate and streamline the product notification process. It would also reduce the likelihood of NHPs being sold that contain unsafe ingredients thereby reducing risks such as adverse reactions or interactions with other drugs, and consumers delaying seeking conventional medical treatment.

27. Further policy work is required to analyse and consider options for product notification fees, including whether to charge annual fees to maintain registrations. We propose consulting on the following options for charging fees:

    a. charging for each product notification

    b. charging based on a sliding scale for a tranche of products notified

    c. charging based on a group of products of a similar nature or type of use ('grouped product approval').

28. A substantial amount of previous work has been done to develop draft lists of permitted ingredients and health claims. Further work will also be required to update, expand and finalise these lists. We propose consulting on:

    a. what constitutes acceptable standards of evidence for health claims

    b. how to regulate advertising and marketing compliance (eg, whether to rely on industry self-regulation)

    c. a pathway for assessment of new ingredients and health claims.

Do you broadly agree with the proposed approach to product notification and the options identified for further analysis?	**Yes/No**
Would you like to discuss the proposed approach to product notification and the options identified for further analysis with officials?	**Yes/No**

Manufacturing standards

29. Robust manufacturing standards will also be part of the regulatory scheme. This will help ensure the manufacture of NHPs meets appropriate standards to prevent NHPs from being sold that were manufactured in an unsafe way.

30. Further policy work is needed to analyse options for manufacturing standards. Options we are analysing and intend to test through consultation include:

a. using relevant Good Manufacturing Practice standards

b. developing a specific code of manufacturing practice for NHPs

c. developing a sliding scale tiered approach to manufacturing requirements based on product and process risk (eg, using a combination of a and b)

d. whether licences issued by trusted overseas regulators would be recognised based on the principle of mutual recognition or as part of existing international frameworks (eg, recognising the Pharmaceutical Inspection Co-operation Scheme, an arrangement between regulatory authorities around Good Manufacturing Practice of medicines)

e. how manufacturing requirements and audits could be streamlined where several regulatory schemes apply (for example the Food Act 2014 and the Animal Products Act 1999 NHP).

Do you broadly agree with the proposed approach to manufacturing standards and the options identified for further analysis?	**Yes/No**
Would you like to discuss the proposed approach to manufacturing standards and the options identified for further analysis with officials?	**Yes/No**

Exemptions

31. Consideration will need to be given to what exemptions might be suitable for particular NHPs. This could include exempting NHPs:

a. provided as part of one-on-one practitioner-client relationships, including by Rongoā Māori practitioners

b. very low risk products (such as homeopathic products containing very dilute substances).

32. The scheme is not proposed to unduly regulate the practice of traditional medicine, such as Rongoā Māori or Traditional Chinese Medicine, or the practitioners themselves. The scheme would however, regulate products that are commercialised by practitioners and sold outside a practitioner-patient relationship.

33. Further work will be required to clarify whether there are any circumstances for exemptions from the regulatory scheme, and to ensure there are no unintended restrictions on cultural practices of traditional medicine.

Do you broadly agree with the proposed approach to exemptions?	**Yes/No**
Would you like to discuss the proposed approach to exemptions with officials?	**Yes/No**

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Regulator

34. A regulator would need to be established to oversee the scheme. Current thinking is that this regulator would likely sit within the Ministry of Health. Further consideration is needed in this area.

35. The powers and role of the regulator would be consulted on but are likely to include an ability to undertake spot-checks of product notifications (eg, to verify information such as evidence for claims), and audit manufacturers to ensure they meet appropriate standards.

Do you broadly agree with the proposed approach to the regulator?	**Yes/No**
Would you like to discuss the proposed approach to the regulator with officials?	**Yes/No**

Interface with other work

36. As advised in HR 20191586, it is highly desirable for legislation regulating NHPs to precede the Therapeutic Products Bill. This provides certainty to the NHP sector and consumers, and reduces the potential to slow progress on the Therapeutic Products Bill. The new therapeutic products regulatory scheme is expected to commence prior to 2023, which means the new NHP bill would need to be enacted prior to this date. Officials are working together closely to ensure alignment between these pieces of work.

37. Ministry of Health officials are also coordinating with the Ministry for Primary Industries (MPI) who administer the Food Act. As there is uncertainty when a new NHP bill would be enacted, officials from MPI are progressing work to enable an extension to the Dietary Supplements Regulations 1985 as an amendment to the Food Act during 2020 (if required). These regulations cover some orally consumed NHPs and are due to expire on 1 March 2021. The extension would prevent the possibility that dietary supplements could become non-compliant foods and be unable to be sold while a new NHP regime is being developed.

Next steps

38. Your feedback and direction on the proposed regulatory scheme for NHPs will enable us to progress drafting of a Cabinet paper proposing a new regulatory scheme for NHPs, an associated Regulatory Impact Statement and a consultation document on the proposed regulatory scheme.

39. This Cabinet paper would:

    a. outline the key elements of a regulatory scheme for NHPs, including how the scheme would work for consumers, the NHP sector and regulators, and options for giving effect to them

    b. seek approval to consult publicly on the proposed scheme. This could be either through approving a draft discussion document for consultation or seeking delegated approval for you to endorse a discussion document.

40. As outlined in the indicative timeline in Appendix 1, we will provide you with a draft of this Cabinet paper by mid-November 2019. This would enable the Social Wellbeing Cabinet Committee to consider the paper at their meeting on 4 December 2019.

41. Subject to Cabinet agreement in December 2019, consultation on a new regulatory scheme for NHPs could be undertaken over four weeks in early 2020.

42. Following the proposed stakeholder consultation in early 2020 (and subject to allocation of legislative priority in late 2019), further Cabinet decisions will be required to enable the drafting of a new NHP bill. This would focus on seeking any further policy decisions on more detailed aspects of the regulatory scheme, and seeking permission to issue drafting instructions to the Parliamentary Counsel Office. Introduction of the new NHP bill could occur subsequently, once a bill is drafted.

43. Once the new NHP bill is introduced, further work would still be required. This includes work to develop accompanying regulations, standards and guidance, and implementation considerations (eg, how and when to transition to the new scheme).

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Appendix 1: Indicative timeline for reporting to Cabinet in December 2019

Milestone	Timing
Minister receives a draft Cabinet paper for ministerial consultation	Monday 11 November 2019
Ministerial consultation ends	Friday 22 November 2019
Minister receives a final draft Cabinet paper, memo and talking points	Monday 25 November 2019
Cabinet paper lodged for Cabinet Social Wellbeing Committee (SWC)	Thursday 28 November
SWC consideration of Cabinet paper	Wednesday 4 December
Cabinet consideration of Cabinet paper	Monday 9 December

Rongoā Māori – wānanga and hui May/July 2022

This document reflects experiences and discussions that took place during a series of wānanga and hui held between Manatū Hauora, Te Kāhui Rongoā, and the interim Māori Health Authority between May and July 2022. It reflects the outcomes, issues, priorities and principles raised by participants for the purpose of informing advice to the Minister for Health on embedding Te Tiriti o Waitangi | the Treaty of Waitangi (Te Tiriti) in the Therapeutic Products Bill (the Bill) and providing for the recognition and protection of rongoā Māori.

As a record of discussions, this document does not reflect Ministry or Government policy.

Background

Since September 2021, Manatū Hauora has been working to finalise the Therapeutic Products Bill (the Bill) for introduction to Parliament. The purpose of the Bill – based on a 2018 exposure draft – is to introduce a modern, comprehensive and fit-for-purpose regulatory regime for therapeutic products: medicines and medical devices, including vaccines and biologics (e.g., genetic, blood and cell and tissue-based treatments). A Cabinet decision in mid-2021 extended the scope of the Bill to also include the regulation of natural health products (NHPs). In agreeing to include NHPs, Cabinet noted that doing so also afforded an opportunity to better 'recognise and protect' rongoā Māori.

At the invitation of rongoā practitioner and spokesperson for Te Kāhui Rongoā, s 9(2)(g)(ii) officials from Manatū Hauora participated in two wānanga on the practice of rongoā on 10 and 12 May 2022. Building on these wānanga, the Ministry hosted a series of hui on 31 May and 2 and 7 June 2022 involving s 9(2)(g)(ii) s 9(2)(a) and officials from the interim Māori Health Authority - Te Aka Whai Ora. The meeting on 7 June 2022 was limited to Māori attendees, who developed up some high-level models for recognising and protecting rongoā in the Bill. A final hui was held on 30 June 2022 between s 9(2)(g)(ii) s 9(2)(a) and the Ministry's Therapeutics team and Māori Health Directorate, which discussed specific proposals for giving effect to the models developed on 7 June 2022.

Meeting	Date	Attendees
First hui	31 May	Manatū Hauora, Te Kāhui Rongoā
Second hui	2 June	Manatū Hauora, Te Kāhui Rongoā, s 9(2)(a) Interim Māori Health Authority
Third hui	7 June	Te Kāhui Rongoā, s 9(2)(a) Interim Māori Health Authority
Fourth hui	30 June	s 9(2)(g)(ii) s 9(2)(a) Therapeutics team and Māori Health Directorate (Manatū Hauora)

The purpose of the wānanga was to provide an opportunity for the Therapeutics team and other Ministry officials to experience rongoā Māori with experienced and expert practitioners and within the wider context of Te Ao Māori. The subsequent hui were designed to explore issues and opportunities for rongoā Māori and hauora Māori generally in the future therapeutic products regulatory regime. They also sought to identify possible revisions to the Bill to recognise and protect rongoā Māori and embed the principles of Te Tiriti.

Acknowledgements

The Therapeutics team wishes to record its deepest appreciation to s 9(2)(g)(ii) for the opportunity to walk in the ngahere (the bush) to see rongoā in practice first hand. Tēnā koe.

The team also acknowledges and thanks the support and guidance from our tangata whenua colleagues in the interim Māori Health Authority - Te Aka Whai Ora, Māori Health Directorate and Strategy Policy and Legislation. Tēnā koutou, tēnā koutou, tēnā koutou katoa.

Wānanga 1

10 May 2022, Zealandia, Wellington

The first wānanga took place in the Zealandia ecosanctuary, providing attendees with a chance to walk in the ngahere and be introduced to a number of the plants that are used in the practice of rongoā.

This wānanga was an opportunity for the Therapeutics team to establish a relationship with s 9(2) [redacted] to learn about her work as a rongoā practitioner and to hear first-hand the pūrākau (stories) and mātauranga Māori (systems of knowledge) that underpin the contemporary practice of rongoā. Discussion centred on conceptions of health and wellbeing – in particular within a Māori context – and emphasised the holistic nature of rongoā and the interconnectedness of tangata whenua, wairua; the seen and unseen, and the force that binds them together: mauri.

Wānanga 2

12 May 2022, Space Place and Botanic Gardens, Wellington

The themes of the first wānanga continued into a second wānanga that took place at Space Place and in the grounds of the Botanic Gardens, Wellington. This venue provided a further opportunity to spend time outside and to learn first-hand about the plants used in rongoā rākau. Pūrākau related to kawakawa and the pōhutukawa were also shared. There was a recognition that – as with the practice of rongoā itself – the stories, lore and tikanga associated with plants, animals and other natural materials vary across the motu and from iwi to iwi, hapū to hapū and between whānau.

This wānanga was an opportunity for the Therapeutics team to build on the foundation established in the first wānanga and discussion again centred on conceptions of health and wellbeing within a Māori context. The social dimensions of health and ill-health were emphasised, with an acknowledgement of the space for modern therapeutics in the treatment of acute conditions and as a support for chronic conditions.

S9(2)(a), S9(2)(g)(ii) [redacted]
experiences engaging with Manatū Hauora and Government over the regulation of NHPs and rongoā. She drew a distinction between the practice of rongoā (holistic and with the whenua as its starting point) and 'green pharmacy' – an extractive practice where the properties of New Zealand's plants are isolated from their natural source and from the whenua and mauri that sustains them.

First hui

31 May 2022, Manatū Hauora, 133 Molesworth Street Thorndon

Item	Agenda item
1:00pm	Lunch and health system sticky note session
1:20pm	Opening karakia Welcome
1:30pm	Therapeutic Products Bill overview
1:45pm	Natural health products (NHPs) overview
2:15pm	The Te Kāhui Rongoā view on legislation and rongoā Māori (and discussion)
2:45pm	Afternoon tea and NHP label activity
3:00pm	Small group exercise – issues and opportunities relating to rongoā?
3:45pm	Wrap up and reflections
3:55pm	Preparing for the next workshop
4:00pm	Closing karakia

The first hui provided an opportunity for s 9(2)(g)(ii) , s 9(2)(a) and officials from the Ministry's Māori Health Directorate and from the interim Māori Health Authority - Te Aka Whai Ora to develop a common understanding of the conceptual basis for the Bill, including its approach to NHPs.

Discussion focused on important elements of a health and wellbeing system that embedded Te Tiriti and recognised rongoā. Attendees also reflected on the contribution that products (including therapeutic products, NHPs and products used in rongoā) can make to New Zealand's health system.

Key themes and issues that arose from the first hui are set out on the following page.

Common themes:
a health system provides for…

- **Holistic approaches**
  - Care as the goal (not profit or product)
  - Empathy
  - Interconnectedness
- **Person and whānau-centred**
  - Choices / options
  - Empowering / enablement
  - Accessibility / availability
  - Attention when needed
  - Support through treatment / system
- **Best chance for person**
  - Effectiveness
  - Reliability
  - Strong workforce & expertise
  - Inclusivity
- **Equity and Te Tiriti**
  - Equitable
  - Indigenousness
  - Recognition of Māori system and mātauranga Māori
  - Support and resourcing for options
  - Accessibility / availability

Figure 1 - Common themes from 1st hui

Common themes:

therapeutic products contribute to the system through…

- **Holistic approaches**
  - Ethical production systems
  - Lifecycle approach to regulation
  - Products support, but don't replace, other elements of H&W system (e.g., clinical contact)

- **Person and whānau-centred**
  - Choices / options
  - What works for the person (i.e., people, not profits)
  - Natural

- **Best chance for person**
  - Timely availability
  - Safety, Quality, Efficacy
  - Claims supported by evidence
  - Product is appropriate for need
  - Industry support and development

- **Equity and Te Tiriti**
  - Protecting Māori authenticity and the indigeneity of product / Protection from unauthorised commercialisation
  - Protection of whānau, nannies, aunties, uncles tōhunga being able to practice
  - Māori control and authority including regulation and decision-making of Māori products and indigenous rākau

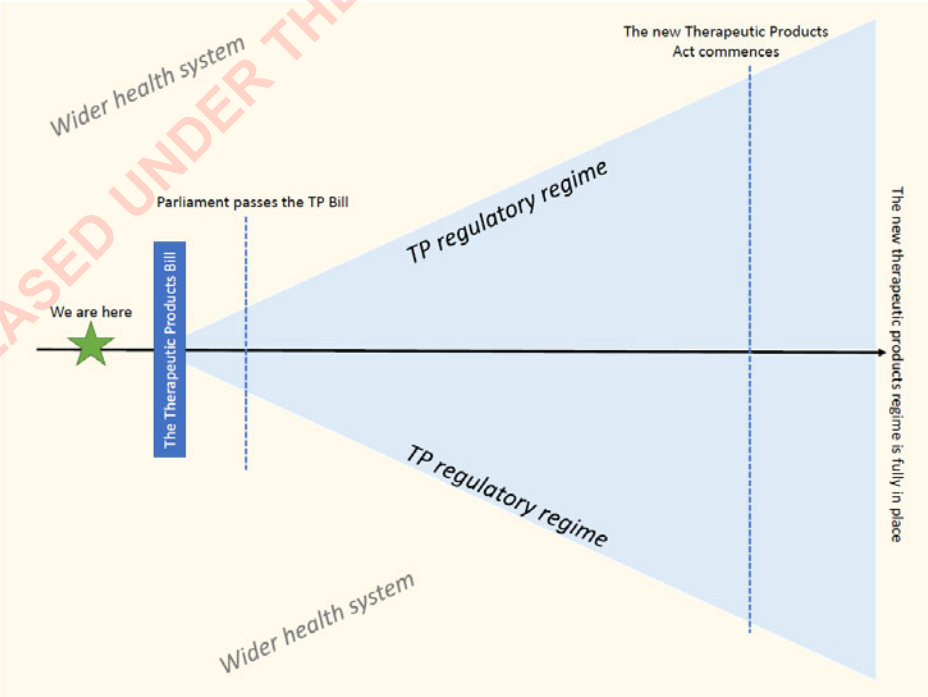
Figure 2 - Common themes from 1st hui

Second hui

2 June 2022, Manatū Hauora, 133 Molesworth Street Thorndon

Item	***Agenda item***
12:30	*Lunch for those attending in person*
1:00pm	*Opening karakia* *Welcome*
	Recap from Monday workshop
	Therapeutic Products Bill - *Timing for the Bill* - *Implementation of the wider regime*
	Small group session – what would a successful therapeutic products regime look like for Māori and rongoā? *Discussion tool to be provided by Tim*
2:45pm	*Afternoon tea*
	Group session – from the ideal state to the Bill: what we want and what is needed
	Wrap up and reflections on what this means for recognising and protecting rongoā Māori
	Getting ready for the next meetings
4:00pm	*Closing karakia*

The second hui focused on the history of work to develop a NHP regulatory regime for Aotearoa and Te Kāhui Rongoā's involvement and views on a new regime for NHPs. Attendees also discussed the timeframes for the introduction of the Bill to Parliament and the longer process of developing the secondary legislation necessary to establish the new regulatory regime. A discussion tool (extract below) was used to help attendees work backwards from an ideal future state to the revisions to the Bill necessary to support and enable that future state.



Support for all the proposals was not established at this hui and Te Kāhui Rongoā would continue to engage with the Bill as it went through Parliament. In response to questions from participants about the benefits of the Bill generally to Māori, whānau and Aotearoa, the Therapeutics team outlined the Bill's focus on product and public safety.

Themes and questions from the second hui, included:

- How do we bring mātauranga Maori into the kāwanatanga legal framework, without dissecting it?
- It is not for the Crown to decide what is te ao Maori.
- How do we capture whānau voice - so those who are protected will have a say?
- Rongōa as a product and the practice around it, how to capture those complexities when setting up a regulatory scheme?
- Approaching rongoā, we must be cognisant of te taiao, whenua, to climate change. There are broad linkages between the holistic nature of rongoā and sustainability: environmental, cultural and economic. Does the Bill's lifecycle approach to regulation provide an opportunity for considering such issues, including waste?
- How can a future regime devolve to and rely on the existing networks within and between hapū and iwi that controlled, nurtured and ensured the safe practice of rongoā?
- What capability does the regulator need (including growing capability in dealing with matters of concern to Māori and with respect to the Crown's Treaty obligations) to be able to operate with a good understanding of cultural context, rongoā Māori, mātauranga Māori?
- How will the Bill align with other work and necessary reforms: e.g., health workforce issues under the Health Practitioners Competency and Assurance Act and reforms to tertiary and vocational education led by the Ministry of Education?
- What opportunities are created through the establishment of Te Aka Whai Ora in relation to how the health system as a whole (including therapeutic products) are delivering equitable health outcomes for Māori.
- The implementation of the Bill needs alignment with practitioners on the ground in the delivery of healthcare.
- Not including rongoā in the Bill (with appropriate protections) may leave it exposed to future challenges, however more work needs to be done to understand what this would mean in practice.

The second hui closed with an open discussion on options for rongoā, Te Tiriti and the Bill. A suggestion to consider the potential 'Tiriti dividends' for Māori and all New Zealanders. As part if this discussion, the meeting explored the potential benefits of making rongoā services more available as part of a reformed health system (the "gift of rongoā to all New Zealanders"), and recognising Māori (whānau, hapū and iwi) as the kaitiaki of rongoā. There was a general support for a set of principles related to rongoā.

s 9(2)(g)(ii) suggested that advice to the Minister could include that the 'Crown supports Māori to be the architects and kaitiaki [of rongoā]... [and] acknowledge the diverse mātauranga Maori knowledge systems underpinning the practice.'

Third hui

7 June 2022, Manatū Hauora, 133 Molesworth Street Thorndon

Item	***Agenda item***
12:30	*Lunch for those attending in person*
1:00pm	*Opening karakia* *Welcome*
	Recap from Monday and Wednesday's workshop
	Therapeutic Products Bill: - *Recap of decisions to date* - *Where in the Bill are the key 'hooks' to realise the opportunities for rongoā and interests and aspirations for Maori*
	Discussion, including early development of options *Rules for engagement: critiquing options = Workshop 4.*
2:30pm	*Afternoon tea*
	Tino rangatiratanga and kāwanatanga

	Further discussion of options
	- *Framing of options with regards to:*
	  ○ *products used in rongoā*
	  ○ *rongoā products (e.g., rongoā and 'green pharmacy'; use, exports etc…); and*
	  ○ *the practice of rongoā*
	- *expectations for modes of leadership*

	Getting ready for the final workshop *Wrap up*

The third hui continued to work through the issues and principles identified at the previous session. Part way through the hui, it was agreed that the Māori membership of the workshop – including s 9(2) [redacted], s 9(2)(a) [redacted] and officials from the Ministry's Māori Health Directorate – would meet separately to discuss and develop options for the recognition and protection of rongoā Māori. These would be provided to the Therapeutics team and serve as the basis for the model ultimately developed as part of the Ministry's advice to the Minister.

During this hui, the Engagement Framework developed by Te Arawhiti was used to guide discussions around boundary setting and how to facilitate Crown/Māori relations in this space. In particular, the meeting explored "how to engage" meaningfully, using the diagramme below to discuss different degrees and types of engagement that might be appropriate on different matters.

Minor

Māori interests are limited or not affected in any special way.

Moderate

Māori interests exist or are affected but wider interests take priority.

Specific Māori interests are affected.

Significant

Māori interests are significantly affected.

Māori interests are overwhelming and compelling.

Māori interests are central and other interests limited

Inform
The Crown will keep Māori informed about what is happening. Māori will be provided with balanced and objective information to assist them to understand the problem, alternatives, opportunities and/or solutions.

Consult
The Crown will seek Māori feedback on drafts and proposals. The Crown will ultimately decide. The Crown will keep Māori informed, listen and acknowledge concerns and aspirations, and provide feedback on how their input influenced the decision.

Collaborate
The Crown and Māori will work together to determine the issues/problems and develop solutions together that are reflected in proposals. The Crown will involve Māori in the decision-making process but the Crown will ultimately decide.

Partner/Co-design
The Crown and Māori will partner to determine the issue/problem, to design the process and develop solutions. The Crown and Māori will make joint decisions.

Empower
Māori will decide. The Crown will implement the decision made by Māori.

Based on Te Arawhiti's tool: https://www.tearawhiti.govt.nz/te -kahui-hikina-maori-crown-relations/engagement/

Fourth hui

30 June 2022, Manatū Hauora, 133 Molesworth Street Thorndon

At the fourth hui, s 9(2)(g)(ii) , s 9(2)(a) and officials from the Ministry's Māori Health Directorate met with the Therapeutics team to outline options developed for the recognition and protection of rongoā Māori within the Bill. This work will inform advice to the Minister regarding the inclusion of rongoā into the Bill, currently being developed by the newly established Te Aka Whai Ora. More information on the different options developed and presented at this hui, as well as Te Aka Whai Ora's recommendations to the Minister, will be made available in the future as the work progresses.

From: Eli Toeke
Sent: Tuesday, 17 August 2021 4:42 pm
To: s 9(2)(g)(ii)
Cc: Eugene Rewi
Subject: Request for a hui with Te Kahui Rongoa

Importance: High

Tēnā koutou e ngā rangatira o Te Kāhui Tāwharautanga ō Ngā Rongoā,

Tēnei aku mihi mahana ki a koutou katoa i roto i ngā āhuatanga o te wā.

We have been working with our colleagues in the System Strategy & Policy directorate at the Ministry of Health who are leading work on regulation of natural health products. Work in this area is now at a point where it is timely to engage with Te Kāhui Rongoā.

We and our System Strategy & Policy colleagues would appreciate meeting with you to provide an update on the status of this work and to talk with you about the areas of interest and importance for Te Kāhui Rongoā.

We would like to start this refreshed conversation as part of the draft relationship agreement we have been developing together.

Can you please indicate your availability to meet with us, either in person or virtually, over the next two weeks and I will organise for us to meet.

I look forward to hearing from you.

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
I Pronouns: He/Him/His I Kaitātari Kaupapahere (Policy Analyst) I Māori Health Strategy & Policy I Māori Health I Ministry of Health I

From: s 9(2)(g)(ii)
Sent: Thursday, 30 December 2021 10:27 pm
To: Fiona Ryan
Cc: Eli Toeke; Eugene Rewi; s 9(2)(g)(ii); John Whaanga; Caroline Flora; Vicky Scott; Nadine Neale
Subject: RE: Therapeutics Bill

As per our discussions over the last few years – I continue to look forward to an opportunity to meet you in person Fiona and get to know you and how we might work together in progressing the Bill before we start to consider the content and scope of the proposed legislation.

Ngā mihi

s 9(2)(g)(ii)

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Friday, 24 December 2021 1:42 pm
To: s 9(2)(g)(ii)
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; s 9(2)(g)(ii) John Whaanga <John.Whaanga@health.govt.nz>; Caroline Flora <Caroline.Flora@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>
Subject: RE: Therapeutics Bill

Kia ora s 9(2)

As promised when we spoke on 17 December, please find attached a detailed letter outlining the current status of work on regulation of natural health products and the Therapeutic Products Bill.

I was hoping to have a kōrero with you again with Eugene and Eli before sending this letter. As that has not been possible, I thought it important to this letter anyway and for you to have the opportunity to consider it at your convenience.

I would like wish you and your whānau a Meri Kirihimete me te Hape Nū Ia
Look forward to working more closely with you in 2022.

Nāku noa, nā

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | Ph S9(2)(a) | www.moh.govt.nz

From: s 9(2)(g)(ii) >
Sent: Thursday, 16 December 2021 1:21 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; s 9(2)(g)(ii) John Whaanga <John.Whaanga@health.govt.nz>
Subject: Therapeutics Bill

Kia ora Fiona

I hope this finds you well. It has been a few months since you asked to urgently meet with Te Kahui Rongoa regarding the Therapeutics Bill and a couple of years since we have been requesting to meet face to face with you and your team.

I learned today that the Natural Health Products industry attended a meeting with several Ministers about the progress of the Bill and its proposed contents.

Is there a reason why rongoa Maori advocates were not afforded the same courtesy?

This is yet another slap in the face for us and I am sorry but your words and your commitment do not match your actions. Nothing appears to have changed in all the years we have contributed to this korero. To say I am disappointed is a gross understatement, you led us to believe that we could expect better from you and your new team.

Ngā mihi

s 9(2)(g)(ii)

From: s 9(2)(g)(ii) @oranewzealand.com>
Sent: Tuesday, 8 February 2022 4:14 pm
To: Eugene Rewi; Ellie Debouci; Fiona Ryan
Cc: Eli Toeke; Vicky Scott; Kirsty Doig; Nadine Neale
Subject: RE: Catch up on NHPs and Rongoa

Thanks Eugene – yes that was her name.

Ngā mihi

s 9(2)(g)(ii)

From: Eugene Rewi <Eugene.Rewi@health.govt.nz>
Sent: Tuesday, 8 February 2022 3:27 pm
To: s 9(2)(g)(ii) Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>
Subject: RE: Catch up on NHPs and Rongoa

That would be Hinemaua Rikirangi

Eugene Rewi
Manager
Māori Health Service Improvement
Māori Health Directorate
Ministry of Health
DDI: (04) 816 3447
Mobile: S9(2)(a)

http://www.moh.govt.nz
mailto:eugene.rewi@health.govt.nz

From: s 9(2)(g)(ii) @oranewzealand.com>
Sent: Tuesday, 8 February 2022 3:14 pm
To: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>
Subject: RE: Catch up on NHPs and Rongoa

Kia ora Ellie thanks for the invite

I have accepted it.

Can I also ask that a representative/s from the Maori advisory group within your team or the Ministry join our meetings. I think that will help us to ensure that we are all singing from the same hymn sheet from the outset and it enables us to expand the resources available to us to resolve any tricky situations we might find ourselves in as we attempt to break new ground in the way these things are done in future.

I did meet one lady at the signing of the MoH / TKR relational agreement that seemed to know a bit about the proposed legislation already but her name has slipped my mind Hine…….? Fiona might recall it?

Ngā mihi

s 9(2)(g)(ii) [redacted]

From: Ellie Debouci <Ellie.Debouci@health.govt.nz>
Sent: Tuesday, 8 February 2022 11:44 am
To: s 9(2)(g)(ii) [redacted]@oranewzealand.com>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>
Subject: RE: Catch up on NHPs and Rongoa

Kia Ora s 9(2) [redacted]

I have sent your way an invitation for an hour meeting on the Wednesday 16th February, please don't hesitate to let me know should dthis time not suit, and I would be happy to offer more options.

Thanking you in advance,
Best,

Nga mihi mahana

Ellie Debouci

M: S9(2)(a) [redacted]

Executive Assistant to Wendy Illingworth and Fiona Ryan
Public Health System Policy & Therapeutics
Ministry of Health

http://www.health.govt.nz
ellie.debouci@health.govt.nz

From: s 9(2)(g)(ii) [redacted]@oranewzealand.com>
Sent: Friday, 4 February 2022 6:46 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>
Subject: Re: Catch up on NHPs and Rongoa

Kia ora Fiona

Yep that would be great. Just let me know when suits you and I will do my best to accommodate.

Nga mihi

s 9(2)

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From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Friday, February 4, 2022 6:42:14 PM
To: s 9(2)(g)(ii) @oranewzealand.com>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>
Subject: Catch up on NHPs and Rongoa

Kia ora s 9(2)

It was lovely to finally meet with you in person recently and to start our kōrero for 2022 in a refreshed way.
It was also a real privilege for me to be present at the signing ceremony for the Relationship Agreement between the Ministry and Te Kāhui Rongoā.

We agreed to meet again in February. Hence I am getting in touch to enquire about your availability to meet over the next few weeks. It would also be good to schedule regular meetings over the next few months to enable us to continue to deepen our relationship. As COVID continues to provide uncertainty I suggest we also consider virtual option as a backup, although my preference is to meet with you in person if possible.

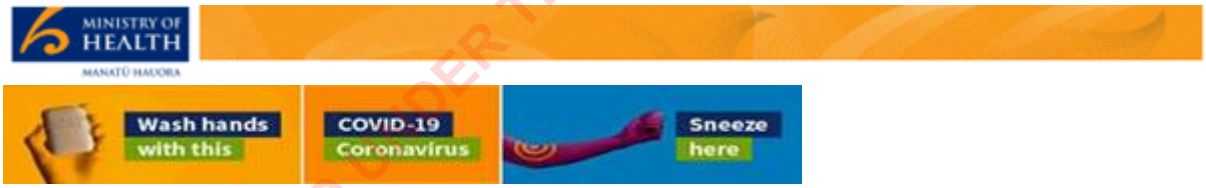
I look forward to hearing from you soon.

All the best for Waitangi Day ahead.

Ngā mihi

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | Ph S9(2)(a) | www.moh.govt.nz



From: s 9(2)(g)(ii) >
Sent: Tuesday, 8 March 2022 6:46 pm
To: Fiona Ryan; Ellie Debouci; s 9(2)(g)(ii)
Cc: Vicky Scott; Eli Toeke; Eugene Rewi; Lisa Ramanui; Nadine Neale; Lily Zhang; Tim Vines; Saerom Shin; Kirsty Doig; Hinemaua Rikirangi
Subject: Re: Proposed Agenda for our meeting today

It's a good thing we will be outside for most of the day. Better than sitting in an office any day.

Nga mihi
s 9(2)

Get Outlook for Android

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Tuesday, March 8, 2022 6:34:31 PM
To: s 9(2)(g)(ii) >; Ellie Debouci <Ellie.Debouci@health.govt.nz>; s 9(2)(g)(ii)
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: Re: Proposed Agenda for our meeting today

Kia ora s 9(2)(g)(ii)

That is indeed exciting, we really appreciate you both being available for the planned hui which we are also very much looking forward to.

I am currently working through internal approval processes including for funding of travel and other costs and logistics for the two days.

I am conscious that the timing of this long-awaited hui is now timed just a Covid Omicron rates are increasing nationally and in Wellington. This means I will also need to address Ministry health & safety guidance for the hui.

As we are fast approaching the scheduled dates I will give you a call tomorrow with an update on progress.

Regards

Fiona

From: s 9(2)(g)(ii) >
Sent: Tuesday, March 8, 2022 5:50:54 PM
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>; s 9(2)(g)(ii)
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale

<Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: Re: Proposed Agenda for our meeting today

Great news Fiona

Rob McGowan is able to join us on Monday and Tuesday. I have ccd him on this email so that you can liase directly with him about travel arrangements

We are both really looking forward to it.

Nga mihi
s 9(2)

Get Outlook for Android

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Tuesday, 1 March 2022, 6:31 pm
To: s 9(2)(g)(ii) @oranewzealand.com>; Ellie Debouci <Ellie.Debouci@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Kia ora s 9(2)

It was great to meet with you again recently over zoom and for you to meet the Therapeutics team and some of our wider team in the Ministry, some of whom you already know well.

I really appreciate your generous offer to spend two days with us sharing some of your knowledge and traditions and to help us build a deeper understanding of rongoa.
We are all looking forward to the rongoa hui and to learning more from you and possibly s 9(2) The team are very excited.

Thank you for your suggestion of possible venues. They are all wonderful locations I know well.
Your suggestion of 10-3pm each day also works well. Are there any other supplies or equipment you would like?

I have asked my EA Ellie to look into logistics, including arrangements for your travel and accommodation.
It would be helpful to have a sense of some travel options that would work for you.

Ngā mihi

Fiona

Fiona Ryan I Manager Therapeutics Policy
System Strategy and Policy I Ministry of Health I Ph S9(2)(a) I www.moh.govt.nz

From: Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Sent: Monday, 28 February 2022 5:20 pm
To: s 9(2)(g)(ii) Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Tēnā koe s 9(2) it was a great hui and opportunity to sew new seeds and begin new kōrero for this kaupapa. And actually, to listen. Such an amazing and generous offer for the two day wānanga – kia ora. I can make most of Monday and I am booked out all day Tuesday for a quarterly advisory board hui. Rongoa wānanga is where my heart and wairua will want to be, however I'll have to put in my apologies for the Tuesday (but also tentative, in case there are changes!).

I was fortunate to have recently met Rob McGowan at another wānanga and it was very inspiring to hear some of his kōrero and what he has been doing back at home in Tauranga, that sure would be another treat.

Hēoi anō, ka nui te mihi
Hinemaua

From: s 9(2)(g)(ii) @oranewzealand.com>
Sent: Monday, 28 February 2022 4:05 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Kia ora e te whanau

Thank you all for making the time to meet with me at Fiona's request a couple of weeks ago. It was really nice to see your smiley faces over zoom. I hope that I can still put names to faces when we meet again in couple of weeks on the 14th & 15th for our rongoa hui.

I have to say you are the first team in all these years to actually commit to learning a bit about rongoā despite the many promises in the past to do so. We are off to a good start whanau.

Firstly I can think of a number of places in an around Wgtn that might be good to host our hui, such as Kaitoke Regional Park (but not so good if it rains, BYO lunch & drinks), alternatively we could go to Zealandia (admission $23pp / café onsite or BYO lunch – there is a conference room we could hire as a wet weather retreat) or perhaps even Otari Gardens/ Wiltons Bush (BYO lunch & drinks – there is small conference room there we could hire as well). But I will leave that up to you guys to arrange.

Does 10 – 3pm both days sound good to you all? Hard to cram the essence of a life time of learning into 2 days but after all these years I think we have found the sweet spot for giving you just enough so you can understand what

we are talking about in the context of rongoa and also feel what rongoa is for your own growth but not so much that we overwhelm you.

I have to say I am very excited about spending some really good quality time with you outside the office and sharing with you an insight into what rongoa is really about. Please don't be worried you won't need any prior knowledge other than to have an interest in different perspectives on what makes us well. I have seen before the personal transition that takes place when we see the world through a new lens and how that sets in place a solid connection between us for our shared journey over the next few months.

Fiona, would you like to arrange my flights and accommodation or would you prefer I did this directly? I am happy to donate my time. I hope as many as possible of our little group will be able to make it. I will also invite Rob McGowan to join us if he can make it (now, that is a real treat to have him join us).....but if not I will do my best to step up to the bar that he sets.

Ngā mihi nui kia koutou

s 9(2)(g)(ii) [redacted]

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Wednesday, 16 February 2022 11:44 am
To: s 9(2)(g)(ii) [redacted]
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Proposed Agenda for our meeting today

Kia ora s 9(2) [redacted]

I hope you are well. I am looking forward to our meeting this afternoon and to continuing to deepen our discussions. I have asked all my team to attend our meeting today, so that you have an opportunity to meet them all and get to know who we are.

Please let me know if you have any additions or changes you would like to the agenda.

Ngā mihi

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | Ph S9(2)(a) [redacted] | www.moh.govt.nz

From: s 9(2)(g)(ii)
Sent: Thursday, 10 March 2022 7:26 pm
To: Fiona Ryan; s 9(2)(g)(ii)
Cc: Hinemaua Rikirangi; Eli Toeke; Eugene Rewi; Lisa Ramanui; Vicky Scott; Nadine Neale; Lily Zhang; Tim Vines; Saerom Shin; Kirsty Doig; Ellie Debouci; Caroline Flora
Subject: Re: Postponing rongoā Māori session planned for next week.

As discussed last evening please just let me know when you are ready to host the program and we will do what we can to accommodate

Regards
s 9(2)

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From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Thursday, March 10, 2022 6:29:35 PM
To: s 9(2)(g)(ii)
Cc: Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>; Caroline Flora <Caroline.Flora@health.govt.nz>
Subject: FW: Postponing rongoā Māori session planned for next week.

Kia ora s 9(2)

As I shared with you when we spoke yesterday, I am very sorry to advise that we need to postpone the long planned 2 day rongoā Māori training session scheduled for Mon 14 and Tues 15 March.

This is necessary due to the increasing prevalence of COVID nationally, and the Ministry's policy and guidance on COVID safe work practices while we are in the Red light setting and as the Omicron variant starts to peak in NZ. As some members of my team or their whānau have come down with COVID, the risk is real and I am particularly mindful that we take care of our visitors and the communities they are visiting us from and will return to. Nonetheless, I and my team and colleagues are very disappointed that this has been necessary.

I apologise for the inconvenience this will have caused you and s 9(2) We are appreciative of your generous offer to meet with us and to share your knowledge and traditions with us. I am also very mindful that – while this is new work for many of my team – you and your community have been engaged in this work for a very long time and that this delay comes on top of past ones.
For now it is not clear when we may be able to meet kanohi ki te kanohi, but we will look to do so as soon as it is safe and prudent to do so. I can also assure you that I have the support of my senior leaders on this session taking place as soon as it is safe.

When we last met we agreed that we should meet on a regular basis. As such I would like to propose that we schedule a meeting on Teams or Zoom perhaps next week to continue the conversation we have started and deepen our relationship over 2022, as we have discussed on the last two occasions we met. I recognise that virtual meetings are not ideal, especially for building our relationship and I am eager that we can move to in person meetings.

Ngā manaakitanga

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | Ph S9(2)(a) | www.moh.govt.nz

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Tuesday, 8 March 2022 6:35 pm
To: s 9(2)(g)(ii) Ellie Debouci <Ellie.Debouci@health.govt.nz>; s 9(2)(g)(ii)
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: Re: Proposed Agenda for our meeting today

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From: s 9(2)(g)(ii) >
Sent: Tuesday, March 8, 2022 5:50:54 PM
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>; s 9(2)(g)(ii)
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: Re: Proposed Agenda for our meeting today

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Nga mihi
s 9(2)

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From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Tuesday, 1 March 2022, 6:31 pm
To: s 9(2)(g)(ii) >; Ellie Debouci <Ellie.Debouci@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Kia ora s 9(2)

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I really appreciate your generous offer to spend two days with us sharing some of your knowledge and traditions and to help us build a deeper understanding of rongoa.
We are all looking forward to the rongoa hui and to learning more from you and possibly s 9(2) The team are very excited.

Thank you for your suggestion of possible venues. They are all wonderful locations I know well.
Your suggestion of 10-3pm each day also works well. Are there any other supplies or equipment you would like?

I have asked my EA Ellie to look into logistics, including arrangements for your travel and accommodation.
It would be helpful to have a sense of some travel options that would work for you.

Ngā mihi

Fiona

Fiona Ryan I Manager Therapeutics Policy

System Strategy and Policy I Ministry of Health I Ph S9(2)(a) I www.moh.govt.nz

From: Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Sent: Monday, 28 February 2022 5:20 pm
To: s 9(2)(g)(ii) [redacted] >; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Tēnā koe s 9(2) [redacted] it was a great hui and opportunity to sew new seeds and begin new kōrero for this kaupapa. And actually, to listen. Such an amazing and generous offer for the two day wānanga – kia ora. I can make most of Monday and I am booked out all day Tuesday for a quarterly advisory board hui. Rongoa wānanga is where my heart and wairua will want to be, however I'll have to put in my apologies for the Tuesday (but also tentative, in case there are changes!).

I was fortunate to have recently met Rob McGowan at another wānanga and it was very inspiring to hear some of his kōrero and what he has been doing back at home in Tauranga, that sure would be another treat.

Hēoi anō, ka nui te mihi
Hinemaua

From: s 9(2)(g)(ii) [redacted] >
Sent: Monday, 28 February 2022 4:05 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: RE: Proposed Agenda for our meeting today

Kia ora e te whanau

Thank you all for making the time to meet with me at Fiona's request a couple of weeks ago. It was really nice to see your smiley faces over zoom. I hope that I can still put names to faces when we meet again in couple of weeks on the 14th & 15th for our rongoa hui.

I have to say you are the first team in all these years to actually commit to learning a bit about rongoā despite the many promises in the past to do so. We are off to a good start whanau.

Firstly I can think of a number of places in an around Wgtn that might be good to host our hui, such as Kaitoke Regional Park (but not so good if it rains, BYO lunch & drinks), alternatively we could go to Zealandia (admission $23pp / café onsite or BYO lunch – there is a conference room we could hire as a wet weather retreat) or perhaps even Otari Gardens/ Wiltons Bush (BYO lunch & drinks – there is small conference room there we could hire as well). But I will leave that up to you guys to arrange.

Does 10 – 3pm both days sound good to you all? Hard to cram the essence of a life time of learning into 2 days but after all these years I think we have found the sweet spot for giving you just enough so you can understand what we are talking about in the context of rongoa and also feel what rongoa is for your own growth but not so much that we overwhelm you.

I have to say I am very excited about spending some really good quality time with you outside the office and sharing with you an insight into what rongoa is really about. Please don't be worried you won't need any prior knowledge other than to have an interest in different perspectives on what makes us well. I have seen before the personal transition that takes place when we see the world through a new lens and how that sets in place a solid connection between us for our shared journey over the next few months.

Fiona, would you like to arrange my flights and accommodation or would you prefer I did this directly? I am happy to donate my time. I hope as many as possible of our little group will be able to make it. I will also invite Rob McGowan to join us if he can make it (now, that is a real treat to have him join us).....but if not I will do my best to step up to the bar that he sets.

Ngā mihi nui kia koutou

s 9(2)(g)(ii) [redacted]

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Wednesday, 16 February 2022 11:44 am
To: s 9(2)(g)(ii) [redacted] >
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Proposed Agenda for our meeting today

Kia ora s 9(2) [redacted]

I hope you are well. I am looking forward to our meeting this afternoon and to continuing to deepen our discussions. I have asked all my team to attend our meeting today, so that you have an opportunity to meet them all and get to know who we are.

Please let me know if you have any additions or changes you would like to the agenda.

Ngā mihi

Fiona

Fiona Ryan | Manager Therapeutics Policy

System Strategy and Policy | Ministry of Health | Ph S9(2)(a) [redacted] | www.moh.govt.nz

From: Fiona Ryan
Sent: Wednesday, 11 May 2022 6:07 pm
To: Eli Toeke; s 9(2)(g)(ii) ; S9(2)(a)
Cc: Lily Zhang; Saerom Shin; Ellie Debouci; Kirsty Doig; Suzanne McGifford; Lisa Ramanui; Hinemaua Rikirangi; Vicky Scott; Tim Vines
Subject: RE: Rongoā Wānanga (no. 2)

Kia ora Eli and s 9(2)

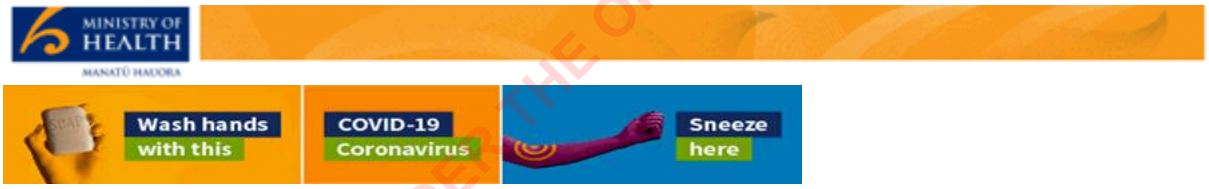
Unfortunately I will now not be able to attend the second day of the wonderful wānanga, S9(2)(a)
I am very disappointed. I found yesterday very inspiring and thought provoking. I look forward to hearing from my team members and colleagues about their reflections and insights from the two days of wānanga.

s 9(2) – I would like to thank you for generously sharing your knowledge and perspectives with my team and wider Ministry colleagues yesterday (Tuesday) and for the further guidance and learning that will occur on the second day. These two days of wānanga provide a wonderful basis for us coming together for the next series of workshops in the next few weeks.
I look forward to continuing to deepen out conversations.

Ngā mihi

Fiona

Fiona Ryan I Manager Therapeutics Policy
System Strategy and Policy I Ministry of Health I Ph S9(2)(a) I www.moh.govt.nz



-----Original Appointment-----
From: Eli Toeke <Eli.Toeke@health.govt.nz>
Sent: Wednesday, 27 April 2022 4:14 pm
To: Eli Toeke; s 9(2)(g)(ii) ; S9(2)(a) ; Lisa Ramanui; Hinemaua Rikirangi; Fiona Ryan; Tim Vines; Vicky Scott
Cc: Lily Zhang; Saerom Shin; Ellie Debouci; Kirsty Doig; Suzanne McGifford
Subject: Rongoā Wānanga (no. 2)
When: Thursday, 12 May 2022 9:30 am-3:00 pm (UTC+12:00) Auckland, Wellington.
Where: Space Place at Carter Observatory (40 Salamanca Road, Wellington 6140)

Kia ora tātou,

Confirming this wānanga.

As with the first wānanga, there is no formal agenda for this wānanga. This wānanga will be about applying our understanding from the first wānanga and learning about the gifts and lessons held within te taiao.

Catering will be supplied for the day.

Please dress appropriately as we may be outside for parts of the day.

Transport will be provided from the Ministry (departing at 9am). Please let me know if you require transport on this day.

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
I Pronouns: He/Him/His I Kaitātari Kaupapahere (Policy Analyst) I Māori Health Strategy & Policy I Māori Health I Ministry of Health I

From: s 9(2)(g)(ii)
Sent: Wednesday, 18 May 2022 9:10 pm
To: Vicky Scott; s 9(2)(a)
Cc: Eli Toeke; Ellie Debouci; Tim Vines
Subject: RE: Potential dates for our workshops

Kia ora Vicky

I have marked the dates below that I can't make due to existing commitments.

Black dates I am good to go on for now but please let me know confirmed times asap as some of the available dates will start to drop off quite quickly over the next few days (as is par for the course) and I am still to schedule time for the pending Corrections & InterRai hui as well.

Ngā mihi

s 9(2)(g)(ii)

From: Vicky Scott <Vicky.Scott@health.govt.nz>
Sent: Wednesday, 18 May 2022 12:57 pm
To: s 9(2)(g)(ii) >; S9(2)(a) >
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Ellie Debouci <Ellie.Debouci@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: Potential dates for our workshops

Kia ora s 9(2) and s 9(2)(a)

Thank you for accommodating our need to reschedule the dates for our workshops. Our team met today and we went through our calendars to look at all our possibilities for the workshops, which I've provided below. Hopefully some of the dates will suit both of you. We are happy to have two workshops within a week if those are the dates that best work for everyone. As you will see, I have suggested either morning or afternoon sessions.

I suggest that if we choose a morning session, which is ideal but may not always work, then we finish with a lunch, and if we choose an afternoon session, we start with a karakia and then lunch. Does that sound ok?

s 9(2)(a) – can you tell me what your ideal times are for a morning session and the best times for an afternoon session, according to the trains you catch?

Potential dates for the four workshops:

- Wednesday 25 May – afternoon
- Monday 30 June – morning or afternoon – assumed this is 30 May
- Tuesday 31 June – afternoon – assumed this is 31 May
- Wednesday 1 June - morning or afternoon
- Thursday 2 June – afternoon
- Tuesday 7 June – afternoon
- Wednesday 8 June – afternoon
- Thursday 9 June – afternoon

- Friday 10 June – morning or afternoon
- Tuesday 14 June – afternoon
- Thursday 16 June – afternoon
- Friday 17 June – morning or afternoon
- Monday 20 June - morning

Ngā mihi

Vicky Scott I **Principal Analyst, Therapeutics**
System Strategy and Policy I Ministry of Health I www.moh.govt.nz

From: Vicky Scott
Sent: Wednesday, 18 May 2022 9:15 am
To: s 9(2)(g)(ii) ; s 9(2)(a)
Cc: Eli Toeke; Tim Vines
Subject: RE: Therapeutics workshops

Mōrena s 9(2)(g)(ii) s 9(2)(a)

s 9(2)(g) it was lovely to hear your voice again and thank you for working with me to find new dates. Hopefully we will secure them before the end of the week.

s 9(2)(a) – I rang s 9(2) to say that Friday doesn't work for us for our first workshop, nor some of the other dates. I apologise for not contacting both of you earlier to say this. I was hoping to provide new dates today but it's proving harder than I thought. This was my mistake. s 9(2) said she will let us know tonight what dates she has free between now and mid-June/Matariki while I work further on new dates.

I will be in touch again soon.

Ngā mihi

Vicky

Vicky Scott I Principal Analyst, Therapeutics
System Strategy and Policy I Ministry of Health I www.moh.govt.nz

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From: s 9(2)(g)(ii)
Sent: Wednesday, 18 May 2022 6:00 am
To: Eli Toeke <Eli.Toeke@health.govt.nz>; S9(2)(a) Tim Vines <Tim.Vines@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: Therapeutics workshops

Ata marie e hoa mā

Out of Scope so just letting you know my travel requirements for tomorrow.

Can I please fly down tomorrow/ Thursday evening around 6 or 7pm. I will be flying from Auckland and will need accommodation for the evening in Wellington, and returning on Friday to Auckland after our hui.

If you do need to get in touch with me in order to confirm the travel arrangements, please text me and I will attempt to call you back in my breaks today. I will arrange my airport parking directly.

Ngā mihi

s 9(2)(g)(ii)

From: Eli Toeke <Eli.Toeke@health.govt.nz>
Sent: Friday, 13 May 2022 8:33 am
To: s 9(2)(g)(ii) >; S9(2)(a) Tim Vines <Tim.Vines@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: Therapeutics workshops

Sorry. I forgot to mention that we will be inviting the following people from the interim Māori Health Authority to attend these workshops as well:

- Bernard Te Paa
- Nicola Ehau
- Kelly Palmer
- Eugene Rewi

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
| Pronouns: He/Him/His | Kaitātari Kaupapahere (Policy Analyst) | Māori Health Strategy & Policy | Māori Health | Ministry of Health |

From: Eli Toeke
Sent: Friday, 13 May 2022 8:29 am
To: Tim Vines <Tim.Vines@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; s 9(2)(g)(ii) s 9(2) @oranewzealand.com>; S9(2)(a)
Subject: Therapeutics workshops
Importance: High

Kia ora koutou,

Now we have completed the rongoā wānanga, it's time to get into the therapeutic products bill space. We are intending to have up to 4 workshops on the following dates:

- 20th May – What is the therapeutic products bill?
- 25th May – How should / could the Crown "recognise and protect"
- 31st May – How can we shape the current Therapeutic Products bill (part 1)
- 7th May – How can we shape the current Therapeutic Products bill (part 2)

These workshops are in-person. @Tim Vines @Vicky Scott can you please organise someone in your team to book flights, accommodation and venues for the workshops as they will be funded through the therapeutics team?

I will have discussion paper signed out next week (ready for the 2nd workshop).

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
| Pronouns: He/Him/His | Kaitātari Kaupapahere (Policy Analyst) | Māori Health Strategy & Policy | Māori Health | Ministry of Health |

From: s 9(2)(g)(ii) >
Sent: Monday, 23 May 2022 10:07 am
To: Vicky Scott; s 9(2)(a)
Cc: Ellie Debouci; Fiona Ryan; Eli Toeke; Tim Vines
Subject: RE: Further planning on our workshops | Urgent

Lets say 10.30am at the earliest, 11am would be better

Ngā mihi

s 9(2)(g)(ii)

From: Vicky Scott <Vicky.Scott@health.govt.nz>
Sent: Monday, 23 May 2022 9:55 am
To: s 9(2)(g)(ii) >; S9(2)(a) >
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: RE: Further planning on our workshops | Urgent

Kia ora

A change to Monday is no problem for us and Monday afternoon works well.

On that basis s 9(2)(g) we have planned for a 1pm start in the afternoons but we could start a bit later on the first session to make the time work better for you if you would prefer it that way. Please let me know. Also, what time do you think you would be available for a flight from Akl to Wtn (allowing for a half hour check-in) on Mon 30 May? And, just to confirm, do you want to stay in Wtn until Wed 1 June and fly Wgtn – Akld straight after our mtg (i.e., stay two nights rather than go somewhere else for a night) as per the original plan?

Ngā mihi

Vicky

From: s 9(2)(g)(ii) @oranewzealand.com>
Sent: Monday, 23 May 2022 9:41 am
To: S9(2)(a) >; Vicky Scott <Vicky.Scott@health.govt.nz>
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: RE: Further planning on our workshops | Urgent

Arohamai – I can't make Monday morning but afternoon would work well for me on the 30th. I have some mahi to do in Tamaki until 9am and then still have a 2 hr drive to the airport.

Ngā mihi

s 9(2)

s 9(2)(g)(ii)

From: S9(2)(a) >
Sent: Monday, 23 May 2022 9:37 am
To: Vicky Scott <Vicky.Scott@health.govt.nz>
Cc: s 9(2)(g)(ii) >; Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: Re: Further planning on our workshops | Urgent

Aroha mai. Apologies all round.

Out of Scope
I had mistakenly thought that was Monday, but I got the day wrong and Im speaking on Tuesday.

Could our first meeting please revert to Monday 31 May.
I've checked with s 9(2) and she can do Monday 31 May.
I suggest afternoon but morning also works

- Monday 31 May – morning or afternoon
- Wednesday 1 June - afternoon
- Tuesday 7 June – afternoon
- Thursday 9 June – afternoon

This will also change travel and logistics.
Apologies.

s 9(2)(g)(ii)

On 20/05/2022, at 11:35 AM, Vicky Scott <Vicky.Scott@health.govt.nz> wrote:

That's great s 9(2) and thank you s 9(2)(a) for the chat. Ellie and I will move on to the logistics now and keep you informed as we further plan our first workshop on what the Therapeutic Products Bill (which includes natural health products) is all about. Having said that, I know you have more history on this s 9(2) than anyone else!

From: s 9(2)(g)(ii) >
Sent: Friday, 20 May 2022 11:07 am
To: Vicky Scott <Vicky.Scott@health.govt.nz>; S9(2)(a) >
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: RE: Further planning on our workshops

Yep I am still fine for these times Vicky

Ngā mihi

s 9(2)

<image002.png>

From: Vicky Scott <Vicky.Scott@health.govt.nz>
Sent: Friday, 20 May 2022 10:58 am
To: S9(2)(a) s 9(2)(g)(ii) @oranewzealand.com>
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: Further planning on our workshops

Mōrena s 9(2)(a) and s 9(2)

I hope you are both well and looking forward to an enjoyable weekend.

s 9(2)(a) - We are thinking further on our four-hour workshops and I would like to work with you on a few things. Can I call you today or early next week as it might be easier than emailing? At this first stage I'd like to confirm our start and finish times, and work out a process with you for planning the structure of the workshops. Ellie, Fiona's EA, will follow up with other logistics (e.g., invitations, travel, accommodation, venues and catering).

s 9(2)(g) our proposed dates below fitted in with the information you provided on Wednesday. I know other people are constantly wanting you so I'd just like to double check that these new dates still work for you.

- Tuesday 31 May – afternoon
- Wednesday 1 June - afternoon
- Tuesday 7 June – afternoon
- Thursday 9 June – afternoon

Ngā mihi

Vicky

Vicky Scott I Principal Analyst, Therapeutics
System Strategy and Policy I Ministry of Health I www.moh.govt.nz

<image003.png>

From: Fiona Ryan
Sent: Friday, 27 May 2022 10:01 am
To: s 9(2)(g)(ii)
Cc: Ellie Debouci; Vicky Scott; Chloe Reynolds; Eli Toeke; Toby Burnett
Subject: RE: therapeutics hui

Importance: High

Kia ora s 9(2)

I discussed the status of travel arrangements with my EA Ellie yesterday. I understand Tandem have made the changes to the itinerary, and I was assured that itinerary would come through to you (from Tandem) late last night or early today. I am also checking again with the Ministry's travel booking provider Tandem. I agree you need to have your travel itinerary and documents asap today.

Ngā mihi

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | Ph S9(2)(a) www.moh.govt.nz

From: s 9(2)(g)(ii) >
Sent: Friday, 27 May 2022 5:43 am
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: therapeutics hui

Ata marie Fiona

Just a reminder that I have not received a draft itinerary for my travel, accommodation, parking and transfers on Monday. Can I please suggest we also include travel for the following week to avoid the same problem then. We are cutting it fine.

Out of Scope

Ngā mihi

s 9(2)

s 9(2)(g)(ii) [redacted]

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Tuesday, 24 May 2022 5:22 pm
To: s 9(2)(g)(ii) [redacted]@oranewzealand.com>
Cc: Ellie Debouci <Ellie.Debouci@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: therapeutics hui

Kia ora s 9(2) [redacted]

Thank you for letting me know about your airline preference – I totally understand.

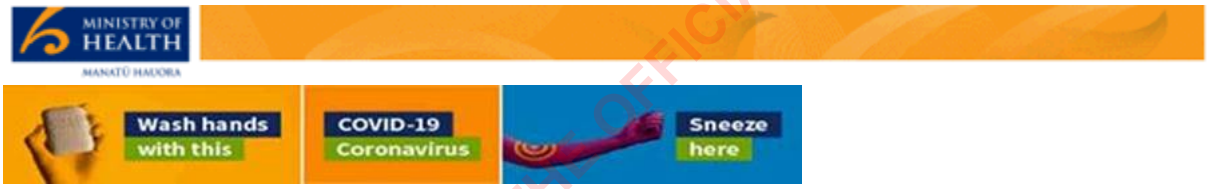
We are working through our internal Directorate processes, which seem slightly different to those of our colleagues in the Maori Health Directorate.
We will keep working to ensure we are able to get arrangements for your travel etc sorted appropriately and to communicate things as we go.

I will ask for these arrangements to be revised tomorrow.

Ngā mihi

Fiona

Fiona Ryan I Manager Therapeutics Policy
System Strategy and Policy I Ministry of Health I Ph S9(2)(a) [redacted] I www.moh.govt.nz



From: s 9(2)(g)(ii) [redacted]
Sent: Tuesday, 24 May 2022 3:38 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: therapeutics hui

Kia ora Fiona

Out of Scope [redacted]

I have also since accepted a 6pm meeting on 1 June so will have to change the flight home on that date to another flight. Usually the Ministry checks flights with me before they confirm.

Ngā mihi

s 9(2) [redacted]

From: s 9(2)(g)(ii) @oranewzealand.com>
Sent: Friday, 27 May 2022 5:44 am
To: Vicky Scott; Eli Toeke; s 9(2)(a)
Cc: Fiona Ryan; Tim Vines; Hinemaua Rikirangi
Subject: RE: Agenda for workshops 1 and 2, and thinking about workshops 3 and 4

Ae – tautoko the korero thus far. I did notice the same when I glanced at your email Vicky but didn't have time to respond then.

Ngā mihi

s 9(2)(g)(ii)

From: Vicky Scott <Vicky.Scott@health.govt.nz>
Sent: Thursday, 26 May 2022 6:37 pm
To: Eli Toeke <Eli.Toeke@health.govt.nz>; S9(2)(a) s 9(2)(g)(ii)
Cc: Fiona Ryan <Fiona.Ryan@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>
Subject: RE: Agenda for workshops 1 and 2, and thinking about workshops 3 and 4

Thank you S9(and Eli for your emails and I look forward to hearing from s 9(2)

For workshops 3 and 4, would it be better if we leave a discussion until next week when we all meet? We're not wedded to any agenda.

Vicky

PS I am not working tomorrow so may not respond to emails. I have asked Fiona to text me if we need to korero.

From: Eli Toeke <Eli.Toeke@health.govt.nz>
Sent: Thursday, 26 May 2022 3:23 pm
To: S9(2)(a) >; Vicky Scott <Vicky.Scott@health.govt.nz>
Cc: s 9(2)(g)(ii) oranewzealand.com>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: RE: Agenda for workshops 1 and 2, and thinking about workshops 3 and 4

Kia ora S9(

I agree with your whakaaro.

The purpose of these workshops is to understand the Therapeutic Products bill and how we can 'recognise and protect' rongoā within the scope of the bill. Before we look beyond rongoā and into Māori health (more generally), we need to have come to an agreed position for rongoā. I don't want to restrict the work needed for this to two workshops. I did indicate this concern to Vicky and Tim at our hui this morning and that workshop 3 and 4 may have to be used for this purpose.

The discussion paper I have drafted for these workshops provides some guiding questions that are to inform these workshops:

- What is the definition of rongoā Māori underpinning our assumptions/mahi?
- How should /could the Crown "recognise and protect" rongoā Māori? What could protection look like? What could recognition look like and how could protection further the interests and aspirations of Māori?
- How should our answers to the above guide the development of the Therapeutics Products bill and the future therapeutic products and natural health products regulatory regime?

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
| Pronouns: He/Him/His | Kaitātari Mātanga (Senior Policy Analyst) | Māori Health Strategy & Policy | Māori Health | Ministry of Health |

From: S9(2)(a) >
Sent: Thursday, 26 May 2022 3:13 pm
To: Vicky Scott <Vicky.Scott@health.govt.nz>
Cc: s 9(2)(g)(ii) Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>
Subject: Re: Agenda for workshops 1 and 2, and thinking about workshops 3 and 4

In terms of the Agenda

Workshop 1 takes a structured and logical approach. Im happy to facilitate our 3 to 3.45 pm session.
Workshop 2 will build on where we get to on day 1, but the suggested agenda provides a good indicative structure. We can revisit if needed. Happy to facilitate the conversation.

Workshops 3 and 4 - Im thinking on the these. One part of me likes to provide as much advance notice as possible to support participation. Another part of me is worried about the extent to which the Rongoa kaupapa will be lost or diminished amongst this number of organisation. However, Rongoa exists within and in relationships to all of these organisations and their services. Maybe its just how we structure these two later sessions. s 9(2) Eli me pehea ou whakaaro?

S9(2)(a)

On 26/05/2022, at 11:40 AM, Vicky Scott <Vicky.Scott@health.govt.nz> wrote:

Mōrena

I hope you are both enjoying today. It's cold here and my dog has curled up under my bed, probably wondering whether he's going to meet any of his friends later today or not. I think he will.

Workshops 1 and 2
The attached document provides draft agendas for the first two workshops. I'm writing to see whether you have any comments, including whether you are ok to lead or facilitate certain items that I hope you see as important for discussion.

If you would like to meet to discuss the agendas, either today or tomorrow, please let me know; otherwise I'm happy to receive emails. Once we have collectively finalised the agenda, I'll send it out to everyone (noting that some of the descriptions under the items may be removed).

Workshops 3 and 4
We haven't developed agendas for the 3rd and 4th workshops yet and would like to check in on your expectations before we go further. Our initial thoughts are to invite other Māori stakeholders and broaden the discussion to include the Therapeutic Products Bill generally (e.g. how do we ensure Māori have access to medicines and medical devices within the context of the Bill?). We are keen to hear your thoughts on that. If you are interested in exploring this further, we could recap where we have got to thus far with rongoā and would expect the discussion on rongoā to continue throughout the two days. As the mahi will be ongoing, we would finish the sessions with thinking about our next steps.

The other potential Māori health stakeholders we were thinking of inviting representatives from, if you see our initial thoughts as worth further exploration, are:

- Te ORA, Te Ohu Rata o Aotearoa - Māori Medical Practitioners
- Nga Kaitiaki o Te Puna Rongoa - Māori Pharmacists' Association
- Te Aō Marama - Māori Oral Health
- Ngā Manukura o Āpōpō – Māori Nursing & Midwifery
- Nga Pou Mana Tangata Whenua Allied Health
- Te Kaunihera o Ngā Neehi Māori - National Council of Māori Nurses
- Te Aō Marama - NZ Māori Dental Association
- Tumu Whakarae (DHB Māori GM Planning & Funding) - Peter Thomas and Phyllis Tangitu.

Please let us know how you would like to discuss workshops 3 and 4 (e.g., when we meet next week or earlier than that).

Travel and accommodation
Your travel and accommodation requirements are still being progressed. We will send you the documents as soon as they become available.

That's all for now! I need a cup of tea.

Ngā mihi

Vicky

Vicky Scott I Principal Analyst, Therapeutics
System Strategy and Policy I Ministry of Health I www.moh.govt.nz

<image001.png>

From: Fiona Ryan
Sent: Sunday, 29 May 2022 10:20 am
To: s 9(2)(g)(ii) ; S9(2)(a)
Cc: Eli Toeke; Hinemaua Rikirangi; Tim Vines; Vicky Scott; Ellie Debouci; Chloe Reynolds; Kirsty Doig
Subject: Apologies -due to bereavement

Kia ora s 9(2)(g)(ii) s 9(2)(a)

We are very much looking forward to continuing our kōrero on Monday.
S9(2)(a) That means I will been unable to attend our first workshop on Monday.

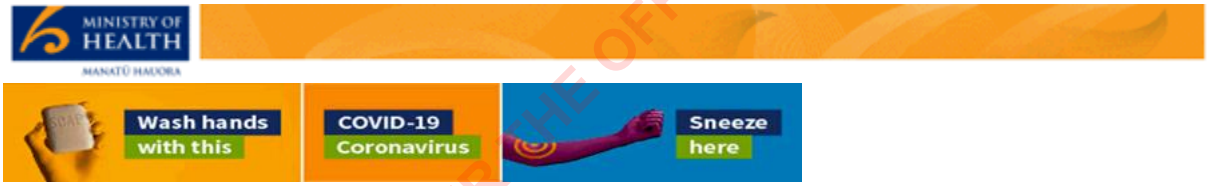
Vicky and Tim, supported by Eli and Hinemaua, are well placed to talk about what the Therapeutic Products Bill (which includes natural health products) is all about, and to start to explore with you the interests, issues and opportunities for Rongoā Māori and more widely.

I wish you all the best for the Workshop tomorrow and am sorry I am not able to be there with you.
I will be attending the 2nd workshop on Wednesday 1 June.

Ngā mihi

Fiona

Fiona Ryan I Manager Therapeutics Policy
System Strategy and Policy I Ministry of Health I Ph S9(2)(a) I www.moh.govt.nz



From: Vicky Scott
Sent: Tuesday, 31 May 2022 4:36 pm
To: s 9(2)(g)(ii) s 9(2)(a) Hinemaua Rikirangi; Eli Toeke; Lisa Ramanui; Bernard Te Paa; Kelly Palmer; Nicola Ehau; Eugene Rewi; Cheree Shortland-Nuku; diana.kopua@tekurahuna.com; Andi Shirtcliffe; Matthew Spencer; Rebecca Murrie; Suzanne McGifford; John McGrath; Kirsty Doig
Cc: Tim Vines; Saerom Shin; Lily Zhang
Subject: Check-in for tomorrow's rongoā Māori workshop

Hi

Thank you to everyone who came to our rongoā Māori workshop yesterday and for your contributions. We are really looking forward to making further progress tomorrow afternoon.

To help with logistics, could everyone who is attending tomorrow's workshop please let me know whether you are coming into the Molesworth office or attending online, noting the following people don't need to reply (unless circumstances change), as I know you will be coming in to the office: s 9(2) s 9(2)(a), Kelly, Eli, Tim, Saerom, Lily.

Ngā mihi

Vicky

Vicky Scott I **Principal Analyst, Therapeutics**
System Strategy and Policy I Ministry of Health I www.moh.govt.nz

From: s 9(2)(g)(ii) >
Sent: Tuesday, 14 June 2022 10:53 pm
To: Eli Toeke; s 9(2)(a) ; Hinemaua Rikirangi; Lisa Ramanui; Fiona Ryan; Tim Vines; Vicky Scott; Saerom Shin; Lily Zhang
Cc: Cheree Shortland-Nuku
Subject: RE: Final workshop for Therapeutic Products bill and Rongoā Māori

Arohamai Eli

S9(2)(a)

At present I can make time next week on

- Monday 20 June after 12 noon
- Wednesday 22 June after 12 noon
- Friday 24 June anytime.

Sorry to be a pain.
s 9(2)

From: Eli Toeke <Eli.Toeke@health.govt.nz>
Sent: Tuesday, 14 June 2022 3:47 pm
To: s 9(2)(g)(ii) >; S9(2)(a) Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Tim Vines <Tim.Vines@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Saerom Shin <Saerom.Shin@health.govt.nz>; Lily Zhang <Lily.Zhang@health.govt.nz>
Cc: Cheree Shortland-Nuku <Cheree.Shortland-Nuku@health.govt.nz>
Subject: Final workshop for Therapeutic Products bill and Rongoā Māori

Kia ora tātou,

Firstly, I would like to thank Fiona and her team for providing Māori the space to kōrero last week. We had very productive hui on Tuesday and Thursday.

I will be following up this email with an invite to join, via teams, our final workshop to discuss the options we developed last week. Our final workshop will be on Thursday 23 June, 1pm – 3.30pm.

Please let me know if you're unable to attend this workshop and I will find another time/date that suits us all.

An agenda for the final workshop will be sent out closer to the day. But the workshop will generally cover the options developed and the pros and cons of each option.

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
| Pronouns: He/Him/His | Kaitātari Mātanga (Senior Policy Analyst) | Māori Health Strategy & Policy | Māori Health | Ministry of Health |

From: s 9(2)(g)(ii)
Sent: Friday, 1 July 2022 8:03 pm
To: Tim Vines; Vicky Scott
Subject: PCO & Pharmacopeia

Kia ora korua

I am pleased to confirm that its not your PCO that is developing the rongoa pharmacoeia – it was another group at Wakatu who have commissioned the work which has nothing to do with the Therapeutic Products Bill or your PCO and unlikely to materialise for several years yet – if at all. They are only planning on doing a 9 plant pilot at this stage so won't be much use to us.

Hope you both have a lovely weekend

s 9(2)

Mānawatia
a Matariki

From: s 9(2)(g)(ii)
Sent: Tuesday, 12 July 2022 12:13 pm
To: Tim Vines
Cc: Vicky Scott; Kirsty Doig
Subject: RE: Invitation to attend a virtual hui on 25 July on the Therapeutic Products Bill

Ata marie Tim

Yes I can make the 25th! Thank you for remembering to include me. I think it would be really useful for me to learn how Māori clinicians are thinking with regard to the Bill.

Please include s 9(2)(a) in the invite. She can decide if she thinks it would be of value. It might also be useful to invite Eli if he can make it????

I really appreciate your style and manner in moving this work forward Tim (and team).

Ngā mihi nui
s 9(2)

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Tuesday, 12 July 2022 11:50 am
To: s 9(2)(g)(ii) @oranewzealand.com>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Invitation to attend a virtual hui on 25 July on the Therapeutic Products Bill

Kia ora s 9(2)

Ko taku tūmanako kei te ora koe. We are well, with our heads down as we race towards introduction of the Bill. No doubt you are also busy too.

You will recall that we said a short time ago that we intended to hold a hui on the Therapeutic Products Bill with Māori clinicians and practitioners, and Māori sector bodies in advance of the Bill's introduction to Parliament. At the time, you expressed an interest in attending the hui.

Would you be able to attend a virtual hui that is planned for Monday 25 July 10am to 12pm? We are seeking interest in the hui but have yet to send out the details for the meeting.

We hope to use the opportunity to provide an overview of the Bill and hear perspectives on the implications of the Bill for different areas of practice, organisations and hauora Māori. The advice and perspectives will help shape the final form of the Bill, our advice to Government and the future direction of the new regulatory regime.

Please let me know if you can and would like to attend. If you think s 9(2)(a) would also be interested in attending, please let me know and I'll send her an invitation as well.

Ngā mihi

Tim

PS. I have finished a draft briefing to the Minster on the Te Tiriti and rongoā proposals. I will send you a copy shortly (today hopefully) for your comment.

Tim Vines (he/him)
Acting Manager, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

From: s 9(2)(g)(ii) >
Sent: Friday, 15 July 2022 10:40 am
To: Tim Vines
Cc: Vicky Scott
Subject: RE: Invitation to attend a virtual hui on 25 July on the Therapeutic Products Bill

Thanks for the update Tim – I did wonder what was happening in the background.

All good – I look forward to reading it and providing support where I can.

When I think my work gets tough, I just think of your job and it doesn't feel so tough anymore.

You guys have a great weekend and hopefully a rest.

Ngā mihi

s 9(2)(g)(ii)

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Friday, 15 July 2022 10:37 am
To: s 9(2)(g)(ii)
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: Invitation to attend a virtual hui on 25 July on the Therapeutic Products Bill

Kia ora s 9(2)

I just wanted to touch base quickly to let you know that I am not able to send through a copy of our advice just yet. I'm still receiving comments from across the Ministry and from Te Aka Whai Ora – the Māori Health Authority (who are still setting up a number of their own policy teams). I should be able to provide the most up-to-date version next week.

I hope your week has gone well and that you have a great weekend!

Ngā manaakitanga

Tim

From: Tim Vines
Sent: Tuesday, 12 July 2022 11:50 am
To: s 9(2)(g)(ii) >
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Invitation to attend a virtual hui on 25 July on the Therapeutic Products Bill

Kia ora s 9(2)

Ko taku tūmanako kei te ora koe. We are well, with our heads down as we race towards introduction of the Bill. No doubt you are also busy too.

You will recall that we said a short time ago that we intended to hold a hui on the Therapeutic Products Bill with Māori clinicians and practitioners, and Māori sector bodies in advance of the Bill's introduction to Parliament. At the time, you expressed an interest in attending the hui.

Would you be able to attend a virtual hui that is planned for Monday 25 July 10am to 12pm? We are seeking interest in the hui but have yet to send out the details for the meeting.

We hope to use the opportunity to provide an overview of the Bill and hear perspectives on the implications of the Bill for different areas of practice, organisations and hauora Māori. The advice and perspectives will help shape the final form of the Bill, our advice to Government and the future direction of the new regulatory regime.

Please let me know if you can and would like to attend. If you think s 9(2)(a) would also be interested in attending, please let me know and I'll send her an invitation as well.

Ngā mihi

Tim

PS. I have finished a draft briefing to the Minster on the Te Tiriti and rongoā proposals. I will send you a copy shortly (today hopefully) for your comment.

Tim Vines (he/him)
Acting Manager, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

From: s 9(2)(g)(ii) >
Sent: Tuesday, 26 July 2022 10:01 pm
To: Tim Vines
Cc: Vicky Scott; Fiona Ryan
Subject: Re: An apology about this morning's Therapeutic Products Bill hui

Thanks Tim

Get Outlook for Android

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Tuesday, July 26, 2022 9:57:08 PM
To: s 9(2)(g)(ii) >
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: RE: An apology about this morning's Therapeutic Products Bill hui

Kia ora s 9(2)

Thanks for the email and I'm sorry for the absence of news from our end and for the mix up on Monday. It would be great if you could make a rescheduled hui. We're looking at 10 August, are you free that day?

Partly in response to discussions we've had with Te Aka Whai Ora – the Māori Health Authority since their official establishment on 1 July we've rethought our approach to presenting the advice on rongoā and Te Tiriti issues to the Minister. I've also been making some revisions to the briefing based on feedback from Fiona, which I'm hoping to have done tomorrow afternoon.

We have a meeting with Te Aka Whai Ora on Thursday and will be outlining our proposed approach to the rongoā advice to the Minister. Afterwards, we would still like to provide a copy of the rongoā to you for your consideration and feedback (including how best to capture and convey Te Kāhui Rongoā's views). I'm sorry things have been pushed back. Hopefully we'll be back on track by the end of the week.

Ngā mihi

Tim

Tim Vines (he/him)
Principal Analyst, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

Document 4

From: s 9(2)(g)(ii) >
Sent: Tuesday, 26 July 2022 6:00 pm
To: Tim Vines <Tim.Vines@health.govt.nz>
Cc: Kirsty Doig <Kirsty.Doig@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: RE: An apology about this morning's Therapeutic Products Bill hui

Kia ora Tim

Thanks for the apology. It was really disappointing not to be included in the meeting yesterday.

Are we still on track to get a copy of the advice next week? It feels like we are operating in a bit of vacuum right now.

Ngā mihi

s 9(2)(g)(ii)

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Monday, 25 July 2022 2:10 pm
To: Alice Marfell-Jones <Alice.Marfell@health.govt.nz>; Russell Bates <Russell.Bates@health.govt.nz>; Meryl Fraser <Meryl.Fraser@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Hinemaua Rikirangi <Hinemaua.Rikirangi@health.govt.nz>; Nadine Gray <Nadine.Gray@health.govt.nz>; Ramai Haeata <Ramai.Lord@health.govt.nz>; Lorraine Hetaraka <Lorraine.Hetaraka@health.govt.nz>; Anne Stewart <Anne.Stewart@health.govt.nz>; s 9(2)(g)(ii) @oranewzealand.com>; S9(2)(a)
Cc: Kirsty Doig <Kirsty.Doig@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: An apology about this morning's Therapeutic Products Bill hui

Kia ora koutou

I hope everyone's week has started well.

There seemed to be an issue this morning with either the meeting invite or MS Office more generally that meant that the invite for this morning's virtual hui on the TPB disappeared from people's calendars. (It disappeared from mine!).

We did end up starting the hui, with some external stakeholders joining, suggesting the issue with the invite was not experienced universally.

I am very sorry if you had planned to attend but couldn't. We will be circulating the slides we presented this morning and are planning to hold another session soon.

Again, I apologise for any confusion and disappointment.

Ngā manaakitanga

Tim

Tim Vines (he/him)
Principal Analyst, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

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Document 4

From: s 9(2)(g)(ii)
Sent: Monday, 8 August 2022 10:42 am
To: Kirsty Doig; Brenda.Close@cdhb.health.nz; S9(2)(a); Kerri.Nuku@nzno.org.nz; Belinda.Tuari-Toma@nzno.org.nz; HineroaH@adhb.govt.nz; rhoena.davis@mahitahihauora.co.nz; admin@ngapoumana.org.nz; admin@maorioralhealth.org.nz; S9(2)(a); S9(2)(a); teaniwa.reedy@teora.maori.nz; S9(2)(a); Geoff.Milner@nhht.co.nz; Rachel@nhc.maori.nz; chris.tooley@tpoom.co.nz; janice@nmo.org.nz; tpwiniata@thc.org.nz; tammy.dehar@korowai.co.nz; Taima Campbell; tonyk@papakuramarae.co.nz; kmaxwell-crawford@poutiri.org; hariata@korowai.org.nz; margareth.broodkoorn@Hokiangahealth.org.nz; hthompson@manaakiora.org.nz; peter.thomas@northlanddhb.org.nz; phyllis.tangitu@lakesdhb.govt.nz; Koha.Aperahama@northlanddhb.org.nz; Maria.Baker@terauora.com; valerie.williams@terauora.com; nmaunsell@thc.org.nz; rmuru@thc.org.nz; Fiona Ryan; Tim Vines; Vicky Scott
Cc: Saerom Shin; Lily Zhang; Eli Toeke; Lisa Ramanui; Lorraine Hetaraka; Ramai Haeata; Nadine Gray; Te Ata Munro
Subject: RE: Therapeutic Products Bill hui

Arohamai Kirsty

Unfortunately, I am unable to attend this very short notice hui. I am really disappointed as it is the 2nd hui we have been unable to contribute to or learn from because of either MoH short notice or errors.

Can we please do better at consulting with our communities? This is not good enough, nor is it respectful.

Ngā mihi

s 9(2)(g)(ii)

-----Original Appointment-----
From: Kirsty Doig <Kirsty.Doig@health.govt.nz>
Sent: Monday, 8 August 2022 10:34 am
To: s 9(2)(g)(ii) Brenda.Close@cdhb.health.nz; S9(2)(a); Kerri.Nuku@nzno.org.nz; Belinda.Tuari-Toma@nzno.org.nz; HineroaH@adhb.govt.nz; rhoena.davis@mahitahihauora.co.nz; admin@ngapoumana.org.nz; admin@maorioralhealth.org.nz; S9(2)(a); S9(2)(a); teaniwa.reedy@teora.maori.nz; S9(2)(a); Geoff.Milner@nhht.co.nz; Rachel@nhc.maori.nz; chris.tooley@tpoom.co.nz; janice@nmo.org.nz; tpwiniata@thc.org.nz; tammy.dehar@korowai.co.nz; Taima Campbell; tonyk@papakuramarae.co.nz; kmaxwell-crawford@poutiri.org; hariata@korowai.org.nz; margareth.broodkoorn@Hokiangahealth.org.nz; hthompson@manaakiora.org.nz; peter.thomas@northlanddhb.org.nz; phyllis.tangitu@lakesdhb.govt.nz; Koha.Aperahama@northlanddhb.org.nz; Maria.Baker@terauora.com; valerie.williams@terauora.com; nmaunsell@thc.org.nz; rmuru@thc.org.nz; Fiona Ryan; Tim Vines; Vicky Scott
Cc: Saerom Shin; Lily Zhang; Eli Toeke; Lisa Ramanui; Lorraine Hetaraka; Ramai Haeata; Nadine Gray; Te Ata Munro
Subject: FW: Therapeutic Products Bill hui
When: Wednesday, 10 August 2022 2:00 pm-3:30 pm (UTC+12:00) Auckland, Wellington.
Where: Microsoft Teams Meeting

Tēnā koutou

Document 4

You are invited to join the Ministry of Health's virtual hui on the Therapeutic Products Bill. The purpose of the Bill is to establish a modern, flexible and comprehensive regulatory regime for medicines, medical devices and natural health products.

We are particularly keen to hear your views on the equity and Te Tiriti issues that the Bill might present to your practice, organisation, patients and their whānau. This may include issues related to the practice of rongoā.

Your advice and perspectives will help shape the final form of the Bill, our advice to Government and the future direction of the new regulatory regime.

If you have any questions in advance of the hui, please feel free to contact the team at:
therapeuticproducts@health.govt.nz

Nāku noa, nā
Therapeutic Products team

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

****

Document 4

From: s 9(2)(g)(ii)
Sent: Monday, 8 August 2022 1:52 pm
To: Lisa Ramanui; Tim Vines
Cc: Vicky Scott; Fiona Ryan; Eli Toeke; s 9(2)(a)
Subject: Re: Seeking availability for joint Te Aka Wahi Ora, Te Kāhui Rongoā, Ministry hui on rongoā proposals

The 18th works for me Tim

Get Outlook for Android

From: Lisa Ramanui <Lisa.Ramanui@health.govt.nz>
Sent: Monday, 8 August 2022, 1:20 pm
To: Tim Vines <Tim.Vines@health.govt.nz>
Cc: s 9(2)(g)(ii) Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; S9(2)(a) <S9(2)(a) >
Subject: RE: Seeking availability for joint Te Aka Wahi Ora, Te Kāhui Rongoā, Ministry hui on rongoā proposals

Kia ora Tim

I could make Monday 15th and Thurs 18th. Māori Health will be out of the office all day Weds 24th.

Ngā mihi

Lisa Ramanui (she/her)
Māori Health Strategy and Policy team
lisa.ramanui@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

From: Eli Toeke <Eli.Toeke@health.govt.nz>
Sent: Monday, 8 August 2022 12:12 pm
To: S9(2)(a) ; Tim Vines <Tim.Vines@health.govt.nz>
Cc: s 9(2)(g)(ii) Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: RE: Seeking availability for joint Te Aka Wahi Ora, Te Kāhui Rongoā, Ministry hui on rongoā proposals

Kia ora Tim,

I can do Monday 15th, Thursday 18th and Wednesday 24th

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
| Pronouns: He/Him/His | Kaitātari Mātanga (Senior Policy Analyst) | Māori Health Strategy & Policy | Māori Health | Manatū Hauora - Ministry of Health |

From: S9(2)(a) [redacted]
Sent: Monday, 8 August 2022 12:09 pm
To: Tim Vines <Tim.Vines@health.govt.nz>
Cc: s 9(2)(g)(ii) [redacted]>; Lisa Ramanui <Lisa.Ramanui@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Fiona Ryan <Fiona.Ryan@health.govt.nz>
Subject: Re: Seeking availability for joint Te Aka Wahi Ora, Te Kāhui Rongoā, Ministry hui on rongoā proposals

Kia ora Tim.
Thanks for the update.
At the moment I can do any of the times mentioned.

s 9(2)(a) [redacted]

On 8/08/2022, at 11:33 AM, Tim Vines <Tim.Vines@health.govt.nz> wrote:

Kia ora s 9(2) [redacted], s 9(2)(a) [redacted] Lisa and Eli

Apologies again, s 9(2) [redacted], about this Wednesday's hui. I'll send through a second email shortly, with some options for us to report back on the discussion.

As discussed on the phone, Te Aka Whai Ora has come back with some proposed times for a joint hui to discuss the rongoā proposals. The intention of the hui would be to settle the Ministry's advice to the Minister on this issue so we can s 9(2)(h) [redacted] to make any necessary revisions to the Bill before introduction. Importantly, our proposals envisage a much longer period of partnering with Te Kāhui Rongoā and rongoā practitioners, and working with Te Aka Wahi Ora, on the operational details (regulations) that would come into force when the Bill commences. This would be 2-3 years after the Bill is enacted by Parliament.

s 9(2)(g)(ii) [redacted] s 9(2)(a) [redacted]: are you available on the following times?

Monday 15 August
- 11am – 1pm **or**
- 2pm-4pm

Thursday 18 August
- A two hour window between 12 – 3:30pm

Monday 22 August
- 2pm-4pm

Wednesday 24 August

- A two hour window between 12 – 3:30pm

Our preference would be to hold the hui sooner, so we can get our advice to the Minister and any s 9(2)(h) . Given the hui would only be 2 hours, would you want to join virtually (I know this isn't your preference though). If neither of these times work – or you are going to be in Wellington on some other day – please let me know and I'll see what I can organise with Te Aka Whai Ora.

@Lisa and @Eli – could you also please let me know what times suit you?

Ngā manaakitanga

Tim

Tim Vines (he/him)
Principal Analyst, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

<image002.png>

Document 4

From: s 9(2)(g)(ii)
Sent: Tuesday, 9 August 2022 6:14 am
To: Tim Vines
Cc: Fiona Ryan; Vicky Scott
Subject: RE: Looking to set up a meeting to report back on discussion from hui

The only day I can do Tim is the 17th.

Ngā mihi
s 9(2)(g)(ii)

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Monday, 8 August 2022 11:39 am
To: s 9(2)(g)(ii)
Cc: Fiona Ryan <Fiona.Ryan@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: Looking to set up a meeting to report back on discussion from hui

Hi again s 9(2)

As discussed, I am keen to set up a time for us to report back on the recent hui. I imagine we'll need an hour and I was going to propose that we meet virtually – Teams, Zoom or phone call.

Would you have any availability on **Thursday 11 August** (between 10am – 1pm); alternatively, would sometime on **Monday 15 August,** or in the afternoon of **Tuesday 16 August** or **Wednesday 17 August** work for you?

Ngā mihi

Tim

Tim Vines (he/him)
Principal Analyst, Therapeutics
Strategy, Legislation and Policy
S9(2)(a)
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

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Document 4

From: s 9(2)(g)(ii) >
Sent: Friday, 11 November 2022 10:53 am
To: Eli Toeke; Eugene Rewi; Russell Bates; Eldon Paea; Tim Vines; Lisa Ramanui; s 9(2)(g)(ii) Albert Ropiha Stewart; Pollyanne Taare; Vicky Scott
Subject: FW: re Te Kāhui Rongoā mtg with Ministers Henare & Little

Kia ora e te whanau whanui

Please see email below to Minister Little and Henare's office re Te Kāhui's meeting with them both on Wednesday.

As promised and rather than rave about the outcome and positivity of the meeting, I thought it easier just to forward our letter of thanks to them both. It pretty much explains the outcome in a nutshell.

Albie – I will leave it to you to inform our Trustee's (past and present) of the meeting outcome.

Ngā mihi

s 9(2)(g)(ii)

From: s 9(2)(g)(ii)
Sent: Friday, 11 November 2022 10:37 am
To: Clyde Smith <Clyde.Smith@parliament.govt.nz>
Cc: Riana Manuel <Riana.Manuel@health.govt.nz>; John Whaanga <John.Whaanga@health.govt.nz>; Albert Ropiha Stewart <S9(2)(a) >
Subject: re Te Kāhui Rongoā mtg with Ministers Henare & Little

Tēnā koe Clyde

It was so nice to meet you on Wednesday. Thank you for the role you played in co-ordinating our meeting with Ministers Henare and Little this week.

Can you please pass on to them both Te Kāhui Rongoā's gratitude for making the time to meet with us and provide reassurance that it is not their intention to regulate rongoā in any way in the Therapeutic Products Bill. It was particularly heart warming to know that they both clearly understood the issues for us and the need to retain the integrity and tikanga that has supported the safe practice of rongoā for hundreds of years and the reasons why the Bill needs to explicitly recognise, protect and enable the continued practice of rongoā as understood by Māori. I am almost tempted to minute the meeting just to reassure myself that I didn't misunderstand their assurances. But I will refrain! While we have no solutions to offer at this point, we do share the Minister's concerns about building in protections from those who would pretend to be us without constraining the practice of legitimate healers.

As we said, we are here to be part of the solution and not the problem after the fact. We welcome the Ministers offers to meet with them regularly throughout the process to provide feedback in person and/or raise any issues directly with Minister Henare by phone message if necessary.

I look forward to seeing more of you over the coming months as we contribute our little bit to assist with the Bill's timely progression.

Ngā mihi

Document 4

s 9(2)(g)(ii)

[redacted]

Document 4

From: s 9(2)(g)(ii) >
Sent: Friday, 18 November 2022 4:42 pm
To: Vicky Scott
Cc: Tim Vines; Kirsty Doig
Subject: Re: Summary of May/June 2022 wānanga and hui

Kia ora Vicky.

What a lot of work.... .wouldn't a face to face with the requestor have been easier and more beneficial to the requestor? I would much rather meet with them and answer any of their questions than go through pages of stuff from months ago.

I agree and accept this is the Ministry's version of events and have no obvious issue with any of it but can't be bothered checking any of my notes so reserve my right to agree or disagree with any part of it.

Thank you for sharing your communique with me.

Nga mihi
s 9(2)(g)(ii)

Get Outlook for Android

From: Vicky Scott <Vicky.Scott@health.govt.nz>
Sent: Friday, November 18, 2022 4:23:37 PM
To: s 9(2)(g)(ii)
Cc: Tim Vines <Tim.Vines@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Summary of May/June 2022 wānanga and hui

Kia ora s 9(2)

I hope you are well. I'm covering for Tim as acting manager while he takes a well-deserved break.

I'm just following up on Tim's previous email, which flagged that we've had a request for the minutes of our wānanga and hui. Attached is the draft summary we're proposing to send.

Can you please let us know by the end of Monday if you have any comments or concerns? If you need more time to consider the attached, please let me know.

Ngā mihi

Vicky

Vicky Scott
Principal Analyst, Therapeutics
Strategy, Policy and Legislation
+S9(2)(a)
vicky.scott@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

Document 4

From: s 9(2)(g)(ii) [redacted]
Sent: Wednesday, 9 November 2022 1:55 pm
To: Tim Vines <Tim.Vines@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: Re: Mtg with Ministers Little & Henare

Thank you so much Tim x

Get Outlook for Android

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Wednesday, November 9, 2022 1:46:08 PM
To: s [redacted]
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>; Kirsty Doig <Kirsty.Doig@health.govt.nz>
Subject: RE: Mtg with Ministers Little & Henare

Kia ora s 9(2) [redacted]

I'm really sorry to hear about campaign against you and Te Kāhui Rongoā. That sounds incredibly stressful. I know everyone in our team is very grateful for the knowledge and time you shared with us as part of this work, so I am sorry to hear how it has been construed.

I'm afraid we aren't able to share the name of the person who requested the information for privacy reasons. Those same reasons would also apply to any OIA request.

What I do propose is that we also provide you with a copy of the documents that are sent out at the same time they are released to the requestor. That way you will know what is 'out there' and have your own copy. (We will just have to dot i's to make sure that is within the Ministry's rules – but I don't see any issues).

In terms of dealing with misinformation, the team and I continue to faithfully represent your role in the development of the Bill and the unwavering position of Te Kāhui Rongoā in relation to rongoā generally. And we will keep doing so before and after the Bill is introduced.

While I am away, please feel free to reach out to Vicky and Kirsty with any concerns. You will likely hear from them in the next week or two in relation to the release of documents.

Best wishes for the next few weeks and S9(2)(a) [redacted]

Ngā mihi

Tim

Tim Vines (he/him)
Acting Manager, Therapeutics
Strategy, Legislation and Policy
S9(2)(a) [redacted]
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

From: s 9(2)(g)(ii) >
Sent: Wednesday, 9 November 2022 1:33 am
To: Tim Vines <Tim.Vines@health.govt.nz>
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: Mtg with Ministers Little & Henare

Kia ora Tim

Thanks for the support.

s 9(2)(g)(ii)

Have a great break!

Ngā mihi

s 9(2)(g)(ii)

From: Tim Vines <Tim.Vines@health.govt.nz>
Sent: Tuesday, 8 November 2022 8:37 pm
To: s 9(2)(g)(ii) >
Cc: Vicky Scott <Vicky.Scott@health.govt.nz>
Subject: RE: Mtg with Ministers Little & Henare
Importance: High

Kia ora s 9(2)

Thank you for your email earlier today. I hope the meeting goes well tomorrow. Just a heads up, I will be on leave for the next couple of weeks from Thursday. Vicky Scott will be filling in for me while I am away.

In an unrelated matter, Manatū Hauora has received a request for information about the wānanga, hui and other engagement the Ministry had with you and Te Kāhui Rongoā earlier this year. This includes copies of minutes from

the hui. In responding to this request we might also provide copies of some of the materials the Ministry developed and presented at those sessions.

As some of the information that we are proposing to release is about you, I'd appreciate your views about how disclosure of this information might affect you or your interests. The person requesting the information knows we met with you but we would endeavour to redact personal details like email address etc…

Please let me know if this raises any concerns for you. We will need to respond to this request by the end of the week.

Hope you can enjoy some of the good weather Wellington is putting on and I look forward to catching up next month.

Ngā manaakitanga

Tim

Tim Vines (he/him)
Acting Manager, Therapeutics
Strategy, Legislation and Policy
S9(2)(a) [redacted]
tim.vines@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

If this email reaches you out of hours, I don't expect a response outside of your office hours, it's just a convenient time for me to send an email.

From: s 9(2)(g)(ii) [redacted]
Sent: Tuesday, 8 November 2022 3:29 pm
To: Tim Vines <Tim.Vines@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; Russell Bates <Russell.Bates@health.govt.nz>; Eli Toeke <Eli.Toeke@health.govt.nz>
Subject: Mtg with Ministers Little & Henare

Kia ora koutou

Just letting you all know that myself and the interim Chair of Te Kahui Rongoa have a confirmed meeting with Ministers Little and Henare at the Beehive tomorrow evening to discuss the Therapeutics Regime.

It will be good to hear first hand their concerns and address them directly with Ministers.

I'm in Wellington today but have mtgs tomorrow 9am to 3 pm if either of you have any questions or advice to share prior to the meeting.

Nga mihi
s 9(2) [redacted]

Document 4

From: Vicky Scott
Sent: Monday, 30 January 2023 4:13 pm
To: Tim Vines; Frankie Ancillotti
Subject: FW: Therapeutics Bill
Attachments: Letter to s 9(2)(g)(ii) - Dec 21.pdf

Here's the final letter that was sent to s 9(2) in December.

From: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Sent: Friday, 24 December 2021 1:42 pm
To: s 9(2)(g)(ii) >
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; s 9(2)(g)(ii) ohn Whaanga <John.Whaanga@health.govt.nz>; Caroline Flora <Caroline.Flora@health.govt.nz>; Vicky Scott <Vicky.Scott@health.govt.nz>; Nadine Neale <Nadine.Neale@health.govt.nz>
Subject: RE: Therapeutics Bill

Kia ora s 9(2)

As promised when we spoke on 17 December, please find attached a detailed letter outlining the current status of work on regulation of natural health products and the Therapeutic Products Bill.

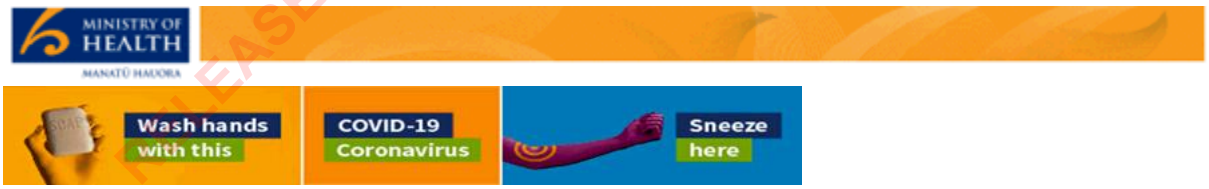
I was hoping to have a kōrero with you again with Eugene and Eli before sending this letter. As that has not been possible, I thought it important to this letter anyway and for you to have the opportunity to consider it at your convenience.

I would like wish you and your whānau a Meri Kirihimete me te Hape Nū Ia
Look forward to working more closely with you in 2022.

Nāku noa, nā

Fiona

Fiona Ryan | Manager Therapeutics Policy
System Strategy and Policy | Ministry of Health | s 9(2)(a) | www.moh.govt.nz



From: s 9(2)(g)(ii) >
Sent: Thursday, 16 December 2021 1:21 pm
To: Fiona Ryan <Fiona.Ryan@health.govt.nz>
Cc: Eli Toeke <Eli.Toeke@health.govt.nz>; Eugene Rewi <Eugene.Rewi@health.govt.nz>; s 9(2)(g)(ii) John Whaanga <John.Whaanga@health.govt.nz>
Subject: Therapeutics Bill

Document 4

Kia ora Fiona

I hope this finds you well. It has been a few months since you asked to urgently meet with Te Kahui Rongoa regarding the Therapeutics Bill and a couple of years since we have been requesting to meet face to face with you and your team.

I learned today that the Natural Health Products industry attended a meeting with several Ministers about the progress of the Bill and its proposed contents.

Is there a reason why rongoa Maori advocates were not afforded the same courtesy?

This is yet another slap in the face for us and I am sorry but your words and your commitment do not match your actions. Nothing appears to have changed in all the years we have contributed to this korero. To say I am disappointed is a gross understatement, you led us to believe that we could expect better from you and your new team.

Ngā mihi

s 9(2)(g)(ii) [redacted]

Document 5

Eli Toeke

From: Eli Toeke
Sent: Tuesday, 17 August 2021 4:42 pm
To: s 9(2)(g)(ii)
Cc: Eugene Rewi
Subject: Request for a hui with Te Kahui Rongoa

Importance: High

Tēnā koutou e ngā rangatira o Te Kāhui Tāwharautanga ō Ngā Rongoā,

Tēnei aku mihi mahana ki a koutou katoa i roto i ngā āhuatanga o te wā.

We have been working with our colleagues in the System Strategy & Policy directorate at the Ministry of Health who are leading work on regulation of natural health products. Work in this area is now at a point where it is timely to engage with Te Kāhui Rongoā.

We and our System Strategy & Policy colleagues would appreciate meeting with you to provide an update on the status of this work and to talk with you about the areas of interest and importance for Te Kāhui Rongoā.

We would like to start this refreshed conversation as part of the draft relationship agreement we have been developing together.

Can you please indicate your availability to meet with us, either in person or virtually, over the next two weeks and I will organise for us to meet.

I look forward to hearing from you.

Noho ora mai i roto i ngā manaakitanga,

nā, Eli Toeke
I Pronouns: He/Him/His I Kaitātari Kaupapahere (Policy Analyst) I Māori Health Strategy & Policy I Māori Health I Ministry of Health I