Briefing

Establishing a rongoā work stream alongside the Therapeutic Products Bill

Date due to MO:	18 November 2022	**Action required by:**	<N/A>
Security level:	IN CONFIDENCE	**Health Report number:**	HR 2022017070
To:	Hon Peeni Henare, Associate Minister of Health (Māori)		
Copy to:	Hon Andrew Little, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☒		

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Establishing a rongoā work stream alongside the Therapeutic Products Bill

Security level:	IN CONFIDENCE	**Date:**	18 November 2022
To:	Hon Peeni Henare, Associate Minister of Health (Māori)		

Purpose of report

1. This report responds to Minister Little's request for advice to Minister Henare about establishing a work stream to consider how rongoā might be appropriately scheduled in legislation so that it is protected, patient safety is assured, and export market access is protected for rongoā practitioners providing direct services to patients (alongside those providing therapeutics and products with health benefit claims). [HR 20220828 refers].
2. This report includes information to support an announcement of the rongoā work stream at the introduction of the Therapeutic Products Bill (the Bill). Appendix 1 refers.
3. This report discloses all relevant information and implications.

Summary

4. When the Bill is introduced to Parliament, rongoā will not be explicitly named in the Bill. However, due to the definitions and terminology used in the Bill, including the definition of natural health products, rongoā will be captured within the regulatory regime.
5. We propose that establishing a rongoā work stream will involve a targeted engagement process with Māori. This will enable Māori to provide clarity to their diverse views and guide the development of our proposals within the limited time frame.
6. Work by officials will occur over the next 4-5 months to provide the requested advice from Minister Little on how rongoā Māori may be appropriately scheduled in legislation via a Supplementary Order Paper to the Bill and/or companion legislation.

Recommendations

a)	**Note** if requested, you will be provided with an update of the progress of the work stream in February 2023.	**Noted**
b)	**Note** the targeted engagement process with Māori to inform the advice of officials. This includes engaging with independent Māori groups to provide expert advice and help navigate complex issues for rongoā.	**Noted**

c) **Note** that officials have provided draft advice for the announcement of the rongoā Māori work programme (Appendix 1) including a press release, back-pocket frequently asked questions, and talking points. **Noted**

John Whaanga
Deputy Director-General Māori Health
Te Pou Hauora Māori
Date:

Hon Peeni Henare
Associate Minister of Health (Māori)
Date:

Establishing a rongoā work stream

Background

7. HR 20220828 sets out Minister Little's decision to progress with introducing the Therapeutic Products Bill (the Bill) to the House of Representatives in November/December 2022. However, Minister Little has directed further work on rongoā.

8. Minister Little requested officials provide advice to you about a separate work stream to consider how rongoā might be appropriately scheduled in legislation to provide for the protection of rongoā, the assurance of patient safety and ensuring access to the export market for rongoā practitioners providing direct services to patients (alongside those providing therapeutics and natural health products with health benefit claims) [HR 20220828 refers].

9. Minister Little also requested that the advice is provided in a timely manner to enable announcement of the work stream at the same time as the introduction of the Bill.

10. The work stream must enable timely mechanisms which provide flexibility for the Government to either introduce a Supplementary Order Paper to the Bill substantially prior to its return from Select Committee, or to create companion legislation.

The Therapeutic Products Bill and rongoā

11. The Bill does not specifically refer to or mention rongoā. However, rongoā is not excluded from the Bill as elements are currently captured within the definition of natural health products.

12. The Bill enables the regulator to design and implement regulations for natural health products that may impact on rongoā. This may include quality and safety standards, rules about where, how and who can produce these products, labelling and advertising standards, market authorisation, requirements for health benefit claims, offences, and penalties.

Establishing a rongoā work stream

Government agencies' representation and involvement

13. The rongoā work stream will be led by Manatū Hauora, in consultation with Te Aka Whai Ora. Other agencies currently engaged by the work stream include Te Puni Kōkiri and ACC. It is our intention to engage other government agencies as appropriate.

Scope of the rongoā work stream

14. The rongoā work stream will analyse the Bill to identify gaps and opportunities to protect rongoā, assure patient safety, and ensure access to the export market for rongoā practitioners through a Supplementary Order Paper (SOP) and/or companion legislation.

15. The rongoā work stream will also explore the risks and benefits of a SOP and/or a companion Bill and identify where matters for rongoā are being addressed through other government work programmes.

16. Potential areas of the Bill that may impact on rongoā include:

    - licences and permits

- products standards
- market authorisation (either to supply domestically or to export, except when manufacturing and supplying as part of a consultation)
- health benefit claims.

17. Other policy considerations within the scope of the Bill include:
    - guiding principles for how rongoā interfaces with the Bill (and subsequent regulatory regime)
    - the interface with health legislation (eg, Pae Ora Act 2022, Health Practitioners Competence Assurance Act 2003)
    - the interface with other government work programmes (eg, Te Puni Kōkiri work programme for WAI 262 Te Pae Tawhiti)
    - Māori governance
    - the total or partial exclusion of rongoā from the Therapeutic Products Bill.
18. The work stream will consider activity already underway that is considered a form of regulation, for example, tikanga and kawa. This may also include consideration of other regulatory regimes in place that interface with taonga, such as the Fisheries (Kaimoana Customary Fishing) Regulations 1998.
19. Matters for rongoā that lie outside the scope of the Bill but impact on achieving the protection of rongoā, assuring patient safety and access to the export market may be considered through companion legislation.

Protection of rongoā under Te Tiriti o Waitangi and engagement with Māori

20. Under Te Tiriti o Waitangi (Te Tiriti), the Crown has the obligation of actively protecting rongoā. This protection is in both the benefit and enjoyment of rongoā, as well as the mana to exercise control over it.
21. The degree of protection is dependent on the nature and value of the rongoā to Māori. The value placed on rongoā is a matter for Māori to determine. Additionally, such value is not confined to, or restricted by, traditional uses of rongoā. It includes present day usage, and such potential usage as may be thought appropriate by those having rangatiratanga over rongoā.
22. Further policy considerations of the impact of the Bill on rongoā will require engagement with Māori to inform the development of advice and give effect to the protection of rongoā (as a taonga within the scope of the Bill). It is also important for the rongoā work stream to understand the diverse views of Māori and rongoā.
23. The period for delivering advice to Ministers in a timely manner does not provide ample opportunity to engage broadly with Māori. A targeted engagement approach will enable engagement with various key stakeholders, Māori partners and expert groups within the requested time frames. This will also build the foundations for further engagement to inform future rongoā work.
24. Given the significance of rongoā and the complexity of the issues, we will establish relationships with independent Māori groups to provide expert advice and navigate these complex issues.

25. In addition to receiving feedback from public submissions through the Select Committee process, there is also opportunity for the work stream to build off planned engagement with Māori and key stakeholders, such as the engagement on the strategies pursuant to the Pae Ora Act 2022. The rongoā work stream will also consider previous engagements with Māori and other key stakeholders that raised matters about rongoā.

26. It is anticipated that engagement on rongoā will raise matters that are outside the scope of this work stream. However, these matters will be referred to the appropriate work programmes, for example, feedback on commissioning and service delivery can be provided to ACC and Te Aka Whai Ora to inform their work programmes for rongoā.

Time frames and key deliverables

27. The introduction and first reading of the Bill is anticipated to be in 2022 and remain with the Select Committee for up to six months. This requires the work stream to provide the requested advice to Ministers by April 2023.

Announcement of the Bill

28. Draft communication material has been prepared and attached as **Appendix 1**.

29. Officials will work with your office to continue to develop this material to support the announcement of the rongoā work stream.

30. Final advice will be provided to your office the week of 21 November 2022.

Strategic development of rongoā

31. Te Aka Whai Ora does not support rongoā being covered by the regulations under the Bill and they intend to initiate a complementary work stream that considers wider rongoā issues, including sustainability, commissioning, and cross government coordination.

32. This workstream will engage whānau voice and the rongoā sector to address the wider issues and concerns affecting the viability of rongoā in the health sector.

33. Te Aka Whai Ora will provide a briefing about the scope and intended outcomes of this proposed work in December.

Next steps

34. If requested, the officials will report back to you about the progress of the work stream in February 2023.

35. The final advice to you about the rongoā work stream is due by March/April 2023.

ENDS.

Minister's Notes

Appendix One – Communications material

Media release

New rongoā workstream announced alongside Therapeutic Products Bill

A new workstream has been established within government to consider how rongoā might be protected in legislation. This comes as the Therapeutic Products Bill is introduced to Parliament today, says Associate Minister for Health (Māori) Hon Peeni Henare.

“Under Te Tiriti o Waitangi, the Crown has an obligation to actively protect rongoā Māori. We also have a responsibility to provide all New Zealanders with health products and services that are safe, high-quality, and effective. That is why we have introduced the Therapeutic Products Bill to Parliament today.

"Our vision for the Bill is that it protects, promotes, and improves individual and community wellbeing, and enables the delivery of high-quality services that meet the needs of whānau.

"We recognise the importance of rongoā, and we have been carefully considering how to recognise and protect it as part of our work on the Bill. This has included consulting with Te Kāhui Rongoā, a governance body for rongoā practitioners, Māori clinicians and health providers.

“However, we’ve heard the concerns shared by many across the rongoā Māori sector and by whānau themselves, and so I’ve directed officials to establish a workstream that can help address these issues and create a new pathway forward,” says Minister Henare.

This new rongoā work stream will explore the interface of the Therapeutic Products Bill and rongoā. The group will also explore whether rongoā matters are being addressed through other government work programmes.

“Officials within the workstream will analyse the Therapeutic Products Bill to identify any gaps and opportunities to protect rongoā Māori, assure whānau safety, and ensure access to the export market for practitioners.

“This will present a whole new world of opportunities for both rongoā practitioners and whānau living abroad who have been wanting to access rongoā and other natural health products from Aotearoa,” says Minister Henare.

Now the Bill has been introduced to Parliament, there will be an opportunity for people to have their say at Select Committee. The rongoā workstream will also engage with Māori partners and stakeholders to capture their views.

“Rongoā practitioners, whānau and expert groups will have the opportunity to share their whakaaro through targeted engagement that will be led by the rongoā work stream. This will

ensure their thoughts, experiences and aspirations for rongoā are appropriately reflected in legislation," says Minister Henare.

The rongoā Māori workstream is expected to provide advice to the Minister in April 2023, following targeted engagement over the next few months.

Editor's notes:

The Therapeutic Products Bill aims to provide for acceptable safety, quality, and efficacy of medicines and medical devices, and the safety and quality of natural health products. It will help protect, promote, and improve the health of all New Zealanders.

Regulation will be proportional to the risk of a product to ensure the controls are appropriate. It will also be flexible to ensure products are available in a timely manner.

The new regulatory scheme will align with international best practice to support imports and exports.

It will also be as efficient and cost-effective as possible and uphold the quality of regulation currently carried out by Manatū Hauora, the Ministry of Health.

Natural health products are categorised as a therapeutic product because they are intended to have a therapeutic purpose (ie, they benefit health). They will be regulated as a separate category to medicines and medical devices.

Natural health products include herbal remedies, vitamin and mineral supplements, traditional Chinese medicine, homeopathic remedies, rongoā Māori, and remedies based on animal products, such as deer velvet and fish oil capsules.

Natural health products are not risk-free. They are generally lower risk products than medicines.

While there are similarities between natural health products and therapeutic products, there are also differences. The differences are accounted for in the Bill, along with the different regulations. Natural health products are varied in their risk profiles and the Bill provides for that.

Introducing the Therapeutic Products Bill and announcing a rongoā work stream

Talking points

Setting the scene

- Kei aku rangatira, tēnā rawa atu koutou katoa.
- It is my great pleasure to be here with you today to announce the introduction of the Therapeutic Products Bill to the House and the establishment of a rongoā work stream to better understand how to protect and respect rongoā.

Regulating natural health products in the Bill

- Natural health products (NHPs) are categorised as a therapeutic product because they are intended to have a therapeutic purpose (ie, they benefit health). They will be regulated as a separate category to medicines and medical devices.
- Natural health products include herbal remedies, vitamin and mineral supplements, traditional Chinese medicine, homeopathic remedies, rongoā, and remedies based on animal products, such as deer velvet and fish oil capsules.
- 'Rongoā' is not mentioned or referred to in the Bill. However, because of the inclusion of natural health products in the Bill, rongoā is also captured through definition.
- Rongoā is a Māori way of being, doing and knowing to preserve and heal te taiao (the natural environment) including tāngata (people), to achieve balance and sustain mauri (life-force) and wairua (spirit/soul).

Protection of rongoā under Te Tiriti o Waitangi

- Under Te Tiriti o Waitangi, the Crown has an obligation to actively protect rongoā.
- This protection is in both the benefit and enjoyment of rongoā and the mana for Māori to exercise control over it.
- The rongoā work stream must consider the weighting of the Crown's obligations within the scope of the Bill and the exercise of mana over rongoā by Māori.
- The degree of protection is dependent on the nature and value of rongoā to Māori. The value placed on rongoā is a matter for Māori to determine.
- Additionally, such value is not confined to, or restricted by, traditional uses of rongoā. It includes present day usage, and such potential usage as may be thought appropriate by those having rangatiratanga over rongoā.

What does this mean for rongoā?

- When details for the Bill were first released, I understand many in the rongoā sector had genuine concerns about what the Bill would mean for them and their mahi.

- ‘Rongoā’ is not mentioned or referred to in the Bill. However, because of the inclusion of natural health products in the Bill, rongoā is also captured through definition.

Why have natural health products been included?

- So, why have we included natural health products in the Bill?
- It is important consumers have the information they need to make informed decisions about the products they use and have access to safe and high-quality products.
- Natural health products are not risk-free. They are generally lower risk products than medicines.
- While there are similarities between natural health products and therapeutic products, we know there are also differences.
- The differences are accounted for in the Bill, along with the different regulations. Natural health products are varied in their risk profiles and the Bill provides for that.
- Having a single Bill that includes natural health products will help clarify interfaces with other products in the Bill and other pieces of legislation such as food and cosmetic legislation.
- It will also provide a timely approach to put robust, modern regulation for natural health products in place.
- In developing the new regime, the Ministry of Health is drawing on previous work on natural health products, which entailed several rounds of consultation and significant input from stakeholders.
- The aim of including natural health products in this Bill is to:
    - support consumer safety by helping to provide for natural health products that are safe and of high quality, and that users can make an informed choice about whether to use; and
    - support the natural health products industry and exports by making clear and fair rules and assuring other countries that New Zealand products are safe.
- The regulatory scheme will include:
    - a list of permitted NHP (Natural Health Product) ingredients (to be developed in secondary legislation)
    - a requirement that most NHPs obtain a ‘market authorisation’ before being imported into, supplied in or exported from New Zealand. Applying a risk-proportionate approach, market authorisation of NHPs will be via a self-assessment/declaration pathway. This is a less onerous process than for medicines or medical devices, but still allows the regulator to take appropriate safety action (eg, it can recall specific products when necessary)
    - an authorisation for natural health practitioners to manufacture and supply NHPs to their clients as part of a natural health consultation

- provisions for making 'health benefit claims' which relate to maintaining and promoting health, nutritional supplementation such as vitamin and mineral supplements, and the relief of symptoms. There will also be the potential for the regulator to develop pre-authorised claims for other therapeutic purposes, where those claims are substantiated
- provisions that will support exports and innovation through exemptions to meet requirements in importing countries and improved export certifications
- identified boundaries between this regime and the schemes for foods, cosmetics, medicines and medical devices.

Engagement with Māori

- Further policy considerations of the impact of the Bill on rongoā will require engagement with rongoā practitioners, whānau and expert groups to inform the development of advice and give effect to the protection of rongoā, patient safety and access to the export market within the scope of the Bill.
- The rongoā work stream will also need to engage with government stakeholders, such as ACC (Accident Compensation Corporation), Department of Corrections Ara Poutama Aotearoa, and Te Puni Kōkiri.
- The rongoā work stream will consider previous engagements and existing relationships with Māori and other key stakeholders concerning rongoā and the Therapeutic Products Bill.

Establishing a rongoā work stream

- Nō reira, in addition to introducing the Therapeutics Product Bill to the House today, I would also like to announce the establishment of a rongoā work stream within government to consider how rongoā might be appropriately scheduled in legislation.
- The work stream will focus on three areas.
- Firstly, it will analyse the Bill to identify gaps and opportunities to protect rongoā, assure patient safety, and ensure access to the export market for rongoā practitioners through a Supplementary Order Paper and/or companion legislation.
- Secondly, it will explore the risks and benefits of a Supplementary Order Paper and companion legislation and identify where matters for rongoā are being addressed through other government work programmes.
- Thirdly, and most importantly, the work stream will engage closely with Māori partners and key stakeholders to ensure their thoughts, experiences and aspirations for rongoā are appropriately reflected in the advice of the work stream.

What next?

- When the Bill reaches Select Committee stage there will be an opportunity for people to have their say.
- In addition to the Select Committee process, Māori partners and stakeholders will have the opportunity to share their whakaaro through targeted engagement that will be led by the Ministry of Health.

- I would encourage anyone who is interested in the Bill, especially in the impact on rongoā, to share their whakaaro and views.

Closing

- Heoi anō tāku, if you have any questions or feedback, please refer to the Ministry of Health website.
- If you would like to be involved in the engagement process for the rongoā work stream, please contact the Ministry of Health at maorihealth@health.govt.nz
- I'll make sure to keep you updated as the Bill goes through its various stages in Parliament, and as the rongoā work stream progresses its mahi.
- Nō reira, tēnā koutou, tēnā koutou, tēnā tātou katoa.

Introducing the Therapeutic Products Bill and announcing a rongoā work stream

Frequently Asked Questions

What is the Therapeutic Products Bill?

We are working on a modern, comprehensive, cost-effective regulatory regime for therapeutic products and natural health products in New Zealand, which will replace the Medicines Act 1981.

The Therapeutic Products Bill is the legislation being introduced to Parliament as part of this programme.

The Bill will regulate how products are manufactured, tested, imported, promoted, supplied, and exported. This will include:

- regulating medicines from general sale products like paracetamol to gene, cell and tissue therapies
- medical devices that range from tongue depressors to implantable pacemakers.

Both medical devices and gene, cell and tissue therapies are currently not fully regulated in New Zealand.

What is rongoā?

Rongoā is a Māori way of being, doing and knowing to preserve and heal te taiao (the natural environment), including tāngata (people), to achieve balance and sustain mauri (life-force) and wairua (spirit/soul).

What are therapeutic products?

Therapeutic products (medicines, medical devices and biologics) are used by New Zealanders in their daily lives, and in all parts of the health system.

It is an umbrella term for products that are intended to be used in or on people for a therapeutic purpose to prevent, diagnose, monitor, alleviate, treat, or cure a disease, ailment, defect, or injury. It's also about maintaining and promoting health and vitamin, mineral and other nutritional supplementation.

What are natural health products?

Natural health products support health and wellness and are made from natural ingredients, or synthetic equivalents such as synthetic vitamins.

Natural health products include herbal remedies (in the form of capsules, tonics, and skin creams), vitamin and mineral supplements, traditional Māori remedies, traditional Chinese medicine, homeopathic remedies, and some remedies based on animal products, such as deer velvet and fish oil capsules.

Supplemented foods, such as bread or juice fortified with vitamins and minerals, are not considered natural health products. They are regulated by the Ministry for Primary Industries.

Why are we regulating therapeutic products?

Therapeutic products can harmful, if used inappropriately. Ensuring the benefits of therapeutic products outweigh possible risks of harm to consumers is fundamental to the delivery of safe, high-quality health and disability services.

Why are we regulating natural health products?

It is important that consumers have the information they need to make informed decisions about the products they use and have access to safe and high quality products.

Natural health products are not risk-free. They are generally lower risk products than medicines. Regulations can help ensure:

- products contain safe ingredients at a safe dose
- high quality manufacturing processes are in place to provide assurance that products are not contaminated
- product information is clear on the use and recommended dose
- health claims are based on evidence
- New Zealand producers are in a positive position in the global marketplace.

How are natural health products currently regulated?

Natural health products are regulated in the following ways:

- **Dietary supplements** such as vitamin and mineral tablets are regulated under the Dietary Supplements Regulations 1985. The Food Act 2014 enables the regulations to stay in effect until 1 March 2026, when we intend to have a new regulatory regime well in place. The Ministry for Primary Industries regulates manufacture of dietary supplements, while Medsafe administers the Regulations.
- **Beauty products** that support health and wellbeing through the addition of certain active ingredients are regulated by the Environmental Protection Authority through the Cosmetic Products Group Standard 2017, under the Hazardous Substances and New Organisms Act 2017.
- **Some products derived from animals** are regulated by the Ministry for Primary Industries, under the Animal Products Act 1999. Read more on the Animal Products Act. Legal framework for food safety in New Zealand | NZ Government (mpi.govt.nz)
- **A natural health product** will be a medicine under the Medicines Act 1981 if its main purpose is therapeutic, as defined in Section 4 of the Medicines Act. If a product contains an ingredient listed in Schedule 1 of the Medicines Regulations 1984, this implies the product has a therapeutic purpose.
- **The commercial sale and promotion** of natural health products are also regulated under general consumer legislation (Fair Trading Act 1986 and Consumer Guarantees Act 1993). Read more on business obligations under consumer legislation. Consumer laws | Consumer Protection

Why is rongoā being regulated by the Therapeutic Products Bill?

Under Te Tiriti o Waitangi, the Crown has an obligation to actively protect rongoā. This protection is in both the benefit and enjoyment of rongoā, and the mana for Māori to exercise control over it.

'Rongoā' is not mentioned or referred to in the Bill. However, because of the inclusion of natural health products in the Bill, rongoā is also captured through definition.

Has there been engagement with Māori?

Yes. Key Māori stakeholders have been engaged. Manatū Hauora and Te Aka Whai Ora will continue to engage with key Māori stakeholders and other Māori groups.

What is the rongoā work stream?

A new rongoā work stream has been established to consider how rongoā might be appropriately scheduled in legislation.

The work stream will focus on three areas.

Firstly, it will analyse the Bill to identify gaps and opportunities to protect rongoā, assure patient safety, and ensure access to the export market for rongoā practitioners through a Supplementary Order Paper and/or a companion Bill for rongoā.

Secondly, it will explore the risks and benefits of a Supplementary Order Paper and a companion Bill and identify where matters for rongoā are being addressed through other government work programmes.

Thirdly, and most importantly, the work stream will engage closely with Māori partners and key stakeholders to ensure their thoughts, experiences and aspirations for rongoā are appropriately reflected in the advice of the work stream.

How can people share their views?

When the Bill reaches the Select Committee stage there will be an opportunity for people to have their say.

In addition to the Select Committee process, rongoā practitioners, whānau, Māori partners and stakeholders will also have the opportunity to share their whakaaro through targeted engagement that will be led by the rongoā work stream.

Briefing

Update on the Rongoā Work Stream (Therapeutics Products Bill)

Date due to MO:	N/A	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2023019009
To:	Hon Peeni Henare, Associate Minister Māori Health		
Copy to:	Hon Andrew Little, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

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Cheree Shortland-Nuku	GM, Māori Health Strategy & Policy	s 9(2)(a)

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Update on the Rongoā Work Stream (Therapeutic Products Bill)

Security level:	IN CONFIDENCE	**Date:**	16 January 2023
To:	Hon Peeni Henare, Associate Minister Māori Health		

Purpose of report

1. This briefing provides you with an update on the Rongoā Work Stream led by Manatū Hauora, and related information on the select committee process.

Summary

2. We have planned engagement with key stakeholders, Māori partners and expert groups for January and early February 2023.
3. The Rongoā Work Stream has a shorter time frame for engagement to align with the considerations of the Health Select Committee.
4. To ensure as much feedback as possible, we are using a multi-faceted approach that includes face to face hui, an online webinar and an online survey.

Recommendations

We recommend you:

a) **Note** the engagement approach of the Rongoā Work Stream from January to February 2023 **Yes/No**

c) **Note** that outcomes of the Rongoā Work Stream will be reported to you again in March 2023. **Yes/No**

John Whaanga
Deputy Director-General Māori Health
Te Pou Hauora Māori
Date:

Hon Peeni Henare
Associate Minister Health (Māori)
Date:

Update on the Rongoā Work Stream (Therapeutics Products Bill)

Context

5. Manatū Hauora has previously provided you with advice on the establishment, including the scope, of the Rongoā Work Stream alongside the Therapeutic Products Bill (the Bill) and officials intention to undertake targeted engagement with expert groups and Māori organisations [HR2022017070 refers].

6. Since we last briefed you the Health Select Committee's has shortened its timeframes for consideration of the Therapeutics Products Bill.

Current progress of the Rongoā Work Stream

Engagement with Māori

Health Select Committee shortened timeframes

7. We had previously advised before the Bill was introduced, that planned targeted engagement would happen from February through to March 2023.

8. After the first reading of the Therapeutics Products Bill (the Bill) on 14 December 2022, the Bill was referred to the Health Select Committee (the Committee). The Committee has decided for public submissions to be open until 15 February 2023. As of 9 January 2023, no submissions had been received.

9. Manatū Hauora, as advisors to the Committee, will be providing information on the draft legislation and issues associated with its implementation; commenting on evidence received by the Committee; producing a departmental report on submissions and making recommendations for amendments. The Committee intends to report back to the House of Representatives on 14 June 2022.

10. Manatū Hauora, as an advisor to the Committee, must maintain the confidential nature of committee proceedings. On this basis, we are not planning to engage as part of the Rongoā Work Stream after the closing of public submissions to ensure there is no risks, either real and/or perceived, of undermining the considerations of the Committee.

Planned engagements

11. With the shorter than expected select committee process, we will be using a multi-faceted approach (face to face, online and survey) to maximise the stakeholder reach of the engagement.

12. An online zoom webinar, hosted by the Deputy Director-General, Māori Health, is taking place on January 17, with invitations being sent to all providers with rongoā contracts (with Te Aka Whai Ora) and rongoā practitioners registered with ACC. For those not able to attend the webinar, an online survey will be publicly available from January till February 2023.

13. A hui is planned for January 25 and 26 with Te Kāhui Rongoā Trust. This hui is primarily to uphold the relational agreement with Manatū Hauora, as well as to build relationships

with the newly appointed trustees of Te Kāhui Rongoā. We have been invited to this hui to hear from this rōpū on the Therapeutics Products Bill.

14. We are also in discussions to organise a hui with the Aotearoa Rongoaa Maaori Collective, s 9(2)(a) The Collective's mission is to empower, enrich and inspire the tangata whenua to heal their whaanau with regular Rongoaa Maaori waananga. The Collective strongly opposes the Therapeutic Products Bill and is concerned that tangata whenua have not been consulted. The Aotearoa Rongoaa Maaori Collective have a petition before the House (Prevent Rongoaa Maaori being monitored under the Therapeutic Products Bill).

15. We have received an invitation from a group of rongoā practitioners based in Northland to discuss their concerns and feedback on the Therapeutic Products Bill and rongoā. This hui is intended to be held at Parawhenua marae, Ōhaeawai, on January 23.

16. Further engagements to take place include a focus group with academics and researchers, as well as convening an officials group.

17. We have continued to work with Te Aka Whai Ora and have included them in the planning of the engagement with Māori. Te Aka Whai Ora will also be attending all engagements planned by Manatū Hauora to observe and respond to any questions or discussions that fall outside the scope of the Manatū Hauora-led part of the Rongoā Work Stream.

Next steps

18. We will report back to you on the final outcomes and advice from the planned engagement in March 2023.

ENDS.

Minister's Notes

Briefing

Recognising rongoā and Te Tīriti o Waitangi in the Therapeutic Products Bill

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To:	Hon. Dr Ayesha Verrall, Minister of Health Hon. Peeni Henare, Associate Minister of Health (Māori Health)		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Recognising rongoā and Te Tīriti o Waitangi in the Therapeutic Products Bill

Security level:	IN CONFIDENCE	**Date:**	24 March 2023
To:	Hon. Dr Ayesha Verrall, Minister of Health Hon. Peeni Henare, Associate Minister of Health (Māori Health)		

Purpose of report

1. This is a report back on opportunities to appropriately recognise and protect rongoā in the Therapeutic Products Bill (the Bill).

2. This report discloses all relevant information and implications.

Summary

3. As part of the rongoā workstream commissioned in November 2022 [HR 20220828 refers], Manatū Hauora, the Ministry of Health (the Ministry), led targeted engagement with Māori groups and experts which has been captured in a draft summary report [**Appendix 4**].

4. Insights from that engagement have informed the development of options to give effect to the protection of rongoā, assurance of patient safety and ensuring access to the export markets for rongoā practitioners, within the scope of the Bill.

5. A theme that strongly came through the engagement is rongoā is taonga tuku iho to Māori and under Article 2 of Te Tiriti o Waitangi (Te Tiriti) Māori are guaranteed the undisturbed possession of taonga, including rongoā.

6. Recognising that, officials propose 4 options to determine a pathway forward for rongoā and the Bill:

   Option 1 – revise the current Bill to exclude rongoā entirely

   Option 2 – revise the Bill to exclude rongoā from the operative regulatory provisions of the Bill, however, the Bill will continue to acknowledge the Crown's responsibilities under Article Two of Te Tiriti in relation to rongoā

   Option 3 – revise the Bill for partial inclusion of rongoā in the Bill, where rongoā is recognised under Article 2 of Te Tiriti which requires a definition, and with management of rongoā defined in a holistic way, to be led by Māori

   Option 4 – inclusion of rongoā in the Bill with Māori working in partnership with the Regulator as part of secondary legislation, yet to be developed. This retains the status quo in the current Bill, with rongoā products captured as one type of Natural Health

Products (NPH) but legislating for greater Māori partnership in the development of secondary legislation (e.g., around product standards and recognised NHP ingredients).

7. Because of how the NHP provisions in the Bill are intended to operate, exempting rongoā (Options 1, 2 or 3) requires *adding* language to the Bill rather than removing existing provisions. Importantly, this means that all options (except, potentially, Option 4) require the Bill to be revised– at a minimum – to include explicit definitions for the following terms: 'rongoā' and 'rongoā practitioner'

8. The Bill will also need to contain explicit language on what activities are exempted from the 2 chief regulatory principles in the Bill:

   a. that all NHPs imported into, supplied in, and exported from New Zealand need to be authorised[1]

   b. that manufacturing and exporting NHPs in the course of a business or undertaking requires a licence from the Regulator or for the activity to be otherwise authorised.[2]

9. Defining these terms in the Bill, and potentially setting boundaries around the scope of the exemption (Option 3 and, potentially, 4), will be sensitive for Māori. However, to the extent possible, definitions could ground these concepts in te ao Māori and defer to existing and evolving mātauranga, tikanga and kawa as it applies to rongoā.

10. It is important for the Bill to provide for an arbiter, to determine whether a person or product meets the definition of rongoā, with the ability to delegate to a committee, or to seek advice from specialist persons to make their determination.

11. Without this, NHP provisions may be unenforceable, as anyone could claim they meet the definition. The Regulator is unlikely to be qualified to make this decision, limiting the ability for action to be taken against those falsely claiming to be rongoā practitioners to avoid regulation.

12. Officials consider the manner that Te Tiriti is included in the Bill as dependent upon the preferred option. For Option 1, where rongoā is excluded from the Bill, a clause for Te Tiriti is not required. For Option 2, 3 or 4, officials advise inclusion of either a general and/or descriptive Te Tiriti clause.

13. Implementation of the preferred option may occur either by including recommendations in the Departmental Report, via a Supplementary Order paper or developing separate legislation.

14. There are significant time pressures on providing advice and implementing all options proposed. All policy decisions needed for the proposed options must be settled before the return of the Departmental Report on 6 April. The Bill is intended to be returned from Select Committee to Parliament on14 June. After this, any changes will need to be via SOP.

[1] Authorisation can be via the Bill directly (e.g., Part 3 of the Bill authorises many activities)

[2] For example, under an explicit provision in the Bill (e.g., the NHP practitioner exemption in clause 112), or via regulations, or under a licence or permit issued by the Regulator.

Recommendations

We recommend you:

a) **Note** the 4 proposed options for rongoā in the Bill and that Options 1, 2 and 3 would require the Bill to be revised to include, at a minimum, explicit definitions for rongoā and rongoā practitioner. **Noted**

b) **Agree** that Manatū Hauora begin drafting advice to implement your preferred option:

i. Option 1 (exclusion) – excluding rongoā from the Bill. **Yes/No**

ii. Option 2 (partial exclusion) – excluding rongoā from the Bill with recognition of rongoā under Article 2 of Te Tiriti o Waitangi **Yes/No**

iii. Option 3 (partial inclusion) – recognition of rongoā under Article 2 of Te Tiriti o Waitangi, and the devolvement of authority to Māori as part of secondary legislation development, for the management of rongoā **Yes/No**

iv. Option 4 (inclusion) – the status quo, with strengthened clauses for the Regulator's responsibilities to Māori, mātauranga and rongoā. Māori are included in the regulatory regime as: **Yes/No**

1. In the Regulator as an office **Yes/No**
2. Another statutory office **Yes/No**
3. An employee of the Regulator **Yes/No**
4. A leadership role in the branded business unit **Yes/No**

c) **Note** there are 3 options for the inclusion of Te Tiriti o Waitangi but are only relevant to Options 2, 3 and 4. **Noted**

d) **Agree** that Manatū Hauora begin drafting advice to implement your preferred option:

i. *Descriptive Te Tiriti clause* - providing detailed guidance on implementing Te Tiriti within the regulatory regime **Yes/No**

ii. *Operative Te Tiriti clause* - providing a high-level, wide reaching commitment to Te Tiriti within the regulatory regime **Yes/No**

iii. *A hybrid descriptive and operative Te Tiriti clause* - providing a high-level, wide reaching commitment to Te Tiriti and detailed guidance for implementing Te Tiriti in the regulatory regime. **Yes/No**

e) **Note** there are significant time pressures to implement all proposed options. All policy decisions needed for the proposed options must be settled before the return of the Departmental Report on 6 April. The Bill is intended to be returned from Select Committee to Parliament on14 June. After this, any changes will need to be via SOP. **Noted**

f) **Note** Manatū Hauora's intention to share the summary report of engagement with participants and publish it on the Ministry's website in the next few weeks. **Noted**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date:

Hon Dr Ayesha Verrall
Minister of Health
Date:

John Whaanga
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Te Pou Hauora Māori
Date:

Hon Peeni Henare
Associate Minister of Health (Māori Health)
Date:

Recognising rongoā and Te Tīriti o Waitangi in the Therapeutic Products Bill

Context

1. The previous Minister for Health requested advice be provided to Minister Henare about establishing a workstream that specifically considers [HR 20220828 refers, **Appendix 1**]:
   a. how rongoā might be appropriately scheduled in legislation for protection,
   b. the assurance of safety for rongoā practitioners providing direct services to patients, and
   c. protecting export market access (alongside those providing therapeutics and products with health benefit claims).
2. Further analysis of the scope of the rongoā workstream is set out in **Appendix 2**.
3. Advice was provided to the previous Minister for Health and Minister Henare on 18 November 2022. It covered establishment of the rongoā workstream, its scope, and approach to engagement with Māori [HR 2022017070 refers, **Appendix 3**].
4. Between 17 January and 13 February 2023, 2 online hui, 2 in-person hui and an online survey were completed as part of the rongoā workstream. A draft summary report of engagement is attached as **Appendix 4**[3].
5. These engagements were to enable the rongoā workstream to understand the concerns and thoughts within the rongoā sector on the implications of the Bill for rongoā. The insights gathered from these engagements have been used to inform the advice provided in this briefing.
6. The rongoā workstream has also engaged with other agencies to understand their work programmes for rongoā. An overview of other Government work programmes indicates rongoā has a wide scope and the rongoā workstream directly impacts upon other government work programmes that include aspects of tino rangatiratanga and health services. Further detail is discussed in **Appendix 5**.
7. This paper sets out 4 options for recognising rongoā in the Bill, followed by Te Tīriti options (related to how rongoā is either excluded or included in the Bill).

Options for rongoā and the Therapeutic Products Bill

8. 4 options have been developed to determine which pathway for rongoā and the Bill is most appropriate. A summary of the key areas and options is attached as **Appendix 6**.
9. These options have been developed across the 3 areas of the rongoā workstream scope and analysed against Te Tiriti principles outlined in Wai 2575 Hauora.

[3] Publication of the summary report is still being processed by the Ministry. However, a draft version has been received by the Ministry and is provided as Appendix 4.

10. Understanding the breadth and depth of rongoā was essential to developing the proposed options to ensure the interface between rongoā and the Bill is fully recognised. An analysis of rongoā was undertaken by the rongoā workstream [**Appendix 7**].

11. We also undertook analysis of key areas of the current version of the Bill to ensure the interfaces between rongoā and the Bill is fully recognised. This is attached as **Appendix 8**.

Option 1 – Exclude rongoā from the Bill

12. This option proposes rongoā is explicitly excluded from the Bill and subsequent regulatory regime. This means the Regulator will not have a legislative basis to develop rules or intervene via regulatory measures (e.g., recall orders, prohibited product orders or product moratorium orders) for rongoā or matters pertaining to rongoā, regardless of perceived or real safety issues. This option provides strong protection of rongoā from regulation by the Crown.

13. Exclusion of rongoā at this time and in this Bill may also present the opportunity for stand-alone legislation to be developed to address matters for rongoā in the wider health system, that are not confined to therapeutic products. This may also include matters for rongoā across Government.

14. This option requires rongoā to be defined so there is clarity on which people and products are in and out of scope for the Regulator. As highlighted by the targeted engagement, there is significant mistrust of the Crown by Māori, and Māori may not share the required knowledge to provide an adequate definition of rongoā for the purpose of excluding it from the regulatory regime.

15. Defining rongoā will require Māori to provide expertise and knowledge of rongoā. This could be achieved through establishing a Ministerial committee, or advisory group, or extensive engagement with Māori. However, there is no time for engagement with Māori before the Bill is intended to pass through the House.

16. Defining rongoā may occur during the development of secondary legislation by embedding a process for doing so in the Bill. However, this may be unacceptable practice to exclude a group and leave the definition to be developed through secondary legislation

17. A Ministerial committee or advisory group could act as an arbiter for rongoā.

Protection of rongoā

18. This option enables Māori to determine the management of rongoā and to assert their mana over this taonga (both domestically and internationally). As such, while this option provides strong protection for rongoā from the Crown, it does not promote opportunities for Māori nor protect mātauranga rongoā from use by other individuals and businesses.

19. There is also a continued risk that anyone could claim to be a rongoā practitioner or to be making rongoā, to be excluded from accountability and liability under the regulatory regime.

20. Additionally, this option may result in a lack of equitable funding and resourcing of Māori to achieve the protection of rongoā.

Assurance of patient safety

21. This option does not provide for recognition of the existence or value of mātauranga, tikanga and kawa relevant to rongoā. This may hinder the assurance of patient safety as Māori will not be resourced to ensure tikanga and kawa are consistently adhered to throughout their tribal territories.

22. If significant harm is caused and public safety compromised by rongoā products, the Regulator would need to intervene. However, the Regulator may not have the required knowledge and skill of mātauranga Māori to make informed, appropriate decisions on rongoā, regardless of the current requirement of the Regulator to consider Te Tiriti, mātauranga and Māori perspectives.

23. Full exclusion of rongoā may extend to the ability for the Minister to 'prohibit' a product outright, meaning there will be no available tool to respond to safety risks, such as prohibition.[4]

24. If you did wish to remove even this power, the only mechanism for accountability for harm would likely be provisions in the Crimes Act 1961 relating to poisoning, disabling or other crimes against the person.

Ensuring access to the export markets for rongoā practitioners

25. Māori will be able to express tino rangatiratanga within the domestic context only. Rongoā practitioners would still be required to meet the standards of the country they are exporting to and obtain export certificates from the Ministry of Primary Industries.

26. The full exclusion of rongoā will limit the ability for the Regulator to create an authorisation pathway for NHPs made by rongoā practitioners where those practitioners voluntarily wish to obtain an authorisation for their product.

27. Reasons for a practitioner to seek authorisation might include gaining access to export markets or securing funding from commercial lenders or business partners, that require a product to have New Zealand authorisation.

28. Because ingredients used in some rongoā products (e.g., kawakawa and manuka honey) would remain as 'recognised NHP products', other businesses and individuals would be able to make and market NHPs containing those ingredients. These individuals could also, potentially, be able to substantiate any health benefit claims for those products using mātauranga Māori.

29. Clause 237 refers to the ability for the Regulator to issue 'Official Statements' for export.[5] These are increasingly demanded by importing countries. The Regulator will have no

[4] Clause 33 provides that 'The Minister must not recommend that regulations be made [to prohibit a product] unless satisfied on reasonable grounds that:

a) the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness; and

b) the risk cannot be adequately managed by the exercise of the Regulator's powers under this Act.

[5] For example, an Office Statement might include a certification from the Regulator that:

a) that the product has a market authorisation of a specified kind

b) that the product meets the product standards or export standards (or both) that apply to it

c) that any other criteria, standards, or requirements applying to the product under this Act are met or complied with.

requirement to support rongoā practitioners accessing the export market with a NZ Government imprimatur or official endorsement. This is due to the Regulator not being able to hold rongoā practitioners accountable and not being able to be certain that the rongoā product will meet the standards of the importing country. This significantly restricts options for rongoā practitioners accessing the export market.

30. It would be difficult for the Regulator to develop 'product' or 'export standards' for rongoā if it is excluded entirely from the Bill.

Option 2 – Partial exclusion from the Bill

31. This builds on the option of exclusion but provides additional protections by including an acknowledgment of rongoā by the Crown, however, this option faces many of the same issues as option 1.

Protection of rongoā

32. Māori can maintain their own rangatiratanga (authority) over rongoā and the Bill may acknowledge the Crown's responsibilities under Article 2 of Te Tiriti in relation to rongoā. Partnership will not be explicit within the Bill but may be developed through government agency policy.

33. Although partial exclusion prevents the unjustified interference in rongoā, it may also restrict the Crown's obligations and ability to actively protect rongoā.

34. Equity will not be implemented through the Bill, however, this could be achieved through the development of government agency policy. Options to protect rongoā within the Bill and subsequent regulatory regime are limited except for protection from the Crown. Each of these being subject to the request of Māori.

Assurance of patient safety

35. Acknowledging rongoā is a taonga to Māori may indirectly recognise tikanga and kawa in the Bill as valid and sufficient systems of safety managed by Māori. However, this will be reliant on interpretation of the law by the Courts.

36. The Crown may have a limited role in the active protection of Māori or patient interests, and options for the assurance of patient safety would be determined by Māori, outside the Bill and regulatory regime.

Ensuring access to the export markets for rongoā practitioners

37. Acknowledging rongoā is a taonga, Māori will be recognised as kaitiaki over rongoā and will be able to express tino rangatiratanga domestically. Rongoā practitioners would still be required to meet the standards of the country they are exporting to and obtain export certificates from MPI.

38. As Māori will be recognised as kaitiaki, there may be partnership between Māori and the Regulator as requested by Māori and occurring over time.

39. No New Zealand Government imprimatur will be provided as there will be no mechanism for involvement of the Regulator.

40. Rongoā practitioners may have difficulty accessing the export market as there will be limited equitable prioritisation of rongoā. Options for access to the export market will be

significantly restricted for rongoā practitioners, as per Option 1. This could be mitigated through government agency policy but only as far as requested by Māori.

Option 3 – Partial inclusion of rongoā in the Bill

41. This option proposes rongoā is recognised in the Bill and the Crown's obligations under Article 2 of Te Tiriti. Management of rongoā is also devolved to Māori. This model is designed from existing regulatory regimes that interface with taonga.

Protection of rongoā

42. Partial inclusion in the Bill requires explicit acknowledgment of rongoā and the Crown's obligations under Article 2 of Te Tiriti. This requires the Bill to devolve the management of rongoā (issuing of licences and permits) to Māori.

43. Māori may also apply their own criteria for the issuing of licences and permits through the development of secondary legislation. For example, fit and proper persons must satisfy criteria such as a certain number of years of experience, demonstrated sustainable harvesting of taonga species, and ongoing mentorship or tutorage.

44. This option would require the Regulator (and branded business unit) to possess a minimum level of capability to ensure meaningful engagement with Māori when matters for rongoā are raised to the Regulator by Māori. Current mechanisms in the Bill pertaining to the requirements of the Regulator can be strengthened. This includes the compulsory requirement to establish a Ministerial committee for mātauranga and rongoā.

Assurance of patient safety

45. Tikanga and kawa are recognised in the Bill as valid and sufficient systems of rules and laws that ensure safety and is managed by Māori. Māori are resourced by the Crown partner to implement and manage their mātauranga, tikanga and kawa for their tribal territory.

46. Resourcing Māori to manage their own affairs accounts for the plurality of mātauranga, tikanga and kawa amongst Māori. However, Māori will require equitable funding and resourcing to manage their own tikanga and kawa.

Ensuring access to the export markets for rongoā practitioners

47. Māori would be able to express tino rangatiratanga at a localised level. However, when rongoā practitioners enter the international market, they will be subject to conditions set out by MPI as well as the rules and laws of the importing country.

48. Māori will need to be supported by the Crown partner to access the export market to meet the importing country rules and laws as well as any other rules and laws imposed domestically. This may require equitable funding and resourcing to support rongoā practitioners and additional funding to that of the Regulator.

49. When the importing country requires New Zealand Government assurance of rongoā, New Zealand Government imprimatur could be provided based on the recognition of mātauranga, tikanga and kawa by the Regulator. Māori may lead the development of options for accessing export markets through co-designed pathways with the Regulator.

Option 4 – Inclusion of rongoā in the Bill

50. This option proposes the status quo - rongoā is included in the scope of the Bill and also legislates partnering with Māori.

Protection of rongoā

51. This option requires Māori with expert skill and knowledge of mātauranga to be included alongside the Regulator and as part of the branded business unit. This could be achieved through 4 pathways:

    a. Inclusion with the Regulator as an office, or

    b. Another statutory office, or

    c. An employee of the Regulator, or

    d. A leadership role in the branded business unit.

52. There are varying limitations of each pathway on Māori to operate within the regulatory regime and to have influence on decisions made by the Regulator for rongoā, including the incorporation of tikanga and kawa. This could be mitigated by explicitly providing for Māori to be empowered to make decisions about rongoā. However, these decisions would have to align with and be in scope of the regulatory framework, which may be complex, as tikanga and kawa vary across Aotearoa.

Assurance of patient safety

53. Tikanga and kawa are recognised in the Bill as valid systems of safety.

54. There is a risk of the Regulator interference, unless Māori are empowered to make decisions regarding rongoā.

55. There is a risk of tikanga and kawa being limited and universalised to ensure the regulatory system is able operate with consistent decision making.

Ensuring access to the export markets for rongoā practitioners

56. Māori will be able to express tino rangatiratanga in certain situations. This would be dependent on the circumstances, for example, when the importing country requires assurance of rongoā from the New Zealand Government or when the importing country has rules and laws in place.

57. Rongoā practitioners will be supported by the Crown partner to access the export market. This could be through equitable funding and resourcing. New Zealand Government imprimatur would be provided, regardless of the recognition of mātauranga, tikanga and kawa.

58. The Regulator will lead the development of options for accessing export markets through co-designed pathways with rongoā practitioners.

Options for Te Tiriti o Waitangi in the Bill

59. Analysis of Te Tiriti jurisprudence has been undertaken to inform the options proposed [**Appendix 9**]. The status quo of the Bill is the principles of Te Tiriti woven throughout the Bill.

60. It is important to note, the inclusion of a Te Tiriti clause here is specific for rongoā and is only required if rongoā is partially or entirely included in the Bill. There may be a case for the inclusion of a Te Tiriti clause for broader Māori health reasons. However, this is outside the scope of the rongoā workstream.

Operative clause

61. An operative clause would give high level guidance on considering or giving effect to Te Tīriti. It would have broad applicability for most issues for rongoā and makes it easier to consider Te Tiriti issues in any context relevant to rongoā.

62. Because the Regulator will have wide powers and functions, an operative clause is most likely to capture these. Unless developed in previous policy, the Regulator will have minimal guidance on implementing Te Tiriti, as previous legislation for the regulatory regime (Medicines Act 1981) was silent on this.

63. Officials previously provided advice on including a range of mechanisms to weave Te Tīriti throughout the Bill (such as consultation on secondary legislation with Māori and establishing a Māori Advisory Committee to advise the Regulator) [HR 20220828 refers, **Appendix 1**].

Descriptive clause

64. A descriptive clause provides more clarity regarding specific obligations for the Crown to give effect to the principles of Te Tiriti by referencing these throughout legislation. The Pae Ora (Healthy Futures) Act 2022 is an example of a descriptive Te Tiriti clause in legislation.

65. If the preferred option is partial inclusion or inclusion of rongoā in the Bill, Officials recommend at a minimum a descriptive clause that sets out how the Crown intends to meet its Te Tīriti obligations for rongoā. This will give clarity to the Regulator on how to give effect to Te Tiriti.

66. A potential risk with a descriptive clause is it may be designed relevant only to the current context. Meaning longevity of applying Te Tiriti may be compromised and become outdated in the future.

Hybrid operative and descriptive clause

67. Inclusion of both an operative and descriptive clause in the Bill allows for the benefits of both an operative and descriptive clause whilst countering the shortcomings of both approaches to Te Tiriti clauses.

68. The operative clause will provide for flexibility and adaptability to endure, while the descriptive clause will provide detailed guidance to facilitate implementation of the Bill and regulatory regime that meets the needs of Māori in the current context.

Ways to implement preferred option for rongoā

69. There are 3 methods that can be used to implement the preferred option:

    a. Supplementary order paper; or

    b. Stand-alone legislation; or

c. Included as a recommendation in Departmental Report to the Health Committee, assuming there are submissions on the inclusion of a Te Tiriti clause.

70. Implementing your preferred option through the Departmental Report was not include in the original scope of the rongoā workstream.

71. Subject to your preferred option, officials will provide further advice on how to implement the option.

72. There are time pressures for implementing all options. There is no time to further engage with Māori and the Departmental Report is currently due to Select Committee on 6 April. All policy decisions needed for this proposed way of implementation must be settled before then.

73. The Bill is intended to be returned from Select Committee to Parliament on14 June. After this, any changes will need to be via SOP.

74. The development of stand-alone legislation for rongoā will need to be developed before the regulatory regime comes into force, otherwise rongoā will be captured as a NHP by default.

75. Officials note that the Bill has priority 4 classification.

Next steps

76. The Ministers and their offices meet to discuss the proposed options outlined in this briefing.

77. The Ministry will await your direction on the preferred option to begin work on the consequent processes.

ENDS.

Minister's Notes

Appendix 2 – Scope of rongoā workstream

The scope of the rongoā workstream was set at the time by Minister Little when he requested for the establishment of the rongoā workstream. This scope was:

1. the protection of rongoā,
2. the assurance of patient safety, and
3. ensuring access to the export market for rongoā practitioners.

Matters for rongoā, and rongoā itself, is much vaster than the scope set out for the rongoā workstream. Additionally, many matters for rongoā are intertwined and root causes of these matters go outside the scope of health and the rongoā workstream.

This section gives detail analysis of the interface of the rongoā workstream with other government work programmes section of this paper.

Area 1: Understanding the scope of the rongoā workstream – protection of rongoā

Due to the breadth and depth of rongoā, it is difficult to protect rongoā without taking a wider approach that recognise all aspects of rongoā practice. Additionally, rongoā is specific to each whānau, hapū and iwi with its own whakapapa, and associated mātauranga, tikanga and kawa.

It is proposed that the protection of rongoā can be defined according to the cause of harm (causation). Understanding the main causes of harm to rongoā provides a tangible and applicable approach to protecting rongoā.

The three main causes of harm to rongoā have been identified as:

1. the Crown and its Government
2. exploitation by 'bad agents,' and
3. practitioner incompetence.

The Crown and its Government

Wai 2575 and the Stage One report Hauora highlighted the continued failing of the Crown and health system to Māori and the consequent breaches of Te Tiriti. Beyond the health system, the Waitangi Tribunal, through numerous inquiries and reports, has highlighted the failings of the Crown and its systems, in general, for Māori. This has deeply embedded a significant mistrust of the Crown for Māori.

The decades of continued failure by the Crown demonstrates the incompetence of the Crown to protect Māori and their interests across various matters. It also emphasises the Crown's inability to possess the requisite competencies to adequately engage with, and respond to, matters of significant importance to Māori. Furthermore, the deeply embedded mistrust of the Crown by Māori prevents Māori from sharing mātauranga for rongoā with the Crown and its agents given the historic oppression of rongoā by the Crown.

There has been active policies and systems of colonisation and assimilation put in place by the Crown and its Government to disempower Māori in many shapes and forms since

Parliament was first formed in Aotearoa New Zealand. For rongoā, this is commonly referenced with the Tohunga Suppression Act 1907 which intended to stop people using traditional Māori healing practices that had a supernatural or spiritual element. Although only nine convictions were obtained under this Act and was eventually repealed in 1962, the effect of this Act is still remembered and experienced by Māori today.

The Medicines Act 1981 has also placed significant restrictions on rongoā through applying a legal framework on rongoā that restricts the scope of rongoā and rongoā practice. Policies implemented by the Ministry of Health for the funding of rongoā services is also seen as restricting the scope of rongoā.

Exploitation by 'bad agents'

Like many other professions, there are ill-intention people (bad agents) that see the potential of exploiting rongoā. This can be through various forms, such as: misrepresentation of rongoā in pursuit of profit; restricting access to, and over consumption of, natural resources and the design of tools used in rongoā through legal mechanisms such as intellectual property (copyright and patent); and misuse of rongoā.

Exploitation can lead to various bad outcomes such as mistrust of rongoā, inadequate quality rongoā practice and products, limited natural resources, and misapplication of mātauranga.

Practitioner incompetence

The poor or incompetent capabilities of practitioners can cause serious harm to the validity of rongoā and its reputation within New Zealand society and internationally. This can be due to several reasons, such as insufficient experience and learning and lack of guidance and mentorship. Rongoā is a lifetime of learning and working within whānau, hapū, iwi and hapori (communities).

Ao Mai te Rā – the anti-racism programme led by Manatū Hauora, alongside the reports of the Human Rights Commission Ki te whaiao, ki te ao Mārama and Maranga mai, highlights the existence of racism within our health system and wider system. This amplifies the mistrust and misconceptions of rongoā which is exacerbated by the poor or incompetent abilities of practitioners.

Area 2: Assurance of patient safety

A key principle of the Bill is to ensure patient safety. This has led to a common misconception of rongoā is that it is unsafe. There is no evidence available to show this is the case. Within many professions, if not all, there is a risk to patient safety if the professional delivering the healthcare is incompetent and does not possess the required skills and knowledge.

The breadth and depth of rongoā requires the practitioner to have an extremely broad and diverse skill set and knowledge base to ensure the delivery of rongoā to the patient is safe.

This skill and knowledge base includes, but is not limited to, cultivation, harvest, preparation, manufacture, production of [medicine], as well as, determining aetiology, diagnosis, treatment/therapy, and prognosis of [illness/disease].

If you were to compare a rongoā practitioner to the Western model of health care worker/practitioner - a rongoā practitioner could be considered a pharmaceutical scientist, pharmacist, doctor, nurse, dentist, optometrist, therapist, physiotherapist, psychologist/psychiatrist, social worker, and many other health professions.

Rongoā is unlike any other profession in the health system and is unique to Aotearoa New Zealand.

Many products and tools used in health care are inherently dangerous and can cause significant harm and even death if they are used by someone who lacks the required skills and knowledge. For example, if a person who is untrained as a surgeon were to be given a scalpel to use in a surgical operation, the consequences could be life-threatening. . Furthermore, surgeons do not create the tools and medicines they use in their practice – rongoā practitioners generally do.

The safety of the patient in rongoā is directly related to the competency of the practitioner. Patient safety is best assured through practitioner competency as rongoā spans across many disciplines.

Area 3: Access to the export market

From as early as the arrival of Europeans in New Zealand, Māori have always demonstrated trade and entrepreneurial practical intelligence- supplying fish to new arrivals in the late 1700s, to when Māori visited Australia for commercial trade in the early 1800s.

From the 1820s Māori began exporting firstly flax, then wheat, oats, and potatoes. During the 20th century, while forestry and farming become our primary sector, Māori businesses expanded into honey and, more recently, hemp and rongoā products.

Engagement with Māori highlighted that many rongoā practitioners do not access the export markets, yet there is a growing number of Māori businesses. A report published by Te Puni Kōkiri identified 23,300 economically significant Māori-owned businesses and 38,200 Māori sole traders (Māori earning self-employed income). Between 2010 and 2020, the total indicative margin (total revenue from sales minus purchases and expenses, not including salaries and wages) for all Māori-owned businesses almost doubled from $3.7 billion to $7.3 billion. Over the same period, the total indicative margin for all non-Māori owned businesses increased by 75%.

The current version of the Bill allows for rongoā practitioners to export rongoā products in the course of a consultation. However, market authorisation is required for rongoā products exported in the course of business.

Domestic obligations for export

All exports need to be declared. Often, Ministry for Primary Industries (MPI) will also need to verify the goods meet the requirements of the country they are being exported to. To declare goods, documentation needs to be lodged for export entry clearance with Customs.

Depending on the type of product and the requirements of the importing country, assurance may need to be obtained – such as export certificates – from MPI that the

product meets biosecurity requirements. Some goods may need cleaning or treatment to make sure they are free from pests and diseases. Exports will not be cleared to leave New Zealand until Customs has verified the details of the export entry clearance and checked with MPI.

International reputation of Aotearoa New Zealand

New Zealand Government imprimatur or official endorsement provides creditability to help open doors for companies in markets around the world. This is particularly useful if the country importing does not have regulation or standards for the product being imported from New Zealand and relies on the New Zealand Government to provide assurance of the product.

Appendix 5 – Overview of other Government work programmes

Rongoā interfaces with various facets of government agencies as matters for rongoā are vast and cover many distinct aspects. Root causes of these matters often lay outside the health system and are already being addressed by other government agencies. The rongoā workstream has explored these interfaces to ensure the Bill and options developed in this advice does not encroach on the other government agencies' work programmes.

Below is a summary of each government agency work programme that includes (directly or indirectly) rongoā. Those included are: Te Aka Whai Ora, ACC, Ara Poutama Aoteoroa, Te Puni Kōkiri, Ministry for the Environment, Ministry of Primary Industry, Ministry of Business, Innovation and Employment.

Te Aka Whai Ora

Te Aka Whai Ora's rongoā Māori work programme has three key workstreams intended to:surface Māori priorities and aspirations for preserving, protecting, and supporting rongoā Māori; understand the mechanisms that are needed within the health system to support those Māori priorities and aspirations for the sustainability and viability of these important services; and identify the funding paths and other resources needed for a sustainable rongoā Māori sector.

Accident Compensation Corporation (ACC)

ACC are seeking to deliver equity and options for whānau Māori by improving access to rongoā Māori, as culturally appropriate traditional healing. ACC's rongoā Māori service is a programme by Māori, with Māori, for Māori and people of all ethnicities which incorporates a holistic, kaupapa Māori approach to wellbeing.

Since mid-2020, ACC has held a policy position of supporting rongoā Māori as a rehabilitation option for injured claimants, to the extent permitted by the Accident Compensation legislative framework. The intention of this policy position is to help improve Māori access, experience, and outcomes from the Accident Compensation Scheme by providing rehabilitation pathways based in mātauranga Māori and uphold the Te Tiriti principle of options.

Most ACC-funded rongoā is currently purchased on a non-contracted basis. ACC is undertaking further policy work to enable a shift to contracted services over the short- to medium-term.

Ara Poutama Aotearoa Department of Corrections

Ara Poutama Aotearoa is in the process of transforming our current health services as part of Hokai Rangi 2.4 Develop a Kaupapa Māori Health Service inclusive of rongoā Māori. Ara Poutama Aotearoa have undertaken an in-depth scope of current rongoā activities within sites as well as engaging with partners and stakeholders who are delivering rongoā Māori e.g., ACC.

Additionally, they are exploring whole of workforce readiness and the wider Department capacity to deliver rongoā. The operationalising of rongoā will require an understanding of how we do this both from a health and custodial context.

1. Current Work Activity:
   a) Establishment of Kaitiaki Roopū
   b) Engaging key relationships with whānau, hapū and Iwi
   c) Building on existing relationships with rongoā Māori Practitioners
   d) New National Rongoā Māori Manager position advertised
   e) Socialising and building knowledge of rongoā Māori
   f) Understanding site readiness and practitioner readiness
2. Areas of development (early stages of development):
   a) Development of a National Rongoā Māori Framework
   b) Development of policy and procedures
   c) Access pathways for those in our care
   d) Dedicated rongoā Māori health budget
   e) Developing policy frameworks specific to rongoā
   f) Developing procedures and guidelines specific to rongoā

Te Puni Kōkiri

Te Puni Kōkiri are leading two major pieces of work that interface with rongoā – Te Pae Tawhiti Wai 262 and the development of the Declaration plan for the United Nations Declaration of the Rights of Indigenous Peoples.

Wai 262 Te Pae Tawhiti

Te Pae Tawhiti, hosted by Te Puni Kōkiri as the lead agency for Wai 262, has a programme of work called Te Tumu mō te Pae Tawhiti. This lays the foundation for realising our national identity's potential. Further information on Te Pae Tawhiti and Te Tumu mō te Pae Tawhiti can be found here https://www.tpk.govt.nz/en/a-matou-whakaarotau/te-ao-maori/wai-262-te-pae-tawhiti

Programme priorities include establishing a domestic bioprospecting regime, a Māori-Crown partnership-based system for mātauranga, strengthening Māori involvement in international agreement making and measuring progress in these areas. These priorities are focussed on intellectual property of mātauranga and its protection.

Declaration plan for the United Nations Declaration of the Rights of Indigenous Peoples

The United Nation's Declaration on the Rights of Indigenous Peoples (the Declaration) is a comprehensive international human rights document on the rights of indigenous peoples. It covers a broad range of rights and freedoms including, the right to self-determination,

culture and identity, and rights to education, economic development, religious customs, health, and language.

In March 2019, the Minister for Māori Development sought Cabinet agreement to develop a plan that included time-bound, measurable actions that show how we are making a concerted effort towards achieving the Declaration's aspirations. This plan includes actions that:

- come from the intersect between government priorities, Māori aspirations and international indigenous rights discourse
- contribute to enhancing the self-determination of Māori as the indigenous peoples of Aotearoa New Zealand
- contribute to improving intergenerational Māori wellbeing
- demonstrate ambitious actions as opposed to business as usual.

Te Puni Kōkiri leads the development of a Declaration Plan, to guide the Government's progress towards the Declaration's aspirations and is working closely with the National Iwi Chairs Forum and the Human Rights Commission.

Ministry for the Environment

Ministry for the Environment (MfE) and the Department of Conservation are developing a National Policy Statement for Indigenous Biodiversity (NPSIB). The NPSIB will set out objectives, policies, and implementation requirements to manage natural and physical resources to maintain indigenous biodiversity under the Resource Management Act 1991.

The NPSIB will fill a significant gap in the way biodiversity is managed. It will provide national direction and guidance to local councils on how to improve biodiversity management across the country. It will apply across public and private land including terrestrial ecosystems and (in part) wetlands. It includes the management of biodiversity on private land where many threatened species, habitats, and ecosystems are found.

Te Mana o te Taiao (launched in August 2020) sets out a strategic framework for the protection, restoration and sustainable use of biodiversity (particularly indigenous biodiversity) in Aotearoa New Zealand from 2020 to 2050.

Te Ohu Māori are responsible for ensuring Māori rights and interests are considered in policy across MfE. Three key areas for Te Ohu Māori are:

- to develop, improve and monitor the relationship between the Ministry and Māori so we can deliver effective legislation, regulation and policy that meets our obligations to Māori as a Treaty partner
- to lead the negotiation of natural-resource related redress with iwi and hapū groups in Treaty of Waitangi settlements
- to implement our agreements and commitments with settled iwi and hapū groups. This requires developing good working relationships with iwi and hapū groups, as well as partnering with them on environmental work programmes.

Ministry of Primary Industry

Minister Whaitiri as Food Safety Minister has priority work programmes ensuring that the food safety regulatory system includes actively protecting Māori interests in the use of whenua, natural resources, kaitiakitanga of taonga species and mātauranga Māori.

Current focus areas include ensuring that the Joint Food System with Australia supports greater recognition of indigenous culture and food knowledge (including mātauranga Māori and tikanga Māori). There is also work in train to ensure that the food safety regulatory system is enabling Māori economic aspirations for kai as described in Rautaki mo te Taurikura.

Ministry of Business, Innovation and Employment

The Ministry of Business, Innovation and Employment (MBIE) understands that Māori success is New Zealand's success and that unlocking the science and innovation potential of Māori knowledge, people and resources will benefit New Zealand. For this reason, MBIE has embedded Vision Mātauranga policy across all priority investment areas. This resulted in the establishment of Te Pūnaha Hihiko, the Vision Mātauranga Capability Fund. This fund aims to:

- strengthen capability, capacity, skills and networks between Māori and the science and innovation system, and
- increase understanding of how research can contribute to the aspirations of Māori organisations and deliver benefit for New Zealand.

The Fund invests in the development of skilled people and organisations that plan to undertake, or are undertaking, research that supports the themes and outcomes of our Vision Mātauranga policy.

MBIE invests in a range of Research, Science and Innovation that looks at rongoā Māori, including the High-Value Nutrition National Science Challenge (funding up to $83.8 million over 10 years, hosted by the University of Auckland: High-Value Nutrition | Ko Ngā Kai Whai Painga | Ministry of Business, Innovation & Employment (mbie.govt.nz), High-Value Nutrition (highvaluenutrition.co.nz)). They fund a range of research on natural health products and health benefit claims (as well as research on health benefit claims for food, which appears to be outside the scope of the proposed legislation). Examples include:

- Ārepa | High-Value Nutrition (highvaluenutrition.co.nz)
- BerriQi® | High-Value Nutrition (highvaluenutrition.co.nz)
- Greenshell™ Mussel: Musseling-up 2.0 | High-Value Nutrition (highvaluenutrition.co.nz) (the research involves mussel extract – hence within scope for the legislation)

Ministry of Culture and Heritage

The Cultural Sector Regeneration Fund is managed by the Ministry of Culture and Heritage and is designed to support the arts, culture, and heritage sectors to recover from the impacts of COVID-19, and help the sector thrive in the future.

The fund has five outcomes:

1. Improved sustainability and resilience of the arts, culture, and heritage sectors
2. Improved safeguarding of Mātauranga Māori and support of Toi Māori
3. Improved access and participation in arts, culture, and heritage sectors
4. Increased the use of arts, culture, and heritage as a tool to improve wellbeing
5. Increased employment and skill development opportunities.

This fund has been used to support projects related to rongoā, including the Pōhuehue Project, an online rongoā Māori training portal and an online rongoā Māori reference library for enrolled learners of rongoā.

Interface of the rongoā workstream with other Government work programmes

The overview of other Government work programmes that interface with rongoā indicates the wide scope rongoā has. Key areas include:

- Intellectual property (including bioprospecting)
- Tino rangatiratanga
- Investment in sector and community
- Biodiversity and access to taonga species
- Science
- Food systems
- Health services
- Sustainability and funding

The scope of the rongoā workstream and subsequent advice only directly impacts on other government work programmes that include aspects of tino rangatiratanga and health services. However, the outcomes of the rongoā workstream may support the outcomes sought by all these work programmes.

Te Aka Whai Ora has previously advised their position to exclude rongoā from the Bill [HR 20220828 refers] and were initially part of the rongoā workstream. Te Aka Whai Ora has since diverged from the workstream to focus on broader priorities for rongoā, as outlined above. Te Aka Whai Ora may also provide their own advice to you on the exclusion of rongoā from the Bill.

ACC's rongoā services may be impacted, either positively or negatively, depending on whether rongoā practice is enabled or restricted under the proposed regulatory regime and outcome of this advice.

There are known and unknown challenges to traverse. Whilst ACC, Manatū Hauora and Te Aka Whai Ora are supportive of our kaupapa, there is an acknowledgement that our context is very different and will require unique and innovative pathways. The National Rongoā Māori Manager position will provide the direction of travel whilst developing the

areas identified. This position will also have a dedicated Senior Advisor to support what needs to be done.

Te Puni Kōkiri's work to develop a Declaration plan may also be impacted by the outcome of this advice. The Declaration plan is exploring how to build tino rangatiratanga alongside kāwanatanga.

Appendix 6 – Summary of key areas and options

Protection of rongoā				
Principles of Te Tiriti	**Exclusion**	**Partial exclusion**	**Partial inclusion**	**Inclusion**
Tino Rangatiratanga	Māori maintain their own rangatiratanga (authority) over rongoā outside of the Therapeutic products Bill and subsequent regulatory regime.	Māori maintain their own rangatiratanga (authority) over rongoā as rongoā is acknowledged as a taonga to Māori in the Bill.	Authority / mechanisms, alongside resourcing and funding, for regulation are devolved to Māori, and Māori can express their tikanga and kawa.	Limitations for Māori to express tino rangatiratanga over rongoā, as it is entirely within the regulatory framework.
Partnership	Exclusion does not entail genuine partnership with Māori within the scope of the Bill.	Partnership will not be explicit within the Bill and may be developed through government policy.	Partnership exists with resourcing and the ability for Māori to utilise the regulator's mechanisms to hold practitioners accountable (if requested)	Partnership is to the extent the regulator works with Māori and implements decisions made by Māori for rongoā.
Active Protection	Exclusion prevents the unjustified interference of rongoā but restricts the Crown's obligations and ability to actively protect rongoā.	Partial exclusion prevents the unjustified interference of rongoā but restricts the Crown's obligations and ability to actively protect rongoā.	The Crown's interference of rongoā is at arm's length – recognising Māori capability to manage matters for rongoā and enabling Māori tino rangatiratanga and resourcing, whilst also enabling Māori to use the Crown when Māori decide their measures may be insufficient or inappropriate to hold practitioners accountable for harm caused.	May provide more active protection as matters for rongoā will be closer to the regulator. However, the mistrust of the Crown by Māori may cause information to not be shared with the Crown and cause further harm to rongoā. Additionally, the regulator may not understand the nuances with local and regional variations of rongoā.
Equity	Equity will not be implemented through the Bill and subsequent regulatory regime.	Equity will not be implemented through the Bill and subsequent regulatory regime. However, this may be achieved through government agency policy.	Equitable funding and resourcing are more likely to occur as this option is implicitly part of the regulatory regime, whilst also supporting Māori tino rangatiratanga.	Equitable funding and resourcing are more than likely to occur as this option is explicitly part of the regulatory regime.
Options	Allows no options to protect rongoā within the Bill and subsequent regulatory regime, except protection from the Crown.	Allows limited options to protect rongoā within the Bill and subsequent regulatory regime, except protection from the Crown.	Māori can develop localised/regional systems that interfaces with the health system, according to tikanga and kawa.	Limited options for rongoā as it will be restricted to the regulatory framework.

Assurance of patient safety				
Principles of Te Tiriti	**Exclusion**	**Partial exclusion**	**Partial inclusion**	**Inclusion**
Tino Rangatiratanga	No recognition of tikanga and kawa as systems of safety for rongoā. Māori can manage rongoā and express their tikanga and kawa.	Tikanga and kawa may be indirectly recognised in the Bill as valid and sufficient systems of safety and is managed by Māori.	Tikanga and kawa are directly recognised in the Bill as valid and sufficient systems of safety and is managed by Māori.	Tikanga and kawa are recognised in the Bill as valid systems of safety and is managed by the Regulator on the advice of Māori.
Partnership	No partnership required under the Bill and subsequent regulatory regime.	No partnership required under the Bill and subsequent regulatory regime. However, this could be developed through government agency policy.	Māori are resourced by the Crown partner to implement and manage their tikanga and kawa for their locality / region.	The regulator will need to ensure tikanga and kawa are exercised appropriately for rongoā within the branded business unit.
Active Protection	No active protection of Māori or patient interests.	No active protection of Māori or patient interests. However, this could be developed through government agency policy.	Māori are active protectors of their tikanga and kawa and the Crown enables and supports this.	The regulator will need to be able to manage matters efficiently as rongoā will be directly within their scope of practice. However, there is a risk of the regulator unjustifiably interfering with matters on rongoā and not possessing the required skill and knowledge of tikanga and kawa to sufficiently manage matters on rongoā.
Equity	No equitable approaches are required as rongoā is excluded.	No equitable approaches are required as rongoā is excluded. However, this could be developed through government agency policy.	Māori are equitably funded and resourced to manage their own tikanga and kawa.	Māori are equitably funded and resourced to be included in the decision-making of the regulator on matters pertinent to rongoā to ensure tikanga and kawa are the guiding factors for safety.
Options	Options are determined by Māori and are outside the regulatory regime.	Options are determined by Māori and are outside the regulatory regime. This could be developed through government agency policy.	The variation of tikanga and kawa amongst Māori are managed by Māori.	Options for the inclusion of tikanga and kawa in the regulatory regime may be limited and universalised to ensure an operable system.

Ensuring access to the export market				
Principles of Te Tiriti	**Exclusion**	**Partial exclusion**	**Partial inclusion**	**Inclusion**
Tino Rangatiratanga	Māori will be able to express tino rangatiratanga, domestically.	Māori will be able to express tino rangatiratanga, domestically.	Māori will be able to express tino rangatiratanga at a localised level.	Māori will be able to express tino rangatiratanga in certain circumstances.
Partnership	There will be no partnership between the Regulator and Māori.	There will be limited partnership between Māori and the Regulator. This would need to be developed through policy.	Rongoā practitioners will be supported by the Crown partner to access the export market.	Rongoā practitioners will be supported by the Crown partner to access the export market.
Active Protection	No NZ Government imprimatur is provided.	No NZ Government imprimatur is provided. This could be developed through government agency policy and as far as Māori want a partnership.	NZ Government imprimatur could be provided based on the recognition of mātauranga, tikanga and kawa by the Regulator.	NZ Government imprimatur would be provided, regardless of the recognition of mātauranga, tikanga and kawa.
Equity	Rongoā practitioners may have difficulty accessing the export market as there will be no equitable prioritisation of rongoā.	Rongoā practitioners may have difficulty accessing the export market as there will be limited equitable prioritisation of rongoā.	Equitable funding and resourcing will be required to support rongoā practitioners to lead processes.	Equitable funding and resourcing will be required to support rongoā practitioners to work alongside the Regulator.
Options	Options for access to the export market will be significantly restricted for rongoā practitioners.	Options for access to the export market will be significantly restricted for rongoā practitioners. This could be mitigated through government agency policy. But only as far as required by Māori.	Māori will lead the development of options for accessing export markets through co-designed pathways with the Regulator.	The Regulator will lead the development of options for accessing export markets through co-designed pathways with rongoā practitioners.

Appendix 7 – An analysis of rongoā

A pronounced theme that came through all the engagement is that the absence of a definition of rongoā in the Bill, the ambiguity of whether rongoā would be regulated or not has highlighted a fundamental lack of cultural understanding of rongoā as a knowledge system and practice.

In February 2022, Manatū Hauora published a review of Ministry of Health-funded rongoā sector. A finding of this review was rongoā is an expression of mātauranga.

To build the Ministry's capability and understanding rongoā in the development of the Bill, several wānanga were held. These wānanga drew on the expertise of Te Kāhui Rongoā, a national rongoā collective. Through these wānanga, an understanding of rongoā was formed – that rongoā is a way of being (knowing and doing) to preserve and heal te taiao (nature), including tāngata (people), to achieve balance and sustain mauri (life-force) and wairua (spirit).

However, this understanding of rongoā does not provide for the full scope of rongoā because it focuses on rongoā used for the living. An aspect of rongoā that is not considered here is tūpāpakurau – rongoā used for the deceased. This form of rongoā is similar (although not the same) to embalming, burial and cremation.

Rongoā is not just a practice for the physical. The term rongoā is knowledge and practice that spans across cultivation, harvest, preparation, manufacture, production, aetiology, diagnosis, treatment/therapy, prognosis – all according to tikanga and kawa. Every aspect of rongoā includes wairua or spiritual elements that is usually expressed through karakia.

Māori are not a homogenous people. Mātauranga, including rongoā, varies across whānau, hapū, iwi and rohe (region). This is due to localised experiences, contexts and environments influencing the way Māori understand and practice rongoā. For example, historically the knowledge and use of kūmarahou was only available to rongoā practitioners from the Northern region of New Zealand due to the northern environment being the only place in Aotearoa that supported the growth of kūmarahou. This also enabled the trade of kūmarahou across Aotearoa as it was seen as a valuable commodity and it would at times be traded for various items, including pounamu (greenstone) with southern Māori.

Kawa and tikanga are commonly known as protocols, rites, rituals, rules, and practices. This is a narrow understanding of these terms and do not acknowledge the full breadth and depth of these terms. Kawa is the underlying ideology and practices that inform tikanga. Kawa has also been described as strongly associated with atua (Māori gods or deities). Tikanga is the right way of doing things according to kawa. Mātauranga encompasses both tikanga and kawa.

Rongoā, as an expression of mātauranga, encompasses kawa and tikanga. Kawa and tikanga can be thought of as the underlying knowledge and regulation of rongoā.

Appendix 8 – Key areas of the current version of the Bill that interfaces with rongoā

Inclusion of rongoā in the Bill

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

Whether a particular rongoā product is an NHP under the Bill depends if the ingredients in the product are also on a list of recognised NHP ingredients. This list would be determined in secondary legislation following enactment of the Bill and with public consultation, including consultation with Māori (clause 332 (l)).

Regulator - decision-making

The Regulator's decision-making authority under the Bill will be extensive. The Regulator will be responsible for not only setting standards and approving products across an array of categories (medicines, medical devices, cell and tissue and genetic therapies, blood products and natural health products) but also issuing licences for clinical trials and pharmacy, export, and prescribing activities. Decisions in relation to these 'controlled activities' ought to be made after applying an appropriate Te Tiriti and equity lens.

Clause 333 requires the Regulator to ensure they have capacity and capability to give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi and take account of mātauranga Māori, including rongoā, and Māori perspectives in relation to therapeutic products.

Controlled activities

The Bill provides for the regulation of a range of controlled activities. For medicines and medical devices, controls are imposed onmanufacturing, wholesale and non-wholesale supply, exporting, and conducting a clinical trial with the product. Additional controls are placed on the use of medicines, including prescribing, compounding, dispensing, and administering. Manufacturing and exporting a natural health product in the course of business are controlled activities.

The Bill gives the Regulator broad powers that will impact on rongoā. Much of the detail of the impact on rongoā will be developed in secondary legislation.

Licenses

Clause 151 provides that a licence may be granted to allow a person to carry on one or more controlled activities. Licences are intended to allow people to carry on a business or undertaking doing at least one controlled activity on an ongoing basis. If a person wants to carry on a controlled activity for a brief period or to do something on an ad hoc basis, a permit under subpart two may be more appropriate.

In addition to allowing the licensee to carry on the controlled activity, it may also allow the licensee to do other things (for example, a licence allowing the licensee to supply

medical devices might allow them to transport and store the devices is a way that is different from what is required by the rules under clause 72).

A licence may also allow other persons to do things (for example, a licence allowing the licensee to conduct a clinical trial of a medicine might allow someone else to import the medicine even though the medicine does not have a market authorisation).

Clause 153 explains the effect of a licence for the licensee, for the licensee's workers, and for other persons who are specified in the licence as being allowed to do things. A licence only allows things to be done in relation to a therapeutic product covered by the licence and only if they are done in accordance with the terms and conditions of the licence.

Rongoā practitioners will require a licence to practice aspects of rongoā and not breach the subsequent regulatory regime.

Permits

Regulations will be able to prohibit all activity with a product if it directly or indirectly exposes any individual to a risk of death, severe injury, or serious illness, and the risk cannot be adequately managed by the exercise of the Regulator's powers under the Bill. A prohibited product cannot be used or supplied unless a permit issued by the Regulator expressly allows it.

If the Regulator makes ingredients used in rongoā practice a prohibited ingredient, rongoā practitioners will be required to hold a permit for the use of such ingredients. This may restrict rongoā practitioners' ability to practice or prevent it all together.

Health benefit claims

Clause 61 defines health benefit claims and permitted health benefit claim. The sponsor of an NHP is allowed to make only permitted health benefit claims (see clause 192). Rules made for clause 62 will set out standard health benefit claims that can be made about NHPs.

If an NHP has a market authorisation, its authorisation will identify which of the standard health benefit claims can be made about the NHP and may set out additional custom health benefit claims, if the Regulator is satisfied that they are substantiated.

For an NHP that does not have a market authorisation, the only permitted health benefit claims are those in the rules that apply to the product. Clause 62 provides for the rules setting out the standard health benefit claims.

The Regulator may only include a health benefit claim in the rules if satisfied that the claim is substantiated. The claim may be substantiated by scientific evidence, evidence of traditional use, or both. Information about the traditional use of a product or ingredient that is in a pharmacopeia listed in the regulations is prima facie evidence of that use.

Rongoā relies heavily on oral tradition. There may be great reluctance to disclose such evidence to the Regulator due to the mistrust of the Crown by Māori (as discussed in the previous section Protecting rongoā). Policy for the evidence of traditional use is derived from the World Health Organisation's policy of traditional use – continued use for 75 years. This does not work within the New Zealand context as the Tohunga Suppression

Act 1907 was repealed in 1961, 61 years ago with the consequences still felt today by rongoā practitioners.

Advertising

While advertising is not a controlled activity, the Bill allows the Regulator to impose restrictions on advertising of therapeutic products. The Bill does allow direct to consumer advertising of therapeutic products.

Under the current Medicines Act, rongoā practitioners are restricted in advertising andthe proposed approach holds the same position. Additionally, rongoā practitioners rely on consumer testimony to promote their products and/or services andthe proposed approach prohibits this practice, further restricting rongoā practitioners.

Product standards

Clause 63 provides for the Regulator to make rules setting product standards. They may relate to any of the matters listed in this clause or any other matters the Regulator thinks are appropriate. Product standards are minimum standards that a product must meet before a market authorisation can be issued. Once a product has a market authorisation, the sponsor must ensure that it continues to meet those standards.

Detail of the product standards is to be developed in secondary legislation. The current version of the Bill requires the Regulator to consider mātauranga Māori and Māori perspectives to therapeutic products. However, the Regulator may find mātauranga Māori and Māori perspective insufficient to develop product standards if they do not possess adequate capability for this. This would mean rongoā will be subject to 'western' or mainstream product standards.

Manufacturing

Risk can arise because of a product's manufacture, such as contamination or counterfeiting. Manufacturing of a NHP in the course of business is a controlled activity. Manufacturing a therapeutic product usually involves many steps that may be carried out by different people. Anyone who does any of those steps is a manufacturer of the product. Some requirements of the Bill apply to all manufacturers of a product, but most apply only to the responsible manufacturer.

Clause 42 defines the responsible manufacturer of a therapeutic product to be the person who is in fact primarily responsible for its manufacture. The clause lists several factors that are relevant in determining who the responsible manufacturer is. Clause 48 defines manufacturing an NHP. It covers everything that is part of producing the NHP or bringing it to its final state. It also covers the activities involved in producing the NHP ingredients (clause 30).

Many rongoā practitioners produce their own products. This means they will be subject to the manufacturing requirements set out in the regulatory regime. Compliance with the manufacturing requirements may be burdensome to rongoā practitioners and prevent them from either engaging with the regulatory regime or not practicing that aspect of rongoā.

Supply and supply chain activities

Clause 55 defines supply to mean supply of a therapeutic product in New Zealand. It covers any kind of supply of a therapeutic product regardless of how it is supplied, how much is supplied, whether it is paid for, or whether the supplier and recipient are in the same place (so it includes online sales). Many provisions in the Bill refer to supplying a product to a patient. Clause 55(4) means that this covers supplying it to a person who has authority to receive it for the patient.

Supply is divided into wholesale supply and non-wholesale supply. Clause 56 defines those terms. Wholesale supply of a therapeutic product means supply to someone who is going to use it in the course of their business or undertaking (such as supply to a pharmacist, a doctor, or a hospital). Note that business or undertaking is defined in clause 14. Non-wholesale supply means any supply of therapeutic product that is not wholesale supply.

The effectiveness or safety of products can be affected by inappropriate supply. The Bill's aim and guiding principles mean therapeutic products will be regulated across their lifecycle with obligations being imposed on people involved in a product's supply chain. Clause 57 lists the activities that are supply chain activities. Anyone who carries on any of these activities is a person in the supply chain.

To address safety issues arising after a therapeutic product enters the supply chain, the Regulator will have the power to issue a range of orders, including recall orders, advertising remediation orders, directions orders, and product moratorium orders.

As with manufacturing, supply (and the supply chain) is part of many rongoā practitioners' practice. The requirements of the regulatory regime may be burdensome for rongoā practitioners and result in rongoā practitioners not engaging with the regulatory regime or not practicing that aspect of rongoā.

Market Authorisation

The Bill provides that therapeutic products must receive a market authorisation before they can be imported into, exported from, or supplied in New Zealand. Significant penalties attach to the unlawful importation, supply, or export of therapeutic products.

Market authorisations are required for natural health products imported into, supplied in, or exported from New Zealand in the course of business. Reflecting they are generally lower-risk, natural health products will be evaluated against different standards than those for medicines and medical devices.

The Bill allows the Regulator to issue an export authorisation for a product that does not meet one or more criteria for a product supplied in New Zealand. This is intended to support the export of safe, quality products from New Zealand to overseas markets that have different requirements for therapeutic products.

Many rongoā practitioners do not engage with the international market. However, there is an emergence of Māori businesses that do. Market authorisation should reflect a Te Tiriti-based approach for Māori businesses and rongoā practitioners that engage with the international market.

Surveillance and monitoring

Clause 142 requires the sponsor of a therapeutic product to have a post-market surveillance and response system to provide surveillance of the product's safety and quality, and efficacy (for a medicine) or performance (for a medical device) and for the sponsor to respond to issues relating to those matters.

The system must provide for surveillance and responses that are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the product. It must also comply with any requirements in the rules.

Clause 204 requires the Regulator to have systems in place to monitor compliance with the Bill by sponsors, licensees, permit holders, persons in the supply chain, and other persons to whom the Bill applies.

Many rongoā practitioners do not possess the capability or capacity to monitor and survey their products on the market. There will need to be investment to assist rongoā practitioners on developing the capability and capacity for surveillance and monitoring to meet requirements under the regulatory regime.

Search and entry related to specific places

Clause 208 allows an inspector, for regulatory purposes, to enter a place where a supply chain activity is being conducted or where an activity to which a licence or permit relates is being done. However, if the place is a home, a marae (or associated building), consultation room, or treatment room that is in use, an inspector may only enter with consent or under a search warrant and must consider the matters set out in clause 209. The process for obtaining a warrant is set out in the Search and Surveillance Act 2012. Having entered the place, the inspector may do any of the things listed in clause 210.

Many rongoā practitioners operate in their home, marae, or other place of significant cultural value. The current version of the Bill acknowledges this.

Appendix 9 – Analysis of Te Tiriti o Waitangi

Te Tiriti o Waitangi (Te Tiriti) is a founding document of Aotearoa New Zealand. It is fundamental to social and health policy in Aotearoa New Zealand.

Mātauranga has been previously acknowledged by the Waitangi Tribunal as "a highly valued and irreplaceable taonga for New Zealand – this taonga exists nowhere else." This was also echoed in 2011 in Wai 262 Ko Aotearoa Tēnei, where the Waitangi Tribunal held that mātauranga and rongoā are taonga.

Additionally, in Wai 262, the Waitangi Tribunal held that there are some Crown agencies for which mātauranga is very much core business. This includes Manatū Hauora as mātauranga, including rongoā, interfaces with the health system in many ways.

As such the Crown and its agents, alongside Māori, are practically in the seat of kaitiaki for rongoā. Supporting mātauranga Māori and according kaitiaki interests enables appropriate recognition and protection for rongoā.

On 30 November 2016, the chairperson of the Waitangi Tribunal prioritised an inquiry into nationally significant health issues. This signalled the commencement of the Health Services and Outcomes Kaupapa Inquiry (Wai 2575). Stage One of Wai 2575 inquired into the legislative and policy settings of the primary healthcare system.

The subsequent Stage One report Hauora was released in July 2019 and provided iterations of the principles of Te Tiriti appropriate and relevant to the health system. These principles of Te Tiriti are tino rangatiratanga, active protection, partnership, options, and equity.

As emphasised in the engagement with Māori, there is a distinction between the principles of Te Tiriti and the articles of Te Tiriti. The main distinction being that the articles of Te Tiriti is what was committed to by tūpuna who signed Te Tiriti, not the principles of Te Tiriti.

The health system is committed to fulfilling the special relationship between Māori and the Crown under Te Tiriti o Waitangi (Te Tiriti). Regarding the text of Te Tiriti and declarations made during its signing – the Ministry of Health (the Ministry), as the kaitiaki and steward of the health and disability system (under article 1 of Te Tiriti), has the responsibility to enable Māori to exercise authority over their health and wellbeing (under article 2) and achieve equitable health outcomes for Māori (under article 3) in ways that enable Māori to live, thrive and flourish as Māori (Ritenga Māori declaration1).

Meeting our obligations under Te Tiriti is necessary if we are to realise the overall aims of He Korowai Oranga: Māori Health Strategy (He Korowai Oranga) and achieve outcomes for the health and disability system as a whole. This includes a desire to see all New Zealanders living longer, healthier, and more independent lives.

Articles of Te Tiriti o Waitangi

The Ministry's Te Tiriti o Waitangi framework provides a current expression of the Crown's Te Tiriti obligations in the context of the health system.

The text of Te Tiriti, including the preamble and the three articles, along with the Ritenga Māori declaration, are the enduring foundation of our approach. Based on these

foundations, we will strive to achieve the following four goals, each expressed in terms of mana:

Mana whakahaere: effective and appropriate stewardship or kaitiakitanga over the health and disability system. This goes beyond the management of assets or resources.

Mana motuhake: Enabling the right for Māori to be Māori (Māori self-determination); to exercise their authority over their lives, and to live on Māori terms and according to Māori philosophies, values and practices including tikanga Māori.

Mana tangata: Achieving equity in health and disability outcomes for Māori across the life course and contributing to Māori wellness.

Mana Māori: Enabling Ritenga Māori (Māori customary rituals) which are framed by te ao Māori (the Māori world), enacted through tikanga Māori (Māori philosophy & customary practices) and encapsulated within mātauranga Māori (Māori knowledge).

Principles of Te Tiriti o Waitangi

Tino Rangatiratanga

Tino rangatiratanga denotes Māori authority to govern themselves and determine their own destinies, to participate in Crown governance, law, and policy, and to have their rights protected. Māori possess centuries of mātauranga, kawa and tikanga for rongoā and has been passed down for numerous generations. This is something that the Crown and Government will not obtain in the near future.

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

Active Protection

The Crown has the obligation of actively protecting rongoā. This protection is in both the benefit and enjoyment of rongoā, as well as the protection of mana (authority) to exercise control over it.

The degree of protection is dependent on the nature and value of the rongoā to Māori. The value placed on rongoā is a matter for Māori to determine. Additionally, such value is not confined to, or restricted by, traditional uses of rongoā. It includes present day usage, and such potential usage as may be thought appropriate by those having rangatiratanga over rongoā. The rongoā workstream has heard through engagement, and previous Waitangi Tribunal reports, that rongoā is a highly valued taonga tuku iho to Māori.

Partnership

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

Equity

In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes.

For rongoā, equity ensures that rongoā should be available to meet the health needs of people, should they choose to access it.

Options

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