Te Aka Whai Ora
Māori Health Authority

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

Reflecting Te Tiriti o Waitangi, including rongoā Māori, in the Therapeutic Products Bill

Date due to MO:	**19 September 2022**	**Action required by:**	**3 October 2022**
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To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Peeni Henare, Associate Minister of Health		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Reflecting Te Tiriti, including rongoā Māori, in the Therapeutic Products Bill

Security level:	IN CONFIDENCE	**Date:**	19 September 2022
To:	Hon Andrew Little, Minister of Health		
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Purpose of report

1. This briefing provides the joint advice of Manatū Hauora and Te Aka Whai Ora on proposals to ensure Te Tiriti o Waitangi (Te Tiriti) is recognised appropriately in the Therapeutic Products Bill (the Bill). This includes advice on proposals to recognise and protect rongoā Māori, and to regulate some elements of rongoā.

2. This report discloses all relevant information and implications.

Summary

3. Manatū Hauora and Te Aka Whai Ora have worked together to develop proposed revisions to the 2018 exposure draft of the Bill to better reflect Te Tiriti o Waitangi. This work has been informed by decisions to date about the entity form of the Therapeutic products regulator [CBC-21-MIN-0017] and the decision to regulate natural health products (NHPs) under the Bill [SWC-21-MIN-0109].

4. The Bill will be the first major health legislation to be progressed after the implementation of the July 2022 health system reforms. Māori communities will be looking to see what tangible impact the reforms have made.

5. Te Aka Whai Ora considers rongoā Māori to be a taonga and an intrinsic part of te ao Māori. As such, Te Aka Whai Ora suggest it needs to be protected, recognised and supported. The Bill provides an opportunity to achieve this. It is important we get it right, both as a significant step in the right direction in the new health system, and because of what is at stake for Māori.

6. Three options are presented in this report for how the principles of Te Tiriti and the Health Sector Principles (HSPs) can be reflected in the Bill:

   a) weaving the principles through the Bill but not including a Tiriti clause,

   b) in addition to a), including a descriptive Tiriti clause (Manatū Hauora recommendation),

   c) in addition to a) b), including a descriptive and an operative Tiriti clause. (Te Aka Whai Ora recommendation).

7. Manatū Hauora proposes to exempt most rongoā products used as part of rongoā practice, including by whānau, hapū and rongoā practitioners from a requirement to be authorised as a Natural Health Product (NHP) under the Bill unless there is a

demonstrated risk of serious harm or injury. This exemption would not apply for rongoā products produced for wholesale supply or commercial export.

8. This briefing proposes a statutory committee that would provide a mechanism for the regulator to work with a Māori advisory group to identify and develop solutions to safely manage any risks identified in NHPs used in the practice of rongoā, and to provide advice to the regulator on other matters.

9. Te Aka Whai Ora and Te Kāhui Rongoā Trust, a peak sector body for rongoā practitioners, disagree with the Manatū Hauora's proposals in relation to rongoā and recommend instead exempting all rongoā activities and products from regulation under the Bill.

10. Te Aka Whai Ora caution that, if rongoā is subject to any regulation under the Bill (including in relation to potential future safety concerns or wholesale supply or export), it is highly likely these proposals will be subject to litigation by some Māori. S9(2)(h) [redacted] Manatū Hauora notes this concern has also been raised by Te Kāhui Rongoā Trust.

11. Manatū Hauora considers its proposals, including around the scope and approach to the regulation making power and how it might be used, elevate and centre Māori interests so that regulations made under this proposal are based on clearly identified risks and the Crown's legitimate role (and the expectations of the community) to regulate for public safety for all New Zealanders. S9(2)(h) [redacted]

Recommendations

We recommend you:

a)	**Note** that Cabinet has not made any explicit decisions on the application of Te Tiriti o Waitangi (Te Tiriti) in relation to the Therapeutic Products Bill (the Bill), other than to recognise and protect rongoā Māori (agreed to when natural health products was included in the Bill in July 2021) [SWC-21-MIN-0109]	**Noted**
b)	**Note** that past breaches of Te Tiriti by the Crown in relation to rongoā and its practitioners, make any regulation in this sector highly sensitive and likely to attract attention during debate over the Bill	**Noted**
c)	**Note** that the relevance of Te Tiriti to the Bill relates to multiple areas and presents opportunities to contribute to improved Māori health outcomes including improved access to medicines and medical devices, delivery of health services (e.g., pharmacy activities, prescribing authorities, and clinical trials); and to recognise and protect rongoā Māori	**Noted**

Updating the Bill to reflect te Tiriti more explicitly

d) **Note** there are three options to reflect the principles of Te Tiriti into the Bill, which are: **Noted**

> **Option A** (status quo in the draft Bill) - weaving the principles of Te Tiriti and the Health Sector Principles through the Bill, but *not including an 'operative' or 'descriptive' Te Tiriti clause*
>
> **Option B** (Pae Ora Act model) **–** Option A *plus a specific descriptive clause* in order to provide for the Crown to give effect to the principles of Te Tiriti
>
> **Option C** (operative clause) – in addition to Options A and B, include an operative clause that would require the regulator and other decision makers to 'take into account' or 'uphold' the principles of Te Tiriti when making decisions or exercising functions under the Act

e) **Note** that Te Aka Whai Ora also supports the inclusion of an operative clause (Option C), but Manatū Hauora does not for reasons outlined later in this report **Noted**

f) **Note** S9(2)(g)(i) [redacted] engagement with TPOG is ongoing. **Noted**

g) **Note** Manatū Hauora recommend that you discuss the contents of this briefing (oral item) with your Cabinet colleagues at Cabinet on 27 September 2022 before making decisions. **Noted**

h) **Note** that if you agree to recommendation g) Manatū Hauora and Te Aka Whai Ora will work together to provide you with talking points for Cabinet **Noted**

i) Agree that Manatū Hauora instruct PCO to update the Bill in line with **EITHER**:

i. ***Option A***, (status quo) - weaving the principles of Te Tiriti and the health sector principles through the Bill (as described in paragraph 27), but not including an 'operative' or 'descriptive' Te Tiriti clause; **OR** **Yes / No**

ii. ***Option B***, which includes both Option A (weaving te Tiriti principles through the Bill) and including a specific descriptive clause (**recommended by Manatū Hauora**), **OR** **Yes / No**

iii. ***Option C***, which includes both Options A and B, and an operative clause specifying that the regulator and other **Yes / No**

decision makers must 'take into account' or 'uphold' the principles of Te Tiriti (**recommended by Te Aka Whai Ora**).

j) **Note** the view of Te Aka Whai Ora that rongoā Māori should not be subject to regulation by the Crown and that avoiding Crown regulation of rongoā is required to uphold Article 2 of Te Tiriti — **Noted**

k) **Note** that Te Aka Whai Ora's view differs from Manatū Hauora's in that the latter believes there are situations where there is a strong Crown interest in providing assurance of product safety, ensuring traceability for all New Zealanders, and export requirements — **Noted**

l) **Agree** to establish a statutory Māori advisory group to advise the regulator on Māori interests, and matters concerning mātauranga Māori and Rongoā Māori in the therapeutic products context. — **Yes / No**

m) **Agree** that, in order to avoid regulating the practice of rongoā wherever possible, while also taking account of potential safety considerations, Manatū Hauora recommend that the Bill be revised, to: — **Yes / No**

   i. exempt rongoā products used within whānau, hapū and by rongoā practitioners from a requirement to be authorised as a NHP prior to their manufacture, supply and administration, except where:

      a. there is an ingredient with a demonstrable risk of serious harm or injury, or death; or
      b. the mode of administration carries inherent risks (e.g., penetrating the skin or administering to the eye); and
      c. the risks could not otherwise be managed sufficiently by a less restrictive measure than legal regulation; or
      d. rongoā products are manufactured for wholesale supply or commercial export, in order to support the Bill's public safety aims and to reduce the risk of gaming by commercial operators.

   ii. Where the regulator seeks to make regulations or rules that restrict the practice of rongoā (as described in Recommendation m(i) above), require the regulator to work with and seek advice from the statutory Māori advisory group above to identify and manage the safety risks with these products

n) **Agree** that either

   i. Manatū Hauora instruct PCO to revise the Bill to incorporate its proposals for the recognition and protection of rongoā and the regulatory mechanisms as outlined at — **Yes / No**

recommendation (m) above (i.e. **Manatū Hauora's advice**);
OR

ii. Manatū Hauora instruct PCO to revise the Bill to make it clear that Crown must recognise and protect rongoā Māori, but not regulate rongoā Māori in any way (i.e. **Te Aka Whai Ora's advice**). **Yes / No**

Riana Manuel
Tumu Whakarae
Te Aka Whai Ora
Date: 19/09/2022

Dr Diana Sarfati
Director-General of Health
Manatū Hauora
Date: 19/09/2022

Hon Andrew Little
Minister of Health
Date:

Hon Peeni Henare
Associate Minister of Health
Date:

Reflecting Te Tiriti, including rongoā Māori, in the Therapeutics Products Bill

Problem definition

Why an explicit Treaty reference is needed in the Bill

Purpose of this report

1. This report provides you with advice on proposed revisions to the 2018 exposure draft of the Bill to better reflect Te Tiriti, including providing for the recognition and protection of rongoā Māori. These are final outstanding policy decisions needed to enable Manatū Hauora to instruct PCO so the Bill can be finalised for introduction to Parliament.

Why the Treaty needs to be addressed explicitly in the new Bill

2. The history of Crown-Māori relations has been beset since 1840 by differences in readings and interpretations of the Treaty of Waitangi | Te Tiriti o Waitangi. This includes 182 years of Tiriti breaches, some of which are still playing out in the Courts and through the Waitangi Tribunal. These include contemporary claims, for example, the ongoing Government response to the matters raised in the Māori Culture and Identity claim (WAI 262), and the Health Services and Outcomes Kaupapa Inquiry (WAI 2575) which the Waitangi Tribunal handed down its Stage One report on in 2019.

3. The Medicines Act 1981 is silent on Te Tiriti and its principles as is the 2018 Exposure draft Bill. This effectively leaves it to either the Courts or the Waitangi Tribunal to ultimately make decisions on whether the Crown has upheld its obligations under Te Tiriti. Manatū Hauora sees significant potential to improve Crown-Māori relations with respect to Te Tiriti by:

    a) providing more clarity regarding the specific obligations on the Crown to give effect to the principles of Te Tiriti by specifying the intended obligations on the Crown, making it less likely that there will be differences of view between Te Tiriti partners after the fact on whether a Te Tiriti breach has occurred, and

    b) avoiding the need for subsequent processes to resolve disputes pertaining to Te Tiriti breaches, which are neither guaranteed nor timely for either treaty partner. It is notable that both the Courts and the Waitangi tribunal have often taken years to reach a conclusion on whether Te Tiriti was breached in a given situation.

4. One of the intended impacts of the health reforms is that the health system will better uphold Te Tiriti. This is reflected in the interim Government Policy Statement where embedding Te Tiriti across the sector is a priority for the health sector over the next two years. Whakamaua; the government's Māori Health Action Plan, also provides support for including Te Tiriti in the Bill: action 8.4 says "Implement legislative changes to reflect a commitment to Te Tiriti and Māori health equity across the health and disability system." The Pae Ora (Healthy Futures) Act 2022 also provides an example of how this can be achieved.

5. The Waitangi Tribunal's report, *Ko Aotearoa Tēnei* (WAI 262), further strengthens the case to revise the Bill to ensure it is clear that the Crown has a responsibility to act to prevent the kind of situation outlined that gave rise to the WAI 262 claim [see CAB-19-MIN-0138.01 and CBC-22-MIN-0004].

6. In 2011, the Tribunal asserted in *Ko Aotearoa Tēnei* that the Crown needed to shift its mindset regarding rongoā. One of Tribunal's summary of recommendations regarding rongoā was "Adequately support Te Paepae Matua [at the time the national rongoā governance body] to play the quality-control role that the Crown should not and cannot play itself." The full summary of recommendations from the report is included at Appendix 1.

7. In setting expectations around governance in the new health and disability system, Te Tiriti should be explicitly addressed in new legislation. Te Aka Whai Ora believes that the Bill should contain both an operative Te Tiriti clause and a more detailed, descriptive Te Tiriti/Māori interests clause. The rationale for this is the view that it would provide the strongest level of expectation for the regulator around protecting Māori interests and working in partnership with Māori to recognise and uplift rongoā.

8. In developing our respective views, Te Aka Whai Ora and Manatū Hauora have both sought the views of the Te Aka Whai Ora Board. Te Kahui Rongoā Trust presented their position to the Board and support Te Aka Whai Ora's position. However, due to our different perspectives and roles in the health system, the advice from Manatū Hauora and Te Aka Whai Ora on how to manage rongoā differ.

9. Manatū Hauora and Te Aka Whai Ora expect that your Cabinet colleagues will have a strong interest in how Te Tiriti and rongoā are addressed in the Bill. Consequently, Manatū Hauora and Te Aka Whai Ora suggest you may want to discuss this briefing with your Cabinet colleagues prior to making decisions. If you agree, Manatū Haoura and Te Aka Whai Ora suggest that an oral item at Cabinet on 27 September 2022 might be appropriate and we will work together to provide you with talking points.

Analysis

Why the regulator should act consistently with te Tiriti

10. The regulator's decision-making authority under the Bill will be extensive. The regulator will be responsible for 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). The regulator will also issue licences for clinical trials, manufacture, pharmacy activities, export and prescribing activities. Decisions in relation to these 'controlled activities' ought to be made while ensuring a Tiriti and equity lens is applied.

11. In the proposed Bill, Manatū Hauora has identified both opportunities to improve Māori health outcomes though enabling health service innovation via pharmacy services and prescribing authorities, and active consideration of Māori interest and priorities (eg, in clinical trials). Manatū Hauora has also identified some risk of creating further breaches should the Bill not reflect the principles of Te Tiriti sufficiently.

12. In seeking to achieve the purpose of the Bill, the regulator will need to look beyond 'technocratic' models of regulation and instead to also consider Māori perspectives and priorities when regulating generally.

13. Even largely technical decisions by the regulator, such as determining product and manufacturing standards, give rise to potential equity and Te Tiriti issues. As these standards will be developed over time, it is important to build in the desired principles now to ensure the future regime is designed and administered in a way that reflects and gives effect to the principles of Te Tiriti and aligns with the Health Sector Principles (HSPs).

14. At times upholding Te Tiriti will require the new regulator to engage with Māori during the exercise of some functions across a broad range of products and processes.[1] In the context of rongoā, upholding Te Tiriti would ideally exclude some rongoā products and practices entirely from the new regime (or even all of rongoā). Because the Bill is a framework law (with most of the detail to be set out in secondary legislation), it is necessary to ensure the right principles and settings are 'baked in' at the primary legislation stage.

15. Specifying how the regulator should operate to be consistent with the principles of Te Tiriti in the Bill helps clarify the legal requirements on the regulator. This includes both specifying an obligation for the regulator to work collaboratively with Māori and as a good Te Tiriti partner and, equally, a requirement for the regulator to develop the necessary capabilities, so it can engage with Māori, reflect mātauranga Māori in the therapeutic products context where appropriate, and uphold the principles of Te Tiriti.

Relevance of Te Tiriti to the Bill as a whole - not just rongoā Māori

16. Te Aka Whai Ora's focus has been on rongoā Māori as it is directly considered under the Bill. However, the broader impacts of the Bill mean it is likely to affect Māori in many other ways, including Māori access to medicines and medical devices, health outcomes for Māori, Māori data use, recognition of mātauranga Māori within the health system, and Māori interests in whenua and te taiao (through the regulation of natural health products). This means that the two Tiriti clauses are important not just in relation to rongoā, but in relation to the Bill as a whole and the future role of the regulator.

17. Māori are less likely to receive medicines to prevent illness yet more likely to receive older or higher risk medicines for symptomatic disease. Diseases for which antibiotics are indicated affect Māori and Pacific peoples more than people of other ethnicities, yet Māori do not always receive antibiotics when needed.[3]

18. This Bill presents an opportunity to help reverse the inequitable health outcomes currently experienced by Māori, and to improve Māori access to medicines, but this will not happen without a strong and explicit Te Tiriti and equity focus included in the legislation.

Overview of rongoā Māori

19. Te Aka Whai Ora recognises that rongoā is a taonga Māori. For centuries whānau, hapū and iwi have cultivated, cared for and used rongoā that they discovered in the world around them. The knowledge and the practice of rongoā have been passed down through the generations within whānau, hapū and iwi.

[1] **'Engage' is used as a general term. In practice, the regulator would apply frameworks such as Te Arawhiti's *Crown engagement with Māori Framework* which outlines different degrees of engagement.**

20. Because rongoā has been developed by Māori living in geographically distinct areas, often with cultural and spiritual beliefs unique to their iwi or hapū, and with different flora, fauna and natural resources, there is no singular shared practice of rongoā. Different whānau, hapū and iwi are the kaitiaki of different forms of rongoā, based upon different mātauranga Māori. They use rongoā in different ways, and regulate it according to their own tikanga.

Safety and efficacy of rongoā Māori

21. Rongoā has generally not been prioritised within our health system for either funding or research, despite this there is still some evidence that rongoā rākau products are clinically effective[2] or are likely to be clinically effective.[3] From the perspective of Te Kahui Rongoā, the key reason rongoā still exists today is because it works. In addition, there is no evidence of harm (see discussion at paragraphs 56 – 59). Te Aka Whai Ora would not support taking a purely biomedical approach to the utility of rongoā, as it is fundamentally underpinned by Māori worldviews, mātauranga Māori and whakapapa (relational) connections to te ao Māori.[4]

22. The Waitangi Tribunal[5] has asserted:

> *"it would be wrong to conclude, however, that the practice of rongoā was by any means focused upon herbal remedies. In the holistic Māori view of health, outward manifestations of sickness reflect broader environmental, family, or spiritual problems. Rākau rongoā are not considered effective on their own. Indeed, the most important form of treatment by tohunga was and remains spiritual."*

23. It is also important to understand that rongoā is not 'unregulated' – it is just not regulated by the Crown. The mātauranga and tikanga that inform rongoā are what guide its safe use. Te Aka Whai Ora is of the view that challenges to the survival and revitalisation of rongoā, such as disconnection from te ao Māori; threats to rongoā credibility; preventing knowledge transfer; lack of systemic support; and health system denial of wairua experiences[6] require the Crown's protection of rongoā rather than Crown regulation. In turn, Te Aka Whai Ora believes that Crown protection of mātauranga Māori and rongoā will support the safe practise of rongoā Māori.

Rongoā in the public health system

24. Rongoā has not always been included in the mainstream health system. In recent years, demand for rongoā services both inside and outside of the public health system has grown. Within the public health system, rongoā Māori services have been funded by Manatū Hauora and the District Health Boards (and now Te Whatu Ora), Te Aka Whai Ora and ACC.

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[2] **Shortt, N., Martin, A., Kerse, K., Shortt, G., Vakalalabure, I., Barker, L., ... & Semprini, A. (2022). Efficacy of a 3% Kānuka oil cream for the treatment of moderate-to-severe eczema: A single blind randomised vehicle-controlled trial. EClinicalMedicine, 51, 101561**

[3] **Koia, J. H., & Shepherd, P. (2020). The potential of anti-diabetic rākau rongoā (Māori herbal medicine) to treat type 2 diabetes mellitus (T2DM) mate huka: A review. Frontiers in Pharmacology, 11, 935.**

[4] **Wikaire, E. (2020). The past, present and future of traditional Indigenous healing: What was, is, and will be, rongoā Māori (Doctoral dissertation, ResearchSpace@ Auckland).**

[5] **https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_68356054/KoAotearoaTeneiTT1W.pdf**

[6] **Wikaire, E. (2020). The past, present and future of traditional Indigenous healing: What was, is, and will be, rongoā Māori (Doctoral dissertation, ResearchSpace@ Auckland).**

25. Rongoā services are provided safely and effectively through ACC, as a part of its Māori Health work programme. For more detail on ACC rongoā services see Appendix 2. In addition, Te Aka Whai Ora is also developing a programme of work to support rongoā Māori and rongoā practitioners. This includes further funding of rongoā providers, development of the rongoā workforce, plans for a Māori-led pathway for recognition of rongoā practitioners, and the drafting of a relational agreement with national rongoā governance body Te Kāhui Rongoā Trust.

Historical treatment by the Crown

26. The Tohunga Suppression Act (1907) denied Māori the right to make any claims with regard to the spiritual elements of rongoā practice. The Quackery Prevention Act (1908) denied Māori the right to claim any health benefits derived from the practice or application of rongoā. Te Aka Whai Ora and Te Kāhui Rongoā Trust consider that the Medicines Act (1981) reinforced these limitations.

27. This history of both unmet need and Crown interference has caused many Māori to be very anxious about what the Bill intends to do and what it will achieve in practice. The insertion of both operative and descriptive Te Tiriti clauses would – in Te Aka Whai Ora's view – be a strong message to both Māori and the Crown about new expectations in the new health system, while also serving a real and functional purpose.

Three options are proposed to embed Te Tiriti in the Bill

28. Manatū Hauora have identified three options for reflecting the principles of Te Tiriti in the Bill:

a. **Option A** – 'weaving' the principles of Te Tiriti and the Health Sector Principles through the Bill but not including an 'operative' or 'descriptive' Te Tiriti clause.

b. **Option B** – Option A *plus* having a specific clause that points to these provisions as providing for the Crown's intention to give effect to the principles of Te Tiriti (i.e., a 'descriptive' clause).

c. **Option C** – Options A and B *plus* including an enforceable operative Te Tiriti clause that would require the regulator and other decision makers (including the Minister of Health) to 'take into account' or 'uphold' the principles of Te Tiriti.

Table 1: Options to embed Te Tiriti in the Bill

Option A	Option B	Option C
Revisions to the Bill Including rongoā proposals	Revisions to the Bill Including rongoā proposals	Revisions to the Bill Including rongoā proposals
	A descriptive Te Tiriti clause	A descriptive Te Tiriti clause
		An operative Te Tiriti clause

Option A – strengthening specific provisions within the Bill

29. Option A involves revising the 2018 Bill to better reflect the principles of Te Tiriti (as articulated by the Waitangi Tribunal in WAI 2575) and the Health Sector Principles. This involves:

    a) revising a clause in the Bill setting out decision making principles – to align these principles with the HSPs and the Pae Ora Act's approach to codifying the principles of Te Tiriti

    b) functions and duties for the regulator – including requiring greater collaboration between the regulator and Te Aka Whai Ora and imposing an obligation on the regulator to build its Te Tiriti and Te Ao Māori capabilities

    c) internal review mechanisms – to require panels to include mātauranga Māori knowledge holders where relevant

    d) consultation requirements for secondary legislation – to ensure the regulator engages with Māori in a manner that reflects the nature and extent of Māori interests in a given matter. Importantly, although the clause in the Bill is currently titled 'consultation', the level of engagement with Māori may be higher than 'consultation', and will be determined by:

        i. the strength or nature of Māori interests in the matter, and

        ii. the interests of other health consumers and the Crown in the matter.

    e) establishing a statutory,[7] Māori advisory committee to provide advice to, and develop guidelines with, the regulator on:

        i. the Regulator's Regulatory Strategy – including how it will work with Māori and iwi

        ii. regulatory matters relating to rongoā products that fall within the scope of the Bill, such as the need for any controls on permitted ingredients and modes of administration, where they relate to rongoā products and where there is an elevated safety risk.

        iii. mātauranga Māori where it may arise in relation to rongoā or another aspect of the Bill

        iv. nominees for other expert committees established by the regulator.

    The regulator would be obliged to receive and consider the advice of the group and would need to publish its reasons for not accepting its advice (except in the case of nominees (vi)).

30. Manatū Hauora considers Option A represents the baseline, essential revisions to the Bill necessary to embed the principles of Te Tiriti. Additional detail on the proposed revisions to the Bill under Option A are set out at **Appendix 3**.

31. Manatū Hauora proposes that Māori be included in the relevant non-statutory committees that provide expert advice to the regulator e.g., classification and adverse event committees. In addition a statutory Māori advisory group would consider and provide

[7] **Reflecting its importance, this would be the only committee provided for the primary legislation. All other expert advisory committees will be established via secondary legislation.**

advice to the regulator on matters of importance to Māori with respect to therapeutic products.

Option B – including a descriptive Te Tiriti clause

32. Option B builds on the revisions proposed under Option A and would also revise the Bill to include a clause that points to these provisions as providing for the Crown's intention to give effect to the principles of Te Tiriti (i.e., a 'descriptive' or 'Māori interests' clause). This is the Pae Ora (Healthy Futures) Act model, where section 6 of that Act describes how the Act 'provide[s] for the Crown's intention to give effect to the principles of te Tiriti'. It then points to specific provisions within the Pae Ora Act.[8]

33. A descriptive Te Tiriti/Māori interests clause, in a similar format to the Pae Ora Act, would set out clear and specific expectations for what is required in order to uphold Te Tiriti in the context of therapeutic products and rongoā Māori. However, Te Aka Whai Ora is concerned that these requirements are only able to cover situations that were envisaged during the drafting of the legislation.

34. The strength or weakness of such a clause also depends on the specific requirements it sets out. As the draft text has not yet been prepared by PCO, Te Aka Whai Ora is unable to take a view on how strong the expectations for the regulator would be, and therefore how well a descriptive clause would uphold Te Tiriti.

35. Final wording for the descriptive Te Tiriti clause will reflect advice from Treaty Provision Oversight Group (TPOG), PCO and Crown Law. It would refer to those specific provisions within the Bill that embed the principles of Te Tiriti.

Option C – including an operative Te Tiriti clause

36. Option C adds to options A and B and, would revise the Bill to include an operative Tiriti clause that would require the regulator and other decision makers to 'take into account' or 'uphold' the principles of Te Tiriti.

Manatū Hauora and Te Aka Whai Ora agree te Tiriti should be woven through the Bill and that a new descriptive clause is needed

37. Manatū Hauora and Te Aka Whai Ora agree that it is both possible and desirable to set out in the Bill how the Crown intends to meet its Te Tiriti obligations with respect to the regulation of therapeutics. There should also be explicit reference to Te Tiriti in the Bill in the form of a descriptive Te Tiriti clause to provide clarity of expectations for the regulator and of the key mechanisms in the Bill for doing so.

38. Manatū Hauora believes that the Pae Ora Act provides a useful model for this mixed approach (**Option B**) to setting out the Crown's responsibilities to regulate therapeutics in a way that is consistent with principles of te Tiriti. A descriptive Te Tiriti clause at section 6 of the Pae Ora Act lists these specific provisions as instances of the Crown giving effect to the principles of Te Tiriti. The descriptive clause, however, does not create a new, enforceable right on its own – rather it would be the substantive provisions in the Bill that the clause 'describes' that would be enforceable.

[8] **Other laws that contain a descriptive clause include the Taumata Arowai-the Water Services Regulator Act 2020 and the Education and Training Act 2020.**

39. Te Aka Whai Ora holds the view that all Te Tiriti/Māori interest clauses should be legally enforceable. While the primary justification for including such clauses is to set clear expectations for the regulator, it is not good regulatory practice to deliberately create unenforceable legislation.

40. Our engagement with the new TPOG, hosted by Te Arawhiti has revealed S9(2)(g)(i) [redacted] some support for the model adopted in Pae Ora to be employed – i.e. embedding the Treaty and using a descriptive Treaty clause. It is likely that TPOG is going to further consider and advise on these matters. If we do get further input from TPOG prior to you potentially taking an oral item to Cabinet and making decisions, Manatū Hauora and Te Aka Whai Ora will jointly update you.

Te Aka Whai Ora supports the inclusion of an operative Te Tiriti clause

41. An operative Tiriti clause does not set any specific requirements in the legislation, other than requiring decision-makers to give effect to Te Tiriti o Waitangi. However, it has broad applicability for most issues that makes it easier to consider Te Tiriti issues in any context relevant to the Bill that they arise in, while still referring back to the specific commitments set out in Te Tiriti itself. Te Aka Whai Ora believe this flexibility will help to future-proof the legislation.

42. Moreover, Te Aka Whai Ora consider that an operative clause is justified because a widely recognised taonga Māori[9] (rongoā Maori) is explicitly considered within the Bill – a fact which makes this Bill different to (and prevents a direct comparison with) the Pae Ora (Healthy Futures) Act 2022. The status of rongoā Māori as a taonga means that Article 2 of Te Tiriti o Waitangi applies directly to rongoā. Although operative clauses apply more broadly to other issues, Article 2 of Te Tiriti o Waitangi is clear when it comes to taonga Māori. The most straightforward and effective way to uphold this existing commitment in modern legislation is through the use of an operative clause. See further discussion on Article 2 at paragraph 54.

43. Because operative and descriptive clauses have different functions, Te Aka Whai Ora suggest that the strongest protection and recognition of rongoā and other Māori interests will be facilitated by legislation which contains both. The strongest protection and recognition available is justified by the history in this space, the status of rongoā Māori as a taonga, the inequities in Māori health and the commitment and intent of the health system to work differently in the post-July 2022 system reforms.

Why Manatū Hauora does not support an operative clause in the Bill

44. Manatū Hauora believe a well-defined Te Tiriti/Māori interests clause would be the best way to specify clearly how the Crown intends to give effect to te Tiriti. Manatū Hauora considers a descriptive clause to be most consistent with good regulatory practice since it is more specific than an operative clause about how the Crown should be giving effect to

[9] **The Waitangi Tribunal report on Wai 262, Ko Aotearoa Tēnei, states that "Taonga include tangible things such as land, waters, plants, wildlife and cultural works ; and intangible things such as language, identity, and culture, including mātauranga Māori itself." The Ministry of Health's Māori Health Action Plan, Whakamaua, further clarifies that rongoā is "a key application of mātauranga Māori in the health and disability system." We note that the Ministry of Health recognises rongoā as a taonga Māori in their 2006 document Taonga Tuku Iho – Treasures of our Heritage: Rongoā Development Plan and in the relational agreement between the Ministry and national rongoā governance body Te Kāhui Rongoā Trust, signed in February 2022.**

te Tiriti in the context of regulating therapeutic products.[10] S9(2)(h) [redacted] Manatū Hauora believes it is better regulatory practice for the law to provide clarity to decision makers and that will reduce the likelihood of Te Tiriti breaches occurring.

45. Secondly, Manatū Hauora support the inclusion of a descriptive clause but not an operative one because we believe that Ministers have already conducted a similar conversation in the context of the Pae Ora Act and concluded that the best approach was to include a descriptive clause but not an operative one. The reasons for that decision are a matter of public record and already codified in law, meaning Manatū Hauora's proposed approach would be most consistent with the Pae Ora Act.

Legal measures proposed to recognise, protect and regulate rongoā Māori

Manatū Hauora proposes exempting most elements of rongoā from the Bill explicitly

46. Manatū Hauora recommends that the Bill specifically exempt a range of products involved in rongōa activities that have occurred within whānau, hapū and by practitioners from a requirement to be authorised as a NHP prior to their manufacture, supply and administration. These include products made:

    a) by a rongoā practitioner to be administered to a particular person or in consultation with a person and their whānau, according to the practitioner's judgement; and

    b) and supplied in a manner consistent with the customs and traditions of the iwi or hapū where it is made or supplied. This is intended to cover most whānau and hapū-based practice and is not limited to recognised 'rongoā practitioners'.[11]

47. This exemption would, in practice be given effect to via a 'NHP practitioner exemption' in the Bill. Similar – but narrower – NHP practitioner exemptions are proposed for other complementary health practices, including traditional healing practices in other cultures. Manatū Hauora proposes that an exemption for rongoā is included in the Bill given its importance to Māori and the Crown's duties as a Te Tiriti partner. This would also give statutory recognition to the role and importance of rongoā. Similar NHP practitioner-level exemptions are likely to be established via secondary legislation.

Manatū Hauora propose that regulations apply for wholesale supply or commercial export of rongoā products

48. To support the Bill's public safety aims (e.g., traceability and recalls), and to reduce the risk of gaming by commercial operators, Manatū Hauora recommends that exemptions not apply to rongoā products produced for wholesale supply or commercial export. The design of rules governing these activities for rongoā products would be undertaken by the regulator with input from the Māori advisory group.

49. Rongoā practice includes specific practices that have developed over centuries which provide some safety controls embedded in them. However, Manatū Hāuora's view is that

[10] **NZ Treasury (April 2017). 'Government Expectations for Good Regulatory Practice',** https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

[11] **The definition of rongoā practitioner will be centred around Māori understandings and practices.**

where rongoā products are made and supplied at commercial scale (i.e., wholesale) and exported in commercial quantities overseas, such embedded safety practices and protocols cannot be assumed and there is a strong Crown interest in providing assurance of ensuring product safety and ensuring traceability for all New Zealanders.

Manatū Hauora proposals if rongoā safety concerns arise

50. Likewise, Manatū Hauora considers that there may be some circumstances where certain rongoā products may need to be authorised or prohibited via the NHP authorisation pathway, in rare cases via a medicine's pathway, or prohibited, due to the nature of the risks associated with a particular ingredient and/or the mode of administration for the product. The regulator may also prohibit rongoā practitioners and whānau from using certain modes of administration in their practice. The ability for the regulator to make a rule that had the effect of restricting the practice of rongoā would be conditional on the regulator being satisfied that:

    a) there is a demonstrable risk of serious harm, serious injury or death, and

    b) the risks could not otherwise be managed sufficiently by a less restrictive measure.

51. The intention of these conditions would be to require the regulator to work with the Māori advisory group to identify and manage safety risks associated with these products. In some instances, the management of any identified risk(s) might be accomplished through low-level regulatory tools (e.g., information sharing, education and public announcements) as opposed to higher-level regulatory tools (e.g., minimum product quality and process standards, prohibitions, licensing obligations or supply and use restrictions). Te Aka Whai Ora is concerned that the Māori advisory group proposed does not have decision-making power and the regulator may overrule its view when deciding on whether regulations are necessary, and if so, to what degree.

52. These proposals represent Manatū Hauora's view of how the Crown can best balance its stated goals of providing for safety and quality therapeutic products and NHPs in a manner consistent with Te Tiriti.

53. Manatū Hauora has not sought the endorsement of Te Kāhui Rongoā Trust of these proposals (and it has not been offered). However, Te Kāhui Rongoā Trust is aware of the Manatū Hauora's proposals and their rationale.

Te Aka Whai Ora does not support Crown regulation of rongoā

54. Because rongoā rākau would otherwise be captured under the NHP regulations by default, Te Aka Whai Ora agrees that the Bill does need to directly consider rongoā. However, the view of Te Aka Whai Ora is that rongoā Māori should be protected, recognised and supported by the Bill, but not subject to regulation by the Crown.

Rongoā should not be regulated by the Crown

55. In the view of Te Aka Whai Ora, excluding rongoā from regulation under the Bill is required in order to uphold te Tiriti o Waitangi commitment set out in Article 2. Through Te Tiriti, Māori granted the Crown the right to govern and enact laws, but that right was qualified by the guarantee of 'tino rangatiratanga' (full authority) for iwi and hapū over their 'taonga katoa' (all their treasured things) in Article 2.

56. 'Protecting' and 'recognising' rongoā in the Bill, as articulated by Cabinet in 2021, does not require setting regulations for rongoā. In fact, protecting rongoā requires

recognising its special status for Māori and preventing Crown regulation in this space. This is because historically, the greatest risk to rongoā Māori has been the Crown.

57. Manatū Hauora's primary rationale for regulating some rongoā products, ingredients and 'modes of administration' is to protect public health and consumer safety. However, Te Aka Whai Ora has requested evidence that rongoā presents a safety risk and this has not been provided. Nor have we been able to find evidence of harm.

58. Te Aka Whai Ora notes that, since the inception of the ACC rongoā Māori service two years ago, they have provided more than 18,000 rongoā treatments to clients. Manatū Hauora / Te Aka Whai Ora rongoā providers have delivered more than 47,000 rongoā client contacts during the same period. With a combined total of more than 65,000 rongoā treatments in that time period, no complaints about safety have been received by any of these agencies during that time.

59. Te Aka Whai Ora has also not seen evidence that, if a risk to safety exists, alternative options to Crown regulation would be unable to manage such a risk. Te Aka Whai Ora's view therefore is that there is no justification for Manatū Hauora to regulate rongoā on safety grounds. We note that the Tōhunga Suppression Act 1907 and Quackery Prevention Act 1908 superficially had a health and safety rationale.

60. In its joint briefing to Manatū Hāuora and the Board of Te Aka Whai Ora, Te Kāhui Rongoā Trust state that "To regulate any aspect of rongoā Māori (ie. our tools of the trade, what claims we can make, modes of administration we can use, who can make or sell our products here and abroad) serves to over-ride the very tikanga that has sustained and protected the safe and effective practice of rongoā for generations. Instead we need to consider how new legislation (the Therapeutic Products Bill) could provide further legal protection of rongoā, not constrain it."

Issues around rongoā can be addressed outside of the Therapeutic Products Bill

61. Te Aka Whai Ora and Manatū Hauora agree that protecting rongoā Māori from commercial exploitation by bad actors is important. However, the Bill does not set out to consider issues of intellectual property. Te Aka Whai Ora's view is that this issue is better addressed outside of the Bill, and not within a regulatory context where an independent statutory officer within Manatū Hauora is the decision-maker.

62. Preventing the exploitation of mātauranga Māori and false use of rongoā claims, without imposing a Crown view of either mātauranga Māori or rongoā Māori, is a complex issue that Te Aka Whai Ora is continuing to work on. The solution may require strengthening of existing consumer and fair-trade laws, and better resourcing of rongoā experts to enable Māori to develop and implement their own solutions. Te Aka Whai Ora is also reviewing international examples where the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) was used to develop legislation or regulations that have protected the intellectual property of indigenous people. The Government response to the matters raised in Wai 262 will also be important.

Significant risk of legal action

63. If rongoā is subject to regulation under the Bill, it is highly likely these proposals will be subject to litigation by some Māori. S9(2)(h) [redacted]

64. In its briefing to Manatū Hauora and the Board of Te Aka Whai Ora, Te Kāhui Rongoā Trust stated, "If the Crown are unwilling to give due credence to Māori rights on this matter, Te Kāhui Rongoā Trust will have little option but to make application under urgency to the Waitangi Tribunal."

Te Aka Whai Ora response to Manatū Hauora proposals

65. Te Aka Whai Ora understands that Manatū Hauora's proposals would exempt some aspects of rongoā from regulation by the Crown. However, rongoā products produced for wholesale or commercial scale export *would* be subject to regulation. In addition, certain ingredients or modes of administration ***could*** be subject to regulation by the Regulator, including prohibition. We have set out our view on regulation above. Next, we will respond to specific elements of the Manatū Hauora's proposals for the regulation of rongoā under the Bill.

Māori advisory group

66. Manatū Hauora is proposing that a Māori advisory group be established to guide and advise the regulator when making decisions about issues affecting Māori, including regulation of rongoā. The group would not have decision-making authority. In our view, it is not enough for Māori to 'participate' in regulatory processes for rongoā, without any real authority. Te Aka Whai Ora also consider that Article 2 of Te Tiriti would not be upheld by the Crown even if it were to regulate rongoā in a partnership or co-governance model with Māori.

67. Manatū Hauora holds a relational agreement with Te Kāhui Rongoā Trust. One of the objectives of the agreement is "to **protect the practice of rongoā as understood by Māori** and support cross Government agency communications." In our view, imposing regulations on rongoā through the authority of Manatū Hauora does not align with protecting the practice of rongoā *as understood by Māori*.

68. Te Aka Whai Ora has considered alternative models to the regulatory model currently proposed by Manatū Hauora. Ultimately, Te Aka Whai Ora has reached the position that the Crown should not be governing rongoā Māori, even within a partnership model. Partnership was not what was envisaged by Te Tiriti when it comes to taonga Māori; it was tino rangatiratanga, with iwi and hapū exercising full authority over their taonga. We also recognise that rongoā practitioners, rather than the Crown, are the experts when it comes to rongoā. People and entities who do not hold expertise should not be exercising regulatory power over those who do.

69. In summary, Te Aka Whai Ora believe that rongoā is a taonga tuku iho and regulation is outside the remit of the Crown. Manatū Hauora's current regulatory proposals do not provide for Māori leadership in this space, even though rongoā is part of te ao Māori.

Exclusion based on traditional practice

70. Although rongoā has a long history of traditional practice, it is not a static body of knowledge or practice that remains the same over time. This means that from a Te Aka Whai Ora perspective, excluding rongoā as a 'traditional practice' is not sufficient, because rongoā has always been both a traditional and a contemporary practice based in mātauranga Māori, with a long history of use and refinement. Furthermore, there is a long history of rongoā ingredients or products being traded by iwi and hapū. This means that commercially produced rongoā is not a new concept that can be separated from the 'traditional practice' of rongoā.

Regulations reflect a singular viewpoint

71. Finally, Te Aka Whai Ora's view is that it is not appropriate for the Crown to impose regulations on rongoā that reflect a single understanding of what rongoā is or how it is used. Nor could the establishment of a Māori advisory group be expected to adequately reflect the different views of iwi, hapū and whānau when it comes to rongoā Māori. This is particularly true in the context of the regulator setting rules around rongoā; for example the quality, acceptable use or acceptable mātauranga for rongoā products that will be exported or produced for wholesale. Any such rule would necessarily reflect a single view of that issue. As set out above, this approach is fundamentally incompatible with what rongoā is.

Consultation

Advice from the Treaty Provisions Oversight Group

72. Manatū Hauora officials first met with TPOG on 17 August 2022 to discuss the proposals in an earlier draft of this briefing. During discussions with TPOG, one group member proposed including an operative Te Tiriti clause that applied only in relation to any regulatory action involving rongoā. As there remain differences in opinion between Manatū Hauora and Te Aka Whai Ora on the extent to which the Bill will intersect with rongoā, this model has not been developed further.

73. Initial written feedback from the membership of TPOG earlier highlighted the importance of establishing a clear policy rationale for including an operative Te Tiriti clause, supported by a comprehensive analysis and identification of Māori interests. TPOG's advice has subsequently partly informed Manatū Hauora's advice in relation to not including an operative clause given concerns it may not be specific enough or clear enough in its intent. It is likely TPOG will consider these matters further. Manatū Hauora will update your Office if/when we get further input from TPOG prior to you potentially taking an oral item to Cabinet and making decisions. If we do get further input prior to Cabinet, Manatū Hauora and Te Aka Whai Ora will jointly update you.

Te Kāhui Rongoā Trust and Māori clinicians

74. This briefing was developed following a series of wānanga and hui, involving Manatū Hauora officials, officials from the interim Māori Health Authority and representatives from Te Kāhui Rongoā Trust. This has built on an existing relational agreement between the Manatū Hauora and Te Kāhui Rongōa Trust.

75. The proposals in this report represent the Manatū Hauora and Te Aka Whai Ora's views of how the Crown can best balance its stated goals of providing for the safety and quality of therapeutic products and NHPs in a manner consistent with Te Tiriti. Manatū Hauora has not sought the endorsement of Te Kāhui Rongōa Trust of these proposals (and it has not been offered). However, Te Kāhui Rongōa Trust is aware of our proposals and their rationale. They disagree with Manatū Hauora proposals to allow for the regulation of rongoā products as NHPs where those products are manufactured for wholesale supply, commercial-scale export or where there are demonstrable safety risk(s) associated with a specific ingredient or mode of administration.

76. Manatū Hauora has commenced wider engagement with Māori clinicians and health service providers on the Bill and our efforts to reflect Te Tiriti. To date, this engagement has demonstrated a keen interest from Māori in how the Bill will recognise and elevate

rongoā Māori within the wider health system. While some Māori have expressed interest in the opportunities the Bill might present for rongoā, there is significant concern from many about the possibility of Crown interference with and regulation of rongoā.

77. It is expected that Māori, including Te Kāhui Rongōa Trust, will actively engage with the Bill at Select Committee and Manatū Hauora will continue to engage with tāngata whenua in advance of the Bill's introduction to Parliament. It is important to stress that the Crown's future relationship with rongoā Māori must recognise historic Treaty breaches and look to define legislation that avoids them.

Equity

78. Many of the above considerations about Crown involvement in the regulation of NHPs used in the practice of rongoā apply equally to other traditional healing practices. To the extent the Bill engages with and limits the practice of those traditions, this will be considered as part of a Bill of Rights Act analysis that will precede the introduction of the Bill.

79. Finally, the Bill seeks to fulfil the Crown's responsibility to provide for a robust, effective and flexible system for the regulation of therapeutic products to ensure all New Zealanders can have the necessary assurance that products supplied to or used on them are safe, meet relevant quality standards and claims can be substantiated. While Te Aka Whai Ora do not believe regulation of rongoā will promote equity, Manatū Hauora believes possible safety considerations mean that it does.

Next steps

80. We recommend that you direct officials to instruct PCO to implement your preferred option for the inclusion of Te Tiriti in the Bill and our proposals for the recognition and protection of rongoā Māori. This will support the introduction of the Bill to Parliament.

ENDS.

Appendix One – Waitangi Tribunal *Ko Aotearoa Tēnei* report recommendations on rongoā Māori

From page 226 of the report[12].

"7.12 Summary of Recommendations

The overall state of Māori health today is of great concern. in response to this the Crown has not promoted rongoā with any urgency. It either lacks a belief in the efficacy of rongoā or is too conscious of the lingering scepticism that previously led to the stigmatisation of tohunga and the Tohunga suppression Act 1907. **The** Crown's defensive mindset must shift. It must work in genuine partnership with Māori to support rongoā and rongoā services. it is time for the Crown to stress the positive benefits of rongoā and its potential to combat the ongoing crisis in Māori health. We recommend the Crown take the following actions as a matter of urgency :

- Recognise that rongoā Māori has significant potential as a weapon in the fight to improve Māori health. This will require the Crown to see the philosophical importance of holism in Māori health, and to be willing to draw on both of this country's two founding systems of knowledge.
- incentivise the health system to expand rongoā services. There are various ways in which this could be done – for example, by requiring every primary health care organisation servicing a significant Māori population to include a rongoā clinic.
- Adequately support Te Paepae Matua [at the time the national rongoā governance body] to play the quality-control role that **the Crown should not and cannot play itself**.
- Begin to gather some hard data about the extent of current Māori use of services and the likely ongoing extent of demand.
- We also recommend that, given the extent of environmental degradation and the challenges of access to the remaining bush, the Department of Conservation and the Ministry of Health coordinate over rongoā policy. Mātauranga rongoā cannot be supported if there are no rongoā rākau left, or at least none that tohunga rongoā can access."

[12] **https://waitangitribunal.govt.nz/news/ko-aotearoa-tenei-report-on-the-wai-262-claim-released/**

Appendix Two: ACC data on rongoā service uptake

ACC data suggests that rongoā services may be a more acceptable treatment for Māori who are uncomfortable with or unable to access mainstream ACC services:

- Māori are more likely to sustain a serious, life-changing injury but are less likely to access ACC services.
- Māori are 25% less likely to make a claim with ACC than non-Māori.
- 67% of the clients accessing rongoā Māori are of Māori descent
- As of the end of August 2021, ACC had approved rongoā Māori for around 1,200 claims and funded nearly 7,245 sessions.
- One in four of those clients hadn't previously received other forms of ACC care or treatment before benefitting from rongoā.
- 87% of ACC's rongoā clients no longer receive ongoing ACC support
- Fewer than 1% of rongoā clients have lodged a subsequent claim for the same injury site.
- Rongoā Māori is available to clients on request and can be used as standalone care or in conjunction with other treatment[13].

[13] https://www.acc.co.nz/newsroom/stories/rongoa-maori-a-traditional-healing-choice-for-all/

Appendix Three – Detailed proposals to revise the Bill to embed the principles of Te Tiriti (Option A)

Location in Bill (section title)	**Proposed revision**	**Gives effect to which Te Tiriti principle(s) and health sector principle in section 7 of Pae Ora Act.**
Principles guiding exercise of powers under this Act	In addition to current factors, the Regulator, Minister and other persons exercising powers under the Act must be guided by the following principles: • Innovation and business growth, including opportunities for Māori and iwi • Equity of access and health outcomes for Māori • Choice of quality services to Māori and other population groups	 Pae Ora Act section 7(1)(d)(i) & (iv) Equity, active protection Pae Ora Act section 7(1)(a) Options Pae Ora Act section 7(1)(d)
Functions of the regulator	In addition to current functions, 'when performing their functions and exercising their powers' the regulator will need to: • Foster a cooperative and consultative relationship with… other health entities under the Pae Ora (Health Futures) Act • Engage with Māori and other population groups, in a manner that supports their needs and aspirations in relation to the regulation of therapeutic products (including NHPs) and rongoā Māori • Maintain systems and processes to ensure the Regulator has the capacity and capability to understand Te Tiriti, mātauranga Māori, and Māori perspectives on the administration of the Act including tāngata whaikaha (disabled Māori)	 HSP 7(1)(e)(iv) HSP 7(1)(b) Equivalent to collective duty of board of Health New Zealand (s 16(1)(d) Pae Ora Act)

Regulatory strategy	Require the regulatory strategy developed by Regulator under Part 6 of the Act to specify how the Regulator will apply the principles of Te Tiriti when performing its regulatory functions. *An additional requirement might be necessary to further protect rongoā (see below)*	HSP 7(1)(b)
Review panels	The Regulator can establish a 'review panel' as an internal, merits review processes for certain 'reviewable decisions'. Currently, panels must include at least three members, one of whom must be a lawyer. We propose to amend the Bill to also require that a review panel that is convened to review an original decision involving a natural health product, or a class of natural health products that are used or intended to be used in traditional Maori healing, to include one or more representatives who have knowledge of rongoā Māori and mātauranga Māori.	HSP 7(1)(d)(vi)
Secondary legislation – consultation requirement	Require the Minister or Regulator (as appropriate) to consult with iwi, Māori, and any other person or organisation who are considered to be expert knowledge holders of rongoā Māori and mātauranga Māori before making Regulations, Rules, a Regulator's notice, or an exemption relating to therapeutic products or natural health products used in rongoā Māori. *This clause is in addition to additional and more stringent requirements for making rules and secondary legislation that would affect the practice of rongoā.*	HSP 7(1)(b)
Statutory Māori voice	This would provide a means by which the regulator can work with Māori (including, as appropriate, iwi and hapū) on matters of importance to Māori. Without prejudicing further decisions of Government, this group might also support the Government's response to the WAI 262 report. As an initial proposal we recommend that the remit of this committee would include: a. developing policy for rules and guidelines issued by the Regulator on: b. product standards for those plant-based remedies used in rongoā that will need to be authorised as NHPs or – in very rare cases – medicines under the Bill c. commercial export of rongoā products and wholesale supply d. the sustainable use of taonga species in the manufacture of NHPs in Aotearoa	

	e. the form of authorised health benefit claims for authorised NHPs that directly or indirectly reference rongoā Māori f. how the regulator should receive mātauranga Māori when submitted to 'substantiate' a NHP claim (whether for a rongoā product or otherwise). g. regulator decisions restricting products used in rongoā, for example controls on permitted ingredients and modes of administration. Other matters the committee could provide advice on include: h. the Regulator's Regulatory Strategy and its approach to the rongoā sector – including how it can partner with, or delegate monitoring powers, to Māori and iwi i. suitable nominees for committees established to review 'reviewable decision' (i.e., the internal review mechanism under the Bill) j. suitable nominees for other technical and advisory committees (e.g., medicine classification panels)	