

Briefing

Rapid briefing on rongoā proposals and agency feedback

Date due to MO: 10 May 2023 **Action required by:** 9am 11 May 2023

Security level: IN CONFIDENCE **Health Report number:** H2023024917

To: Hon Dr Ayesha Verrall, Minister of Health
Hon Peeni Henare, Associate Minister of Health

Consulted: Health New Zealand: Māori Health Authority:

Contact for telephone discussion

Name	Position	Telephone
Tim Vines	Manager, Therapeutics, Strategy, Policy and Legislation	s 9(2)(a)
John Whaanga	Deputy Director-General Te Pou Hauora Māori	s 9(2)(a)

Minister's office to complete:

- | | | |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Decline | <input type="checkbox"/> Noted |
| <input type="checkbox"/> Needs change | <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn | |

Comment:

Rapid briefing on rongoā proposals and agency feedback

Security level: IN CONFIDENCE **Date:** 10 May 2023

To: Hon Dr Ayesha Verrall, Minister of Health
Hon Peeni Henare, Associate Minister of Health

Purpose of report

1. This report provides you with Manatū Hauora’s advice in response to feedback from Te Aka Whai Ora on the draft Cabinet paper proposing to enable exemptions for small-scale NHP producers and rongoā.
2. This paper seeks your advice on two issues raised by Te Aka Whai Ora that could be addressed through changes to the Cabinet paper and subsequent Supplementary Order Paper.
3. This report discloses all relevant information and implications.

Summary

4. Agency consultation on a draft Cabinet paper proposing to enable exemptions for small-scale NHP producers and rongoā closed on 5 May 2023. Agency feedback was received from Te Aka Whai Ora, the Accident Compensation Corporation (ACC), Te Whatu Ora and the Ministry for Foreign Affairs and Trade (MFAT), Te Arawhiti, Te Puni Kōkiri and the Ministry of Business, Innovation and Employment (MBIE).
5. Information on the feedback from MBIE, Te Puni Kōkiri, ACC, Te Whatu Ora, Te Arawhiti and MFAT is discussed in another briefing [H2023024495].
6. **Appendix 1** includes a copy of the agency feedback from Te Aka Whai Ora. A detailed response from Manatū Hauora (the Ministry) to this feedback is included at **Appendix 2**.
7. In feeding back on the Minister’s draft Cabinet paper to exclude small-scale NHPs and rongoā, Te Aka Whai Ora have said that they do not support the proposed approach to exempting rongoā, through a provision that disapplies provisions in the Bill as they would apply to rongoā practitioners. Te Aka Whai Ora also do not support the establishment of a rongoā advisory committee to operationalise this exclusion. Instead, they claim that the approach set out in the Cabinet paper amounts to only ‘partial’ exclusion, stating ‘rongoā Māori should be excluded in its entirety from the Therapeutic Products Bill.’
8. For the reasons set out in this briefing, the Ministry disagrees with this characterisation of the exemption but has proposed two material changes to the draft Cabinet paper (and subsequent Bill) to reflect Te Aka Whai Ora’s feedback. We also recommend that the Cabinet paper and proposal proceed to be considered by the Cabinet Social Wellbeing Committee on 17 May.

9. The Ministry has amended the draft Cabinet paper to respond to general feedback from Te Aka Whai Ora, while noting that the proposal gives effect to your directions regarding the exclusion of rongoā [H2023911741].
10. Two issues raised in their feedback require your decision. These are:
 - a. the extent to which the Regulator must 'have regard' to advice from the proposed rongoā advisory committee on whether a person or activity falls within the scope of the proposed exemption
 - b. the appointment method and qualifications of members of the proposed rongoā advisory committee
11. Following a discussion between Manatū Hauora and Te Aka Whai Ora on 9 May, we recommend that the proposal in the Cabinet paper clarify that if the rongoā advisory committee (Committee) advises that an activity or person does fall within the scope of the exemption, the Regulator should 'give effect to' that advice. If the Committee advises that the activity or person falls outside the scope of the exemption, the Regulator should 'have regard to the advice'.
12. This proposal would ensure the Committee serves its intended role in helping to operationalise the rongoā exemption provision, while ensuring the Regulator maintains discretion in relation to compliance and enforcement activities. This approach also helps to avoid the perception that the Committee is, in effect, part of the Regulator by being directly implicated in potential enforcement action.
13. Te Aka Whai Ora have also suggested a Māori-led nomination process for the rongoā advisory committee. The status quo (ie, Ministerial appointment following consultation with the Minister for Māori Development and others) reflects our understanding of your preference. Given that the committee is intended to have a very narrow role and that other reforms (including future legislation to implement the Government's response to the WAI 262 report) may deal with broader policy issues associated with rongoā, we recommend retaining the status quo. However, we have presented two options for your consideration:
 - a. Retain the status quo but with an additional requirement to consult with the Chief Executive of Te Aka Whai Ora (who would need to seek advice from the iwi-Māori Partnership Boards on nominees).
 - b. Partial appointment by the Minister, with the majority of members nominated by iwi-Māori Partnership Boards.
14. In addition to the two proposed changes outlined above, Te Aka Whai Ora propose other revisions to the Cabinet paper should their first preference ('full exclusion of rongoā') not be accepted. This briefing provides you with advice from Manatū Hauora in relation to those suggestions.
15. Your urgent advice is required to enable changes to the Cabinet paper before it is lodged at 10am, Thursday 11 May. These changes need to be reflected in the Cabinet paper as the paper will serve as the basis for drafting instructions to the Parliamentary Counsel Office (PCO).

Recommendations

We recommend you:

- a) **Note** that Te Aka Whai Ora have provided comments in response to the circulation of the draft Cabinet paper containing proposals on small-scale NHPs and rongoā, and Manatū Hauora has responded (**Appendix 1, 2**) **Noted**
- b) **Note** that while the intent of the draft Cabinet paper is to give effect to your direction in H2023021741 that officials determine a pathway for excluding rongoā from the Bill, Te Aka Whai Ora have characterised the proposed approach as only a 'partial exemption' (with which Manatū Hauora does not agree) **Noted**
- c) **Note** that Manatū Hauora does not recommend a change to the approach outlined in the draft Cabinet paper circulated for Ministerial consultation on 2 May 2023 that would disapply many of the provisions in the Bill from their application to rongoā practitioners, exclude rongoā devices through regulations and establish a rongoā advisory committee to provide advice on the implementation of the exemption. **Noted**
- d) **Agree** to revise the Cabinet paper to provide that, in relation to advice from the Committee on whether a person or activity falls within the scope of the exemption provision:
- a. The Regulator must 'have regard to' the advice of the Committee [*Status quo*] **or** **Yes / No**
 - b. If the Committee advise that a person or activity does fall within the scope of the exemption provision, the Regulator must 'give effect to' the advice of the Committee **and** **Yes / No**
 - c. If the Committee advise that a person or activity does not fall within the scope of the exemption provision, the Regulator must 'have regard to' the advice of the Committee
- e) **Confirm** that the members of the rongoā advisory committee should be appointed by the Minister of Health, following consultation with the Minister for Māori Development and such other people the Minister of Health believes possess the relevant knowledge and expertise [*Status quo – recommended by Manatū Hauora*] **Yes / No**

f) If you disagree with e), **agree** that the members of the rongoā advisory committee should be appointed:

a. By the Minister of Health following consultation with the Minister for Māori Development and the Chief Executive of Te Aka Whai Ora (who should seek advice from iwi-Māori Partnership Boards)

Yes / No

b. Partially by the Minister of Health (eg, 2 of 9 members), but with a majority of members nominated by iwi-Māori Partnership Boards and the Minister for Māori Development

Yes / No



John Whaanga
Deputy Director-General Māori Health
Te Pou Hauora Māori
Date: 10/05/2023

Hon Dr Ayesha Verrall
Minister of Health
Date:



Steve Waldegrave
Associate Deputy Director-General
Strategy, Policy and Legislation
Date: 10/05/2023

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

Rapid briefing on rongoā proposals and agency feedback

Context

1. On 28 April 2023 Manatū Hauora circulated a draft Cabinet paper on regulating rongoā and small-scale NHP producers under the Therapeutic Products Bill (the Bill) for agency consultation. This included providing a copy to Te Aka Whai Ora.
2. Your office circulated the paper for Ministerial consultation on 2 May. Agency consultation closed on 5 May, and Ministerial consultation ends on 10 May.
3. On 2 May your office requested that the date for lodging the Cabinet paper be brought forward a week, with the Cabinet paper now to be considered by the Social Wellbeing Committee on 17 May.
4. Parliamentary rules governing how Manatū Hauora (as advisors to the Health Committee) can engage with submitters have shaped our engagement with Te Aka Whai Ora. As Te Aka Whai Ora lodged a submission on the Bill with Health Committee, Manatū Hauora did not discuss the proposals in the paper with them prior to agency consultation. Te Aka Whai Ora had the same opportunity as other agencies to provide input on the proposals.
5. Manatū Hauora has previously provided joint advice with Te Aka Whai Ora to the former Minister of Health on rongoā and the Therapeutic Products Bill [HR20220828]. The proposals in the Cabinet paper should be seen in the context of that previous briefing and the recent advice provided as part of the rongoā workstream [H2023024495].
6. Officials from Manatū Hauora and Te Aka Whai Ora met on 9 May 2023 to discuss a draft of this briefing.

General position adopted by Te Aka Whai Ora and Manatū Hauora response

7. Manatū Hauora has set out a full response to many of the points raised in the feedback of Te Aka Whai Ora (**Appendix 2**). The next two sections deal with two general matters: the request from Te Aka Whai Ora for rongoā to be excluded in its entirety and the manner in which members of the rongoā advisory committee should be appointed, and how the Committee's advice is to be adopted by the Regulator.

Calls to "fully" exempt rongoā without defining it in the Bill

8. Te Aka Whai Ora maintain their position that any reference to 'rongoā Māori should be excluded in its entirety from the Therapeutic Products Bill.' Te Aka Whai Ora does not support the proposed approach for the exclusion of rongoā Māori, nor the establishment of a rongoā advisory committee to operationalise the proposed exemption clause. This position is generally consistent with their submission to Health Committee and position in previous advice [HR20220828] (although the proposed rongoā advisory committee differs from previous proposals).

9. Manatū Hauora position is that the proposals give effect to your decision to exclude rongoā from the Bill and is consistent with our further advice on how that exemption can be implemented in the Bill. In particular, the proposed amendment to the Bill will clearly and explicitly disapply many of the provisions in the Bill to rongoā, while also not seeking to impose an explicit, Crown-led legislative definition of rongoā. The proposed provision will enable a wide range of manufacturing and supply activities by rongoā practitioners without requiring them to engage with the Regulator. Moreover, the establishment of a rongoā advisory committee will enable a Māori-led process of operationalising the exemption clause, which is consistent with the request from Te Aka Whai Ora for the definition to be left to secondary legislation.
10. Consistent with our assessment in September 2022 [H20220828], Manatū Hauora is also of the view that Te Aka Whai Ora's proposed approach for the exemption of rongoā is not able to be implemented in a manner that will maintain the integrity of the Bill or its timely passage. The approach Te Aka Whai Ora have proposed would likely result in gaming by businesses and individuals who would use 'rongoā' as a way to escape proper regulation under the Bill. With rongoā not mentioned in the Bill, there would be no mechanism to prevent this. This would both undermine the integrity of the new therapeutic product regime and rongoā itself.
11. Should a standalone rongoā Bill (or a Bill giving effect to the Government's response to the WAI262 report) be enacted in the future, that may be an appropriate time to revisit the mechanism for exempting rongoā from the Therapeutic Products Bill. Such a law could provide mechanisms for Māori to exercise control over the practice of rongoā in a way that mitigates the risks identified above.
12. Finally, the proposal in your Cabinet paper represents only one of several mechanisms by which rongoā can be exempted in practice:
 - a. The proposed small-scale NHP producer exemption will likely apply to rongoā practitioners, as will the existing NHP practitioner clause (clause 112).
 - b. Regulations made under clauses 16 and 19 will be made to fully exclude devices made and used in rongoā from the definition of therapeutic product. These regulations could also be used to fully exclude other products.
 - c. Regulations under clause 115 could enable rongoā practitioners (should Māori and the Crown consider it desirable) to engage in controlled activities involving any kind of therapeutic product (including medicines).
 - d. The Regulator can make future, more detailed, exemptions via the exemption power in clause 379.
13. As such, the proposed rongoā exemption as set out in your draft Cabinet paper should be seen as the 'floor' and not the 'ceiling' of how rongoā could be exempted in the future.

Concerns about the rongoā advisory committee

14. In their feedback, Te Aka Whai Ora have requested changes in how the Committee's advice is to be adopted by the Regulator and its method of appointment.
15. One of the grounds raised by Te Aka Whai Ora in its objection to the Committee is the concern that the Committee will be 'vetting' or 'validating' the credentials of rongoā practitioners and making inappropriate judgement calls on the validity of local tikanga

and kawa. While Manatū Hauora acknowledges this concern, we believe it is based on a misunderstanding of how the Committee will operate in practice.

16. On 9 May 2023, Manatū Hauora officials met with officials from Te Aka Whai Ora. In that meeting, we explained that there is no proposal for rongoā practitioners to seek 'approval' to engage in activity protected by the rongoā exemption provision. Individuals can self-assess and continue to practice without applying to the Regulator or the Committee. The Committee's role is limited to providing advice to the Regulator in the event a complaint or concern is received by the Regulator that a person or business is engaging in activity that contravenes the Act.
17. In determining whether a person or business' activities fall within the scope of the rongoā, the Regulator would seek advice from the Committee. The Committee's advice would inform the Regulator's decision whether to initiate compliance and enforcement action against individuals or businesses if there is a suspicion that they are not, in fact, practicing rongoā and so should be complying with other requirements of the Act.
18. **s 9(2)(g)(i)**
Discussion then focused on the extent to which the Regulator should 'give effect to' or 'take account of' the advice of the Committee. Manatū Hauora outlined its concerns that requiring the Regulator to give effect to the advice of the Committee (where the Committee found that an individual did not fall within the scope of the provision) places Committee members in a position of effectively directing the Regulator to imitate compliance actions – potentially against other Māori.
19. This possibility may prove controversial to Māori and members of the Committee. At best, it may make it more challenging to find appropriate nominees for the Committee.
20. Te Aka Whai Ora clarified their position that the Regulator should not be able to disregard the advice of the Committee if it were to advise that a person or activity *did* fall within the scope of the rongoā provision. In this instance, the Regulator should 'give effect to' the advice of the Committee (ie, that a person or business was not contravening the rongoā provision). Where the Committee advised that a person or activity did not fall within the scope of the provision, it would be appropriate for the Regulator to make the final decision (as the matter was not, in fact, about rongoā).
21. Manatū Hauora agrees that this approach would be consistent with the overall mission of the rongoā advisory committee to operationalise the exemption provision and to provide a non-legislative definition of rongoā. As such, we have proposed an amendment to the Cabinet paper, outlined at Recommendation D.
22. The second general concern raised by Te Aka Whai Ora relates to the method of appointment for the Committee. Currently the Committee is proposed to be appointed by the Minister of Health following consultation with the Minister for Māori Development and other people the Minister consider have relevant expertise. Te Aka Whai Ora recommend that Māori nominate and appoint the members of the Committee.
23. **s 9(2)(g)(i)**
Manatū Hauora believes the current proposal is appropriate and could be augmented by informal conventions involving seeking nomination from Māori organisations.
24. However, should you wish for a more explicit obligation, the current Cabinet paper could be amended to require the Minister of Health to consult with the Minister for Māori

Development and the Chief Executive of Te Aka Whai Ora, who would seek advice from the iwi-Māori Partnership Boards. An even stronger option would be to require the Minister to seek nominations from the iwi-Māori Partnership Boards in addition to the Minister for Māori Development.

25. It is important to consider the capacity of Iwi-Māori Partnership Boards to undertake the nomination of members to the Committee. Iwi-Māori Partnership Boards are at varying degrees of establishment and have a wide range of roles and responsibilities as determined by the Iwi-Māori Partnership Boards themselves.

Concluding comments on the feedback from Te Aka Whai Ora

26. Our position on other issues raised by Te Aka Whai Ora is set out in **Appendix 2**. In that response Manatū Hauora has indicated a number of places where changes can or have been made to the draft Cabinet paper. These changes do not alter the substantive policy in the paper. Manatū Hauora officials are available to discuss our response further.

Equity

27. 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 be assured that products supplied to or used on them are safe, meet relevant quality standards and claims can be substantiated. The basis on which the proposed exemption has been developed has applied a safety lens consistently across other healing practices and NHPs. To the extent the rongoā exemption provides for a more favourable treatment of rongoā than other healing traditions under the Bill, this is justified on the unique and important Te Tiriti interests.

Next steps

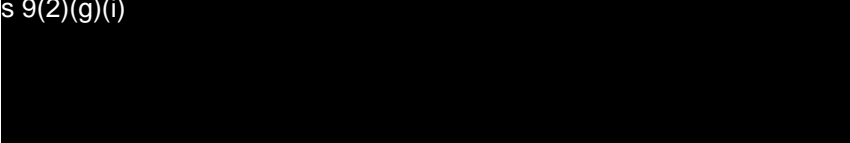
28. We recommend that you confirm your previous decision on the appointment method for the rongoā advisory Committee or provide your advice on an alternative option. We also recommend that you provide your advice on the degree to which the Regulator will need to take into account the advice of the Committee.
29. This briefing has been copied to the Associate Minister of Health and you may wish to discuss this briefing with him. In order to meet the current timetable for the Cabinet paper, **we require a decision by close of business 10 May 2023, to enable the final Cabinet paper to be lodged by 10am 11 May 2023.**

ENDS.

Minister's Notes

Appendix 1 –Te Aka Whai Ora feedback on draft Cabinet paper

s 9(2)(g)(i)

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Appendix 2 – Manatū Hauora responses to Te Aka Whai Ora feedback

Te Aka Whai Ora feedback/request	Manatū Hauora response/proposed action
<p>We recommend the definition [of rongoā] is set in secondary legislation, which will allow time for an engagement process with Māori, and for Māori to lead the crafting of the definition</p>	<p>The proposed SOP will not insert a definition of rongoā into the Bill. Rather it will only insert the word 'rongoā'. The term would then have its 'ordinary meaning' and only the courts could give a binding interpretation of the term.</p> <p>The role of the advisory committee will provide a mechanism for a non-legally binding definition of rongoā to develop over time, but only within the context of how the exemption in the Bill applies.</p> <p>Given this, the Ministry proposed no change.</p>
<p>The definition of rongoā and the exclusion clause should be led by Māori, including by tohunga and mātanga rongoā. In particular, Māori should lead the development of instructions for the Government and PCO to draft the exclusion clause</p>	<p>As above, the Bill is not proposing to define the word rongoā and, as such, no detailed instructions to PCO are required.</p> <p>The proposal by Te Aka Whai Ora is intended to be reflected through the membership and operation of the rongoā advisory committee. Again, this Committee's advice is limited to how the specific clause in the Bill is to be applied by the Regulator.</p> <p>The Bill does include other mechanisms to facilitate a different exemption of rongoā, should the proposed mechanism prove insufficient. For example, regulations made under clauses 16 and 19 and exemptions made under clause 379. However, the current proposal balances removing most obligations from the Bill for rongoā practitioners with maintaining the overall integrity of the Bill (including in its application to medicines).</p>
<p>Te Aka Whai Ora should facilitate and enable Māori to undertake this work</p>	<p>We note Te Aka Whai Ora's current strategic kaupapa in this area. As above, we do not believe that further detail is required in an SOP but that a future rongoā Bill may provide an opportunity to change how rongoā sits within the therapeutic products regime.</p>
<p>Appointment [to the rongoā advisory committee] should be led by Māori and without the input of the Regulator or Government, for example along the lines of Te Mātāwai process</p>	<p>The Ministry has sought the views of Minister Henare on the appointment process for the rongoā advisory committee. The current proposal reflects our understanding of the preferred approach. However, we have also considered other options, including nominations being received by the iwi-Māori partnership boards, or requiring consultation with Te Aka Whai Ora.</p>

	<p>This issue was discussed with Te Aka Whai Ora on 9 May and this briefing now outlines two different options for your consideration.</p> <p>For completeness, we note that two members of the board of Te Mātāwai <i>are</i> appointed by the Minister for Māori development. As a statutory entity, Te Mātāwai also has a different form than the advisory committee proposed in the Cabinet paper, and it helps in the administration of a standalone law on te Reo Māori.</p>
<p>Appointment [to the Committee] should not require having knowledge of matters unrelated to rongoā, such as the machinery of Government</p>	<p>The Ministry has sought the views of Minister Henare on the appointment process for the rongoā advisory committee. The current proposal reflects our understanding of the preferred approach.</p> <p>This issue was discussed with Te Aka Whai Ora on 9 May and no changes are proposed.</p>
<p>Te Aka Whai Ora has had no previous involvement in the drafting of this Cabinet paper, nor did we see any of the preceding advice to Ministers. This makes our inclusion in the consultation section of the Cabinet paper inaccurate as it creates the impression that we had been consulted on the paper which Ministers have received.</p>	<p>We received a similar request from ACC and will amend the Consultation section in the Cabinet paper to make it clear that agency and Ministerial consultation occurred at the same time. As a result, no agencies had the opportunity to provide input to the Cabinet paper before it was circulated to Ministers.</p>
<p>The Cabinet Paper should appropriately consider te Tiriti as a primary justification for excluding rongoā Māori from the Bill.</p>	<p>Te Tiriti issues are acknowledged in the Cabinet paper and the Ministry's view (including the view of its Quality Assurance Panel that reviewed the paper) is that the representation of safety and Te Tiriti issues is appropriate.</p> <p>The rongoā exemption builds on other exemptions, including the existing NHP practitioner exemption (clause 112) and the proposed small-scale NHP producer exemption. These exemptions are premised on risk/safety and so it is logical to frame the rongoā exemption in similar terms, while also noting the unique and compelling Te Tiriti considerations.</p> <p>We note that DPMC guidance is that Cabinet papers are to be no more than 10 pages and we have received explicit instruction from the Minister's office to keep the paper to this length.</p>

<p>The Cabinet Paper would also benefit from a more fulsome analysis of legal jurisprudence on te Tiriti obligations the Crown has to better inform Cabinet of the risks associated with the Paper's proposal.</p>	<p>See above comment on Cabinet paper length.</p>
<p>The alternative proposal of Te Aka Whai Ora to 'exclude rongoā under clause 16(3) in secondary legislation.'</p>	<p>Regulations under clause 16(3) are the intended pathway to exclude devices made and used in rongoā. However, Ministers have been clear that an exemption for rongoā <i>per se</i> should be upfront in the Bill and not left to secondary legislation.</p> <p>As discussed above, clause 16(3) could be used to broaden the exemption following the enactment of the Bill. Likewise, regulations made under clause 115 could enable a wider range of activities to be undertaken by rongoā practitioners (including those not traditionally considered part of rongoā) should Māori and the Government consider this desirable.</p> <p>It would be for the Minister to determine the scope of any future regulations that widened the exemption, and they could consider feedback from Māori or Te Aka Whai Ora on the workability of the proposed exemption. Consequently, the proposed exemption should be seen as creating a floor, and not a ceiling for the future of the exemption.</p>
<p>The Cabinet paper does not articulate a rationale for why a full exclusion of rongoā Māori from the Therapeutic Products Bill was not considered, or is not possible.</p>	<p>We have amended the paper to provide a brief overview of other options considered, but not adopted.</p>
<p>It is unclear to us where the proposal to establish a Māori advisory committee has emerged from.</p>	<p>The advisory committee gives effect to the Ministers' decision in response to the rongoā workstream advice provided by Manatū Hauora. Ministers agreed to excluding rongoā from the Bill and enabling a mechanism by which Māori could determine the scope of the exemption. The rongoā advisory committee creates a practical mechanism to both include an upfront exemption in the Bill and to allow Māori to shape how 'rongoā' is to be understood and applied by the regulator (but only within the context of the Bill).</p>
<p>We recommend:</p> <ul style="list-style-type: none"> a) Noting in the Cabinet Paper that the strategic rongoā kaupapa is currently underway, and b) Decisions in relation to an appropriate mechanism under 	<p>We have amended the paper to reflect point a).</p> <p>The rongoā advisory committee is an essential mechanism to ensure the exemption in the Bill can be implemented from day one. Including explicit terms of reference in the Bill provides certainty for Māori about the scope of the Committee's remit.</p>

<p>the Bill are delayed by moving to secondary legislation while this kaupapa is underway.</p>	<p>There is the ability to amend the proposal to allow for other terms of reference to be added to the Committee via secondary legislation. We have not proposed that approach previously because it would undermine the limited role of the Committee as giving effect to the proposed exemption of rongoā. A Committee with a wider, more policy oriented remit, would be more appropriate in a standalone rongoā Bill.</p>
<p>Exempting 'rongoā practitioners' and not rongoā Māori, and the proposed mechanism to do so, pulls the practice, the mātauranga, tikanga and kawa into the Crown space.</p>	<p>As discussed above, the scope of the Bill is about therapeutic products and not healing practices. As such, the exemption is framed in terms of who can do what with products regulated under the Bill as therapeutic products. To exempt 'rongoā' without referring to products and those who make and use them (ie, practitioners) would require adding additional material into the Bill defining rongoā, which would be contrary to the intention of Ministers to exclude rongoā from the Bill.</p> <p>A standalone rongoā Bill could eventually resolve a number of these issues.</p>
<p>The intention to enable mātanga to continue to exercise their rangatiratanga on a marae or other significant site, but not elsewhere, is problematic. How will the Regulator or advisors know what and where is traditional practice or a significant site and what isn't for any given tohunga, whānau, hāpu or iwi?</p>	<p>The Ministry would welcome further examples from Te Aka Whai Ora that could be considered in drafting the SOP (noting that it would need to be at a high level, with further detail to possibly be developed by the Committee).</p>
<p>Rongoā practitioner is not a term used by Māori or within te ao Māori. It appears the term "rongoā practitioner" has been created by drafters to align with the definition of "health practitioner" in the Bill, and in doing so attempts to apply a definition which has no connection to Māori or rongoā generally.</p>	<p>Manatū Hauora acknowledges this concern. However, it is an unavoidable consequence of drafting an exemption that focuses on a class of people, engaged in certain activities involving certain products. Similar considerations may also have led to Te Aka Whai Ora using the same term in its Find a Rongoā Practitioner list. Likewise, the trust deed establishing Te Kāhui Rongoā refers to 'practitioners of rongoā' and submissions on the Bill from Te Rangiora Rongoā Practitioners and the Aotearoa Rongoā Māori Collective used the terms 'rongoā practitioner and Rongoā Māori practitioners', respectively.</p> <p>The use of a term in law that differs from how a community refers to themselves is not uncommon. For example, the term 'NHP practitioner' (used in clause 112 of the Bill) is not a term used by many (if any) traditional healing practitioners but is helpful to describe a general class of individuals in law.</p>

<p>We recommend further clarification on what is intended to be captured by commercial wholesale</p>	<p>We have revised the paper to clarify this. The exemption is intended to authorise the supply of products that would usually meet the Bill's definition of 'wholesale supply'. What is intended here, is to distinguish between small and closely held supply relationships and large transitions where the connection between manufacturer and consumer is broken by a commercial intermediary (such as a large grocery chain or wholesaler).</p>
<p>Recommendation 3 – minor change to wording</p>	<p>We have made the proposed change to recommendation 3.</p>

PROACTIVELY RELEASED