

March 2023

## Submission on the Therapeutic Products Bill

To the Health Committee,

Te Hīringa Mahara, the Mental Health and Wellbeing Commission, welcomes the opportunity to make a submission on the Therapeutic Products Bill.

Te Hīringa Mahara was established following the *He Ara Oranga : Report of the Government Inquiry into Mental Health and Addiction*. We are an independent Crown entity, with a legislated role to assess, report, and make recommendations on the mental health and wellbeing of people in New Zealand, and the factors and approaches that affect them. We have a legislated role to advocate for the collective interests of people who experience mental distress or addiction (or both), and the persons (including family and whānau) who support them. We also have a legislated responsibility, when carrying out these functions, to have particular regard to the experience of, and outcomes for, Māori. These roles, and responsibilities underpin our submission on this Bill.

This submission stands alone, and so Te Hīringa Mahara does not seek to appear before the committee to speak to it. However, if the Committee wants further clarification on any of the points that follow, we would be happy to advise in writing or in person.

### Our position

Te Hīringa Mahara does not support the Therapeutic Products Bill progressing, in its current form.

### **The Bill is silent on the rongoā Māori products and services that it will have meaningful impacts on.**

Te Hīringa Mahara is supportive of efforts to improve or protect the efficacy and safety of health products in Aotearoa. However, Tāngata whaiora have told us they want services to offer genuine choice, including more accessible kaupapa Māori and peer-led options and holistic supports.

Rongoā Māori plays a key role in many kaupapa Māori health services for many people in Aotearoa. However, the Bill, as currently drafted, can be expected to reduce the availability of Kaupapa Māori and holistic supports, where they include rongoā Māori products.

It is important to note the term 'rongoā' covers a range of products, therapies, and interactions. This has two key impacts on this submission and the development of the Therapeutic Products Bill:

1. Rongoā is not easily defined, and any definition will be somewhat contested. Therefore, it is not as simple as explicitly including or excluding 'rongoā' in the Bill.
2. Rongoā products, including 'rakau rongoā' or plant-based medicines, are often inextricably linked with the therapies they accompany. They can be better considered a part of a model of care than a discrete health product. If the Bill limits the availability of rongoā products, it can be expected to limit the availability of other Kaupapa Māori services. As noted by the Waitangi Tribunal<sup>1</sup>:

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<sup>1</sup> Wai 262 volume 2, 2011, *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity*. Te Taumata Tuarua volume 2

*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.*

Further, beyond the therapeutic benefits that rongoā Māori provides, it is important to understand that there are broader wellbeing benefits from having and accessing rongoā Māori. As the Ministry of Health's 2021 review of the rongoā sector<sup>2</sup> notes:

*“key impacts and benefits of rongoā come about because it is a mātauranga Māori approach to wellbeing . As such, rongoā reconnects whānau to te ao Māori and their identity. It decolonises wellbeing and gives expression to whānau rangatiratanga by encouraging and empowering whānau to be their own healers. Rongoā provides a complementary or alternative approach to mainstream health services . It supports whānau to reclaim traditional healing as a birth right and it reaffirms and elevates traditional Māori healing as a valid and legitimate wellbeing practice for today's society”.*

We recognise the previous Minister of Health's comments on wanting to 'support the traditional practice of rongoā' while providing assurances for safety, and we acknowledge that there is debate about the definition and different tikanga relating to rongoā, and the extent to which rongoā will be affected by the Bill.

Regardless, while there is no mention of 'rongoā' in the Therapeutic Products Bill, some, if not all, products used in rongoā practice appear to be covered by the 'Natural Health Products' definition in the Bill and will therefore be regulated as such. This can be expected to reduce the availability of rongoā products, and consequently services, as:

1. small providers will be less likely to shoulder the burden and cost of obtaining market authorisation;
2. Rakau rongoā from native plants are less likely to be previously recognised or studied by international bodies, so will face greater barriers to approval than many western health products; and
3. the regulatory scheme is unlikely to recognise the broader wellbeing benefits of rongoā Māori, as described above.

The incidental regulation and limitation of rongoā Māori raises a further, fundamental, issue with the Bill: by regulating rongoā Māori in this way, the Crown fails to uphold its te Tiriti obligations.

**The process which has developed the Bill does not reflect the importance of rongoā under te Tiriti o Waitangi.**

Rongoā is an Indigenous body of knowledge and, as recognised by Te Aka Whai Ora (the Māori Health Authority), is considered a taonga<sup>3</sup>:

*For centuries, whānau, hapū and iwi have cultivated, cared for, and used rongoā. The knowledge and the practice of rongoā have been passed down through the*

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<sup>2</sup> [https://www.health.govt.nz/system/files/documents/publications/Rongoā\\_report\\_full\\_report\\_final\\_master.pdf](https://www.health.govt.nz/system/files/documents/publications/Rongoā_report_full_report_final_master.pdf)

<sup>3</sup> <https://www.teakawhaiora.nz/our-work/rongoa/>

*generations within whānau, hapū and iwi, with Māori tino rangatiratanga over rongoā protected under Te Tiriti o Waitangi.*

The Crown therefore has a responsibility to protect rongoā as a taonga and to honour Māori tino rangatiratanga. However, the Bill does not mention rongoā, and gives very little consideration to the impacts on Māori of the regulation it describes.

We recognise that the Government is carrying out a parallel process while the Bill progresses, whereby a “rongoā work stream will explore the interface of the Therapeutic Products Bill and rongoā”, to strengthen this. However, given this workstream was only announced on the same day the Bill was presented to the House, it has not been reflected in the development of the Bill so far - this does not reflect a good process, or a relationship built on trust.

Further, Manatū Hauora states it will “provide advice to the Minister in April 2023, following targeted engagement with key stakeholders, Māori partners and expert groups”. Given the different tikanga and kawa around rongoā across iwi and hapū, this consultation period is concerningly short, and the resulting advice will come after submissions to the Health Committee have closed and after the public window to engage.

Given the status of rongoā as taonga, this additional workstream and late engagement do not appear to reflect the partnership principle in te Tiriti. The order of this process needs to be reversed, with meaningful engagement with Māori shaping the Bill.

Referring to the Ministry of Health rongoā review again:

*We see in rongoā the typical clash of te ao Māori and te ao Pākehā worldviews. This phenomenon is not new but reflects a process whereby the rongoā sector must assert their views, values, and position if they are to be understood by the Ministry and its policy, legislation, and funding arms. Ministry engagement with the rongoā sector is best described as patchy and the sector feel they have often not been consulted nor resourced to enable this to occur.*

Given that this review was published in 2021, it is concerning that these findings do not appear to have been heeded in the development of the Therapeutic Products Bill.

**The Bill in its current form does not allow or provide for Māori to exercise and determine control over rongoā and undermines tino rangatiratanga.**

Perhaps unsurprisingly, given the process followed above, the Bill presents an imbalance in the te Tiriti partnership, with the Crown having full control over a Taonga Māori:

1. Through the design of the Bill, especially the definitions in Part 2, the Crown decides whether and how rongoā products are covered by law.
2. Through its regulator, especially Part 9 of the Bill, the Crown controls the authorisation and use of rongoā products, and the approval of rongoā product manufacturers and providers to practice.

At the same time, the Bill expects very little of the regulator, beyond:

1. ensuring “they have the capacity and capability to understand and give effect to the principles of te Tiriti [...]; and to understand and take account of mātauranga Māori and Māori perspectives in relation to therapeutic products”; and

2. having the function to “to engage with Māori and other population groups in a manner that reflects their needs and aspirations in relation to therapeutic products”.

Given the recognition of rongoā as taonga, this imbalance and focus on ‘engaging’ and ‘taking views into account’ does not appear to uphold the Crown’s te Tiriti obligations.

**The Bill should be put on hold, until these issues can be addressed.**

The Ministry’s own rongoā review (referenced earlier) notes: that “Rongoā as an expression of mātauranga Māori means governance and oversight needs to reside with Māori and the rongoā sector.” As such, we do not assume to describe the wording that would make this work in the Bill and in practice, but reflecting such governance and oversight in the Bill might look like changing Parts 2 and 9 of the Bill to ensure Māori can exercise:

1. Determination of what the scope of ‘rongoā’ is, in giving effect to the Bill.
2. Determination of whether a product does or does not come under the Bill.
3. Co-regulation of health products, including market authorisation decision-making
4. Devolved decision-making on approval of practicing rongoā providers under the Bill, to tribal councils (e.g., hapū, marae)

A precedent for devolved decision-making has already been set through by the Fisheries (Kaimoana Customary Fishing) Regulations 1998, which enables hapū and marae to administer the assessing, reporting and granting of permission of non-commercial fishing permits in their respective rohe, and in accordance with kawa and tikanga. A similar approach could likely be followed for rongoā practices, with sufficient resourcing to accompany the devolution of this decision making.

Such changes could be made alongside effort to deliver on the Waitangi Tribunal’s WAI262 findings, in which it recommended that the Crown take the following actions “as a matter of urgency”:

1. Recognise that rongoā Māori has significant potential as a weapon in the fight to improve Māori health.
2. Incentivise the health system to expand rongoā services.
3. Adequately support Te Paepae Matua (the national body that supports and represents tohunga) to play the quality control role that the Crown should not and cannot play itself.
4. Begin to gather some hard data about the extent of current Māori use of services and the likely ongoing extent of demand.

## **In summary**

Te Hiringa Mahara does not support the Therapeutic Products Bill proceeding in its current form.

- The Bill will have a detrimental effect on the provision of Rongoā products and services, and the wellbeing that they support.
- The process that has developed the Bill and related work falls short of the partnership approach expected of the Crown and does not serve Māori well.
- The Bill restricts Māori control over the taonga that is Rongoā, and therefore undermines tino rangatiratanga and fails to uphold te Tiriti.
- The Bill should not proceed until an appropriate partnership process can be put in place, and Māori can exercise tino rangatiratanga through both the development and administration of the Bill.