Minister of Health

Cabinet material and briefings: Therapeutic Products Bill

24 August 2023

These documents have been proactively released by the Ministry of Health on behalf of the Minister of Health, Hon Dr Ayesha Verrall and the Associate Minister of Health, Hon Peeni Henare.

Title of Cabinet papers:

Supplementary Order Paper to the Therapeutic Products Bill: Approval for Introduction

The regulation of small-scale producers of natural health products, and rongoā under the Therapeutic Products Bill

Titles of minutes:

Report of the Cabinet Legislation Committee: Period Ended 30 June 2023 (CAB-23-MIN-0286)

Therapeutic Products Bill: Supplementary Order Paper (LEG-23-MIN-0108)

Regulation of Small-Scale Producers of Natural Health Products, and Rongoā under the Therapeutic Products Bill (Cab-23-MIN-0188)

Regulation of Small-Scale Producers of Natural Health Products, and Rongoā under the Therapeutic Products Bill (SWC-23-MIN-0054)

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Key to redaction codes:

s9(2)(a): to protect personal privacy

s9(2)(f)(iv): to protect constitutional conventions protecting for the time being the confidentiality of advice tendered by Ministers and officials

s9(2)(g)(i) to maintain the effective conduct of public affairs through the free and frank expression of opinions

s9(2)(h): to protect legal professional privilege

Out of scope of the subject of this proactive release.

CAB-23-MIN-0286

Cabinet

Minute of Decision

Report of the Cabinet Legislation Committee: Period Ended 30 June 2023

On 3 July 2023, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 30 June 2023:

Out of scope	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
LEG-23-MIN-0108	**Therapeutic Products Bill: Supplementary Order Paper** Portfolios: Health / Associate Health (Māori Health)	CONFIRMED
Out of scope	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Diana Hawker
Acting Secretary of the Cabinet

LEG-23-MIN-0108

Cabinet Legislation Committee

Minute of Decision

Therapeutic Products Bill: Supplementary Order Paper

Portfolio **Health / Associate Health (Māori Health)**

On 29 June 2023, the Cabinet Legislation Committee:

1 **noted** that the Therapeutic Products Bill (the Bill), which this Supplementary Order Paper (SOP) amends, holds a category 2 priority on the 2023 Legislation Programme (must be passed before the 2023 general election);

2 **noted** that the Bill will repeal the Medicines Act 1981 and Dietary Supplements Regulations 1985;

3 **noted** that the new legislation will regulate medicines, medical devices, active pharmaceutical ingredients and natural health products;

4 **noted** that in May 2023, Cabinet agreed to amend the Bill to disapply certain obligations in the Bill relating to rongoā and small-scale producers of natural health products (NHPs) by introducing a Supplementary Order Paper [CAB-23-MIN-0188];

5 **noted** that this SOP will implement the decision referred to in paragraph 4 by amending the Bill to:

5.1 enable the making of regulations to disapply some of the obligations in the Bill for particular categories of producers of natural health products (NHPs)

5.2 expressly disapply provisions in the Bill that would impose a range of regulatory obligations on rongoā practitioners

5.3 establish a rongoā advisory committee to advise the Minister and the Regulator on matters related to rongoā and the application of the disapplication

5.4 make minor, technical amendments to maintain the protection of confidential information associated with innovative medicines

5.5 implement other technical and minor changes required by the Parliamentary Counsel Office for drafting;

6 **noted** that to remove many of the obligations in the Bill from applying to rongoā the SOP will add the terms ‘rongoā’, ‘rongoā practitioner’ and ‘rongoā product’ to the Bill. Once established, the rongoā advisory committee will provide advice on these terms;

7 **agreed** that the Minister of Health may authorise minor changes to the SOP that are not inconsistent with the policy recommendations in this paper up until the time that the SOP is tabled;

8 **noted** that we propose to report back to Cabinet on the effectiveness of these provisions within two years of the Act's commencement and whether strong controls on advertising, including prohibiting direct-to-consumer advertising of prescription medicines are warranted;

9 **approved** the SOP to the Therapeutic Products Bill [PCO 19563-1/5.3] for release, subject to the final approval of the government caucus and sufficient support in the House of Representatives.

Rebecca Davies
Committee Secretary

Present:
Hon Grant Robertson (Chair)
Hon Andrew Little
Hon Nanaia Mahuta
Hon Barbara Edmonds
Hon Willow-Jean Prime
Hon Rachel Brooking

Officials present from:
Office of the Prime Minister
Officials Committee for LEG

In confidence

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet Legislation Committee

Supplementary Order Paper to the Therapeutic Products Bill: Approval for Introduction

Proposal

1 This paper seeks approval for the introduction of a Supplementary Order Paper (SOP) to the Therapeutic Products Bill (the Bill).

Policy

2 The Bill will repeal the Medicines Act 1981 and Dietary Supplements Regulations 1985 (made under the Food Act 2014). The Bill will provide for the comprehensive and risk-proportionate regulation of medicines, medical devices, active pharmaceutical ingredients and natural health products (NHPs).

3 The rationale for the Bill, including the policy rationale for regulating NHPs and ingredients used in some rongoā products, is set out in previous Cabinet papers:

3.1 The regulation of NHPs in the Bill [SWC-21-SUB-0109];

3.2 Therapeutic Products Bill: Approval for Introduction [LEG-22-SUB-0212];

3.3 The regulation of small-scale NHP producers, and rongoā [SWC-23-SUB-0054].

4 This SOP gives effect to Cabinet's decision [CAB-23-MIN-0188] to amend the Bill via SOP to address concerns relating to the regulation of small-scale NHP producers and rongoā practitioners. The SOP will disapply legal provisions in the Bill as they currently relate to rongoā, create a regulation-making power to disapply provisions for small-scale NHPs producers, and make other minor amendments, including those necessary to ensure consistency with New Zealand's international obligations.

5 The Bill is currently before Parliament and has a category 2 priority (must be passed before the 2023 general election).

6 The Minister of Health will report back to Cabinet on the operation of the small-scale NHP producers and rongoā provisions within two years of the commencement of the Bill. They will also report on the impact of legislative provisions in relation to rongoā practitioners who operate as small-scale producers. Finally, the Minister will also report back on the effectiveness and appropriateness of provisions in the Bill that continue the status quo in relation to direct-to-consumer advertising of prescription medicines (DTCA-PM).

Content and effect of the Supplementary Order Paper

7 The SOP will amend the Bill to enable the making of regulations to allow manufacture and export of a NHP without market authorisation and/or a manufacturing licence for certain NHPs. The regulations would relate to products made and supplied in New Zealand and not intended for resale or wholesale supply.

8 The SOP will amend the Bill to:

8.1 disapply provisions which would otherwise require a rongoā practitioner, or an associate of the practitioner, to obtain a market authorisation or manufacturing license to manufacture or supply a rongoā product as part of a rongoā service or activity;

8.2 give effect to Cabinet's decision to include a statement that the intent of the new rongoā provisions is to provide for the Crown's obligations under Te Tiriti o Waitangi in relation to rongoā.

9 The SOP will also amend the Bill to establish a rongoā advisory committee (the Committee). The functions of the Committee would be:

9.1 to advise the Regulator on matters relating to the Regulator's performance of their functions and exercise of their powers in relation to rongoā;

9.2 to advise the Minister and Regulator on other matters relating to rongoā and the Act;

9.3 to give any other advice requested by the Minister or Regulator;

9.4 any other advisory functions conferred on the Committee by the Minister by written notice.

10 The SOP makes consequential amendments to the Bill to ensure other provisions in the Bill are consistent with Cabinet's decision in relation to rongoā and small-scale NHP producers. This includes provisions relating to the permitted health benefit claims that can be made in relation to unauthorised NHPs, and advertising of unauthorised NHPs (products made under both new exemptions will be 'unauthorised products').

11 In order to give effect to Cabinet's policy decision to 'exclude rongoā from regulation [under the Bill], except for commercial wholesale or export', the amended Bill would not require pre-approval of health benefit claims for rongoā products (in contrast to other NHPs that will be limited to a pre-determined list of permitted health benefit claims). A regulation making power is proposed to limit what claims could be made, in order to maintain a distinction between medicines and NHPs and to prevent unsubstantiated claims that a product, for example, cures or prevents cancer; or is a substitute for vaccination.

12 Another consequential amendment will enable practitioners and manufacturers to advertise products covered by the new rongoā and small-scale NHP producers' provision, notwithstanding that those products will be 'unauthorised' products. This would, for example, allow a small-scale NHP producer (or rongoā practitioner) to

advertise their products at a point of supply or sale (eg, stall at a farmers' market). In relation to NHPs made and supplied under the proposed exemption, the ability to advertise is balanced with the requirement that supply occurs directly to the end-user.

13 Finally, following feedback from the Ministry of Foreign Affairs and Trade and the Ministry of Business, Innovation and Employment, the SOP makes amendments to provisions related to intellectual property rights for innovative medicines to ensure the Bill complies with New Zealand's international obligations. The amendments are technical in nature and ensure the protection of confidential information associated with innovative medicines is not unintentionally lost because an application for the innovative medicine is not determined by the Regulator within five years.

14 The SOP implements other technical and minor changes proposed by the Parliamentary Counsel Office for drafting.

Report back on direct-to-consumer advertising of prescription medicines (DTCA-PM)

15 In October 2021, Cabinet agreed to maintain the status quo in relation to DTCA-PM. The Bill as introduced therefore continues to permit DTCA-PM, subject to an enhanced regulatory regime, including stricter penalties and the ability to set additional advertising requirements in secondary legislation.

16 The issue of DTCA-PM received significant attention during Health Committee's (the Committee) consideration of the Bill, with many submitters calling for it to be prohibited outright. While a majority of the Committee did not recommend prohibiting DTCA-PM, we recognise the concerns of health practitioners and academics about DTCA-PM. As the Bill will implement new controls on DTCA-PM (and other advertising activities), we propose to report back to Cabinet on the effectiveness of these provisions within two years of the Act's commencement and whether strong controls on advertising, including prohibiting DTCA-PM are warranted.

Impact analysis

17 A regulatory impact statement was attached to the SWC paper seeking approval to draft the SOP [SWC-23-SUB-0054].

Compliance

18 The Bill was assessed for its compliance with relevant requirements prior to introduction. This SOP complies with each of the following:

18.1 the principles of Te Tiriti o Waitangi. The new rongoā provision includes a statement that the intent of the rongoā provision is to provide for the Crown's obligations under Te Tiriti. This is operationalised by disapplying provisions in the Bill that would apply to rongoā practitioners. This SOP also includes a requirement for the Regulator to consult with the rongoā advisory committee when exercising powers related to rongoā;

18.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;

18.3 the disclosure statement requirements;

18.4 the principles and guidelines set out in the Privacy Act 2020;

18.5 s(6)a [redacted]

18.6 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

19 At the time of lodgement, advice had not yet been received from the Treaty Provisions Officials Group on the proposed statement of intent. We will provide a verbal update on any advice to the Committee.

Consultation

20 The following agencies were consulted on this paper: the Department of the Prime Minister and Cabinet, the Ministry of Foreign Affairs and Trade, the Ministry of Business, Innovation and Employment, Ministry for Primary Industries, Treasury, Te Aka Whai Ora, Te Puni Kōkiri, Te Whatu Ora, Te Arawhiti and the Accident Compensation Corporation.

21 Te Aka Whai Ora supports the exclusion of rongoā from regulation under the Bill. Te Aka Whai Ora disagreed with the specific drafting of parts of the draft SOP. Changes have been made to the draft SOP to respond to specific concerns about the remit of the rongoā advisory committee to provide general advice on rongoā and Te Tiriti matters. As discussed above, other changes to the SOP will ensure that health benefit claims in relation to rongoā products can relate to traditional and current practice. Requested changes to fully exclude rongoā from requirements about advertising have not been made, as this would limit the ability of the regulator to respond to people misrepresenting themselves as rongoā practitioners, among other matters.

22 Te Arawhiti advised that if a clause was to be added that appeared to function as a descriptive or operative Te Tiriti clause that it should apply to all provisions of the Bill rather than only provisions that apply to rongoā. This clause has since been amended and better reflects Cabinet's decisions and the clause's limited function as an introductory statement of intent for the new rongoā provisions. Similarly, Te Arawhiti's comments in relation to clarifying the role of the rongoā advisory committee have been resolved by clarifying that the Committee's advice is limited to matters arising under the Bill.

23 s(6)a, s 9(2)(h) [redacted]

s(6)a [redacted]

24 The Ministry of Business, Innovation and Employment welcomes the amendments associated with protected information periods for innovative medicines.

25 During departmental consultation, the Department of the Prime Minister and Cabinet noted that the Hauora Māori Advisory Committee could be consulted when nominating or appointing members to the rongoā advisory committee. At this stage, the SOP is consistent with Cabinet's decisions and so would not require Ministers to consult with the Hauora Māori Advisory Committee.

26 Because this Cabinet decision was made shortly before the Bill was reported back to the House, there has been very limited time to consult on the SOP. ACC noted that, due to the substantial nature of the amendments proposed, this SOP would have benefitted from further meaningful engagement with Māori. We note that there have been opportunities for consultation on the issues addressed in the SOP prior to its development, for example through the Health Committee process and rongoā workstream. However, we also acknowledge that passing the Bill before the General Election is a priority and that further consultation with Māori would prevent the Bill passing this term.

Binding on the Crown

27 The Bill is binding on the Crown [LEG-22-MIN-0212].

Creating new agencies or amending law relating to existing agencies

28 No new agencies are created by the SOP.

Allocation of decision-making powers

29 The SOP does not allocate decision-making powers between the executive, the courts, and tribunals.

Associated regulations

30 Developing regulations associated with the SOP will require defining who is a small-scale producer of NHPs and identifying products and activities that should not fall within the scope of the exemption. Consistent with other secondary legislation to be made under the Bill, the specific details of the exemption will be consulted on. The regulations are expected to take two years to develop following enactment of the Bill.

Other instruments

31 The Bill enables other instruments to be made that will be relevant to the scope of the small-scale NHP producers and rongoā exemptions. Specific instruments related to small-scale NHP producers will include a list of recognised NHP ingredients, minimum product standards and a list of permitted health benefit claims.

32 Rules will be developed in parallel with regulations. They are also expected to take two to three years to develop following enactment of the Bill and prior to its commencement on 1 September 2026.

33 The explanatory note in the Bill and accompanying SOP sets out the reasons for provisions empowering the making of other instruments.

Definition of Minister/department

34 This SOP does not include a standard definition of Minister or department. The Bill defines Minister as 'the Minister of the Crown who, under the authority of a warrant or with the authority of the Prime Minister, is responsible for the administration of this Act.'

Commencement of legislation

35 The Bill that this SOP amends has a commencement date of 1 September 2026. The SOP will not affect the commencement date of the Bill.

Parliamentary stages

36 The Bill that this SOP amends was introduced on 30 November 2022 and was referred to the Health Committee following its first reading on 14 December 2022. Health Committee reported back to the House on 13 June 2023. Following the second reading on 28 June 2023, the Bill was referred to the committee of the whole House, which we understand is currently scheduled for 20 July 2023. If approved by the legislation committee, this SOP will be introduced on 17 July 2023for consideration by committee of the whole House.

Proactive Release

37 We intend to proactively release this paper, subject to any necessary redactions as appropriate under the Official Information Act 1982, within 30 days of the SOP being introduced to Parliament.

Recommendations

We recommend that the Cabinet Legislation Committee:

1 **note** that the Therapeutic Products Bill (the Bill), which this Supplementary Order Paper (SOP) amends, is classified as a category 2 priority on the 2023 Legislation Programme (must be passed before the 2023 general election);

2 **note** that the Bill will repeal the Medicines Act 1981 and Dietary Supplements Regulations 1985. The new legislation will regulate medicines, medical devices, active pharmaceutical ingredients and natural health products;

3 **note** Cabinet's decision to amend the Bill by introducing a Supplementary Order Paper [CAB-23-MIN-0188];

4 **note** that this SOP will implement the decision referred to in recommendation 3 by amending the Bill to:

4.1 enable the making of regulations to disapply some of the obligations in the Bill for particular categories of producers of natural health products (NHPs)

4.2 expressly disapply provisions in the Bill that would impose a range of regulatory obligations on rongoā practitioners

4.3 establish a rongoā advisory committee to advise the Minister and the Regulator on matters related to rongoā and the application of the disapplication

4.4 make minor, technical amendments to maintain the protection of confidential information associated with innovative medicines

4.5 implement other technical and minor changes required by the Parliamentary Counsel Office for drafting;

5 **note** that to remove many of the obligations in the Bill from applying to rongoā the SOP will add the terms 'rongoā', 'rongoā practitioner' and 'rongoā product' to the Bill. Once established, the rongoā advisory committee will provide advice on these terms;

6 **agree** that the Minister of Health may authorise minor changes to the SOP that are not inconsistent with the policy recommendations in this paper up until the time that the SOP is tabled;

7 **note** that we propose to report back to Cabinet on the effectiveness of these provisions within two years of the Act's commencement and whether strong controls on advertising, including prohibiting DTCA-PM are warranted;

8 **approve** the SOP to the Therapeutic Products Bill for introduction, subject to the final approval of the government caucus and sufficient support in the House of Representatives.

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health

Hon Peeni Henare

Associate Minister of Health (Māori Health)

CAB-23-MIN-0188

Cabinet

Minute of Decision

Regulation of Small-Scale Producers of Natural Health Products, and Rongoā under the Therapeutic Products Bill

Portfolios **Health / Associate Health (Māori Health)**

On 22 May 2023, following reference from the Cabinet Social Wellbeing Committee (SWC), Cabinet:

1 **noted** that in 2021, SWC agreed to the inclusion of natural health products (NHPs) in the Therapeutic Products Bill (the Bill), including providing for the recognition and protection of rongoā and applying the regulatory mechanisms in the Bill as appropriate to NHPs, in a way that is relevant to the risk/benefit profile of NHPs [SWC-21-MIN-0109];

2 **noted** that the Bill is being considered by the Health Committee with a report back to the House due on 14 June 2023;

Small-scale NHP exemption

3 **noted** that the Bill, as introduced, requires licensing of businesses and market authorisation for each natural health product, with few exceptions;

4 **noted** that following many submissions to the Health Committee in relation to NHPs in the Bill, there is justification for removing some of the obligations as they currently apply to small-scale producers of NHPs;

5 **agreed** to amend the Bill to:

5.1 enable regulations to be made to disapply parts of the Bill that require certain classes of NHP producers to obtain market authorisation and/or a manufacturing licence for certain natural health products, made or supplied in New Zealand and not intended for resale, wholesale or export;

5.2 provide criteria for any exemption that include consideration of the product risk, the frequency and scale of operations (e.g., whether it was online or in-person), the competence and knowledge of producers, and any product and manufacturing standards that ought to apply as baseline requirements;

Rongoā

6 **noted** that the Bill, as introduced, will regulate some rongoā products, which a significant number of Māori submitters to the Health Committee and those consulted as part of the Bill's development have argued does not uphold the rights guaranteed to Māori under Article 2 of Te Tiriti o Waitangi (Te Tiriti);

7 **noted** that while existing clauses in the Bill, including clause 112 (personalised NHPs), and the proposed small-scale natural health product producers' exemption will authorise or exempt a range of activities engaged in by rongoā practitioners, additional measures are necessary to:

7.1 provide certainty to Māori as the Crown's Te Tiriti partners;

7.2 give effect to the Crown's obligations under Te Tiriti in relation to rongoā;

8 **agreed** to amend the Bill to exclude rongoā from regulation, except for commercial wholesale or export, by:

8.1 amending the Bill to include a clause that expressly disapplies, for products made by a rongoā practitioner (that would otherwise be considered NHPs), the requirement to seek market authorisation before products can be:

8.1.1 supplied by non-wholesale supply, if the product is made with the intention that it will be supplied or used in the course of a rongoā service or activity;

8.1.2 exported from New Zealand to a patient of the rongoā practitioner, or at the request of another rongoā practitioner;

8.1.3 are supplied by wholesale supply for use in a rongoā service or activity operating out of a marae or other culturally significant site, or in a rongoā service delivered by another rongoā practitioner;

8.2 amending the Bill to include references to rongoā and rongoā practitioner that centre both within a Te Ao Māori understanding of rongoā;

8.3 amending the Bill to provide that nothing should prevent a rongoā practitioner from applying for a market authorisation for any therapeutic product or licence to engage in a controlled activity;

9 **agreed** to amend the Bill to establish a rongoā advisory committee with members to be appointed by the Minister of Health and the Minister for Māori Development, following consultation with such other people the Ministers believe possess the relevant knowledge and expertise, noting that a mechanism could be included in the Bill to specify some individuals who would need to be consulted, including the Associate Minister of Health (Māori Health) and the Deputy Director-General Māori Health at Manatū Hauora;

10 **agreed** that appointments to the above committee take into account a nominee's knowledge of rongoā, mātauranga, the machinery of government, and any other knowledge and skills required to fulfil the functions of the rongoā advisory committee;

11 **agreed** that the Bill be amended to specify that the functions of the rongoā advisory committee are to provide advice:

11.1 on matters related to rongoā and the application of the exemption clause;

11.2 to the Regulator to determine whether a person meets the definition of a rongoā practitioner or is engaging in an activity within the scope of the exemption (if the question arises);

11.3 to the Minister and Regulator on other matters related to rongoā, for example in relation to regulations declaring products not to be therapeutic products, and proposals to declare something a 'prohibited product';

12 **agreed** that, in relation to paragraph 11.1 above, the Regulator would have to have regard to this advice in administering the exemption provision;

13 **agreed** that, in relation to paragraph 11.2 above, the Regulator would need to have regard to the advice of the rongoā advisory committee;

14 **agreed** that, in relation to paragraph 11.2 above, the rongoā advisory committee would be able to invite submissions from the affected individual and any other party who can provide relevant advice on local tikanga and kawa as it relates to the person's practice;

15 **agreed** that, in relation to paragraphs 11.1 and 11.3 above, the rongoā advisory committee would need to acknowledge and reflect local tikanga and kawa in relation to the practice of rongoā;

16 **agreed** that the new rongoā provision include a statement that the intent of the provision is to provide for the Crown's obligations under Te Tiriti o Waitangi in relation to rongoā by disapplying provisions in the Bill that would apply to rongoā practitioners (or words to that effect);

17 **agreed** that the new rongoā provision should not limit the ability of rongoā practitioners to seek market authorisation (including export authorisation) for their products, should they so wish;

18 **noted** that some restrictions on NHPs will continue to apply to products made by rongoā practitioners, including a prohibition on injecting an NHP;

19 **noted** that regulations made under clauses 16 and 19 of the Bill (which define what is and is not a therapeutic product) are expected to exclude many devices used in the practice of rongoā from the future regime;

20 **invited** the Minister of Health to instruct the Parliamentary Counsel Office to draft a Supplementary Order Paper that gives effect to paragraphs 5 and 8 to 17 above;

21 **noted** that the final wording in the Supplementary Order Paper for the statement referred to in paragraph 16 above will reflect advice from the Parliamentary Counsel Office and Crown Law;

22 **authorised** the Minister of Health to provide in-confidence drafts of the Supplementary Order Paper to Te Aka Whai Ora prior to its tabling in Parliament;

23 s 9(2)(h) [redacted]

24 **agreed** to rongoā decisions being announced by the Associate Minister of Health (Māori Health) and small-scale producers of NHPs being announced by the Minister of Health;

25 s 9(2)(f)(iv) [redacted]

26 **invited** the Minister of Health to report back to Cabinet on the operation of the small-scale NHP producers and rongoā provisions within two years of the commencement of the Therapeutic Products Act, including the impact of legislative provisions in relation to small scale rongoā practitioners.

Rachel Hayward
Secretary of the Cabinet

SWC-23-MIN-0054

Cabinet Social Wellbeing Committee

Minute of Decision

Regulation of Small-Scale Producers of Natural Health Products, and Rongoā under the Therapeutic Products Bill

Portfolio **Health / Associate Health (Māori Health)**

On 17 May 2023, the Cabinet Social Wellbeing Committee **referred** the submission under SWC-23-SUB-0054 to Cabinet on 22 May 2023, revised as appropriate given discussion at the meeting.

Rachel Clarke
Committee Secretary

Present:
Rt Hon Chris Hipkins
Hon Carmel Sepuloni (Chair)
Hon Grant Robertson
Hon Kelvin Davis
Hon Dr Megan Woods
Hon Jan Tinetti
Hon Dr Ayesha Verrall
Hon Willie Jackson
Hon Kiri Allan
Hon Peeni Henare
Hon Nanaia Mahuta
Hon Priyanca Radhakrishnan
Hon Kieran McAnulty
Hon Barbara Edmonds
Hon Rino Tirikatene
Hon Jo Luxton

Officials present from:
Office of the Prime Minister
Office of the Chair
Officials Committee for SWC

In Confidence

Office of the Minister of Health

Office of the Associate Minister of Health (Māori Health)

Social Wellbeing Committee

The regulation of small-scale producers of natural health products, and rongoā under the Therapeutic Products Bill

Proposal

1 This paper seeks agreement to amend the Therapeutic Products Bill (the Bill) via a Supplementary Order Paper (SOP) to:

1.1 enable regulations that would disapply some of the obligations in the Bill as they currently apply to small-scale producers of natural health products (NHPs);

1.2 expressly disapply provisions in the Bill that currently impose a range of regulatory obligations on rongoā practitioners.

Relation to government priorities

2 The Bill is currently before Parliament and has a category 2 priority (must be passed before the 2023 general election).

Executive Summary

3 The Health Committee is currently considering the Bill, with a report due to Parliament on 14 June 2023. During public consultation on the Bill, over 16,500 submissions were received by the Health Committee. Just over half of submissions (54 percent) expressed opposition to the inclusion of NHPs in the Bill, with many concerned about the impacts of regulation on access to NHPs.

4 Many submissions also opposed the inclusion of NHPs because it would mean the Bill applies to rongoā.

5 The departmental report, which was provided to the Health Committee on 13 April 2023, stated that the Ministry was seeking further instructions from Government on these issues. This timing enabled advice from a separate rongoā workstream to be considered, alongside the submissions on the Bill from NHP producers and Māori.

6 After considering the views of the public, practitioners and Māori, we propose introducing a SOP to amend the Bill to:

6.1 enable regulations to be made to remove the requirement for any class of person (i.e., certain small-scale NHP producers) to obtain market authorisation and/or a manufacturing licence prior to making and supplying (by non-wholesale supply) certain NHPs within New Zealand;

6.2 expressly remove many obligations in relation to rongoā practitioners (including some in addition to those provided for small-scale NHP producers) by disapplying a number of provisions.

Background: Therapeutic Products Bill

7 The Bill will repeal the Medicines Act 1981 and Dietary Supplements Regulations 1985 (made under the Food Act 2014), because they are no longer fit for purpose, and replace them with new legislation that will regulate medicines, medical devices, active pharmaceutical ingredients and NHPs (therapeutic products).

8 NHPs were included in the Bill in July 2021, when Cabinet agreed that the objectives for a NHP regulatory scheme aligned with the regulatory scheme for other therapeutic products [CAB-21-MIN-0274]. At that time, Cabinet also agreed to provide for the 'recognition and protection of rongoā'.

9 The Bill was introduced to Parliament on 30 November 2022 and is now being considered by the Health Committee, with a report due to the House on 14 June 2023. Our intention is to pass the Bill before the general election and for commencement by 1 September 2026.

10 The purpose of the Bill is to protect, promote, and improve the health of all New Zealanders by requiring the acceptable safety and quality of medicines, medical devices, active pharmaceutical ingredients and NHPs. Importantly, the Bill's focus is on products, and not how a health service is practiced.

11 A central principle of the Bill is that the regulation of therapeutic products should be proportionate to the benefit of those products and any risks associated with them (see clause 4). While this principle will apply to secondary legislation developed under the Bill, it is also relevant to considering whether products can, and should, be excluded from some or all regulation under the Bill.

Small-scale NHP producers

12 Many NHP businesses are small-scale producers and include practitioner producers supplying domestically (including practitioners working from their homes). Meanwhile, the greater volume of NHPs is produced by large-scale operations supplying the New Zealand market directly through online sales or through wholesale arrangements with large retailers.

13 The Bill, as introduced, requires producers and exporters of NHPs to have a licence or permit to make or export their products in the course of business. Each NHP must have market authorisation before being imported or supplied, with few exceptions.

14 Many of the 16,586 written submissions (i.e., more than a quarter but less than half of submissions) to the Health Committee stated that the proposed regulatory scheme would adversely affect small-scale NHP producers, who may not be able to afford market authorisation fees, licence fees, and other compliance costs. Submitters said that some producers are likely to be driven out of business despite their products having little or no risk to the public.

Rongoā

15 The current version of the Bill does not specifically refer to rongoā. However, some products used in the practice of rongoā or made by rongoā practitioners may be captured by the Bill as NHPs, because of the ingredients used (for example, a kawakawa balm made by a rongoā practitioner and sold at a local farmers' market). Some products may also meet the definition of a medical device in the Bill or – in rare cases – medicines.

16 To the extent rongoā is captured by the current Bill, we have considered two main obligations whose disapplication would effectively 'exempt' rongoā from the Bill:

16.1 first, the obligation in the Bill for all therapeutic products to be 'authorised' by the Therapeutic Products Regulator (the Regulator) before those products can be supplied in New Zealand and exported from New Zealand;

16.2 second, the obligation in the Bill for individuals engaged in controlled activities involving therapeutic products to obtain a licence or permit from the Regulator. In relation to rongoā, this includes the need for a licence to manufacture and export NHPs in the course of business.

17 The absence of reference to rongoā in the Bill as introduced is not because the government has not considered this issue. Indeed, the regulation of rongoā featured in earlier work in the mid-2000s (since discontinued) to establish a joint therapeutics regulatory regime with Australia. Options to exclude some aspects of rongoā were also explored during the development of a separate Natural Health and Supplementary Products Bill (which lapsed at the end of 2017). The 2018 exposure draft of the Therapeutic Products Bill did not include NHPs, so rongoā was not a specific area of focus (although Māori groups did participate in stakeholder forums in 2019).

18 Following Cabinet's decision in July 2021 to include NHPs in the Bill, work began in the Ministry of Health to consider how the Bill could 'recognise and protect' rongoā. This work included engagement with Te Kāhui Rongoā, a national governance group for some (but not all) rongoā practitioners, two virtual hui with hauora Māori providers, and a series of hui involving representatives from Te Aka Whai Ora. This work resulted in advice to government in September 2022. At the time, the then Minister of Health considered that the issue deserved further consideration that could not reasonably be undertaken before the Bill's introduction in November 2022.

19 Consequently, a decision was made to not include a specific reference to rongoā in the Bill at its introduction but to establish a separate rongoā workstream. Part of this workstream was to provide advice to government on what amendment – if any – should be made to the Bill or advice on the need for a standalone companion rongoā Bill. This paper represents advice from that process.

Analysis

Creating an exemption scheme for small-scale NHP manufacture

20 The regulatory approach for NHPs in the Bill is intended to support product safety and create a level playing field for all therapeutic product producers. However, we are mindful of the overarching principle that regulation should be 'risk proportionate.'

21 The Ministry of Health commissioned a literature review on the evidence of harm from using NHPs, to assist the Health Committee. The review did not find evidence of harm from products made and supplied by small-scale NHP producers. While under-reporting and a lack of oversight in current legislation contribute to a lack of evidence, it appears that overall, the lack of evidence suggests products made and supplied by small-scale NHPs producers do not pose a significant public health risk.

22 As such, requiring small-scale producers to seek authorisation for each NHP and to be licensed may be disproportionately costly for them (e.g., those who produce them in their own home to sell to a consumer only).

23 We therefore seek agreement to introduce a SOP to amend the Bill to create a new regulation-making power that would enable the Minister of Health to exempt any class of person from the obligation to obtain market authorisation and/or a manufacturing licence for certain NHPs, made and supplied by non-wholesale supply.

Limitations of the exemption

24 We are not proposing a blanket 'exemption' for all small-scale NHP producers, since that could mean that higher-risk NHPs (such as vitamins that are toxic in high concentrations) could be supplied with no regulatory oversight.

25 Likewise, market authorisation would continue to be required for imported NHPs as there would otherwise be no ability to ensure minimal risk-proportionate manufacture standards are complied with. The exemption would also only allow NHP manufacturers to make a product containing 'recognised NHP ingredients' that will be established in secondary legislation.

26 Certain standards may also apply, such as those relating to risk proportionate manufacture, labelling (including informing the purchaser of the exemption and that the product cannot be on-sold), advertising, and health benefit claims for non-authorised products. Products supplied through commercial wholesale arrangements or via direct sales over the internet would not be exempt as the larger volumes require the additional oversight that individual product authorisation brings.

27 We propose that, in developing the necessary secondary legislation, the following matters would need to be taken into account by the Minister of Health:

27.1 any inherent risks associated with the ingredients used in specific NHPs, safe manufacturing and handling requirements and other factors that are relevant in providing for acceptable safety and quality of NHPs;

27.2 the potential impact on consumers, including those related to risk, access and choice of products;

27.3 the frequency and scale of operation, including whether supply is via online;

27.4 the appropriateness of regulatory control in comparison with controls specified for other NHPs or therapeutic products, or types or descriptions of producers.

28 Examples of activities that might apply include NHPs supplied at a physical event a certain number of times a year (e.g., a farmers' market or school fete), or limited numbers or volume that are made in the home and supplied in-person to someone. A condition could be that the products supplied are intended for the use of the purchaser (i.e., they are not intended for resale).

29 These approaches allow a purchaser to ask questions about how the ingredients are sourced and manufactured, and how the business has met requirements in relation to the substantiation of claims. We do not expect large producers to split into small businesses to avoid market authorisation or licensing because the gains are unlikely to be outweighed by the restrictions, such as not being able to make all permitted health benefit claims. Post-market activities would provide a mechanism to monitor suspected adverse reactions, with follow up action possible.

30 Any exemption could be amended or revoked by the Minister, and conditions could apply to the exemption. This enables a flexible regulatory regime and would be consistent with section 33 of the Food Act, which seeks to achieve similar objectives.

31 In addition to this class-wide approach, applications could be made to the Regulator using current provisions in the Bill for similar exemptions. For instance, the Regulator could use existing licensing provisions to issue a single licence to businesses to cover all their manufacturing and supply activities.

Rongoā

32 Similar considerations apply in the context of rongoā, namely whether the current approach adopted in the Bill is proportionate to the evidence of harm and risks of the activities. In assessing whether rongoā should be exempted, we have also considered the views of Māori, the risks to consumer safety and the potential legal risks to the Crown, including the risk of a contemporary Treaty claim.

33 Many submitters on the Bill asserted that Māori already sufficiently regulate the practice of rongoā through specific practices, tikanga and kawa that have developed over centuries. There is no available evidence that the practice and regulation of rongoā to date has created significant risks to the health of the public.

34 A literature review conducted in March 2023 examined reported harms from the use of NHPs. While it was not specifically reviewing evidence of harms from rongoā, none were identified. Combined with the lack of evidence of reported harm, exempting rongoā activities from the Bill would not create a significant risk of harm to Māori or other New Zealanders.

35 In September 2022, the former Minister of Health was advised by Te Aka Whai Ora that, since the inception of the ACC rongoā Māori service, more than 18,000 rongoā sessions have been provided to clients. Manatū Hauora and Te Aka Whai Ora rongoā providers had delivered more than 47,000 rongoā client contacts during the same period. With a combined total of more than 65,000 rongoā sessions in that period, no complaints about safety associated with therapeutic products used in the context of rongoā had been received by those agencies.

36 There are also important Te Tiriti considerations that are relevant. For instance, the Crown must give effect to its responsibility under Te Tiriti to govern for all New Zealanders (kāwanatanga) and its obligations to provide for active protection for Māori and the rights guaranteed to Māori under Article 2 of Te Tiriti.

37 We are cognisant that Māori have significant interests in rongoā, and the Health System Principles in the Pae Ora (Healthy Futures) Act 2022 call for the health system to provide opportunities for Māori to exercise decision-making authority on matters of importance to Māori. This is relevant to whether rongoā should be excluded from the Bill and the manner in which any exclusion is operationalised.

38 Likewise, upholding the principle of active protection includes enabling the recognition of rongoā in the wider health system. Any exemption in the Bill should not have the unintended consequence of preventing funded activities occurring. Similarly, Māori should retain the option to access the potential benefits of the new regime – whether that is for products which are NHPs, medical devices or medicines. As such, any exemption of rongoā in the Bill should not foreclose the ability for Māori to seek market authorisation for their products.

Proposal to exclude rongoā and to provide for a statutory rongoā advisory committee

39 In this context, we seek agreement to introduce a SOP to amend the Bill to expressly disapply many of the provisions in the Bill for rongoā practitioners and products made and supplied by them with the intention that they will be used in or for a rongoā service or activity. We also propose to amend the Bill to establish a rongoā advisory committee that would advise on the operation of this new provision.

40 Specifically, the new provision would remove obligations currently in the Bill requiring rongoā practitioners to:

40.1 apply for a NHP manufacturing licence for making NHPs if the product is intended to be used in a rongoā service or activity;

40.2 obtain a market authorisation for NHPs prior to supplying those products in New Zealand if the product is intended for use in a rongoā activity or service (included limited wholesale supply);

40.3 obtain a market authorisation for NHPs exported to patients of the rongoā practitioner or at the request of another rongoā practitioner.

41 Excluding devices made and used by rongoā practitioners would be achieved via regulations made under existing provisions in the Bill.

42 We propose including a statement in this new provision that would set out the Government's policy intention: namely, that the provision is intended to provide for the Crown's intention to give effect to Te Tiriti o Waitangi by disapplying provisions in the Bill that would apply to rongoā practitioners (e.g., those listed in paragraph 40.1-40.3 and in regulations that exclude rongoā devices). To ensure rongoā practitioners can share in the economic benefits of the new NHP regime, the provision will need to be clear that it does not prevent rongoā practitioners from seeking market authorisation (including export authorisation) for their products, should they so wish.

43 Some wholesale activities would be enabled under this exemption – in particular those operating out of a marae, other culturally significant site or place defined by the proposed rongoā advisory committee, or a rongoā service delivered by another rongoā practitioner. This is based on the observation that there is no evidence of harm occurring to the public as a result of the current practice of rongoā within existing safety protocols by rongoā practitioners.

44 The exemption would not extend to making products for larger wholesale purposes such as wholesale through a large grocery chain or multiple pharmacy franchises. This is because the safety protocols outlined by Māori provide less assurance that the safety risks to consumers can be managed. For instance, for large scale supply, it is important that product recalls can occur, and this may require the ability to impose obligations on downstream, commercial distributors (who will not be practitioners) to remove unsafe products from sale.

45 For a similar reason the exemption would also not apply to products made for commercial export purposes. Products intended to be supplied in these ways would require product authorisation as an NHP or a manufacturing and export licence.

46 Giving legal effect to the exemption requires amending the Bill to insert the terms 'rongoā' and 'rongoā practitioners'. However, any reference to rongoā and rongoā practitioner should be the minimum required, enable understanding according to Te Ao Māori, be limited to this Bill only, and not divide rongoā into 'modalities'.

47 Importantly, the inclusion of rongoā practitioner would not seek to regulate the profession of rongoā practitioners, nor to interfere in matters such as the recognition of tohunga.

48 Nonetheless, there may be disputes over whether a person is a rongoā practitioner or an activity falls within the scope of the exemption. Our preference is that these disputes should first be resolved by Māori, and we note the strategic rongoā kaupapa being led by Te Aka Whai Ora that aims to empower Māori to determine the protection and support needed to flourish. To enable a process for dispute resolution,

we propose to establish a process to help operationalise the exemption, including by shaping the interpretation of rongoā as applied by the Regulator.

49 Specifically, we propose to amend the Bill to establish a rongoā advisory committee (the Committee). The functions of the Committee would be to advise:

49.1 on matters related to rongoā and the application of the exemption clause. The Regulator would have to have regard to this advice in administering the relevant provisions in the Bill;

49.2 the Regulator in determining whether a person meets the definition of a rongoā practitioner or is engaging in an activity within the scope of the exemption. The Regulator would need to have regard to the advice of the Committee;

49.3 the Minister and Regulator on other matters related to rongoā, for example in relation to regulations excluding products from the definition of therapeutic products, and proposals to declare something a 'prohibited product'.

50 In discharging its roles under paragraphs 49.1 and 49.3 the Committee would need to acknowledge and reflect local tikanga and kawa in relation to the practice of rongoā. In discharging its role under paragraph 49.2, the Committee would be able to invite submissions from the affected individual and other parties who can provide relevant advice on local tikanga and kawa as it relates to the person's practice or activity.

51 Importantly, the need for the Committee to provide advice on whether a person or activity falls within the scope of the exemption would only arise if a concern was first raised with the Regulator. It is not our intention that individuals practicing rongoā would need to pro-actively establish their credentials with the Committee. Rather, if a complaint was received by the Regulator that someone was wrongly holding themselves out as a rongoā practitioner (or engaged in an activity outside the scope of the exemption), the Regulator could ask that individual for information and the Committee would provide advice to the Regulator on whether the person fell within the scope of the exemption. The individual's activities might still be covered by other authorising provisions in the Bill (e.g., the NHP practitioner provision at clause 112 or the proposed small-scale NHP producer exemption).

52 The Committee would be appointed by the Minister of Health and the Minister for Māori Development, after consultation with the Associate Minister of Health (Māori), and such other people the Ministers believe possess the relevant knowledge and expertise, such as the person occupying the role of Deputy Director-General of Māori Health at Manatū Hauora (a mechanism in the Bill will be necessary to ensure references to these individuals remain current). Appointments should be based on the members' understanding of rongoā, mātauranga, machinery of government and any other relevant knowledge and skills required for fulfilling the functions of the Committee. To provide for a degree of independence from the Regulator, the Committee would be funded and supported by the Ministry of Health.

53 We have considered other options to implement an exemption, including via secondary legislation (for example, by using the existing exemption power in clause 379 of the Bill) or licenses to disapply parts of the Bill relating to market authorisation. However, our recommended approach provides for the best balance of certainty, Māori leadership and workability. Through the establishment of the Committee, iwi, hapū and marae may influence who they deem as appropriate for providing rongoā and rongoā services within their rohe.

Implementation

54 Terms of Reference outlining how the rongoā advisory committee will operate will need to be developed following enactment of the Bill. The Committee will need to provide initial advice before the regime commences in 2026.

55 The detail of the small-scale NHP producers' exemption will be set out and implemented via secondary legislation. This will be developed following passage of the Bill and prior to the Act's commencement in 2026. Consultation with the sector on the secondary legislation for NHPs (e.g., the exemption, the list of recognised NHP ingredients and health benefit claims) will need to occur in 2024/2025.

56 The Bill currently requires the Minister to conduct a review of the policy and operation of the Act five years from the commencement of the Act, and after each subsequent five years. In addition, we recommend that an assessment is undertaken within the first two years of the new regime to determine how the new small-scale NHP producers and rongoā provisions are operating, and to identify any unintended consequences. The outcomes of this assessment should be reported back to Cabinet.

Financial Implications

57 We are not seeking specific financial decisions in this paper. However, as previously advised, the establishment of the new Regulator will require new funding to enable timely implementation of this scheme [CAB-21-MIN-0117]. s 9(2)(g)(i) [redacted]

Legislative Implications

58 The amendments to the Bill which are proposed in this paper would be introduced via a Supplementary Order Paper, during the Committee of the whole House stage.

59 At the Bill's first reading, all political parties supported the Bill being read a first time, except for Te Pāti Māori who opposed First Reading because of the Bill's lack of protection of rongoā, and, most importantly, its tohunga and practitioners. The Green Party also expressed concern around the impact of the Bill and Crown enforcement on tikanga Māori, especially in relation to rongoā.

60 This paper seeks to address these concerns by proposing to amend the Bill to expressly remove obligations that are currently imposed on rongoā practitioners.

61 The ACT party were interested in whether the costs outweigh the benefits, as they want to ensure any new regulatory body would not impose a heavy burden on anybody. This paper includes proposals that would allay such concerns for small-scale NHP businesses.

Impact Analysis

Regulatory Impact Statement

62 The Ministry of Health QA panel has reviewed the Impact Statement titled "The regulation of small-scale producers of natural health products, and rongoā under the Therapeutic Products Bill", produced by the Ministry of Health and dated May 2023.

63 The panel considers that the Impact Statement Partially Meets the quality assurance criteria. The Impact Statement is concise, complete and consulted. The analysis is clear and convincing with respect to small-scale NHP manufacturers but the panel

considered that the RIS would benefit further clarity and information on the rongoā proposals to be fully clear and convincing, such as further detail on the precise nature of the rongoā advisory committee and to what extent Māori will influence appointments.

64 The Impact Statement is attached at Appendix One.

Climate Implications of Policy Assessment

65 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal as the threshold for significance is not met.

Population Implications

Implications for Māori

66 The proposals in this paper are intended to benefit Māori. A carefully crafted 'disapplication' provision can also enable the further development of rongoā and the rongoā sector in Aotearoa New Zealand.

Implications for women

67 An Australian 2019 study indicates that the majority of NHP users are women.[1] Many NHP practitioners are also women and the requirements in the Bill will be a cost burden that will affect their livelihood. A risk-proportionate exemption power for most small-scale NHP producers will alleviate this issue.

Human Rights

68 The proposals in this paper are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Consultation

69 The Ministry of Health consulted the following government organisations on the development of this paper, at the same time as ministerial consultation: the Ministry of Foreign Affairs and Trade (MFAT), Ministry of Business, Innovation and Employment, Ministry for Primary Industries, Treasury, Te Aka Whai Ora, Te Puni Kōkiri, Te Whatu Ora, Te Arawhiti, Accident Compensation Corporation (ACC), Department of Corrections, and the Department of the Prime Minister and Cabinet. Agencies did not have an opportunity to provide input prior to the paper and proposals being circulated for Ministerial consultation.

70 Approximately 300 Māori were engaged by the Rongoā Workstream through two online hui, two in-person hui and an online survey. This included rongoā practitioners, researchers and academics.

71 s 9(2)(h) [redacted]

[1] Roy Morgan Research (2019). Women more likely to buy vitamins than men. This survey of 50,000 Australians indicated that 47% of women buy vitamins, minerals, and other supplements compared with 35% of men.

s 9(2)(h) [redacted]

72 Te Aka Whai Ora argued that rongoā should be 'excluded in its entirety from the Bill' to enable Māori to exercise tino rangatiratanga over rongoā. They disagreed that the proposals in the Bill achieved a full exemption. Te Aka Whai Ora also recommended the definition of rongoā be set in secondary legislation to allow time for an engagement process with Māori, and drafting instructions for the definition and exclusion clause be led by Māori. ACC held similar views and also noted that introducing the rongoā changes via an SOP with no changes to the timeline for the Bill does not allow for meaningful engagement, and creates a risk for the Crown.

73 As outlined above, however, the proposal in this paper does not require a definition of rongoā to be included in the Bill. Rather, the terms 'rongoā' and 'rongoā practitioner' need to be inserted to give effect to the provision disapplying parts of the Bill in their application to rongoā and rongoā practitioners. These words would then rely on their ordinary meaning. The rongoā advisory committee's advice will provide an operational definition for the Regulator to apply in the context of the Bill and the provision.

74 As such, we believe that the proposal balances the need for certainty for Māori that rongoā activities will not be regulated under the Bill and will enable to the rest of the Bill to pass this term of Parliament. We also note that future regulations (including under clauses 16 and 115 of the Bill) may further widen the scope of the exemption. Te Puni Kōkiri were supportive of the approach landed on as a pragmatic step forward in realising the benefits of rongoā and said that the rongoā advisory committee would need to have a clear role in maintaining relationships with iwi, hapū, tohunga and others involved in rongoā.

Communications

75 Decisions made for rongoā are intended to be announced by the Associate Minister of Health (Māori Health). The Minister of Health will announce decisions relating to small-scale producers of NHPs. The Ministry of Health will provide a full suite of communications to support the introduction of the SOP to Parliament.

76 s 9(2)(f)(iv) [redacted]

Proactive Release

77 We intend to proactively release this paper, subject to any necessary redactions as appropriate under the Official Information Act 1982, within 30 days of the SOP being introduced to Parliament. It is intended the SOP will be introduced in the week of 17 July 2023.

Recommendations

The Minister of Health recommends that the Committee:

1 **note** that Cabinet agreed to the inclusion of natural health products (NHPs) in the Therapeutic Products Bill [CAB-21-MIN-0274], including providing for the recognition and protection of rongoā and applying the regulatory mechanisms in the Bill as appropriate to natural health products, in a way that is relevant to the risk/benefit profile of NHPs;

2 **note** that the Therapeutic Products Bill is being considered by the Health Committee with a report back to the House due on 14 June 2023;

Small-scale NHP exemption

3 **note** that the Therapeutic Products Bill, as introduced, requires licensing of businesses and market authorisation for each natural health product, with few exceptions;

4 **note** that following many submissions to the Health Committee in relation to NHPs in the Therapeutic Products Bill, there is justification for removing some of the obligations as they currently apply to small-scale producers of NHPs;

5 **agree** to amend the Bill to:

5.1 enable regulations to be made to disapply parts of the Bill that require certain classes of NHP producers to obtain market authorisation and/or a manufacturing licence for certain natural health products, made or supplied in New Zealand and not intended for resale, wholesale or export;

5.2 provide criteria for any exemption that include consideration of the product risk, the frequency and scale of operations (e.g., whether it was online or in-person), the competence and knowledge of producers, and any product and manufacturing standards that ought to apply as baseline requirements;

Rongoā

6 **note** that the Bill, as introduced, will regulate some rongoā products, which a significant number of Māori submitters to the Health Committee and those consulted as part of the Bill's development have argued it does not uphold the rights guaranteed to Māori under Article 2 of Te Tiriti o Waitangi (Te Tiriti);

7 **note** that while existing clauses in the Bill, including clause 112 (personalised NHPs), and the proposed small-scale natural health product producers' exemption will authorise or exempt a range of activities engaged in by rongoā practitioners, additional measures are necessary to:

7.1 provide certainty to Māori as the Crown's Te Tiriti partners;

7.2 give effect to the Crown's obligations under Te Tiriti in relation to rongoā;

8 **agree** to amend the Bill to exclude rongoā from regulation, except for commercial wholesale or export, by:

8.1 amending the Bill to include a clause that expressly disapplies, for products made by a rongoā practitioner (that would otherwise be considered NHPs), the requirement to seek market authorisation before products can be:

8.1.1 supplied by non-wholesale supply, if the product is made with the intention that it will be supplied or used in the course of a rongoā service or activity;

8.1.2 exported from New Zealand to a patient of the rongoā practitioner, or at the request of another rongoā practitioner;

8.1.3 are supplied by wholesale supply for use in a rongoā service or activity operating out of a marae or other culturally significant site, or in a rongoā service delivered by another rongoā practitioner;

8.2 amending the Bill to include references to rongoā and rongoā practitioner that centre both within a Te Ao Māori understanding of rongoā;

8.3 amending the Bill to provide that nothing should prevent a rongoā practitioner from applying for a market authorisation for any therapeutic product or licence to engage in a controlled activity;

9 **agree** to amend the Bill to establish a rongoā advisory committee with members to be appointed by the Minister of Health and the Minister for Māori Development, following consultation with such other people the Ministers believe possess the relevant knowledge and expertise. A mechanism could be included in the Bill to specify some individuals who would need to be consulted, including the Associate Minister of Health (Māori) and the Deputy Director-General Māori Health at Manatū Hauora;

10 **agree** that appointments take into account a nominee's knowledge of rongoā, mātauranga, the machinery of government and any other knowledge and skills required to fulfil the functions of the rongoā advisory committee;

11 **agree** that the Bill be amended to specify that the functions of the rongoā advisory committee are to provide advice:

11.1 on matters related to rongoā and the application of the exemption clause;

11.2 to the Regulator to determine whether a person meets the definition of a rongoā practitioner or is engaging in an activity within the scope of the exemption (if the question arises);

11.3 to the Minister and Regulator on other matters related to rongoā, for example in relation to regulations declaring products not to be therapeutic products, and proposals to declare something a 'prohibited product';

12 **agree** that, in relation to recommendation 11.1, the Regulator would have to have regard to this advice in administering the exemption provision;

13 **agree** that, in relation to recommendation 11.2, the Regulator would need to have regard to the advice of the rongoā advisory committee;

14 **agree** that, in relation to recommendation 11.2, the rongoā advisory committee would be able to invite submissions from the affected individual and any other party who can provide relevant advice on local tikanga and kawa as it relates to the person's practice;

15 **agree** that, in relation to recommendations 11.1 and 11.3, the rongoā advisory committee would need to acknowledge and reflect local tikanga and kawa in relation to the practice of rongoā;

16 **agree** that the new rongoā provision include a statement that the intent of the provision is to provide for the Crown's obligations under Te Tiriti o Waitangi in relation to rongoā by disapplying provisions in the Bill that would apply to rongoā practitioners (or words to that effect);

17 **agree** that the new rongoā provision should not limit the ability of rongoā practitioners to seek market authorisation (including export authorisation) for their products, should they so wish;

18 **note** that some restrictions on NHPs will continue to apply to products made by rongoā practitioners, including a prohibition on injecting a NHP;

19 **note** that regulations made under clauses 16 and 19 of the Bill (which define what is and is not a therapeutic product) are expected to exclude many devices used in the practice of rongoā from the future regime;

20 **authorise** the Minister of Health to instruct the Parliamentary Counsel Office to draft a Supplementary Order Paper that gives effect to recommendations 5 and 8-17 above in accordance with Cabinet's decisions;

21 **note** that the final wording in the Supplementary Order Paper for the statement referred to in recommendation 16 will reflect advice from the Parliamentary Counsel Office and Crown Law;

22 **authorise** the Minister of Health to provide in-confidence drafts of the Supplementary Order Paper to Te Aka Whai Ora prior to its tabling in Parliament;

23 s 9(2)(h) [redacted]

24 **agree** to rongoā decisions being announced by the Associate Minister of Health (Māori Health) and small-scale producers of NHPs being announced by the Minister of Health;

25 s 9(2)(f)(iv) [redacted]

26 **request** the Minister of Health to report back to Cabinet on the operation of the small-scale NHP producers and rongoā provisions within two years of the Act's commencement, including the impact of legislative provisions in relation to small scale rongoā practitioners.

Authorised for lodgement

Hon Dr Ayesha Verrall
Minister of Health

Hon Peeni Henare
Associate Minister of Health