Terms of Reference of the NHP Advisory Group

1. Introduction

1.1 These Terms of Reference establish the Natural Heath Products Advisory Group (the Group) and set out the:

- functions, purpose and guiding principles of the Group
- composition of the Group
- work plan development
- reporting requirements
- establishment, review process and end date
- meetings
- duties and responsibilities of Group members
- removal from the Group
- conflicts of interest.

2. Functions, purpose and guiding principles

2.1 In July 2023, Parliament passed the Therapeutics Products Act (2023) (the Act), which establishes a new regulatory regime for medicines, medical devices and natural health products (NHPs). When it comes into force in mid-2026, the Act will regulate how these therapeutic products are manufactured, tested, imported, promoted, supplied, and exported.

2.2 Secondary legislation is currently being developed under the Act (i.e., regulations, rules and Regulator notices). NHPs are low risk therapeutic products but not no-risk.

2.3 Secondary legislation for NHPs requires the development of:

- a large database of recognised NHP ingredients. NHPs will only be able to contain NHP ingredients that are listed in the database
- a list of health benefits for NHPs, which industry will be able to use to self-substantiate their own health benefit claims
- a process for self-substantiating heath benefit claims, including the scientific evidence and evidence of traditional use needed
- a process for applying for market authorisation for NHPs, noting market authorisation will generally be via an online self-declaration process.
- manufacturing NHP requirements
- a process for applying for a license to manufacture or export NHPs
- exemption requirements (eg, for small-scale NHP manufacturers; low concentration NHP and products manufactured by a NHP practitioner for a client following a consultation)
- export standards and certification

- determining whether a product is an NHP, another type of therapeutic product or a product under other legislation
- considering Te Tiriti o Waitangi and the Heath Strategies when developing secondary legislation.

2.4 The purpose of the Group is to provide non-binding advice, guidance and support to the Ministry of Health (the Ministry) on NHPs. The advice will provide for acceptable safety and quality of NHPs across their life cycle and the substantiation of health benefit claims made about those products.

2.5 The work of the Group will help reflect the objective of developing secondary legislation under the Act, as outlined above. The Group will work with the Ministry to provide advice and help to monitor progress of NHP achievements towards this objective.

2.6 The functions of the Group are to:

a) provide expert and objective advice to the Ministry on the development of recognised NHP ingredients, permitted health benefits, manufacture and other topics of interest, consistent with the purpose, principles and provisions of the Act

b) work in conjunction with the Ministry to identify priorities that relate to the regulation of NHPs under the Act

c) champion actions to progress the objectives for the regulation of NHPs under the Act

d) identify the need for, and advise on the establishment of, any working groups required to progress defined projects for the regulation of NHPs under the Act

e) provide advice to the Ministry on the progress of achievements for the regulation of NHPs under the Act

f) recommend ways the Ministry and the sector could support innovation in any areas identified for the regulation of NHPs under the Act

g) facilitate wider engagement on NHP regulatory matters through a range of communication mechanisms

h) explore and provide sector advice on NHP systemic issues that need to be resolved.

2.7 The Group will be led by the following high-level guiding principles:

a) honesty and integrity. Members have a duty to always act honestly and with integrity

b) impartiality and accountability. Members should consider issues on their merits, taking into account the views of others. This means cooperating fully and honestly to ensure the best advice is provided. Members are not appointed as advocates for, or representatives of, a specific company, organisation or professional group

c) openness. Members should be as open as possible about their actions and advice. This includes being willing to listen to different points of view, giving reasons for offering advice, communicating clearly, and taking personal ownership of comments made publicly

d) respect. Members should always treat others with respect. This means not using derogatory language, observing the rights of other people, treating people with courtesy and recognising the different roles others play

e) effectiveness. The work of the Group operates against a background of previously settled policy matters and is limited to advice necessary to inform the development of the secondary legislation. Advice on amendments or revisions to the Act are out-of-scope.

3. Composition of the Group

3.1 The Group will comprise five to seven core members, including a chair.

3.2 Members will be selected to ensure the diverse perspectives across the NHP sector and community are taken into consideration. Members may include:

a) NHP importers, exporters, manufacturers and distributors

b) NHP practitioners, including Māori and Pacific

c) independent scientific subject matter experts such as toxicologists, pharmacists and researchers

d) consumer representatives.

3.3 In addition, a number of associate Group members (13-15 in total) will be identified to provide stakeholder-specific expertise as required and will support the Group members to discharge their responsibilities, where necessary. When engaging with the Group, associate members are subject to these terms of reference.

3.4 Other people may be invited to attend meetings if further perspectives are needed. Members will be well connected to the views of their organisations and networks and, when providing advice or making decisions, will consider these wider perspectives.

3.5 The core Group will meet up to six times between their appointment and February 2025 and the whole Group will meet up to two times online.

3.6 In making themselves available for appointment, members should ensure that:

a) there is no conflict of interest which would preclude their appointment; and

b) they are available to serve for the full term of their appointment.

3.7 At the discretion of the Ministry, the Group may be extended beyond February 2025 and members can be reappointed. The maximum length of service is 2.5 years (May 2026).

3.8 In appointing Group members, the Ministry will consider the following attributes of individuals:

c) a thorough understanding of, and demonstrated commitment to, the natural health product sector in New Zealand

d) demonstrated knowledge of the interests and concerns of people who access NHPs

e) ability to consult and represent a wide range of views

f) commitment to participate fully in Group activities, in accordance with the Terms of Reference.

4. Work Plan Development

4.1 The Ministry will provide the Group with a workplan once it has been established, which can then be agreed by members. The workplan will be reviewed by the Group and Ministry at 12 months.

Reporting Requirements

4.2 Membership details, terms of reference and minutes of Group meetings will be published by the Ministry. A progress report to the relevant Deputy Director-General by the Group at the end of April 2024 will be required, with further reports expected in November 2024 and February 2025.

5. Establishment, Review Process and End Date

5.1 The Group will be established as soon as possible and will conclude at the end of February 2025. Achievement against its objectives and functions will be reviewed as part of the progress reporting schedule in 4.2. Based on progress and any recommendations of the Group, the Ministry may – at its absolute discretion – extend the Group for a further period of 12 months, with or without a change in membership.

5.2 The Group's terms of reference will be confirmed at an initial meeting of the group and again at 12 months after establishment. A review of the terms of reference, Committee membership and rationale will be undertaken in February 2025.

6. Meetings

6.1 It is anticipated that Group meetings will occur initially on a monthly basis in 2024 and then infrequently or not at all in the second half of 2024 when public consultation on secondary legislation for NHPs is undertaken and submissions are summarised. The frequency of the meetings will be monitored and adjusted depending on need. Working meetings may be organised if necessary.

6.2 A draft agenda will be drafted prior to each meeting by the Secretariat in consultation with the Chair. Members can contribute to the agenda by the given date. The agenda will have clear objectives that will advance the Therapeutic Products programme of work. The agenda and related papers are to be circulated to members no less than 5 calendar days prior to the meeting.

6.3 Meetings are to be facilitated by the Chair, or a delegated member. The Ministry provides governance and decision making at a national level. To record the advice of the Group, consensus will be noted. Where consensus cannot be reached a majority vote will be sought and diversity of opinion will be reflected in the advice noted to the Ministry.

6.4 A member who abstains from voting or dissents from the majority ruling can request to have their action recorded in the minutes of the meeting.

6.5 At each meeting, Group members will provide brief verbal reports on any relevant consultations they have attended or held and any significant issues arising.

6.6 The Secretariat supporting the Group should maintain an interests register, listing members' interests relevant to the Group's business. Declaration and discussion of conflicts of interest should be a standing item on each meeting's agenda, and actions arising out of this item should be recorded in the minutes.

7. Duties and Responsibilities of a Member

7.1 This section sets out the expectations regarding the duties and responsibilities of a person appointed as a member of the Group. This is intended to aid members by providing them with a common set of principles for appropriate conduct and behaviour, and serves to protect the Group and its members from being exposed to legal challenges.

7.2 Members have a commitment to work for the public of New Zealand. Members are accountable to the Ministry of Health.

7.3 Group members attend meetings and undertake Group activities as independent persons responsible to the Group as a whole and are not representatives of professional organisations or communities. This issue is particularly important when Group members may, at times, be required to be party to decisions which conflict with the views of other organisations with which they are involved.

7.4 There is an expectation that members will attend all meetings and devote sufficient time to become familiar with the affairs of the Group and the wider environment within which it operates.

7.5 Group members may be required to serve on sub-groups as required.

8. Removal from the Group

8.1 The Ministry may, at any time and entirely at its discretion, remove any member from the Group.

9. Conflicts of Interest

9.1 Members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will enable public confidence in the work of the Group to be maintained.

9.2 When members believe they have a conflict of interest on a subject which will prevent them from reaching an impartial decision or undertaking an activity consistent with the Group's functions, then they must declare a conflict of interest and how the conflict of interest will be managed. This must be done at the earliest possible opportunity, in the regular agenda item around conflicts of interest, and at the point the relevant item of business comes up in the meeting.

10. Liability

10.1 Members are not liable for any act or omission done or omitted in their capacity as a member, if they acted in good faith, and with reasonable care, in pursuance of the functions of the Group.

11. Confidentiality

11.1 Subject to the 5.1 above, meetings, including agenda material and minutes, are confidential. Members must ensure that the confidentiality of Group business is maintained.

11.2 Members are free to, and are expected to, express their own views within the context of meetings, or the general business of the Group. Members must publicly support a course of action decided by the Group, or if unable to do that, must not publicly comment on decisions.

11.3 At no time shall members divulge details of Group matters or decisions to people who are not members, or Ministry employees. Disclosure of Group business to anyone outside the Ministry must be the decision of the Ministry.

11.4 Group members must ensure that documents are kept securely to ensure that confidentiality is maintained. Release of correspondence or papers can only be made with the approval of the Ministry. At the end of a member's term, all Group information must be returned to the Ministry.

12. Remuneration and expenses

12.1 Eligible members of the Group are paid fees for attendance at meetings, in accordance with the Cabinet Office Circular CO (22) 2 Revised Fees Framework for members appointed to bodies in which the Crown has an interest.

12.2 The fee for Group members is currently $700 per day (before tax) and $930 per day (before tax) for the Chair. This is reviewed annually. The daily fee covers meeting preparation time and meeting attendance.

12.3 Members who are employees of the wider State sector are not entitled to be paid fees for Group business if this is conducted during regular paid work time (ie, members cannot be paid twice by the Crown for the same hours).

12.4 Members are entitled to be reimbursed for actual and reasonable travelling and other expenses incurred in carrying out their duties. The expectation is that the standards of travel, accommodation, meals and other expenses are modest and appropriate to reflect public sector norms.