

# **Specialist Advisory Committee (SAC) Terms of Reference**

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# Specialist Advisory Committee Terms of Reference

## CONTENTS

- Specialist Advisory Committee Terms of Reference..... 1**
- Foreword ..... 3**
- Glossary of terms ..... 4**
- 1 Establishment..... 6**
  - 1.1 Specialist Advisory Committees.....6
- 2 Functions ..... 6**
  - 2.1 Activities of Specialist Advisory Committees .....6
  - 2.2 Matters that Specialist Advisory Committees are to consider.....6
  - 2.3 Advice to be given by Specialist Advisory Committees .....7
  - 2.4 Publication of Specialist Advisory Committee Advice.....8
- 3 Relationship Management..... 8**
  - 3.1 Relationship between Pharmac and Specialist Advisory Committees .....8
  - 3.2 Relationship between PTAC and Specialist Advisory Committees.....9
  - 3.3 Indemnity for Members .....9
- 4 Membership ..... 9**
  - 4.1 Te Tiriti o Waitangi expectations .....9
  - 4.2 Health Equity .....10
  - 4.3 Diversity on Specialist Advisory Committees .....10
  - 4.4 Recruitment and appointment of Specialist Advisory Committee Members.....11
  - 4.5 Consumer Member .....11
  - 4.6 Resignation, renewal, and termination of Specialist Advisory Committee Members .....11
  - 4.7 Temporary Members of Specialist Advisory Committee.....12
  - 4.8 Dissolving Specialist Advisory Committees.....12
- 5 Fees and expenses ..... 12**
- 6 Responsibilities of Members..... 12**
  - 6.1 Responsibilities of Specialist Advisory Committee Chair.....12
  - 6.2 Responsibilities of Deputy Chairs of Specialist Advisory Committee.....13
  - 6.3 Responsibilities of all Members.....13
  - 6.4 Interest Reporting .....13
  - 6.5 Confidentiality .....14
  - 6.6 External Communications and Public Statements.....15
- 7 Management of Meetings ..... 15**
  - 7.1 Meetings of Specialist Advisory Committees.....15
  - 7.2 Observers.....15
  - 7.3 Additional Subject Matter Expertise .....16
  - 7.4 Consumer Perspective .....16
- 8 Variation of Terms of Reference ..... 16**

9 Disputes of Specialist Advisory Committee in relation to these Terms of Reference..... 16

10 Review of these Terms of Reference..... 16

11 Appendix One – Relevant Statutory Provisions (*to be reviewed and updated*)..... 17

## Foreword

As a Crown Entity, Te Pātaka Whaioranga Pharmac (Pharmac) is governed by a Board that has authority to make decisions for Pharmac, some of which are delegated to Pharmac staff. Within this document, unless specified, the use of the word Pharmac is to be interpreted as Pharmac's Board, the entity, and its staff.

These Terms of Reference set out the goals, responsibilities, obligations, and procedures for standing Specialist Advisory Committees.

This document is the primary document for standing Specialist Advisory Committee Members when considering their responsibilities, respective roles, and conflicts of interest and confidentiality obligations. Further guidance, including administrative information for meetings, can be found in the *Member handbook for Clinical Committees (Member Handbook)*<sup>1</sup>.

Nothing in these Terms of Reference is intended to restrict or fetter the nature or content of the advice that Specialist Advisory Committees provide to Pharmac.

There are several key pieces of legislation referred to within this document that should be referenced by Specialist Advisory Committee Members, outlined in Appendix One.

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<sup>1</sup> In development

## Glossary of terms

**“Advice Record” (formerly Minutes)** means the written record of discussion and recommendations made at a PTAC or Specialist Advisory Committee meeting (including meetings by Remote Media Conference and recommendations made by other means of communication) which have been finalised by the relevant Chair.

**“Applicant”** means any third party who submits an application or Proposal to Pharmac for consideration. An application can also be made by Pharmac staff.

**“Chief Executive”** means the Chief Executive of Pharmac, or their delegate.

**“Director-General”** and **“Director-General of Health”** means the Director-General of Health (chief executive or acting chief executive of the Ministry of Health), or their delegate.

**“Health Equity”** means the absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically, or geographically. In the Pharmac context, the focus is on medicines access equity as defined at <https://pharmac.govt.nz/achieving-medicine-access-equity-in-aotearoa-new-zealand-towards-a-theory-of-change/>

**“Specialist Advisory Committee”** (formerly PTAC Subcommittee) means a standing Specialist Advisory Committee.

**“Specialist Advisory Committee Chair”** (formerly PTAC Subcommittee Chair) means the Chairperson of the Specialist Advisory Committee.

**“Member”** means a member of a Specialist Advisory Committee.

**“NZPHD Act”** means the New Zealand Public Health and Disability Act 2000 and includes any regulations, amendments, re-enactments, and replacements thereof.

**“OPPs”** means Pharmac’s Operating Policies and Procedures which are published on Pharmac’s website at <http://www.pharmac.govt.nz/suppliers/AboutPHARMAC/procedures>.

**“Pharmac”** and **“Te Pātaka Whaioranga”** means the Pharmaceutical Management Agency, a Crown Entity established under the NZPHD Act, its staff, and Board.

**“Pharmaceutical(s)”** means, as defined in the NZPHD Act, a medicine, therapeutic medical device, or related product, or related thing.

**“Pharmaceutical Schedule”** means the list of the prescription medicines and therapeutic products subsidised by the Crown (<http://schedule.pharmac.govt.nz>).

**“Proposal”** means, either: (a) an application or Proposal made by a third party to Pharmac for the funding of a pharmaceutical or changes to the funding of a pharmaceutical that is already on the Pharmaceutical Schedule (eg a Proposal to widen or restrict access); OR (b) a Proposal made by Pharmac staff.

**“PTAC”** means the Pharmacology and Therapeutics Advisory Committee.

**“PTAC Chair”** means the Chairperson of PTAC.

**“Published Advice Record”** means that part of the PTAC or Specialist Advisory Committee Advice Record published on the Pharmac website at <https://pharmac.govt.nz/about/expert-advice/specialist-advisory-committees-SACs/>

**“Supplier”** means the supplier of a pharmaceutical.

**“Terms of Reference”** means these Terms of Reference for Specialist Advisory Committees.

# 1 Establishment

## 1.1 Specialist Advisory Committees

- 1.1.1 Pharmac's Board may, by resolution,<sup>2</sup> appoint standing committees. Specialist Advisory Committees have been established accordingly to consider, report, or make recommendations and provide advice, either directly to it or through PTAC or Pharmac staff, on Proposals or other issues relating to the Pharmaceutical Schedule, within a specific therapy area. In appointing a standing Specialist Advisory Committee, Pharmac's Board may have regard to the recommendations of the PTAC Chair and Pharmac staff.
- 1.1.2 Specialist Advisory Committees are appointed to reflect specialist knowledge and expertise in the health needs and health benefits of treatments within their own therapeutic groups/areas of practice, including the applicability of evidence to clinical funding settings in New Zealand.
- 1.1.3 Specialist Advisory Committees were previously called subcommittees of PTAC, and all established subcommittees of PTAC continue as Specialist Advisory Committees unless they are separately disestablished.

# 2 Functions

## 2.1 Activities of Specialist Advisory Committees

- 2.1.1 Specialist Advisory Committees are to:
  - provide objective advice to Pharmac to support specific therapeutic areas including category management for community and hospital pharmaceuticals and their benefits, using Pharmac's decision-making framework.
  - where relevant, make recommendations to Pharmac on applications or Proposals related to the management<sup>3</sup> of the Pharmaceutical Schedule which have been referred to it by Pharmac or PTAC
  - consider and report, or make recommendations, to Pharmac or PTAC on any other matters that may be referred to it by Pharmac or PTAC, which may be ad-hoc and outside of formal meetings.

## 2.2 Matters that Specialist Advisory Committees are to consider

- 2.2.1 Nothing in these Terms of Reference is intended to restrict or fetter the nature and content of the advice that Specialist Advisory Committees provide to Pharmac.
- 2.2.2 When providing their advice to Pharmac, Specialist Advisory Committees are to take into account, where applicable, Pharmac's decision-making framework.
- 2.2.3 Should a Specialist Advisory Committee take into account considerations that fall outside of Pharmac's decision-making framework, the specific consideration, and

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<sup>2</sup> Clause 14(1)(a), Schedule 5, Crown Entities Act.

<sup>3</sup> Possible amendments to the Pharmaceutical Schedule are outlined in the Pharmac Operating Policies and Procedures (OPPs). <https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/operating-policies-and-procedures/>

the reasoning for including it must be recorded in its Advice Record (formerly “Minutes”).

- 2.2.4 Subject to the confidentiality provisions in section 7 of these Terms of Reference and Pharmac’s obligations under the Privacy Act 2020 and Health Information Privacy Code 2020, Members may consult with, and seek evidence or information from, such parties as they consider necessary or appropriate, including relevant medical and consumer groups. They may seek evidence or information in relation to a particular pharmaceutical, therapeutic group or subgroup or any other matter that has been referred to them for consideration or recommendation. The fact of any such consultation and the parties consulted with will generally be documented in the relevant Advice Record.
- 2.2.5 Specialist Advisory Committees may use any evidence that can reasonably be obtained. In making recommendations based on this evidence, Specialist Advisory Committees are to use their judgement when considering issues such as quality and relevance.

### **2.3 Advice to be given by Specialist Advisory Committees**

- 2.3.1 Pharmac may request a Specialist Advisory Committee make a recommendation on any Proposal under consideration. When making recommendations to Pharmac, Specialist Advisory Committees are to set out the matters and evidence from Pharmac’s decision-making framework that are primarily relied on in making a recommendation. Each Specialist Advisory Committee makes recommendations, including priority, within its area of expertise, and may:
  - (a) recommend that the pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule (or its access eligibility be widened), and the priority it gives to such a listing (High, Medium, Low, Cost-neutral to another specified pharmaceutical) within that therapeutic group
  - (b) defer a final recommendation, and give reasons for the deferral (such as for the supply of further information) and what is required before further review
  - (c) recommend that Pharmac decline to list (or widen access to) a pharmaceutical on the Pharmaceutical Schedule.
- 2.3.2 Members are to endeavour, at all times, to reach a consensus on recommendations. Further detail on the process to follow where consensus is not met is included in the *Member Handbook*.
- 2.3.3 Members (including the Specialist Advisory Committee Chair) are bound by each recommendation and will not take any steps outside the meeting to the detriment of a consensus or majority recommendation.
- 2.3.4 Specialist Advisory Committees may consider other matters referred by Pharmac or PTAC, which may include any correspondence, new information or resubmissions or Proposals that are provided by applicants.
- 2.3.5 Nothing in the above or this Terms of Reference is intended to prevent Pharmac, at its discretion, from seeking advice from any person or group who it considers has expertise or views that will assist Pharmac to perform its statutory functions.

## **2.4 Publication of Specialist Advisory Committee Advice**

- 2.4.1 The final recommendations (as set out in section 2.3) made by the Specialist Advisory Committee in relation to a Proposal will be published on the Pharmac website (the Published Advice Record), subject to sections 2.4.2.
- 2.4.2 The content of each Published Advice Record of a Specialist Advisory Committee will vary depending on sensitivity of the information in the Record. The Advice Record will be prepared by Pharmac staff and portions of the Advice Record may be withheld from publication in accordance with the Official Information Act 1982. Content which is incidental, administrative, or not related to any Proposal under consideration may also be excluded from the Published Advice Record. The names of all Members and attendees at a meeting who are not Pharmac staff will also be published.
- 2.4.3 Before publication, relevant portions of the draft Published Advice Record will be provided to the Applicant (where applicable), who may provide feedback as to whether it considers specific content should be withheld under the Official Information Act 1982 and the grounds for doing so. Pharmac staff may make changes to the draft Published Advice Record content, but their over-riding obligation is to ensure that the record of SAC discussions remains accurate<sup>4</sup>, and Pharmac will only withhold content of a draft Published Advice Record relating to a specific Proposal where it agrees with the applicant that there are grounds for withholding content under the Official Information Act 1982.

## **3 Relationship Management**

### **3.1 Relationship between Pharmac and Specialist Advisory Committees**

- 3.1.1 Specialist Advisory Committees are standing committees established by Pharmac to provide objective advice to Pharmac on pharmaceuticals and their benefits related to specific therapy areas.
- 3.1.2 The Pharmac Board Chair, or other Pharmac Board member approved in advance by the Specialist Advisory Committee Chair, may attend meetings of Specialist Advisory Committees as an observer. The Pharmac Board Chair may participate in discussion at the invitation of the Specialist Advisory Committee Chair but may not vote on any matter at that meeting.<sup>5</sup> The Pharmac Board Chair may report back to the Pharmac Board on the discussions of Specialist Advisory Committees.
- 3.1.3 A member of Pharmac's Senior Leadership Team, or a delegate, may attend each Specialist Advisory Committee meeting and participate in the discussions where relevant.
- 3.1.4 Pharmac staff member(s) will attend and participate in meetings of Specialist Advisory Committees while discussion and recommendations relevant to their area of work are deliberated. In general, Pharmac staff may respond to questions from

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<sup>4</sup> For example, changes may include typographical errors, facts recorded incorrectly or to clarify any ambiguity.

<sup>5</sup> When attending Specialist Advisory Committee meetings, the Pharmac Board Chair will also remain mindful of the accountabilities of the Specialist Advisory Committee to Pharmac, including consequent perceptions and unconscious impacts on the Specialist Advisory Committee Members' comfort and ability to provide objective advice freely and frankly. The Board Chair and Specialist Advisory Committee Chair will take whatever measures necessary to avoid the Board Chair's presence inadvertently influencing or constraining discussion.

Members and clarify understanding of discussion and recommendations as necessary.

3.1.5 Pharmac staff members may not vote on any matter at a Specialist Advisory Committee meeting.

3.1.6 Pharmac staff will provide secretariat and administrative support to Specialist Advisory Committees.

### **3.2 Relationship between PTAC and Specialist Advisory Committees**

3.2.1 The PTAC Chair is responsible for:

- advising Pharmac on the suitability of appointments to Specialist Advisory Committees
- advising Pharmac on appointments of Specialist Advisory Committee Chairs and Deputy Chairs
- as necessary, reviewing communications by Members related to the activities of Specialist Advisory Committees or Pharmac with the media or professional associations, having first obtained the consent of the Pharmac Chief Executive to the act of communication and having first consulted with Pharmac on the content
- advising Pharmac on the establishment and/or dissolution of Specialist Advisory Committees.

3.2.2 Specialist Advisory Committees will have at least one PTAC Member.<sup>6</sup>

3.2.3 PTAC may seek advice from Specialist Advisory Committees on specific issues relating to a Proposal or the Pharmaceutical Schedule that requires subject matter expertise. Specialist Advisory Committees will give a written opinion to PTAC through the relevant Specialist Advisory Committee Advice Record, and PTAC will consider this opinion.

### **3.3 Indemnity for Members**

3.3.1 Pharmac indemnifies all Members against all costs, liabilities, expenses and claims Members may incur as a direct or indirect result of advice given in their capacity as Members. This indemnity only applies to circumstances where a Member has acted in good faith and in performance or intended performance of a Specialist Advisory Committees' function.

## **4 Membership**

### **4.1 Te Tiriti o Waitangi expectations**

4.1.1 As a Crown Entity, Pharmac understands, and is committed to its obligations and expectations under Te Tiriti o Waitangi. This commitment extends to representation on Specialist Advisory Committees.

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<sup>6</sup> The only exception to this is the Tender Medical Evaluation Advisory Committee (formerly the Tender Medical Subcommittee), which may have a PTAC Member but this is not an absolute requirement.

- 4.1.2 In so far as possible<sup>7</sup>, membership of Specialist Advisory Committees will include a senior health practitioner who is Māori.
- 4.1.3 Pharmac is in the early stages of embedding te Tiriti into its policy and practice. In alignment with Pharmac's [Te Whaioranga strategy](#), the following principles will guide Specialist Advisory Committees as appropriate in providing clinical advice to Pharmac.

Tino rangatiratanga	<i>We recognise and respect the right of Māori to have control over their own health and wellbeing. We support Māori in the exercise of tino rangatiratanga, through self-determination and mana motuhake in the design, delivery, and monitoring of our work. We build enduring relationships and partnerships with our te Tiriti partners.</i>
Equity	<i>Māori are our priority population for all equity work. We consider inequitable access to medicines and poor health outcomes for Māori to be unfair, unjust, and avoidable and we actively work to achieve equitable health outcomes for Māori.</i>
Active protection	<i>Alongside our commitment to equity, we are well informed on the extent and nature of Māori health outcomes and what is being done to achieve Māori health equity. We actively protect tino rangatiratanga through increasing Māori participation in governance, leadership, management, and decision making at all levels of Pharmac. We ensure mātauranga Māori is given respect in any decision-making process.</i>
Options	<i>We deliver for and work with whānau Māori in a sustainable, enduring and culturally appropriate way that recognises and supports the expression of mātauranga Māori.</i>
Partnership	<i>We work in utmost good faith with Māori in the governance, design, delivery, and monitoring of our work to ensure our mutual goals are met. We ensure our governance and management structure guarantees we have capability and capacity to deliver on our commitments. We continually broaden our understanding of te ao Māori and build our capability to deliver on all our priorities.</i>

## 4.2 Health Equity

- 4.2.1 Consistent with Pharmac's strategic direction, Pharmac requires Members to bring an understanding of, and commitment to, achieving health and medicines access equity.
- 4.2.2 Specialist Advisory Committee membership recruitment processes will strengthen the health and medicines access equity expertise of each Specialist Advisory Committee.

## 4.3 Diversity on Specialist Advisory Committees

- 4.3.1 Pharmac is committed to ensuring that decisions on pharmaceuticals meet the needs of all New Zealanders, across the range of patients, whānau and society. In so far as possible, Specialist Advisory Committee membership should reflect the diversity of

<sup>7</sup> Recognising it may not be possible to seek this expertise for every specialist area.

Aotearoa New Zealand, particularly with respects to (but not confined to) gender and ethnicity.<sup>8</sup>

- 4.3.2 Pharmac will actively promote the diversity of Specialist Advisory Committee membership in the appointment process.

#### **4.4 Recruitment and appointment of Specialist Advisory Committee Members**

- 4.4.1 Specialist Advisory Committee Members (including the Specialist Advisory Committee Chair and Specialist Advisory Committee Deputy Chair) are to be appointed by Pharmac. In doing so Pharmac may be guided by the recommendations of the PTAC Chair and Pharmac staff.<sup>9</sup>
- 4.4.2 In general, Specialist Advisory Committees are weighted towards senior health practitioners (who may not be medical practitioners) with relevant expertise and who work within the publicly funded health sector, with experience and knowledge of pharmaceuticals and their therapeutic indications in relevant particular therapeutic areas.
- 4.4.3 Specialist Advisory Committees will also have at least one PTAC Member, who will usually act as the Specialist Advisory Committee Chair. Specialist Advisory Committees will also have a Deputy Chair who is usually a Member of PTAC.
- 4.4.4 Members are usually appointed for a term of three years.
- 4.4.5 Membership of each Specialist Advisory Committee will be published on the Pharmac website: <https://pharmac.govt.nz/about/expert-advice/specialist-advisory-committees-sac>

#### **4.5 Consumer Member**

- 4.5.1 Specialist Advisory Committees may have one or more members who is a consumer, to provide a consumer perspective to Specialist Advisory Committee discussions. This Member is appointed in accordance with section 4.4.1.
- 4.5.2 If appointed, the Consumer Member may participate in the discussions at the PTAC meeting and may also vote on any matter being considered at the meeting.
- 4.5.3 The Consumer Member is bound by these Terms of Reference.

#### **4.6 Resignation, renewal, and termination of Specialist Advisory Committee Members**

- 4.6.1 Members may resign at any time by notice in writing in accordance with the appointment protocol for clinical advisory committee members.
- 4.6.2 A Specialist Advisory Committee Member's appointment may be:
- (a) renewed or extended by Pharmac

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<sup>8</sup> Pharmac values diversity and inclusion across all gender identities, ages, ethnicities, disabilities, sexual orientations, cultures, religions, and groups experiencing disparities. We recognise that it may be difficult to seek this representation across all specialist areas.

<sup>9</sup> Clause 14(1)(a), Schedule 5, Crown Entities Act 2004.

(b) terminated by Pharmac without any right of compensation<sup>10</sup>.

#### **4.7 Temporary Members of Specialist Advisory Committee**

4.7.1 Temporary Members may be appointed to Specialist Advisory Committees by Pharmac for such terms and on such conditions as Pharmac determines appropriate in order to fill any casual vacancy. In doing so Pharmac may have regard to the recommendations of the PTAC Chair and Pharmac staff.

#### **4.8 Dissolving Specialist Advisory Committees**

4.8.1 Specialist Advisory Committees established by Pharmac can be dissolved by the Pharmac Board at any time. In doing so Pharmac may have regard to the recommendations of the PTAC Chair and Pharmac staff. Pharmac will advise the relevant Specialist Advisory Committee Chair in writing of its intention to dissolve a Specialist Advisory Committee.

### **5 Fees and expenses**

5.1.1 Members will be remunerated in recognition of the services they provide to Pharmac, including attendance at meetings, time spent preparing for meetings and for performing any other work as requested by Pharmac

5.1.2 The Public Services Commission administers the Cabinet Fees Framework which determines the level of fees paid, including any exceptions.

5.1.3 Members are advised of the fees upon appointment to a Specialist Advisory Committee.

5.1.4 Pharmac will cover travel and accommodation expenses for Members to attend meetings<sup>11</sup> but will not cover travel time or locum costs as per the Pharmac Travel Policy for Board and Committee Members.

### **6 Responsibilities of Members**

#### **6.1 Responsibilities of Specialist Advisory Committee Chair**

6.1.1 The key responsibilities of a Specialist Advisory Committee Chair are to:

- review the agenda for the Specialist Advisory Committee meetings (Pharmac staff will plan and draft the agenda)
- presiding at each meeting of the Specialist Advisory Committee
- where relevant, representing the Specialist Advisory Committee, and the Specialist Advisory Committee's consensus view and recommendations, at meetings of PTAC<sup>12</sup>

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<sup>10</sup> Section 43, Crown Entities Act 2004.

<sup>11</sup> Travel & Expense Policy for Board Members and Committee Members

<sup>12</sup> Such representing, however, is notwithstanding their own separate views as a separate member of PTAC, and is mindful of them having the dual roles when attending PTAC meetings. This can be managed, for example, by the person speaking twice, once as the Specialist Advisory Committee Chair, the other separately as an individual Member of PTAC

- other administrative tasks as set out in the *Member Handbook*.

## **6.2 Responsibilities of Deputy Chairs of Specialist Advisory Committee**

- 6.2.1 The Deputy Chair is responsible for acting as the Chair of the Specialist Advisory Committee when the Chair is unable or delegates this role to the Deputy Chair.

## **6.3 Responsibilities of all Members**

- 6.3.1 The key responsibilities of all Members are:

- maintaining professional registration and credentialling
- complying with all obligations set out in the Crown Entities Act 2004 and any other legal requirements
- complying with the obligations set out in this Terms of Reference
- providing objective advice that is free, frank, constructive and collegial, and without bias, or the perception of bias, under Pharmac's decision making criteria and consistent with Pharmac's statutory objective.

- 6.3.2 Complying with all relevant policies and responsibilities as set out in the *Member Handbook*.

## **6.4 Interest Reporting**

- 6.4.1 Members are to, at all times, fully disclose and appropriately manage any interests and conflicts of interest in the performance of their duties and obligations, consistent with their role as Members of a Committee of a statutory entity. Members are to avoid, to the greatest extent possible, any conflict with the performance of their duties and obligations as Members. The legislative requirements for disclosure and management of conflicts are set out in Appendix One. Section 62 of the Crown Entities Act 2004 sets out the legal definition of being "interested in a matter". Further guidance on this issue is set out in the *Member Handbook*.

- 6.4.2 A Member who reasonably believes they may have an actual or potential conflict of interest is to disclose the nature of that interest to the Specialist Advisory Committee Chair (via the Specialist Advisory Committee Coordinator) as soon as practicable after they become aware of it.

- 6.4.3 Where a Member declares or discloses an interest of any kind or an actual or potential conflict of interest, this shall be recorded in an interest register, which is to be circulated prior to each meeting of the Specialist Advisory Committee. The interests register is to be considered and confirmed as up to date at the commencement of each meeting. The interests register is managed by Pharmac staff.

- 6.4.4 Where a Member is "interested in a matter" (as defined in section 62 Crown Entities Act 2004) relating to Pharmac, they must not vote or take part in any discussion or decision of the Specialist Advisory Committee relating to the matter, or otherwise participate in any activity of Pharmac that relates to the matter, unless permitted by the Pharmac Board Chair (including under any standing permission issued by the Pharmac Board Chair). The Advice Record of the meeting will record this fact.

- 6.4.5 The Member is to be disregarded for the purposes of forming a quorum for that part of the Specialist Advisory Committee meeting during which a discussion or recommendation in relation to the matter occurs or is made. If a quorum cannot be maintained, then the relevant matter is to be deferred to the next meeting.
- 6.4.6 Should the Specialist Advisory Committee Chair (or Deputy Chair, when the Chair is “interested in a matter”) consider that it is in the public interest to permit one or more Members, or Members with a specified class of interest, to vote or take part in any discussion or decision of Specialist Advisory Committee relating to that matter, or otherwise participate in any activity of Pharmac that relates to that matter, they should apply for such permission from the Pharmac Board Chair through the PTAC Chair. The Pharmac Board Chair may give such permission if they are satisfied it is in the public interest to do so and may state conditions that the Member(s) must comply with.
- 6.4.7 Where the Pharmac Board Chair determines that it is “in the public interest” for a Member to continue to participate in a matter, despite any declared conflict of interest, this will be documented in the Advice Record.
- 6.4.8 The Pharmac Board Chair has authority to make a final determination about the handling of any actual or potential conflict of interest and, in his or her absence, the Chief Executive.

## **6.5 Confidentiality**

- 6.5.1 Subject to sections 7.5.3 and 7.5.4, and subject to any public law obligations of Pharmac in relation to the disclosure of information (including under the Official Information Act 1982), all information, documents and other material relating to matters on a Specialist Advisory Committee agenda, as well as the proceedings of a Specialist Advisory Committee meeting, are confidential to the Specialist Advisory Committee and to Pharmac Members must comply with any communications regarding confidentiality obligations issued by Pharmac and will, if required, sign confidentiality undertakings.
- 6.5.2 Members are required to store all material received from Pharmac in a secure place until the relevant Advice Record has been published, after which time Members must either destroy the material (by secure destruction) or return it to Pharmac in accordance with any instruction from Pharmac
- 6.5.3 Members may confirm that Pharmac has received a Proposal once details of the Proposal have been published on Pharmac’s website. Members may discuss such Proposals with colleagues where Members believe it would assist to obtain information on the use, efficacy, adverse effects etc of the pharmaceutical(s) in question. Members may also discuss Proposals with other third parties as outlined in section 2.2.4. Any action taken by Members under section 7.5.3 is subject to compliance with the Privacy Act 2020 and the Health Information Privacy Code 2020, and maintenance of confidentiality regarding commercial information.
- 6.5.4 Once a Published Advice Record has been made available on the Pharmac website, Members may discuss with colleagues matters considered at the meeting but only on a general basis and only to the extent of the contents of the Published Advice Record.

## **6.6 External Communications and Public Statements**

- 6.6.1 Members may only speak or write to the media or in public fora in relation to the activities of a Specialist Advisory Committee or Pharmac and any matters discussed at or considered by the Specialist Advisory Committee at their meetings if they have the prior agreement of the PTAC Chair and the Pharmac Chief Executive (which may be communicated via Pharmac staff). This restriction includes when speaking to patient interest groups and to pharmaceutical suppliers, signing petitions, letters to newspapers, and co-authoring articles for publication in academic journals and other settings.
- 6.6.2 Members may only report to their professional associations in relation to the activities of a Specialist Advisory Committee or Pharmac or any matters discussed at or considered by Specialist Advisory Committee at their meetings, if they have the prior agreement of the PTAC Chair and the Pharmac Chief Executive (which may be communicated via Pharmac staff). This restriction includes when speaking with colleagues, people, or groups, other than when directly seeking perspectives/advice to inform items for discussion in meetings.
- 6.6.3 Subject to section 7.6.1 and 7.6.2, when speaking or writing in public fora (including signing petitions, letters to newspapers, articles in academic journals), Members need to clear that they will be doing so in their own private capacities as clinicians, and not as being a Member of a Specialist Advisory Committee.

## **7 Management of Meetings**

### **7.1 Meetings of Specialist Advisory Committees**

- 7.1.1 Specialist Advisory Committees will have formal meetings (either via a face-to-face meeting or via Remote Media Conference) on an as-needs basis as determined by Pharmac. This frequency and consistency will vary by committee depending on the advice needed by Pharmac.
- 7.1.2 The quorum for Specialist Advisory Committee meetings is three Members and must include at least two non-PTAC Members and one PTAC Member (who may be the Specialist Advisory Committee Chair).<sup>13</sup>
- 7.1.3 Subject to compliance with these Terms of Reference, Specialist Advisory Committees may regulate their internal procedures in such manner as they see fit.

### **7.2 Observers**

- 7.2.1 At the discretion of the Specialist Advisory Committee Chair and Pharmac staff, observers may be given permission to attend meetings of Specialist Advisory Committees. These observers are not Members and, unless the Specialist Advisory Committee Chair of the meeting otherwise agrees, these observers will not have any rights to speak at or otherwise participate in the meeting.
- 7.2.2 Observers are required to sign confidentiality undertakings and declare any relevant interests they may hold, prior to attending any Specialist Advisory Committee meeting. The attendance of an observer at a meeting will be documented in the Advice Record.

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<sup>13</sup> The only exception to this is the Tender Medical Evaluation Advisory Committee (formerly the Tender Medical Subcommittee), which does not require a PTAC Member for a quorum.

- 7.2.3 Observers should not, by their presence, affect any recommendations of Specialist Advisory Committees, by either influencing or constraining discussion at any Committee meeting. If the Specialist Advisory Committee Chair determines that the presence of an observer is having such an effect, the Chair may require the observer to leave the meeting.

### **7.3 Additional Subject Matter Expertise**

- 7.3.1 At the discretion of the Specialist Advisory Committee Chair and Pharmac staff, additional subject matter experts may be given permission to present (either in person or via Remote Media Conference) on specific issues being considered by the Specialist Advisory Committee. Additional subject matter experts can speak on the specific issues being considered. They are only to be present for the relevant portion of the meeting and cannot be present when the Members make a recommendation.
- 7.3.2 Additional subject matter experts are required to sign confidentiality undertakings and declare any relevant interests they may hold, prior to attending any meeting of a Specialist Advisory Committee. The attendance of an additional subject matter experts at a meeting will be documented in the Advice Record.

### **7.4 Consumer Perspective**

- 7.4.1 To help inform the Specialist Advisory Committee consideration of Pharmac's decision-making framework, they may consider relevant consumer perspectives with respect to a Proposal under consideration. Consumer perspectives can be provided through submissions received and correspondence.

## **8 Variation of Terms of Reference**

- 8.1.1 These Terms of Reference set out Specialist Advisory Committees roles and responsibilities but are not intended to cover every eventuality. They are to be interpreted flexibly and pragmatically, to allow Specialist Advisory Committees the scope to adapt as the need arises.
- 8.1.2 These Terms of Reference may be varied from time to time or revoked (which may, where Pharmac considers it appropriate, involve consultation), by the Pharmac Board.

## **9 Disputes of Specialist Advisory Committee in relation to these Terms of Reference**

- 9.1.1 Any dispute or disagreement as to the meaning or application of any section in these Terms of Reference is to be determined by the Pharmac Chair, whose decision is final.

## **10 Review of these Terms of Reference**

- 10.1.1 These Terms of Reference will be reviewed every three years.

## 11 Appendix One – Relevant Statutory Provisions (*to be reviewed and updated*)

### *New Zealand Public Health and Disability Act 2000*

#### 50 *Board of Pharmac to establish advisory committees*

(1) The board of Pharmac must establish the following advisory committees under clause [14\(1\)\(a\)](#) of Schedule 5 of the [Crown Entities Act 2004](#):

(a) a pharmacology and therapeutics advisory committee to provide objective advice to Pharmac on pharmaceuticals and their benefits

(b) a consumer advisory committee to provide input from a consumer or patient point of view.

(2) [Repealed]

(3) [Repealed]

(4) Despite clause [14\(1\)\(a\)](#) of Schedule 5 of the [Crown Entities Act 2004](#), the members of the pharmacology and therapeutics advisory committee are appointed by the Director-General in consultation with the board of Pharmac.

### *Crown Entities Act 2004*

#### 43 *No compensation for loss of office*

A member of a statutory entity is not entitled to any compensation or other payment or benefit relating to his or her ceasing, for any reason, to hold office as a member.

### **Remuneration and expenses**

#### 47 *Remuneration of members*

(1) A member of a statutory entity is entitled to receive, from the funds of the entity, remuneration not within section [48](#) for services as a member at a rate and of a kind determined by—

(a) the responsible Minister, in the case of a member of a Crown agent or autonomous Crown entity, in accordance with the fees framework

(b) the Remuneration Authority in accordance with the [Remuneration Authority Act 1977](#), in the case of

(i) a member of an independent Crown entity

(ii) a member of a Crown agent or autonomous Crown entity that is a corporation sole.

(2) The following office holders are not entitled to any remuneration for services as a member of the statutory entity in addition to his or her remuneration in respect of that office:

(a) a Judge

(b) a member of Parliament

(c) an employee (including a chief executive) within any part of the State services who is acting as a member of the statutory entity as a representative of all or any part of the State services.

#### 48 *Expenses of members*

A member of a statutory entity is entitled, in accordance with the fees framework, to be reimbursed, out of the funds of the entity, for actual and reasonable travelling and other expenses incurred in carrying out his or her office as a member.

### **Individual duties of members**

#### 57 *Duty not to disclose information*

(1) A member of a statutory entity who has information in his or her capacity as a member that would not otherwise be available to him or her must not disclose that information to any person, or make use of, or act on, that information, except

(a) in the performance of the entity's functions

(b) as required or permitted by law

(c) in accordance with subsection [\(2\)](#)

(d) in complying with the requirements for members to disclose interests.

- (2) A member may disclose, make use of, or act on the information if
  - (a) the member is first authorised to do so by the board or, in the case of a corporation sole, by the responsible Minister
  - (b) the disclosure, use, or act in question will not, or will be unlikely to, prejudice the entity.

### **Conflict of interest disclosure rules**

#### *62 When interests must be disclosed*

- (1) In this section, matter means
  - (a) a statutory entity's performance of its functions or exercise of its powers
  - (b) an arrangement, agreement, or contract made or entered into, or proposed to be entered into, by the entity.
- (2) A person is interested in a matter if he or she
  - (a) may derive a financial benefit from the matter
  - (b) is the spouse, civil union partner, de facto partner, child, or parent of a person who may derive a financial benefit from the matter
  - (c) may have a financial interest in a person to whom the matter relates
  - (d) is a partner, director, officer, board member, or trustee of a person who may have a financial interest in a person to whom the matter relates
  - (e) may be interested in the matter because the entity's Act so provides
  - (f) is otherwise directly or indirectly interested in the matter.
- (3) However, a person is not interested in a matter
  - (a) only because he or she is a member or an officer of a wholly-owned subsidiary of the entity or of a subsidiary that is owned by the entity together with another parent Crown entity or entities
  - (b) because he or she receives an indemnity, insurance cover, remuneration, or other benefits authorised under this Act or another Act
  - (c) if his or her interest is so remote or insignificant that it cannot reasonably be regarded as likely to influence him or her in carrying out his or her responsibilities under this Act or another Act
  - (d) if an entity's Act provides that he or she is not interested, despite this section.

#### *63 Obligation to disclose interest*

- (1) A member who is interested in a matter relating to the statutory entity must disclose details of the interest in accordance with section [64](#) as soon as practicable after the member becomes aware that he or she is interested.
- (2) A general notice of an interest in a matter relating to the statutory entity, or in a matter that may in future relate to the entity, that is disclosed in accordance with section [64](#) is a standing disclosure of that interest for the purposes of this section.
- (3) A standing disclosure ceases to have effect if the nature of the interest materially alters or the extent of the interest materially increases.

#### *64 Who disclosure of interests must be made to*

The member must disclose details of the interest in an interests register kept by the statutory entity and to

- (a) the chairperson or, if there is no chairperson or if the chairperson is unavailable or interested, the deputy or temporary chairperson
- (b) the responsible Minister, if there is neither a chairperson nor a deputy or temporary chairperson, or if both the chairperson and the deputy or temporary chairperson are unavailable or interested.

### 65 What must be disclosed

The details that must be disclosed under section 64 are

- (a) the nature of the interest and the monetary value of the interest (if the monetary value can be quantified)
- (b) the nature and extent of the interest (if the monetary value cannot be quantified).

### 66 Consequences of being interested in matter

A member who is interested in a matter relating to a statutory entity

- (a) must not vote or take part in any discussion or decision of the board or any committee relating to the matter, or otherwise participate in any activity of the entity that relates to the matter
- (b) must not sign any document relating to the entry into a transaction or the initiation of the matter
- (c) is to be disregarded for the purpose of forming a quorum for that part of a meeting of the board or committee during which a discussion or decision relating to the matter occurs or is made.

### 67 Consequences of failing to disclose interest

- (1) The board must notify the responsible Minister of a failure to comply with section 63 or section 66, and of the acts affected, as soon as practicable after becoming aware of the failure.
- (2) A failure to comply with section 63 or section 66 does not affect the validity of an act or matter.
- (3) However, subsection (2) does not limit the right of any person to apply, in accordance with law, for judicial review.

### 68 Permission to act despite being interested in matter

- (1) The chairperson of a statutory entity may, by prior written notice to the board, permit 1 or more members, or members with a specified class of interest, to do anything otherwise prohibited by section 66, if the chairperson is satisfied that it is in the public interest to do so.
- (2) The permission may state conditions that the member must comply with.
- (3) The deputy or temporary chairperson may give the permission if there is no chairperson, or if the chairperson is unavailable or interested.
- (4) The responsible Minister may give the permission if there is neither a chairperson nor a deputy or temporary chairperson, or if both the chairperson and the deputy or temporary chairperson are unavailable or interested.
- (5) The permission may be amended or revoked in the same way as it may be given.
- (6) The board must disclose an interest to which a permission relates in its annual report, together with a statement of who gave the permission and any conditions or amendments to, or revocation of, the permission.

### 69 Entity may avoid certain acts done in breach of conflict of interest rules

- (1) A statutory entity may avoid a natural person act done by the entity in respect of which a member was in breach of section 66.
- (2) However, the act
  - (a) may be avoided only within 3 months of the affected act being disclosed to the responsible Minister under section 67
  - (b) cannot be avoided if the entity receives fair value in respect of the act.
- (3) An act in which a member is interested can be avoided on the ground of the member's interest only in accordance with this section.

### 70 What is fair value

- (1) The entity is presumed to receive fair value in respect of an act that is done by the entity in the ordinary course of its business and on usual terms and conditions.
- (2) Whether an entity receives fair value in respect of an act must be determined on the basis of the information known to the entity and to the interested member at the time the act is done.

### 71 Onus of proving fair value

(1) A person seeking to prevent an act being avoided, and who knew, or ought reasonably to have known, of the member's interest at the time the act was done, has the onus of establishing fair value.

(2) In any other case, the entity has the onus of establishing that it did not receive fair value.

#### *72 Effect of avoidance on third parties*

The avoidance of an act under section [69](#) does not affect the title or interest of a person to or in property that that person has acquired if the property was acquired

(a) from a person other than the entity

(b) for valuable consideration

(c) without knowledge of the circumstances of the act under which the person referred to in paragraph [\(a\)](#) acquired the property from the entity.

### **Miscellaneous provisions relating to board**

#### *77 Vacancies in membership of board*

The powers and functions of a statutory entity are not affected by any vacancy in the membership of its board.

### **Employees**

#### *118 Crown entity to be good employer*

(1) A Crown entity must, if it employs employees,

(a) operate a personnel policy that complies with the principle of being a good employer

(b) make that policy (including the equal employment opportunities programme) available to its employees

(c) ensure its compliance with that policy (including its equal employment opportunities programme) and report in its annual report on the extent of its compliance.

(2) For the purposes of this section, a good employer is an employer who operates a personnel policy containing provisions generally accepted as necessary for the fair and proper treatment of employees in all aspects of their employment, including provisions requiring

(a) good and safe working conditions

(b) an equal employment opportunities programme

(c) the impartial selection of suitably qualified persons for appointment

(d) recognition of

(i) the aims and aspirations of Maori

(ii) the employment requirements of Maori

(iii) the need for involvement of Maori as employees of the entity

(e) opportunities for the enhancement of the abilities of individual employees

(f) recognition of the aims and aspirations and employment requirements, and the cultural differences, of ethnic or minority groups

(g) recognition of the employment requirements of women

(h) recognition of the employment requirements of persons with disabilities.

(3) For the purposes of this section, an equal employment opportunities programme means a programme that is aimed at the identification and elimination of all aspects of policies, procedures, and other institutional barriers that cause or perpetuate, or tend to cause or perpetuate, inequality in respect of the employment of any persons or group of persons.

### **Protections from liability of members, office holders, and employees**

#### *120 Protections from liabilities of statutory entity*

A member, office holder, or employee of a statutory entity is not liable for any liability of the entity by reason only of being a member, office holder, or employee.

#### *121 Immunity from civil liability*

(1) A member of a statutory entity is not liable, in respect of an excluded act or omission,

(a) to the entity, unless it is also a breach of an individual duty under any of sections [53 to 57](#)

(b) to any other person.

- (2) An office holder or employee is not liable to any person in respect of an excluded act or omission.
- (3) Nothing in this section affects
  - (a) the making of an order under section [60](#)
  - (b) the liability of any person that is not a civil liability
  - (c) the right of any person to apply, in accordance with the law, for judicial review.

#### *122 Indemnities in relation to excluded act or omission*

- (1) A statutory entity may only indemnify a member, office holder, or employee in respect of an excluded act or omission.
- (2) An indemnity under subsection [\(1\)](#) is limited to
  - (a) liability for conduct
  - (b) costs incurred in defending or settling any claim or proceeding relating to that liability.

#### *123 Insurance for liability of member, office holder, or employee*

A statutory entity may affect insurance cover for a member, office holder, or employee of the entity in relation to his or her acts or omissions, except an act or omission that is

- (a) in bad faith
- (b) not in the performance or intended performance of the entity's functions.

#### *124 Saving of judicial protections from liability*

A Judge who is appointed as a member of a statutory entity has the same immunities and limitations or other protections from liability when acting as a member of that entity as he or she would have as a Judge.

#### *125 Breach of indemnity and insurance limits*

- (1) A member, office holder, or employee who is indemnified or insured by a statutory entity in breach of this Act must repay to the entity the cost of providing or effecting that indemnity or insurance cover, to the extent that the indemnity or insurance cover exceeds that which could have been provided or effected under this Act.
- (2) The entity may recover the amount as a debt due in a court of competent jurisdiction.

#### *126 Definitions for protections from liability*

In sections [120 to 125](#),

**effect insurance** includes pay, whether directly or indirectly, the costs of the insurance

**employee** includes a person who was an employee at any time after the commencement of this Act but who is no longer an employee

**entity's functions** includes any function that an Act confers separately on a member, office holder, or employee of the entity

**excluded act or omission** means an act or omission by the member, office holder, or employee in good faith and in performance or intended performance of the entity's functions

**indemnify** includes relieve or excuse from liability, whether before or after the liability arises, and indemnity has a corresponding meaning

**member** includes a person who was a member at any time after the commencement of this Act but who is no longer a member

**office holder** includes a person who was an office holder at any time after the commencement of this Act but who is no longer an office holder.

### **Subpart 3—Miscellaneous provisions**

#### *135 Members, office holders, and employees are officials*

- (1) This section applies to
  - (a) members, office holders, and employees of the following Crown entities:
    - (i) a statutory entity
    - (ii) a Crown entity company
    - (iii) a school board of trustees
    - (iv) a Crown entity subsidiary that is wholly owned by 1 or more Crown entities referred to in subparagraphs [\(i\) to \(iii\)](#)
  - (b) office holders and employees of
    - (i) a tertiary education institution
    - (ii) a Crown entity subsidiary that is wholly owned by 1 or more tertiary education institutions or by 1 or more tertiary education institutions and 1 or more Crown entities referred to in paragraph [\(a\)\(i\) to \(iii\)](#).
- (2) A person to whom this section applies is an official for the purposes of sections [105](#) and [105A](#) of the [Crimes Act 1961](#).
- (3) This section does not limit the meaning of **official** in section [99](#) of the [Crimes Act 1961](#).

### **Reporting: Annual report**

#### *152 Disclosure of payments in respect of members, committee members, and employees*

- (1) The annual report must include, in respect of the Crown entity or, in the case of a Crown entity group, for each Crown entity in the group,
  - (a) ...
  - (b) ...
  - (c) ...
  - (d) ...
  - (e) details of any indemnity provided by the entity during the financial year to any member, office holder, or employee
  - (f) details of any insurance cover effected by the entity during the financial year in respect of the liability or costs of any member, office holder, or employee.
- (2) In subsection [\(1\)](#), member and office holder and employee include a person who was a member or office holder or employee at any time after the commencement of this Act but who is no longer a member, office holder, or employee.

### **Transitional and savings provisions**

#### *189 Existing protection from liability provisions*

- (1) This section applies to a member, an office holder, or an employee of a Crown entity who is entitled, immediately before the date of commencement of this section, to be indemnified by a Crown entity in respect of any proceedings for any liability or costs arising from any act or omission as a member, office holder, or employee that occurred before that date.
- (2) This Act does not affect the member, office holder, or employee's entitlement to an indemnity if that entitlement is, in its overall effect, as favourable to that person as, or more favourable to that person than, the entitlement provided for in this Act.

#### *190 Existing insurance cover*

- (1) This section applies to a member, office holder, or employee of a statutory entity who has insurance cover at the commencement of this section in respect of any liability or costs arising from any act or omission as a member, office holder, or employee.
- (2) The insurance cover is not affected by the enactment of this Act.
- (3) However, if the insurance cover expires, or the member, office holder, or employee is reappointed or re-employed, the insurance can be renewed or effected only if permitted by this Act or the entity's Act.

## **Schedule 5 - Board procedure for statutory entities (other than corporations sole)**

### **Procedure of board**

#### 14 Board may appoint committees

- (1) The board may, by resolution, appoint committees
  - (a) to advise it on any matters relating to the entity's functions and powers that are referred to the committee by the board
  - (b) to perform or exercise any of the entity's functions and powers that are delegated to the committee, if the committee includes at least 1 member of the board and any other person or persons that the board thinks fit.
- (2) A person must not be appointed as a member of a committee unless, before appointment, he or she discloses to the board the details of any interest the person may have if he or she were a member of that committee.

#### 15 Provisions relating to committee members

- (1) Sections [43](#), [47](#), [48](#), [57](#), [77](#), [118](#), [120 to 126](#), [135](#), [152\(1\)\(e\)](#), [\(f\)](#), and [\(2\)](#), [189](#), and [190](#) apply to each member of a committee who is not a member of the board with necessary modifications.
- (2) Sections [62 to 72](#) apply to each member of a committee who is not a member of the board as if the committee member were a board member and as if the disclosure must be made to both the committee and the board, and with other necessary modifications.