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**Specialist Advisory Committee (formerly PTAC Subcommittees)  
Terms of Reference  
2020**

**For Public Consultation**

Please note: Appendices have not been attached to this document

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## Foreword

As a Crown Entity, PHARMAC-Te Pātaka Whaioranga (PHARMAC) is governed by a Board which 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 sets 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.

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 the PHARMAC Board.

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

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## 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 and application or proposal to PHARMAC for consideration.

**“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/about/what-we-do/equity/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.

**“Specialist Advisory Committee Coordinator”** means the PHARMAC employee who is allocated to provide support services for each Specialist Advisory Committee, the Specialist Advisory Committee Chairs in performing their roles, and to support Specialist Advisory Committee processes.

**“Medical Director”** means the Medical Director of PHARMAC, or their delegate.

**“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 **“PHARMAC-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://www.pharmac.govt.nz/Schedule>).

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**“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 (e.g. 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://www.pharmac.govt.nz/PTAC/PTACminutes> or <https://www.pharmac.govt.nz/about/committees/ptac/ptac-subcommittees>.

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

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

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## **1 Establishment**

### **1.1 Specialist Advisory Committees**

- 1.1.1 PHARMAC's Board may, by resolution,<sup>1</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's Medical Director.
- 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.

## **2 Functions**

### **2.1 Activities of Specialist Advisory Committees**

#### **2.1.1 Specialist Advisory Committees are to:**

- provide objective advice within specific therapeutic areas to PHARMAC on community and hospital pharmaceuticals and their benefits, using PHARMAC's decision-making framework;
- where relevant, make recommendations to PHARMAC on Proposals related to the management<sup>2</sup> of the Pharmaceutical Schedule which have been referred to it by PHARMAC or PTAC; and
- consider and report, or make recommendations, to PHARMAC or PTAC on any other matters that may be referred to it by PHARMAC or PTAC.

### **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.

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

<sup>2</sup> Possible amendments to the Pharmaceutical Schedule are outlined in the PHARMAC Operating Policies and Procedures (OPPs).  
<https://www.pharmac.govt.nz/about/operating-policies-and-procedures/>

- 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 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 1993 and Health Information Privacy Code 1994, 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; or
  - (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; or
  - (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. If consensus cannot be achieved, a recommendation is to be made based on a majority of the votes cast by the Members present. If a vote is tied, the Specialist Advisory Committee Chair of the meeting is to have a second or casting vote. 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.
- 2.3.3 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.

- 2.3.4 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 Generally, once PTAC has noted the Advice Record of an Specialist Advisory Committee, 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 and 2.4.3.
- 2.4.2 The Published Advice Record of a Specialist Advisory Committee meeting 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 and 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 Specialist Advisory Committee discussions remains accurate<sup>3</sup>, and PHARMAC will only withhold content of a draft Published Advice Record 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 Specialist Advisory Committees may advise PHARMAC on matters referred to them directly by PHARMAC. PHARMAC may utilise the advice of Specialist Advisory Committees in its decision-making without the advice of or the matter being considered by PTAC.
- 3.1.3 PHARMAC may attach a different listing priority or may make a decision that differs from a Specialist Advisory Committee's recommendation. PHARMAC is not bound to accept Specialist Advisory Committees' advice or follow its recommendations.
- 3.1.4 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

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<sup>3</sup> For example, changes may include typographical errors, facts recorded incorrectly or to clarify any ambiguity.

matter at that meeting.<sup>4</sup> The PHARMAC Board Chair may report back to the PHARMAC Board on the discussions of Specialist Advisory Committees.

### **3.2 Relationship of PTAC Chair to Specialist Advisory Committees**

3.2.1 The PTAC Chair is responsible for:

- advising PHARMAC on appointments of Specialist Advisory Committee Chairs and Deputy Chairs;
- as necessary, advising PHARMAC on the suitability of appointments to Specialist Advisory Committees;
- 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; and
- advising PHARMAC on the establishment and/or dissolution of Specialist Advisory Committees;

3.2.2 The PTAC Chair, may attend meetings of Specialist Advisory Committees as an observer (if they are not already a Member of the relevant Specialist Advisory Committee). If so, the PTAC Chair may participate in discussion at the invitation of the Specialist Advisory Committee Chair; but may not vote on any matter at that meeting.

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

3.3.1 Specialist Advisory Committees will have at least one PTAC Member,<sup>5</sup> who will usually act as the Specialist Advisory Committee Chair. Specialist Advisory Committees will also usually have a Deputy Chair who is usually a Member of PTAC.

3.3.2 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.

3.3.3 Where PTAC wishes to seek the advice of the relevant Specialist Advisory Committee on any matter, it will make this clear within the recommendations portion of its PTAC Advice Record.

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<sup>4</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.

<sup>5</sup> The only exception to this is the Tender Medical Evaluation Advisory Committee (formerly the Tender Medical Subcommittee), which may have a PTAC Member.

- 3.3.4 PTAC may attach a different listing priority or may make a decision that differs from Specialist Advisory Committees recommendations. PTAC is not bound to accept Specialist Advisory Committees advice or follow its recommendations.
- 3.3.5 The finalised Advice Record of Specialist Advisory Committee meetings are to be included on the PTAC agenda for discussion and formally noted by PTAC.
- 3.3.6 A copy of the relevant portions of any PTAC Advice Record will be provided to each relevant Specialist Advisory Committee for information and interest.
- 3.3.7 PTAC and Specialist Advisory Committees provide different but complementary perspectives and advice to PHARMAC. PTAC is a statutorily mandated committee and considers Proposals across all therapeutic groups in the Pharmaceutical Schedule. Specialist Advisory Committees provide content knowledge and expert opinion within specific therapy areas. Accordingly, differences in recommendations can arise between PTAC and Specialist Advisory Committees. PHARMAC can utilise, balance and form its own judgement on differences in recommendations or advice between PTAC and Specialist Advisory Committees in its decision making.
- 3.3.8 In the event that PTAC or Specialist Advisory Committees make different recommendations with respect to the same Proposal:
- The relevant PTAC or Specialist Advisory Committee Advice Record (whoever is making the different recommendation) is to clearly outline the reasons for making a different recommendation.
  - PTAC and/or the Specialist Advisory Committee will have opportunity to consider these reasons and respond at a subsequent meeting. The response will be recorded in the relevant Advice Record.
  - For the sake of clarity, notwithstanding the above, PHARMAC is not bound to accept PTAC or Specialist Advisory Committee advice or follow their recommendations.

#### **3.4 Relationship between PHARMAC staff and Specialist Advisory Committees**

- 3.4.1 PHARMAC's Medical Director, or a delegate, may attend each Specialist Advisory Committee meeting and participate in the discussions where relevant.
- 3.4.2 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 Members and clarify understanding of discussion and recommendations as necessary.
- 3.4.3 PHARMAC staff members, including the Medical Director, may not vote on any matter at a Specialist Advisory Committee meeting.
- 3.4.4 The Advice Record of each Specialist Advisory Committee meeting is drafted by PHARMAC staff and reviewed by all Members who attended the meeting. The Advice Record is finalised when it is signed by the Chair of the meeting.

*Specialist Advisory Committee Coordinator*

- 3.4.5 A PHARMAC employee will be chosen and allocated to support each Specialist Advisory Committee, the Specialist Advisory Committee Chairs in performing their roles, and to support Specialist Advisory Committee processes.
- 3.4.6 The PHARMAC employee is not a Member of any Specialist Advisory Committee and does not have voting rights.

### **3.5 Indemnity for Members**

- 3.5.1 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 (Treaty of Waitangi) expectations**

- 4.1.1 As a Crown Entity, PHARMAC understands, and is committed to, its obligations under te Tiriti o Waitangi. This commitment extends to representation on Specialist Advisory Committees.
- 4.1.2 In so far as possible, membership of Specialist Advisory Committees will include a senior health practitioner who is Māori.

### **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 aim to 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. Specialist Advisory Committee membership should reflect the diversity of Aotearoa New Zealand, particularly with respects to (but not confined to) gender and ethnicity.<sup>6</sup>
- 4.3.2 PHARMAC will actively promote the diversity of Specialist Advisory Committee membership in the appointment process.

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<sup>6</sup> PHARMAC values diversity and inclusion across all gender identities, ages, ethnicities, disabilities, sexual orientations, cultures, religions, and groups experiencing disparities.

#### **4.4 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's Board (or their delegate). In doing so the PHARMAC Board (or their delegate) may be guided by the recommendations of the PTAC Chair and PHARMAC's Medical Director.<sup>7</sup>
- 4.4.2 Members are usually appointed for a term of three years.
- 4.4.3 Membership of each Specialist Advisory Committee will be published on the PHARMAC website:<https://www.pharmac.govt.nz/about/advice/ptac-subcommittees/>

#### **4.5 Membership of Specialist Advisory Committees**

- 4.5.1 Specialist Advisory Committees will comprise of at least four Members and, in general, be weighted towards senior health practitioners (who may not be medical practitioners) with relevant expertise and who work within the publicly funded health sector.
- 4.5.2 Specialist Advisory Committees will also have at least one PTAC Member,<sup>8</sup> who will usually act as the Specialist Advisory Committee Chair. Specialist Advisory Committees will also usually have a Deputy Chair who is often a Member of PTAC.

#### **4.6 Resignation of Specialist Advisory Committee Members**

- 4.6.1 Members may resign at any time by notice in writing to the PTAC Chair, Specialist Advisory Committee Chair and PHARMAC's Medical Director.

#### **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's Medical Director.

#### **4.8 Renewal and Termination of Specialist Advisory Committee Appointments**

- 4.8.1 A Specialist Advisory Committee Member's appointment may be:
- (a) renewed or extended by PHARMAC; or
  - (b) terminated by PHARMAC without any right of compensation<sup>9</sup>.

#### **4.9 Dissolving Specialist Advisory Committees**

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<sup>7</sup> Clause 14(1)(a), Schedule 5, Crown Entities Act 2004.

<sup>8</sup> The only exception to this is the Tender Medical Evaluation Advisory Committee (formerly the Tender Medical Subcommittee), which may have a PTAC Member.

<sup>9</sup> Section 43, Crown Entities Act 2004 .

- 4.9.1 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's Medical Director. PHARMAC will advise the relevant Specialist Advisory Committee Chair in writing of its intention to dissolve a Specialist Advisory Committee.

## **5 Remuneration of Specialist Advisory Committee**

- 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 State Services Commission (SSC) administers the Cabinet Fees Framework which determines the level of fees paid. Currently, PHARMAC has an exception, approved by Cabinet, for Members to be paid outside the Cabinet Fees Framework.
- 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>10</sup> but will not cover travel time or locum costs as per the PHARMAC Travel Policy for Board and Committee Members.

## **6 Responsibilities of the Chairpersons**

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

- 6.1.1 A Specialist Advisory Committee Chair is responsible for:
- reviewing 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;
  - casting a deciding vote in the event of a tied vote on the recommendation to be made to PHARMAC;
  - deciding whether a meeting should be held via Remote Media Conference;
  - permitting Members to leave a meeting prior to it being adjourned (including meetings via Remote Media Conference);
  - signing off the final version of the Advice Record for each meeting of the Specialist Advisory Committee;

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<sup>10</sup> Travel & Expense Policy for Board Members and Committee Members

- where relevant, representing the Specialist Advisory Committee, and the Specialist Advisory Committee's consensus view and recommendations, at meetings of PTAC;<sup>11</sup>
- liaising with PHARMAC regarding the resources to be allocated to the Specialist Advisory Committee;
- alongside PHARMAC's Medical Director, deciding whether an observer may attend and contribute at all of or part of a Specialist Advisory Committee meeting;
- alongside PHARMAC's Medical Director, deciding whether additional subject matter experts may present on specific issues being considered by the Specialist Advisory Committee;
- assisting with the assessment and management of all actual and potential conflicts of interest, noting and signing interest declaration forms and ensuring consideration by PHARMAC. For completeness, this does not remove or detract from Members' obligations to properly disclose interests; and
- delegating, in writing, any of his or her responsibilities, to the Deputy Chair of the Specialist Advisory Committee in the first instance, where appropriate and in accordance with any PHARMAC delegation policy.

## **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 to, or delegates this role to the Deputy Chair.

## **7 Responsibilities of all Members**

### **7.1 Full participation in Specialist Advisory Committees**

- 7.1.1 All Members are responsible for:

- 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;
- reviewing all material provided relating to items on meeting agendas;
- acting as the discussion leader for any items allocated to them by the Chair or PHARMAC staff;

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<sup>11</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

- providing objective advice that is free, frank, constructive and collegial, and without perception of bias, under PHARMAC’s decision making criteria and consistent with PHARMAC’s statutory objective;
- reviewing the draft Advice Record, providing feedback to PHARMAC staff on the draft Advice Record, and confirming that the draft Advice Record is an accurate record of the discussion prior to finalisation of the Advice Record, for meetings that they have attended;
- disclosing fully and appropriately managing any interests and conflicts in the performance of their duties and obligations as noted in section 7.2; and
- storing all material received from PHARMAC in a secure place until the Advisory 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.

7.1.2 Members unable to reasonably meet their responsibilities and obligations under Section 7 may have their membership terminated without any right of compensation by PHARMAC.

## **7.2 Interest Reporting**

7.2.1 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 Appendix Two.

7.2.2 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.

7.2.3 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.

7.2.4 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.

- 7.2.5 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.
- 7.2.6 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.
- 7.2.7 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.

### **7.3 Confidentiality**

- 7.3.1 Subject to sections 7.3.3 and 7.3.4, 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 an Specialist Advisory Committee agenda, as well as the proceedings of an 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.
- 7.3.2 Members are required to store all material received from PHARMAC in a secure place until the relevant Advisory 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.
- 7.3.3 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 7.3.3 is subject to compliance with the Privacy Act 1993 and the Health Information Privacy Code 1994.
- 7.3.4 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.

### **7.4 External Communications and Public Statements**

- 7.4.1 Members may only speak or write to the media or in public fora in relation to the activities of an Specialist Advisory Committee or PHARMAC and 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 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.

7.4.2 Members may only report to their professional associations in relation to the activities of an 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.

7.4.3 Subject to section 7.4.1 and 7.4.2, 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 an Specialist Advisory Committee.

## **8 Management of Meetings**

### **8.1 Meetings of Specialist Advisory Committees**

8.1.1 Specialist Advisory Committees shall have a formal meeting (either via a face-to-face meeting or via Remote Media Conference) at least every 18-months and may meet more frequently; dependent on the matters referred to them for advice.

8.1.2 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>12</sup>

8.1.3 Subject to compliance with these Terms of Reference, Specialist Advisory Committees may regulate their internal procedures in such manner as they see fit.

### **8.2 Remote Media Conferences**

8.2.1 Specialist Advisory Committees meetings may be held by remote media conferencing (such as teleconference or videoconference).

8.2.2 The Specialist Advisory Committee Chair is responsible for:

(a) in consultation with PHARMAC staff, deciding whether a meeting should be held by Remote Media Conference;

(b) ensuring, confirming and monitoring (with the help of attending PHARMAC staff) that all attendees can be heard and can communicate adequately via the medium; and

(c) permitting Members to leave a meeting prior to it being adjourned.

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<sup>12</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.

8.2.3 In addition to section 8.1, the following rules apply to Specialist Advisory Committee meetings via remote media conference:

(a) notice must have been given to every Member entitled to receive notice of a meeting; and

(b) each Member taking part in a meeting by Remote Media Conference must:

- at the start of the meeting, acknowledge the Member's participation in the meeting to the other Members taking part;
- be able to hear the other Members taking part at all times throughout the meeting; and
- on any vote, individually express his or her vote at the meeting.

8.2.4 A Member is to be presumed to have been present, and to have formed part of the quorum, at all times during a meeting via Remote Media Conference unless they have been expressly permitted to leave.

8.2.5 A Member must ensure that their participation in a meeting is confidential, and in the event that their comments may be overheard by a third party they must declare this to other Members at the commencement of the meeting.

### **8.3 Recommendations or advice by other means of communication**

8.3.1 Specialist Advisory Committees may provide advice or make recommendations on a Proposal by email or other means of communication without a concurrent meeting having to be held.

8.3.2 In such circumstances, any recommendations made must be unanimous. If a consensus cannot be achieved, then a meeting under section 8.1 or a remote media conference under section 8.2, must be held.

8.3.3 If a unanimous recommendation is achieved, PHARMAC staff must prepare an Advice Record, which is then signed by all Members who participated in the discussion.

8.3.4 None of the above limits PHARMAC's ability to seek advice from Specialist Advisory Committee members, individually or collectively, on an ad hoc basis.

### **8.4 Observers**

8.4.1 At the discretion of the Specialist Advisory Committee Chair and PHARMAC's Medical Director, 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.

8.4.2 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.

8.4.3 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.

## **8.5 Additional Subject Matter Expertise**

8.5.1 At the discretion of the Specialist Advisory Committee Chair and PHARMAC's Medical Director, 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.

8.5.2 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.

## **9 Variation of Terms of Reference**

9.1.1 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.

9.1.2 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.

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

10.1.1 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 Board, whose decision is final.

## **11 Review of these Terms of Reference**

11.1.1 These Terms of Reference will be reviewed every three years.

## 12 Appendices – Not Attached

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