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**PTAC Terms of Reference
Terms of Reference
2020**

For Public Consultation

Please note: Appendices have not been attached to this document

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CONTENTS

Foreword	4
Glossary of terms	5
1 Establishment	7
1.1 Pharmacology and Therapeutics Advisory Committee (PTAC).....	7
2 Functions	7
2.1 Activities of PTAC	7
2.2 Matters that PTAC is to consider	7
2.3 Advice to be given by PTAC.....	8
2.4 Publication of PTAC Advice.....	9
3 Relationship Management	9
3.1 Relationship between PHARMAC and PTAC	9
3.2 Relationship between PTAC and Specialist Advisory Committees	10
3.3 Relationship between PHARMAC staff and PTAC	11
3.4 Indemnity for Members.....	11
4 Membership	12
4.1 Te Tiriti o Waitangi (Treaty of Waitangi) expectations.....	12
4.2 Health equity	12
4.3 Diversity and PTAC membership.....	12
4.4 Appointment of PTAC Members	12
4.5 Consumer Advisory Member	13
4.6 Resignation of PTAC Members	13
4.7 Termination of PTAC Membership	13
4.8 Temporary PTAC Membership.....	13
5 Remuneration of PTAC	13
6 Responsibilities of the Chairpersons	14
6.1 Responsibilities of PTAC Chair	14
6.2 Responsibilities of Deputy Chairs of PTAC.....	15
7 Responsibilities of all Members	15
7.1 Full participation in Committee	15
7.2 Interest Reporting.....	16
7.3 Confidentiality.....	17
7.4 External Communications and Public Statements	17
8 Management of Meetings	18
8.1 Meetings of PTAC	18
8.2 Remote Media Conferences for PTAC	18
8.3 Recommendations by other means of communication	19
8.4 Observers	19
8.5 Additional Subject Matter Expertise.....	19

8.6 Consumer Perspectives20

9 Variation of Terms of Reference..... 20

10 Disputes in relation to these Terms of Reference..... 20

11 Review of these Terms of Reference..... 20

12 Appendices – Not attached 21

DRAFT

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 set out the goals, responsibilities, obligations and procedures of the Pharmacology and Therapeutics Advisory Committee (PTAC).

This document is the primary document for PTAC 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 PTAC provide to the PHARMAC Board.

There are several key pieces of legislation which are referred to within this document and should be referenced by PTAC 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.

“Chair” means the Chairperson of PTAC.

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

“Committee” means PTAC.

“Consumer Advisory Member” means a member of PTAC who is appointed as a consumer member.

“Deputy Chair” means the Deputy Chairperson of PTAC.

“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.

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

“Member” means a member of PTAC.

“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>).

DRAFT PTAC Terms of Reference – For Consultation

“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 Secretary” means the PHARMAC employee who provides secretarial support services to 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 PTAC.

1 Establishment

1.1 Pharmacology and Therapeutics Advisory Committee (PTAC)

- 1.1.1 PTAC is a statutorily mandated advisory committee, under [section 50 of the NZPHD Act](#), established by the PHARMAC Board, to provide objective advice to PHARMAC on pharmaceuticals and their benefits.
- 1.1.2 PTAC considers Proposals across all therapeutic groups in the Pharmaceutical Schedule. It has an overview of the Proposals referred for advice. PTAC provides and promotes critical appraisal of the strength and quality of evidence, applied rigorously, systematically and consistently across all therapeutic groups.

2 Functions

2.1 Activities of PTAC

2.1.1 PTAC is to:

- provide objective advice to PHARMAC on community and hospital pharmaceuticals and their benefits, using PHARMAC’s decision-making framework;
- make recommendations to PHARMAC on Proposals related to the management¹ of the Pharmaceutical Schedule which have been referred to it by PHARMAC;
- subject to the prior agreement of PHARMAC, initiate reviews of any policy adopted by PHARMAC in relation to the management of the Pharmaceutical Schedule and provide reports or make recommendations to PHARMAC arising from those reviews; and
- consider and report, or make recommendations, to PHARMAC on any other matters that may be referred to it by PHARMAC.

2.2 Matters that PTAC is 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 PTAC provides to the PHARMAC Board.
- 2.2.2 When providing its advice to PHARMAC, PTAC is to take into account, where applicable, PHARMAC’s decision-making framework.
- 2.2.3 Should PTAC 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”).

¹ 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/>

- 2.2.4 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 it considers 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 a recommendation. The fact of any such consultation and the parties consulted with will generally be documented in the relevant Advice Record(s).
- 2.2.5 PTAC may use any evidence that can reasonably be obtained. In making recommendations based on this evidence, PTAC are to use their judgement when considering issues such as quality and relevance.

2.3 Advice to be given by PTAC

- 2.3.1 PTAC is to make recommendations to PHARMAC in relation to each Proposal that is referred for consideration and advice.
- 2.3.2 Before making a recommendation, PTAC may refer a Proposal to a Specialist Advisory Committee for further specialist advice.
- 2.3.3 PTAC is to set out the matters and evidence that are primarily relied on in making a recommendation in accordance with PHARMAC's decision-making framework. When making recommendations, PTAC will indicate which parts of PHARMAC's decision-making framework have been particularly relevant in the course of making such recommendations, and:
- (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); 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.
- 2.3.4 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 PTAC Chair is to have a second or casting vote. Members (including the PTAC Chair) are bound by each recommendation and will not take any steps outside the meeting to the detriment of a consensus or majority recommendation.
- 2.3.5 PTAC may consider other matters referred by PHARMAC, which may include any correspondence, new information or resubmissions or Proposals that are provided by applicants.

- 2.3.6 Nothing in 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 PTAC Advice

- 2.4.1 Once a final recommendation about a Proposal has been made by PTAC (as set out in section 2.3), the Advice Record relating to that recommendation will be published on the PHARMAC website (the Published Advice Record), subject to sections 2.4.3 and 2.4.4.
- 2.4.2 In general, once the Advice Record of a Specialist Advisory Committee has been noted by PTAC, it will be published on the PHARMAC website, subject to sections 2.4.3 and 2.4.4.
- 2.4.3 The Published Advice Record of a PTAC 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.
- 2.4.4 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 PTAC discussions remains accurate², 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 PTAC

- 3.1.1 PTAC is a statutory advisory committee established by the PHARMAC Board to provide objective advice to PHARMAC on pharmaceuticals and their benefits.
- 3.1.2 PTAC may advise PHARMAC on matters referred to it by PHARMAC; however, PHARMAC may attach a different listing priority or may make a decision that differs from PTAC's recommendations. PHARMAC is not bound to accept PTAC's advice or follow its recommendations.
- 3.1.3 The Advice Record of each PTAC meeting shall be provided to the PHARMAC Board following finalisation of the Advice Record. In addition, the relevant part of any Advice Record(s) of PTAC discussions will be included in the Board paper when a decision is sought.

² For example, changes may include typographical errors, facts recorded incorrectly or to clarify any ambiguity.

- 3.1.4 The PTAC Chair (or in their absence the Deputy Chair of PTAC), may attend all meetings of the PHARMAC Board as an observer. The PTAC Chair may participate in discussion at the invitation of the Board Chair, but may not vote on any matter at that meeting. The PTAC Chair may, subject to any specific confidentiality undertaking they have agreed with the PHARMAC Board in relation to their participation as an observer, report back to PTAC on the discussions of the Board.
- 3.1.5 The PHARMAC Board Chair, or other PHARMAC Board members approved in advance by the PTAC Chair, may attend all meetings of PTAC as an observer. The PHARMAC Board Chair may participate in discussion at the invitation of the PTAC Chair, but may not vote on any matter at that meeting.³ The PHARMAC Board Chair may report back to the Board on the discussions of PTAC.

3.2 Relationship between PTAC and Specialist Advisory Committees

- 3.2.1 PTAC may seek advice from Specialist Advisory Committees on specific issues relating to a Proposal or the Pharmaceutical Schedule that require subject matter expertise. Specialist Advisory Committees will give a written opinion to PTAC through the Specialist Advisory Committees Advice Record, and PTAC will consider this opinion.
- 3.2.2 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 Advice Record.
- 3.2.3 PTAC may attach a different listing priority or may make a recommendation that differs from Specialist Advisory Committees' recommendations. PTAC is not bound to accept Specialist Advisory Committees' advice or adopt their recommendations.
- 3.2.4 The finalised Advice Records of Specialist Advisory Committee meetings are to be included on the PTAC agenda for discussion and formally noted by PTAC at that meeting.
- 3.2.5 A copy of the relevant portions of any PTAC Advice Record will be provided to each relevant Specialist Advisory Committee for information and interest.
- 3.2.6 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, and may make recommendations, including providing a priority, 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.
- 3.2.7 In the event that PTAC or Specialist Advisory Committees make different recommendations with respect to the same Proposal:

³ When attending PTAC meetings, the PHARMAC Board Chair will also remain mindful of the accountabilities of PTAC to the PHARMAC Board, including consequent perceptions and unconscious impacts on PTAC Members' comfort and ability to provide objective advice freely and frankly. The Board Chair and PTAC Chair will take whatever measures necessary to avoid the Board Chair's presence inadvertently influencing or constraining discussion.

DRAFT PTAC Terms of Reference – For Consultation

- 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.

3.2.8 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 usually have a Deputy Chair who is also often a Member of PTAC.

3.3 Relationship between PHARMAC staff and PTAC

3.3.1 PHARMAC's Medical Director, or a delegate, will attend each PTAC meeting and may participate in the discussions where relevant.

3.3.2 PHARMAC staff member(s) will attend and participate in meetings of PTAC while discussion or 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.

3.3.3 PHARMAC staff members, including the Medical Director, may not vote on any matter at a PTAC meeting.

3.3.4 The Advice Record of each PTAC 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.

PTAC Secretary

3.3.5 A PHARMAC employee will be chosen and allocated to support PTAC, assist the PTAC Chair in performing their role, and support PTAC processes.

3.3.6 The PTAC Secretary is not a Member of PTAC and does not have voting rights at any PTAC meeting.

3.4 Indemnity for Members

3.4.1 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 PTAC functions.

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 ensuring Māori representation on PTAC.
- 4.1.2 Membership of PTAC will include, at a minimum, 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 PTAC membership recruitment processes will aim to strengthen the health and medicines access equity expertise of PTAC.

4.3 Diversity and PTAC membership

- 4.3.1 PHARMAC is committed to ensuring that decisions on pharmaceuticals meet the needs of all New Zealanders. PTAC membership should reflect the diversity of Aotearoa New Zealand, particularly with respects to (but not confined to) gender and ethnicity.⁴
- 4.3.2 PTAC membership recruitment processes will aim to promote the diversity of PTAC membership.

4.4 Appointment of PTAC Members

- 4.4.1 Members of PTAC are appointed by the Director-General of Health in consultation with the PHARMAC Board.⁵
- 4.4.2 The appointment, terms of appointment, resignation and removal process (including for the PTAC Chair and PTAC Deputy Chair) are set out in the Protocol for the Appointment of Members of the Pharmacology and Therapeutics Advisory Committee (see Appendix Two).
- 4.4.3 In general, PTAC comprises senior health practitioners from multiple specialties selected for their expertise in critical appraisal as well as broad experience and knowledge of health need, and pharmaceuticals and their therapeutic indications.
- 4.4.4 The overall membership of PTAC will be generally weighted towards practising clinicians working within the publicly funded health sector and will reflect a wide range of perspectives.
- 4.4.5 Membership of PTAC will be published on the PHARMAC website:
<https://www.pharmac.govt.nz/about/advice/PTAC/>

⁴ PHARMAC values diversity and inclusion across all gender identities, ages, ethnicities, disabilities, sexual orientations, cultures, religions, and groups experiencing disparities.

⁵ Section 50(4), NZPHD Act.

4.5 Consumer Advisory Member

- 4.5.1 PTAC may have one Member who is a consumer, to provide a consumer perspective to PTAC discussions. This Member is called the Consumer Advisory Member, and is appointed in accordance with section 4.4.1
- 4.5.2 If appointed, the Consumer Advisory 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 Advisory Member is bound by these Terms of Reference.

4.6 Resignation of PTAC Members

- 4.6.1 Members may resign at any time by notice in writing in accordance with the Protocol for Appointment of Members to the Pharmacology and Therapeutics Advisory Committee (Appendix Two).

4.7 Termination of PTAC Membership

- 4.7.1 Breaches of this Terms of Reference, particularly Section 7, may result in termination of PTAC membership. The process for termination of members is set out in the Protocol for Appointment of Members to the Pharmacology and Therapeutics Advisory Committee (Appendix Two).

4.8 Temporary PTAC Membership

- 4.8.1 Members can request leave of absence from any PTAC meeting, which may require the appointment of an alternate temporary Member (for example, where the Member's absence will mean the meeting does not have a quorum). Such an appointment will be made in accordance with the Protocol for the Appointment of Members of the Pharmacology and Therapeutics Advisory Committee (Appendix Two).

5 Remuneration of PTAC

- 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 PTAC.
- 5.1.4 PHARMAC will cover travel and accommodation expenses for Members to attend meetings⁶ but will not cover travel time or locum costs as per the PHARMAC Travel Policy for Board and Committee Members.

⁶ Travel & Expense Policy for Board Members and Committee Members

5.1.5 Members are entitled to a Conference and Travel Allowance⁷ for professional development. This entitlement does not apply to Specialist Advisory Committee Members.

6 Responsibilities of the Chairpersons

6.1 Responsibilities of PTAC Chair

6.1.1 The PTAC Chair is responsible for:

- reviewing the agenda for the PTAC meetings (PHARMAC staff will plan and draft the agenda);
- presiding at each meeting of PTAC;
- casting a deciding vote in the event of a tied vote on the recommendation to be made to PHARMAC;
- in consultation with PHARMAC staff, 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 of each PTAC meeting;
- alongside PHARMAC's Medical Director, deciding whether an observer may attend and contribute at all of or part of a PTAC meeting;
- alongside PHARMAC's Medical Director, deciding whether a relevant consumer/s may present on specific issues being considered by PTAC;
- alongside PHARMAC's Medical Director, deciding whether additional subject matter experts may present on specific issues being considered by PTAC;
- assisting with the assessment and management of all actual and potential conflicts of interest, noting and signing interest declaration forms and ensuring consideration by the PHARMAC Board. For completeness, this does not remove or detract from Members' obligations to properly disclose interests;
- liaising with PHARMAC in regard to the resources to be allocated to PTAC;
- advising PHARMAC on the establishment and/or dissolution of Specialist Advisory Committees;
- advising PHARMAC on the suitability of appointments to Specialist Advisory Committees;

⁷ The Pharmacology & Therapeutics Advisory Committee (PTAC) and the Exceptional Circumstances (EC) Panel Conference and Travel Allowance Policy

DRAFT PTAC Terms of Reference – For Consultation

- representing the interests and views of PTAC to Government officials and departments and to the media (having first obtained the consent of the PHARMAC Chief Executive to the act of representation);
- attending meetings of the PHARMAC Board and reporting back to PTAC Members on the discussion;
- as necessary, reviewing communications by Members related to the activities of PTAC or 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;
- as necessary, providing advice to PHARMAC staff on the content of relevant external communications; and
- delegating, in writing, any of their responsibilities to the Deputy Chair in the first instance, where appropriate and in accordance with any PHARMAC delegation policy.

6.2 Responsibilities of Deputy Chairs of PTAC

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

7 Responsibilities of all Members

7.1 Full participation in Committee

- 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;
- 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;

- acting as Members of Specialist Advisory Committees;
- disclosing fully and appropriately managing any interests and conflicts in the performance of their duties and obligations as noted in section 7.2;
- 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.

7.2 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 Three.
- 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 PTAC Chair (via the PTAC Secretary) 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 PTAC. 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 PTAC 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 PTAC 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 PTAC 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 PTAC relating to that matter, or otherwise participate in any activity of PHARMAC that relates to that matter, they should apply for such permission in advance from the PHARMAC Board 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. The PHARMAC Board Chair may issue a ‘standing permission’ in relation to certain categories of interest.

- 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 PTAC agenda, as well as the proceedings of a PTAC meeting, are confidential to PTAC 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 PTAC or PHARMAC and any matters discussed at or considered by PTAC 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 PTAC or PHARMAC or any matters discussed at or considered by PTAC 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 sections 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 be clear that they will be doing so in their own private capacities as clinicians, and not as being a Member of PTAC.

8 Management of Meetings

8.1 Meetings of PTAC

- 8.1.1 The PTAC Chair or the PTAC Deputy Chair is to preside at each meeting of PTAC unless the PTAC Chair, in cases where the Deputy Chair is unavailable, delegates authority to another Member.
- 8.1.2 PTAC meetings are normally held four times per year. The PTAC Secretary, PHARMAC Medical Director and PTAC Chair will, acting together, select the dates for PTAC meetings.
- 8.1.3 The quorum for meetings of PTAC is six Members, of whom one Member (subject to section 8.1.1 above) must be either the PTAC Chair or the PTAC Deputy Chair.
- 8.1.4 Subject to compliance with these Terms of Reference, PTAC may regulate its internal procedures in such manner as it sees fit.

8.2 Remote Media Conferences for PTAC

- 8.2.1 PTAC may hold a meeting by remote media conferencing (such as teleconference or videoconference).
- 8.2.2 The PTAC 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.
- 8.2.3 To the extent practicable, the rules and procedures relating to PTAC meetings set out in section 8.1 will apply to a meeting held by Remote Media Conference. In addition, the following shall apply:
- (a) notice must have been given to every Member entitled to receive notice of a PTAC 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 by other means of communication

8.3.1 PTAC may 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 recommendation 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 PTAC members, individually or collectively, on an ad hoc basis.

8.4 Observers

8.4.1 At the discretion of the PTAC Chair and PHARMAC's Medical Director, observers may be given permission to attend meetings of PTAC. These observers are not Members and, unless the PTAC 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 meeting of PTAC. 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 PTAC, by either influencing or constraining discussion at any Committee meeting. If the PTAC Chair determines that the presence of an observer is having such an effect, the PTAC Chair may require the observer to leave the meeting.

8.5 Additional Subject Matter Expertise

8.5.1 At the discretion of the PTAC 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 PTAC. Additional subject matter experts can speak only 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 PTAC meeting. The attendance of an additional subject matter experts at a meeting will be documented in the Advice Record.

8.6 Consumer Perspectives

- 8.6.1 To help inform PTAC's consideration of PHARMAC's decision-making framework, PTAC may consider relevant consumer perspectives with respect to a Proposal under consideration. Consumer perspectives can be provided through submissions received, correspondence or, subject to section 8.6.2, presenting at a PTAC meeting.
- 8.6.2 At the discretion of the PTAC Chair and PHARMAC's Medical Director, consumers with an interest in a Proposal being considered, may be given permission to present or speak (either in person or via Remote Media Conference) on specific issues deemed relevant, such as the lived experience or health need of a condition. Consumers are only to be present for the relevant portion of the meeting and cannot be present when the Members make a recommendation.
- 8.6.3 Consumers are required to sign confidentiality undertakings and declare any relevant interests they may hold, prior to attending any PTAC meeting. The attendance of a consumer 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 PTAC roles and responsibilities but are not intended to cover every eventuality. They are to be interpreted flexibly and pragmatically, to allow PTAC 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 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 (except in relation to the appointment of PTAC members referred to in section 4.3 above) 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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