

Terms of Reference

for the Pharmacology and Therapeutics Advisory
Committee (PTAC) and PTAC Subcommittees

2016

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Glossary of terms

“**Application**” means an application or proposal made by a third party to PHARMAC for (a) the funding of a pharmaceutical or (b) changes to the funding of a pharmaceutical that is already on the Pharmaceutical Schedule (e.g. a proposal to widen or restrict access).

“**CE Act**” means the Crown Entities Act 2004.

“**Chair**” means the Chairperson of PTAC or the Chairperson of a Subcommittee.

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

“**Committee**” means PTAC or a Subcommittee.

“**Deputy Chair**” means the Deputy Chairperson of PTAC or the Deputy Chairperson of a Subcommittee.

“**Director-General**” means the Director-General of the Ministry of Health, or their delegate.

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

“**Member**” means a member of PTAC or a member of a Subcommittee.

“**Minute(s)**” means the written record of discussion and recommendations made at a PTAC or Subcommittee meeting (including meetings by teleconference and recommendations made by other means of communication) which have been finalised by the relevant Chair.

“**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**” means the Pharmaceutical Management Agency, a Crown Entity established under the NZPHD Act.

“**PHARMAC staff proposal**” means a proposal made by PHARMAC staff that relates to specific clinical therapy area(s).

“**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>.

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

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

“**PTAC Secretary**” means the secretary of PTAC.

“Published Minute” means that part of the PTAC Minute published on the PHARMAC website at <http://www.pharmac.govt.nz/PTAC/PTACminutes>.

“Subcommittee(s)” means a PTAC Subcommittee.

“Subcommittee Chair” means the Chairperson of a Subcommittee.

“Supplier” means the supplier of a pharmaceutical.

“Terms of Reference” means these Terms of Reference for PTAC and PTAC Subcommittees.

1 Establishment

1.1 PTAC

1.1.1 PTAC is an advisory committee established by the PHARMAC Board to provide objective advice to PHARMAC on pharmaceuticals and their benefits.¹

1.2 PTAC Subcommittees

1.2.1 PHARMAC may, by resolution, appoint Subcommittees to consider, report, or make recommendations and provide advice, either directly to it or through PTAC or PHARMAC staff, on Applications or PHARMAC staff proposals related to specific clinical therapy areas². In doing so the PHARMAC Board may have regard to the recommendations of the PTAC Chair and PHARMAC's Medical Director.

2 Terms of Reference

2.1 Activities of PTAC and PTAC Subcommittees

2.1.1 PTAC and PTAC Subcommittees are to:

- provide objective advice to PHARMAC on community and hospital pharmaceuticals and their benefits;
- make recommendations to the PHARMAC Board on Applications or PHARMAC staff proposals related to the management³ of the Pharmaceutical Schedule which have been referred to it by PHARMAC;
- subject to the prior agreement of the PHARMAC Board, initiate reviews of any policy adopted by PHARMAC in relation to the management of the Pharmaceutical Schedule and provide reports or make recommendations to the PHARMAC Board arising from those reviews; and
- consider and report, or make recommendations, to the PHARMAC Board on any other matters that may be referred to it by PHARMAC.

2.2 Matters that PTAC and PTAC Subcommittees 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 PTAC and Subcommittee(s) provide to the PHARMAC Board.

2.2.2 When providing its advice to the PHARMAC Board, PTAC and PTAC Subcommittees are to take into account, where applicable, PHARMAC's current decision-making framework insofar as PTAC or the relevant Subcommittee considers appropriate.

¹ Section 50(1)(a), NZPHD Act.

² Clause 14(1)(a), Schedule 5, CE Act.

³ Possible amendments to the Pharmaceutical Schedule are outlined in the OPPs.

- 2.2.3 If PTAC or a PTAC Subcommittee takes 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 Minutes.
- 2.2.4 Subject to the confidentiality provisions in part 7.3 of these Terms of Reference and PHARMAC's obligations under the Privacy Act 1993 and Health Information Privacy Code 1994, PTAC and PTAC Subcommittees 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 Minute(s).
- 2.2.5 PTAC and PTAC Subcommittees may use any evidence that can reasonably be obtained. In making recommendations based on this evidence, PTAC and PTAC Subcommittees are to use their judgement when considering issues such as quality and relevance.
- 2.2.6 PTAC and PTAC Subcommittees may take into account scales for grading evidence.

3 Relationship Management

3.1 Relationship with PHARMAC

- 3.1.1 PTAC is an advisory committee established by PHARMAC to provide objective advice to PHARMAC on pharmaceuticals and their benefits. PTAC may advise PHARMAC's Board 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.
- 3.1.2 Minutes of each PTAC meeting shall be provided to the PHARMAC Board following finalisation of the Minutes. In addition, the relevant part of any Minute(s) of PTAC and/or Subcommittee discussions will be included in the Board paper when a decision is sought.
- 3.1.3 PHARMAC may seek advice directly from Subcommittees where, for example, time is of the essence. In these circumstances PHARMAC may take into account the advice of Subcommittees without the advice or the matter being considered by PTAC, but shall notify the PTAC Chair before doing so. As with PTAC, PHARMAC may attach a different listing priority or may make a decision that differs from the Subcommittees' recommendations and PHARMAC is not bound to accept the Subcommittees' advice or follow their recommendations.
- 3.1.4 Nothing in these 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.
- 3.1.5 The PTAC Chair (or in their absence, a delegated Member of PTAC), approved in advance by the PHARMAC Board Chair, has the right to 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 signed with the PHARMAC Board in relation to their participation as an observer, report back to PTAC on the discussions of the Board.

3.1.6 The PHARMAC Board Chair (or in their absence, a delegated PHARMAC Board member), approved in advance by the PTAC Chair, has the right to 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. The PHARMAC Board Chair may report back to the Board on the discussions of PTAC.

3.2 Relationship between PTAC and PTAC Subcommittees

3.2.1 PTAC may seek advice from Subcommittees on specific issues relating to the Pharmaceutical Schedule. Subcommittees will give a written opinion to PTAC by way of Subcommittee meeting Minutes and PTAC will consider this opinion.

3.2.2 The finalised Minute of Subcommittee meetings is to be included on the agenda for discussion, usually at the next meeting of PTAC, and formally reviewed by PTAC Members at that meeting.

3.2.3 A copy of the relevant portions of any PTAC Minute will be provided to each Subcommittee for information and interest. Where PTAC wishes to seek the advice of the relevant Subcommittee on any matter it will make this clear within the recommendations portion of its Minutes.

3.3 Relationship with PHARMAC staff

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

3.3.2 In addition to 3.3.1, PHARMAC staff member(s) may attend and participate in meetings of PTAC and Subcommittees while reports or recommendations relevant to their area of work are discussed. In general, PHARMAC staff may respond to questions from PTAC or a Subcommittee and clarify understanding of discussion and recommendations as necessary.

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

3.3.4 PHARMAC staff will provide administrative and support services for PTAC and PTAC Subcommittees (see below).

PTAC Secretary

3.3.5 A PTAC Secretary is to be employed by PHARMAC to support PTAC and PTAC Subcommittees and assist the PTAC Chair in performing their role.

3.3.6 The PTAC Secretary is responsible for ensuring a Minute of each meeting of PTAC (including by teleconference or other means of communications) is kept, and for preparing the Published Minute.

3.3.7 The agenda for each PTAC meeting shall be set after consultation between the PTAC Chair, PHARMAC's Medical Director and the PTAC Secretary taking into account matters referred by PHARMAC to PTAC for advice including Applications, proposals developed by PHARMAC staff and any other matters relevant to the management of the Pharmaceutical Schedule.

- 3.3.8 The agenda and related papers will be sent to Members of PTAC (subject to the deletion of any papers from a Member's pack due to a conflict of interest of that Member), ordinarily four weeks before the relevant meeting.
- 3.3.9 The PTAC Secretary is responsible for managing correspondence between PTAC Members and third parties.
- 3.3.10 The PTAC Secretary is not a Member of PTAC and does not have voting rights at any PTAC meeting.

Subcommittee Secretary

- 3.3.11 A PHARMAC employee will be chosen and allocated as secretary to support each Subcommittee and assist the Subcommittee Chair in performing their role. Generally, the PHARMAC employee chosen will be the individual with responsibility for the therapeutic area relevant to the Subcommittee.
- 3.3.12 The agenda for each Subcommittee meeting shall be set after consultation between the Subcommittee Chair, PHARMAC's Medical Director and the Subcommittee Secretary, taking into account matters referred by PHARMAC or PTAC to the Subcommittee for advice including Applications, proposals developed by PHARMAC staff and other matters relevant to the management of the Pharmaceutical Schedule.
- 3.3.13 The Subcommittee Secretary is responsible for ensuring a Minute of each meeting of the Subcommittee (including by teleconference or other means of communications) is kept.
- 3.3.14 The Subcommittee Secretary is not a Member of the relevant Subcommittee and does not have voting rights at any Subcommittee 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 the Committee's functions.

4 Membership

PTAC

4.1 Appointment of PTAC Members

- 4.1.1 Members of PTAC are appointed by the Director-General in consultation with the Board of PHARMAC.⁴
- 4.1.2 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 1).

⁴ Section 50(4), NZPHD Act.

- 4.1.3 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 pharmaceuticals and their therapeutic indications.
- 4.1.4 The overall membership of PTAC will be weighted towards practising clinicians and will reflect a wide range of perspectives.
- 4.1.5 Membership of PTAC will be listed at www.pharmac.govt.nz/PTAC/PTACmembership

PTAC Subcommittees

4.2 Appointment of Subcommittee Members

- 4.2.1 Subcommittee Members (including the Subcommittee Chair and Subcommittee Deputy Chair) are to be appointed by the PHARMAC Board. In doing so the PHARMAC Board may have regard to the recommendations of the PTAC Chair and PHARMAC's Medical Director⁵.
- 4.2.2 Subcommittee Members are usually appointed for a term of three years, subject to the specific terms of these Terms of Reference.
- 4.2.3 When there is a vacancy on a Subcommittee, PHARMAC staff will request nominations for the vacant position(s) from the appropriate professional groups and endeavour to obtain at least two nominations for every position.
- 4.2.4 Membership of PTAC Subcommittees will be listed at www.pharmac.govt.nz/PTAC/PTACsubcommittees

4.3 Membership of Subcommittees

- 4.3.1 Subcommittees will comprise at least four Members and be weighted towards vocationally trained clinicians and other senior health practitioners (who may not be medical practitioners) with relevant expertise.
- 4.3.2 Subcommittees will also have at least one PTAC Member, who will usually act as the Subcommittee Chair. Subcommittees will usually also have a Deputy Chair.

4.4 Temporary Members of Subcommittees

- 4.4.1 Temporary Members may be appointed to Subcommittees by the PHARMAC Board for such terms and on such conditions as the PHARMAC Board determines appropriate in order to fill any casual vacancy. In doing so the PHARMAC Board may have regard to the recommendations of the PTAC Chair and PHARMAC's Medical Director.

4.5 Renewal and Cancellation of Subcommittee Appointments

- 4.5.1 A Subcommittee Member's appointment may be:
- (a) renewed or extended by the PHARMAC Board; or
 - (b) terminated by the PHARMAC Board without any right of compensation⁶.

⁵ Clause 14(1)(a), Schedule 5, CE Act.

⁶ Section 43, CE Act.

4.6 Dissolving Subcommittees and Resignation of Subcommittee Members

- 4.6.1 Subcommittees established by the PHARMAC Board can be dissolved by the PHARMAC Board at any time. In doing so the PHARMAC Board may have regard to the recommendations of the PTAC Chair and PHARMAC's Medical Director. PHARMAC will advise the relevant Subcommittee Chair in writing of its intention to dissolve a Subcommittee.
- 4.6.2 Subcommittee Members may resign at any time by notice in writing to the PTAC Chair and Subcommittee Chair.

5 Remuneration of PTAC and PTAC Subcommittees

- 5.1.1 PTAC Members and Subcommittee Members will be remunerated in recognition of the services they provide to PHARMAC, including attendance at meetings and time spent preparing for meetings and for performing any other work as requested by PHARMAC.
- 5.1.2 The State Services Commission Fees Framework determines the level of fees paid. Currently, PHARMAC has an exception, approved by Cabinet, for PTAC Members and Subcommittee Members to be paid outside the Fees Framework.
- 5.1.3 PHARMAC will cover travel and accommodation expenses for Members to attend meetings⁷ but will not cover travel time or locum costs.
- 5.1.4 PTAC Members are entitled to a Conference and Travel Allowance⁸ for professional development. This entitlement does not apply to Subcommittee Members.

6 Responsibilities of the Chairpersons

6.1 Responsibilities of PTAC Chair

- 6.1.1 The PTAC Chair is responsible for:
- consulting with PHARMAC's Medical Director and the PTAC Secretary to set the agenda for PTAC meetings;
 - 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;
 - deciding on the appropriateness of a meeting being held via teleconference;
 - permitting Members to disconnect from a meeting via teleconference;
 - signing off the final version of the Minute of each meeting of PTAC;
 - liaising with PHARMAC in regard to the resources to be allocated to PTAC and its Members;
 - recommending, following agreement with PHARMAC's Medical Director, the establishment and/or dissolution of Subcommittees;
 - advising PHARMAC on appointments to Subcommittees;

⁷ Travel & Expense Policy for Board Members and Committee Members

⁸ The Pharmacology & Therapeutics Advisory Committee (PTAC) and the Exceptional Circumstances (EC) Panel Conference and Travel Allowance Policy

- considering, in consultation with PHARMAC staff, the process to be followed in relation to an Application or PHARMAC staff proposal;
- notifying PTAC Members when an Application or PHARMAC staff proposal has been referred by PHARMAC directly to a Subcommittee for advice;
- assisting with the assessment and management of all actual and potential conflicts of interest, noting and signing interests declaration forms and ensuring consideration by the PHARMAC Board. For completeness, it should be noted that this does not remove or detract from Members' obligations to properly disclose interests;
- approving communications by Members related to the activities of PTAC or PTAC Subcommittees 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;
- attending meetings of the Board of PHARMAC and reporting back to the PTAC Members on the discussion;
- delegating, in writing, any of his or her responsibilities where appropriate and in accordance with any PHARMAC delegation policy;
- determining (with the PHARMAC Medical Director) who may attend PTAC meetings as an observer;
- 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; and
- providing advice to PHARMAC staff on the content of relevant external communications.

6.2 Responsibilities of Subcommittee Chair

6.2.1 The Subcommittee Chair is responsible for:

- setting the agenda for Subcommittee meetings (in consultation with PHARMAC's Medical Director and the Subcommittee Secretary);
- presiding at each meeting of the Subcommittee;
- casting a deciding vote in the event of a tied vote on the recommendation to be made to the PHARMAC Board or PTAC;
- deciding on the appropriateness of a meeting being held via teleconference;
- permitting Members to disconnect from a meeting via teleconference;
- signing off the final version of the Minute of each meeting of the Subcommittee;
- liaising with PHARMAC in regard to the resources to be allocated to the Subcommittee and its Members;
- assisting with the assessment and management of all actual and potential conflicts of interest, noting and signing interests declaration forms and ensuring consideration by the PHARMAC Board. 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, where appropriate and in accordance with any PHARMAC delegation policy.

6.3 Responsibilities of Deputy Chairs of PTAC and PTAC Subcommittees

6.3.1 The Deputy Chair is responsible for acting as the Chair of the 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 Committee

7.1.1 All Members are responsible for:

- complying with all obligations set out in the CE Act (refer to Appendix 2);
- reviewing all material provided relating to items on meeting agendas;
- acting as the discussion leader for any items allocated to them by the Chair; and
- reviewing the draft Minute, providing feedback to the Committee secretary and confirming that the Minute is an accurate record of the discussion prior to finalisation of the Minute, for meetings that they have attended.

7.2 Conflicts of interest

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 2. Section 62 of the CE Act sets out the legal definition of being “interested in a matter”. Further guidance on this issue is attached to the interests disclosure form set out in Appendix 3.

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 Committee and the PHARMAC Board 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 or a Subcommittee that the Member is appointed to. The interests register is to be considered and confirmed as up to date at the commencement of each meeting.

7.2.4 Where a Member is “interested in a matter” (as defined in section 62 CE Act) relating to PHARMAC, they must not vote or take part in any discussion or decision of the Committee relating to the matter, or otherwise participate in any activity of PHARMAC that relates to the matter. The Minutes 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 meeting of the Committee during which a discussion or decision 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 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 the Committee relating to a matter, or otherwise participate in any activity of PHARMAC that relates to a matter, they should apply for such permission 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.

- 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 Minutes.

7.3 Confidentiality

- 7.3.1 Subject to paragraphs 7.3.3 to 7.3.5, and subject to any public law obligations of PHARMAC in relation to the disclosure of information (including under the Official Information Act 1982 (“OIA")), all information, documents and other material relating to matters on PTAC or the Subcommittee’s agenda, as well as the proceedings of PTAC or the Subcommittee, are confidential to PTAC, the Subcommittee 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 matter has been finally determined by PHARMAC, after which time Members must either destroy the material (by secure destruction) or return it to PHARMAC.
- 7.3.3 Members may confirm that PHARMAC has received an Application once details of the Application have been published on PHARMAC’s website. Members may discuss such Applications 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 Applications with other third parties as outlined in paragraph 2.2.4.
- 7.3.4 Any action taken by Members under paragraph 7.3.3 is subject to compliance with the Privacy Act 1993 and the Health Information Privacy Code 1994.
- 7.3.5 Once a Published Minute 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 Minutes.

7.4 External Communications and Public Statements

- 7.4.1 Members may only speak to the media in relation to the activities of PTAC, Subcommittees or PHARMAC and any matters discussed at or considered by PTAC or Subcommittees at their meetings, if they have the prior agreement of the PTAC Chair and the PHARMAC Chief Executive (which will be communicated by the Medical Director).
- 7.4.2 Members may only report to their professional associations in relation to the activities of PTAC, Subcommittees or PHARMAC or any matters discussed at or considered by PTAC or Subcommittees at their meetings, if they have the prior agreement of the PTAC Chair and the PHARMAC Chief Executive (which will be communicated by the Medical Director).

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 delegates authority to another PTAC Member.
- 8.1.2 PTAC meetings are normally held in Wellington four times per year. PTAC may also meet by teleconference or make recommendations using email discussion. 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 paragraph 8.1.1 above) must be either the PTAC Chair or the PTAC Deputy Chair.
- 8.1.4 Members can request leave of absence from any particular 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.
- 8.1.5 Members will receive prior written notice of each PTAC meeting, which will either be delivered by hand or sent to the Members by post, facsimile or electronic mail message.
- 8.1.6 Subject to compliance with the above procedures, PTAC may regulate its internal procedures in such manner as it thinks fit.

8.2 Remote Media Conferences

- 8.2.1 PTAC may, if the PTAC Chair agrees (and the meeting has a quorum), hold a meeting by contemporaneously linking together by remote media conferencing (such as teleconference or videoconference). 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 rules shall apply:
- (a) notice must have been given to every Member entitled to receive notice of a meeting of PTAC; 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.
- 8.2.2 A Member may not leave a meeting held under this section by disconnecting his or her remote media connection unless they have first obtained the permission of the PTAC Chair.

8.2.3 A Member is to be presumed to have been present, and to have formed part of the quorum, at all times during a remote media meeting unless he or she has been expressly permitted to leave.

8.2.4 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 In exceptional circumstances, for example where time is of the essence, PTAC may make recommendations (see section 9.3 below) by facsimile, email or other means of communication without a meeting having to be held.

8.3.2 In such circumstances, any recommendation of PTAC must be unanimous. If a consensus cannot be achieved, then a meeting under section 8.1, or a teleconference under section 8.2, must be held.

8.3.3 If a unanimous recommendation is achieved, the PTAC Secretary must prepare a Minute, which is then signed by all PTAC Members who participated in the discussion.

8.4 Meetings of Subcommittees

8.4.1 Subcommittees may need to meet more (or less) frequently than PTAC, depending on the matters referred to them for advice. The quorum for Subcommittee meetings is three Members and must include at least two non-PTAC Members and one PTAC Member (who may be the Chair of the Subcommittee).

8.4.2 PHARMAC staff will endeavour to organise a Subcommittee meeting as soon as possible after PTAC referring an Application to a Subcommittee for rapid review, subject to Member's availability and other factors (see paragraph 9.3.2). At other times Subcommittees will meet as required.

8.4.3 To the extent they are applicable, Subcommittees will follow PTAC's meeting procedures as detailed in sections 8.1 – 8.3 and 8.5.

8.5 Observers

8.5.1 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 PTAC Members and, unless the PTAC Chair of the particular meeting otherwise agrees, these observers will not have any rights to speak at or otherwise participate in the meeting.

8.5.2 Observers are required to sign confidentiality undertakings, prior to attending any meeting of PTAC. The attendance of an observer at a meeting will be documented in the Minutes.

8.5.3 Observers should not, by their presence, affect any recommendations of PTAC, either by influencing or constraining discussion at any PTAC 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.

9 Process for Reviewing New Funding Applications

9.1 Application requirements

- 9.1.1 Applications are expected to meet certain requirements, as detailed in the Guidelines for Applications to PHARMAC.
- 9.1.2 When PTAC considers Applications seeking funding for pharmaceuticals not currently on the Pharmaceutical Schedule, the pharmaceutical should ideally have already gained registration and all consents for marketing in New Zealand from Medsafe.

9.2 Consideration of Applications

- 9.2.1 PHARMAC staff will acknowledge the receipt of each Application. PHARMAC staff will publish the receipt of each Application on PHARMAC's website, including the name of the pharmaceutical that is the subject of the Application and, generally, the name of the person or organisation making the Application.
- 9.2.2 The PTAC Chair and PHARMAC staff may consider:
 - (a) whether a particular Application(s) should be referred directly to PTAC for advice; or
 - (b) whether a particular Application(s) should be referred directly to the relevant Subcommittee (i.e. prior to its consideration by PTAC); or
 - (c) whether they wish to invite relevant medical groups and other interested parties to comment on the pharmaceutical that is the subject of the Application prior to consideration of the Application by PTAC or a Subcommittee. Where comments are sought, the main objective will be to enable interested parties to outline specific issues relating to the pharmaceutical (in relation to PHARMAC's decision-making framework) early in the PHARMAC decision-making process. These comments will then be considered by PTAC or a Subcommittee when it considers the Application. The parties invited to comment and the reasons for selecting these parties will generally be documented in the Minutes.
- 9.2.3 PTAC may consider any correspondence, new information or reapplications that are provided by applicants.

9.3 Recommendations by PTAC

- 9.3.1 PTAC is to make a recommendation to PHARMAC in relation to each Application or PHARMAC staff proposal that is referred to it for consideration and advice.
- 9.3.2 Before making a recommendation, PTAC may refer an Application or PHARMAC staff proposal to a Subcommittee for further advice. In doing so, PTAC is to consider whether the Subcommittee should undertake a rapid review of this Application or PHARMAC staff proposal.
- 9.3.3 PTAC is to set out the matters and evidence that it has primarily relied on in making a recommendation. 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 and the priority it gives to such a listing; 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 a pharmaceutical on the Pharmaceutical Schedule.

9.3.4 Members are to endeavour, at all times, to reach a consensus on recommendations. If consensus cannot be achieved, a recommendation is to be made on the basis of a majority of the votes cast by the Members present. If a vote is tied, the PTAC Chair of the meeting is to have a second or casting vote. A record of any Members who disagree with, or dissent from, a recommendation of PTAC, and the grounds for such disagreement or dissent, shall be set out in the Minutes. Members are bound by each decision and will not take any steps outside the meeting to the detriment of a consensus or majority decision.

9.3.5 To the extent they are applicable, Subcommittees will follow PTAC's processes for making recommendations as detailed in paragraphs 9.3.1, 9.3.3 and 9.3.4 above. When assigning a priority to a listing (as detailed in 9.3.3(a)), Subcommittees are to prioritise within their therapeutic area.

9.4 Publication of PTAC Advice

9.4.1 Once a final recommendation has been made by PTAC (as set out in paragraph 9.3.2 (a) (b) or (c)) the Minute relating to that recommendation will be published on the PHARMAC website, subject to paragraphs 9.4.3 and 9.4.4.

9.4.2 Once the Minute of a Subcommittee meeting has been reviewed by PTAC, it will be published on the PHARMAC website, subject to paragraphs 9.4.3 and 9.4.4.

9.4.3 The Published Minute will be prepared by the PTAC Secretary and portions of the Minute may be withheld from publication in accordance with section 9 of the Official Information Act 1982. The names of all observers and attendees at a meeting will also be published.

9.4.4 Before publication, a draft Published Minute will be provided to the applicant, who may request that specific content is withheld under the Official Information Act. The PTAC Secretary will only make changes to the draft Published Minute content but their overriding obligation is to ensure that the record of PTAC's discussion remains accurate⁹, and PHARMAC will only withhold content of a draft Published Minute where it agrees with the applicant that there are grounds for withholding content under the Official Information Act.

10 Open Days

10.1.1 PTAC may, with PHARMAC's agreement, hold open days for general discussion. Members will not discuss past or current applications at any open days.

⁹ For example, changes may include typographical errors, facts recorded incorrectly or to clarify any ambiguity.

11 Variation of Terms of Reference

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

12 Disputes

12.1.1 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 referred to in section 4.1 above) is to be determined by the PHARMAC Board, whose decision is final.

Appendix One – Protocol for Appointment of Members to the Pharmacology and Therapeutics Advisory Committee (PTAC)

1. Introduction

1.1. Intent of this Protocol

The Pharmacology and Therapeutics Advisory Committee (PTAC) is an expert clinical advisory committee established by the Pharmaceutical Management Agency (PHARMAC) Board. Its role is to support the medicines funding decision-making process by providing PHARMAC with objective advice on pharmaceuticals and their benefits.¹

District Health Boards (DHBs) have overall responsibility for determining spending priorities to improve the health of their communities. PHARMAC's role on behalf of DHBs is:

To secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.²

These are difficult decisions and New Zealanders need to be confident that they are fair, provide value for money and are affordable for New Zealand.

This Protocol seeks to ensure that:

- New Zealanders have confidence in an appointment process that complies with applicable legislation, and has been undertaken with integrity and is open and transparent;
- the PHARMAC Board has access to expert clinical advice needed to make robust medicines funding decisions;
- members of PTAC have confidence in their ability to provide unfettered advice to the PHARMAC Board; and
- PTAC has a balance of experienced members and fresh perspectives on the Committee.

1.2. Spirit of public service

PTAC members contribute their time and expertise to support the medicines funding decision-making process. Their input is a critical element of the process and benefits New Zealand and New Zealanders.

Those who assume a role on PTAC do so in the spirit of service to the community. In undertaking this role, members must demonstrate the highest standards of honesty, integrity, impartiality and diligence.

¹ Section 50(1)(a) of the New Zealand Public Health and Disability Act 2000.

² Section 47(a) of the New Zealand Public Health and Disability Act 2000.

1.3. Legislation

PTAC is a statutory committee established by the PHARMAC Board in accordance with section 50(1)(a) of the New Zealand Public Health and Disability Act 2000 (the NZPHD Act). The NZPHD Act requires that the PHARMAC Board establish “a pharmacology and therapeutics advisory committee to provide objective advice to PHARMAC on pharmaceuticals and their benefits”.³

Section 50(4) of the NZPHD Act provides that members of PTAC are appointed by the Director-General of Health (Director-General) in consultation with the Board of PHARMAC.

Every reference to the Director-General must be taken to include a lawful delegate.

1.4. Appointment Principles

Appointments are made according to the following principles:

- the Director-General of Health makes appointment decisions;
- appointments are made in consultation with the Board of PHARMAC;
- all appointments are based on merit and will also take account of the need for PTAC to have, where possible, a balance of skills, knowledge, experience and perspectives; and
- a fair, open and transparent appointment process.

1.5. Scope

This Protocol sets out the process for appointments to PTAC. In addition, the Protocol contains information about the duration of appointment terms, the process to appoint the PTAC Chair and Deputy Chair and the process for terminating membership.

Related information about membership, including Member responsibilities, the appointment process for PTAC subcommittees and the process for reviewing new funding applications can be found in the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008 (PTAC ToR)* issued by PHARMAC. This document can be found at www.pharmac.govt.nz/PTAC.

Capitalised terms used in this Protocol have the same meaning as set out in the *PTAC ToR*.

1.6. Points of contact

The contact points between the Ministry of Health and PHARMAC for matters in respect of the content of this Protocol are:

- the PHARMAC Relationship Manager, Ministry of Health; and
- the PTAC Secretariat, PHARMAC.

³ s50(1) New Zealand Public Health and Disability Act 2000: The board of Pharmac must establish the following advisory committees under clause 14(1)(a) of Schedule 5 to the Crown Entities Act 2004: (a) a pharmacology and therapeutics advisory committee to provide objective advice to Pharmac on pharmaceuticals and their benefits.

The PTAC Secretariat will take responsibility for moving the appointments and reappointments process forward.

2. Preparation

To ensure continuity in the membership of PTAC and sustainable workloads for Members, the Director-General will take steps, in accordance with this Protocol, to undertake the appointment process in a timely way. In as far as possible, this will occur in advance of the expiry of memberships.

A key aspect of any appointment or reappointment process is consideration of the composition and requirements of PTAC. This will be considered in any appointment or reappointment process.

2.1. Membership (role description)

Membership requirements for PTAC are set out in the *PTAC ToR*. Sections 4.1.3 and 4.1.4 of the PTAC ToR state:

In general, PTAC comprises senior health practitioners from multiple specialities selected for their expertise in critical appraisal as well as broad experience and knowledge of pharmaceuticals and their therapeutic indications.

and;

The overall membership of PTAC will be weighted towards practising clinicians and will reflect a wide range of perspectives.

Members are not appointed as representatives of their primary employer or any other organisation.

2.2. Person specification

A general person specification is available at: www.pharmac.govt.nz/PTAC.

The appointment process provides an opportunity to review the current and anticipated future needs of PTAC. Consideration will be given to ensuring the skills and experience of new Members complement the talents of the existing Members, and meet the anticipated needs of PTAC in the future. This information will be combined with the general person specification to develop a person specification to match these requirements.

The final person specification for each vacancy in question will be developed jointly by the Director-General, the PTAC Chair and PHARMAC.

2.3. Locating suitable candidates

In general, candidates will be New Zealanders with a working knowledge of the New Zealand health and disability system. Applications may be sought or considered from overseas

candidates. To be considered, overseas candidates must be able to demonstrate a sound understanding of the New Zealand health and disability setting. The additional cost of appointing overseas candidates must be balanced against the needs of PTAC.

2.4. Publicising vacancies

Vacancies will be widely publicised, including in major newspapers and sector specific publications, to allow anyone with an interest to either apply for membership or to recommend suitable candidates. Relevant health professional or consumer groups who express an interest in being contacted directly in respect of PTAC vacancies will be invited to forward applications of interested persons.

The Director-General, and/or PHARMAC, may also directly invite applications from suitable candidates.

2.5. Documentation for applicants

Information packs will be sent to all applicants. These will include a person specification, a copy of the *PTAC ToR*, an indication of the required time commitment, remuneration details and information about PHARMAC.

2.6. Term of appointment

2.6.1. New appointments

Members of PTAC are generally appointed for a term of three years.

The Director-General may appoint Members for a term other than three years, in consultation with the PHARMAC Board, for example to:

- avoid terms of appointment expiring at the same time and thereby ensure the Committee retains a balance of experienced Members;
- allow for particular expertise to be appointed where needed for an identified period; and
- bring new skills or perspectives to the Committee.

2.6.2. Reappointments

Recognising that there are a limited number of people with the necessary skills and that it takes time to become an effective Member of the Committee, Members generally can be considered for reappointment for up to three terms, or a total period of service of nine years.

Reappointments will be made in consultation with the PHARMAC Board and the PTAC Chair, following a review of the composition of PTAC, and subject to a satisfactory performance review as set out in paragraph 2.8. A contestable appointment process is not required for reappointments, although the Director-General may choose to follow such an approach.

2.7. Appointment of Chair and Deputy Chair

The PTAC Chair should be a senior health practitioner with recognised standing in their field of expertise. Recognising that potential candidates with the time and level of experience

necessary to undertake this role are limited, the PTAC Chair generally will be able to serve up to a maximum of four terms, or a total of 12 years, on the Committee. This duration includes membership in all capacities.

The Director-General must, in consultation with the PHARMAC Board, by written notice appoint a Member of PTAC as Chair; and may appoint another Member of PTAC as Deputy Chair. The Chair will ordinarily be a person with no less than three years prior membership of PTAC.

The appointment must state the period for which the Member is appointed Chair or Deputy Chair and the date on which he or she comes into that office.

A Member appointed Chair or Deputy Chair and whose appointment has expired, continues in that office until his or her successor is appointed, and is eligible for reappointment to that office so long as he or she continues to be a member of PTAC.

2.8. Review of performance

At the end of their term, if a Member is seeking reappointment, they will be subject to a performance review from the PTAC Chair. The PTAC Chair will subsequently advise the PHARMAC Board and Director-General on that Member's performance to date, and whether or not that Member is suitable for reappointment. After considering the Chair and PHARMAC Board's advice, the Director-General will determine if the Member is reappointed.

The Member may request, and be given, a copy of any report of this review.

2.9. Short-Term or Temporary appointments

The Director-General, in consultation with the PHARMAC Board, may appoint a person to PTAC in order to fill a short-term or temporary membership vacancy. In doing so, the Director-General may deviate from some or all of the steps in the usual appointment process, as appropriate for the particular circumstances. Short-term or temporary appointments should not exceed six months in duration.

2.10. Termination of appointments

Members should inform the Director-General in writing of their intention to resign from PTAC at the earliest available opportunity, copied to the PTAC Chair and the PHARMAC Board for their information.

As the individual responsible for appointments to PTAC, the Director-General may at any time, in consultation with the PHARMAC Board, remove a Member (including the Chair or Deputy Chair) from PTAC. In the case of the Chair or Deputy Chair, their removal may be from those positions only, or also as Members. The Director-General will inform the Member in writing, giving reasons for the termination of their membership or removal from their position.

In accordance with section 91 of the NZPHD Act, PHARMAC may not make any payment to, or otherwise compensate, any person in respect of the person ceasing for any reason to be a member.

3. Selection and Appointment

3.1. Interview panel

The Director-General with the support of PHARMAC will establish an interview panel consisting of at least three people. This will include representation from the Ministry of Health, PHARMAC and the PTAC Chair or their delegate. The interview panel will ordinarily include a person who brings a Māori perspective to the interview process.

3.2. Developing selection criteria

The Director-General, together with the PTAC Chair or their delegate, and PHARMAC will identify the selection criteria in respect of the particular vacancy. These criteria will be identified prior to advertising a position, and will reflect the Person Specification, the membership requirements outlined in the *PTAC ToR* and the particular needs of PTAC at the time. The position will be advertised, but responses to advertisements may not be the only source of applicants.

3.3. Selecting a shortlist

Based on the selection criteria, the interview panel will jointly identify a candidate shortlist to proceed to interview. Confirmation of details contained in a candidate's curriculum vitae and disclosures of interests will be considered at this stage.

3.4. Interviews

The interview panel will interview all short listed candidates. Candidates will be assessed against the selection criteria. The interview panel will then seek to jointly identify a preferred candidate. The shortlist of candidates, along with the interview panel's recommendation will be forwarded to the PHARMAC Board for its consideration and comment. Where the panel cannot reach a consensus, the PHARMAC Board will be briefed on the diverging opinions of the panel.

3.5. Candidate selection

The short list of candidates and their curricula vitae, the interview panel's recommendation(s) and any additional comments or recommendations from the PHARMAC Board will be forwarded to the Director-General for consideration.

Considering this information, the Director-General will determine the successful candidate to be appointed as a PTAC Member. Where the Director-General's preferred candidate differs from the candidate supported by the PHARMAC Board, the PHARMAC Board will be advised in advance of a final appointment decision and given further opportunity to provide comment to the Director-General.

3.6. Conflicts of interest

Candidates (and Members) are required at all times to fully disclose and appropriately manage any interests and conflicts of interest that may affect the performance of their duties and obligations, consistent with the Crown Entities Act 2004 provisions relating to members of a committee of a statutory entity.

The policy for managing conflicts of interest is outlined in detail in section 7 and Appendix 3 of the *PTAC ToR*. This can be found on the PHARMAC website at: www.pharmac.govt.nz/PTAC

Appendix Two – Relevant Statutory Provisions

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; or
- (b) the Remuneration Authority in accordance with the [Remuneration Authority Act 1977](#), in the case of—
 - (i) a member of an independent Crown entity; or
 - (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; or
 - (b) as required or permitted by law; or
 - (c) in accordance with subsection (2); or
 - (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; and
 - (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; or
 - (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; or
 - (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; or
 - (c) may have a financial interest in a person to whom the matter relates; or
 - (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; or
 - (e) may be interested in the matter because the entity's Act so provides; or
 - (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; or
 - (b) because he or she receives an indemnity, insurance cover, remuneration, or other benefits authorised under this Act or another Act; or
 - (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; or
 - (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; or
- (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); or
- (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; and
- (b) must not sign any document relating to the entry into a transaction or the initiation of the matter; and
- (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; and
 - (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; and
- (b) for valuable consideration; and
- (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; and
 - (b) make that policy (including the equal employment opportunities programme) available to its employees; and
 - (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; and
 - (b) an equal employment opportunities programme; and
 - (c) the impartial selection of suitably qualified persons for appointment; and
 - (d) recognition of—
 - (i) the aims and aspirations of Maori; and
 - (ii) the employment requirements of Maori; and
 - (iii) the need for involvement of Maori as employees of the entity; and
 - (e) opportunities for the enhancement of the abilities of individual employees; and
 - (f) recognition of the aims and aspirations and employment requirements, and the cultural differences, of ethnic or minority groups; and
 - (g) recognition of the employment requirements of women; and
 - (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; and
 - (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 effect 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; and
 - (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; or
 - (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.

Appendix Three – Conflicts of Interest declaration form and guidance for Members & Chairs

Members

In making a declaration please consider that your role or position may extend to a range of contexts (for example if you participate in one or more Subcommittees) and different issues will arise according to the context. Therefore please carefully consider the following questions, treating them as a prompt to help identify possible conflicts when contemplating a declaration:

1. What sectors do I work in / what bodies, groups or associations am I a member of / what personal or financial interests do I or members of my family have / what business or personal relationships do I have (including past involvement)?

Consider (without limitation):

- official positions e.g. director, shareholder, trustee;
- personal and social relationships;
- consultant/advisory roles (including provision of expert evidence or opinion);
- involvement in clinical research/development;
- political affiliations;
- your sources of income and other areas of financial benefit or opportunity (or that of your close family members);
- attendance at events funded by industry.

2. Thinking about my role(s) for PHARMAC or one of PHARMAC's committees, what types of information can I expect to see / what responsibilities will I have / what types of judgements or decisions will I be expected to make?

For example:

- Advice to Ministers of Parliament;
- Confidential commercial information from pharmaceutical suppliers;
- Confidential information about PHARMAC strategies;
- Patient information;
- PHARMAC Legal advice in relation to (but not limited to) commercial matters, litigation, intellectual property;
- Operational/financial information;
- Unpublished study information (i.e clinical research).

3. Is there any foreseeable possibility that one of my roles / duties / responsibilities with PHARMAC or a committee might intersect with one of my other interests / relationships / roles and that the latter might influence the way I carry out my PHARMAC/committee role?

Consider specifically whether confidential information you may see could be relevant to another role that you have, or whether your views or interests as a result of another role or relationship could potentially affect your role with PHARMAC or the committee.

When you have considered the above questions, determine whether there are any potential (though realistic – not purely hypothetical and remote) conflicts of interest that should be declared to the PHARMAC Board and PTAC or the Subcommittee. This includes any potential for a **perceived conflict**, whether or not you would actually be influenced by the interest. It may be useful to bear in mind the perspective of someone negatively impacted by a decision and how they might argue that there was a conflict of interest that prevented you acting objectively in

the event they wanted to challenge the process by which a particular outcome was reached. You should always err on the side of caution, and disclose more rather than less. If in doubt, disclose. In each case disclose in such a way that an independent party could properly understand the true nature and extent of the interest.

Chairs

When assessing a declared actual or potential conflict of interest consider:

It is unmanageable?

- The person cannot or will not divest themselves of the conflict i.e. unavoidable; and
- is serious; or
- is pervasive and would affect so many of PHARMAC's/the committee's decisions that management mechanisms are not practical.

Is it Manageable?

- Where the person is prepared to divest themselves of or sever connection with the conflict; or
- the conflict is so minor or remote that it cannot reasonably be regarded as likely to influence the person in carrying out their responsibilities; or
- there is little risk of a negative public perception; or
- the conflict affects a confined area of PHARMAC's/the committee's operations and can be adequately "ring-fenced" from other aspects that it could, or could be seen to, affect.

What are the management and mitigation strategies?

- Divestment – where the person agrees to divest themselves of the interest creating the conflict (this is likely to be necessary where the conflict of interest is serious and pervasive but avoidable through divestment).
- Severing connections – resignation from one or other position or entity (this is likely to be necessary where the conflict of interest is serious and pervasive but avoidable by severance).
- Blind trust – where assets can be transferred to a trust managed by trustees with nearly complete autonomy and the person retains very little knowledge or control over the transferred assets.
- Withdrawing from discussion – must be declared and noted on each occasion in the meeting minutes.
- Abstaining from voting – must be declared and noted on each occasion in the meeting minutes.
- Non-receipt of relevant information – in addition to declaring an interest, withdrawing from the discussions and voting, the person agrees not to be given any information (written or oral) relating to the interest.
- Agreement not to act – where the person does not participate in any other action concerning the interest e.g. signing documents relating to the interest on behalf of PHARMAC/the committee.
- Transferring the person (temporarily or permanently) to another position or project.

- Re-assigning certain tasks or duties to another person.
- Seeking a formal exemption (e.g. from the Board) to allow participation.
- Enquiring as to whether all affected parties will consent to the person's involvement.
- Declarations of interest – where the interest is retained but is declared when related issues arise for discussion or decision (must be declared and noted on each occasion in the meeting minutes).
- Confidentiality agreements – where the person agrees not to pass on confidential information.
- Imposing additional oversight or review over the person (e.g. peer review, where for example a person's role can only be performed by that particular person and the conflict is not viewed as particularly serious).

These methods can be used singly or in combination depending on the nature and extent of the conflict being considered. There may be some situations where a conflict is inevitable and unavoidable, and the matter cannot reasonably be dealt with without the person's involvement. This should be a rare scenario and in such a situation one or more of the above mitigation options may need to be employed.

Objective advice to PHARMAC

Pharmaceutical Management Agency

Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand

Phone: 64 4 460 4990 – Fax: 64 4 460 4995 – www.pharmac.govt.nz Email: enquiry@pharmac.govt.nz

