

Review of the Guidelines for the Pharmacology and Therapeutics Advisory Committee (PTAC) and its Subcommittees

Introduction

PTAC is a statutory committee established “to provide objective advice to PHARMAC on pharmaceuticals and their benefits”. PTAC is currently made up of ten vocationally registered medical practitioners who are active in clinical practice and have expertise in clinical pharmacology, internal medicine or general practice.

The ‘Guidelines for the Pharmacology and Therapeutics Advisory Committee (PTAC) and its Sub-Committees’ (PTAC Guidelines) – which are available on the PHARMAC website at http://www.pharmac.govt.nz/2002/07/09/PTAC_guidelines.pdf - detail the terms of reference for these PHARMAC committees. The Guidelines cover the establishment of the committees, the relationship between the committees and PHARMAC, membership, remuneration, the responsibilities of the committee Chairs and all members, the management of meetings and the process for reviewing medicines funding applications.

As is good practice, PHARMAC from time-to-time reviews its operational documents and those of its Committees. The first PTAC Guidelines were incorporated into PHARMAC’s July 1993 Operating Policies and Procedures (OPPs). The PTAC Guidelines were then comprehensively reviewed in 2002 to align them with the New Zealand Public Health and Disability Act 2000 (the NZPHD Act) and PHARMAC’s revised OPPs.

The current review

In 2006 PHARMAC initiated a review of the PTAC Guidelines to address issues that PHARMAC had identified, and following feedback that had been received from some key stakeholders. Work on the development of a medicines strategy for New Zealand began part-way through the review. The medicines strategy process revealed strong stakeholder interest in the role of PTAC in medicines funding decisions. PHARMAC decided, as a result of this high level of interest, to wait to progress the review until after the medicines strategy had been released.

*Medicines New Zealand*¹ and its action plan, *Actioning Medicines New Zealand*², were released by Government last December. While the documents support current structures in the medicines system, they also signal that within existing broad policies and structures, there is room to improve.

The importance of PHARMAC’s review of the PTAC Guidelines was reinforced by the specification, in *Actioning Medicines New Zealand*, that PHARMAC was to “consult broadly on changes to PTAC’s Operational Guidelines to ensure optimal arrangements are in place for PTAC to provide free and frank advice to the PHARMAC Board”.

Following the release of the medicines strategy, PHARMAC staff again reviewed the contents of the PTAC Guidelines to ensure they reflected the principles of *Medicines New Zealand*.

¹ <http://www.moh.govt.nz/moh.nsf/indexmh/medicines-nz?Open>

² <http://www.moh.govt.nz/moh.nsf/indexmh/actioning-medicines-nz?Open>

This document provides you with background information about:

- the legislative framework that surrounds PTAC and its Subcommittees
- the scope of this review
- the key changes proposed by PHARMAC
- the process for this review.

Review objectives

This review aims to ensure that the PTAC Guidelines:

- enable PTAC & PTAC Subcommittees to carry out their obligations as described in the NZPHD Act and the Crown Entities Act 2004
- support PTAC & Subcommittee members in providing free and frank, objective advice to PHARMAC
- enable the PHARMAC Board to access high quality, clinical expertise via PTAC & PTAC Subcommittees to support evidence-based decision-making about medicines funding
- align with the principles, goals and outcomes identified in *Medicines New Zealand*.

Legislative framework for PTAC and Subcommittees

Establishing PTAC and PTAC Subcommittees

PTAC is established under the NZPHD Act. Section 50(1) of the Act requires that the PHARMAC Board establish “a pharmacology and therapeutics advisory committee to provide objective advice to PHARMAC on pharmaceuticals and their benefits”.

Subcommittees are established under clause 14(1)(a) of Schedule 5 of the Crown Entities Act 2004. This empowers the PHARMAC Board to “appoint committees to advise it on any matters relating to the entity’s functions”.

A pharmacology and therapeutics advisory committee has been in existence in various forms since the 1960’s, providing advice to government about medicines funding. Following the establishment of PHARMAC in 1993, PTAC was established as an advisory committee of PHARMAC. Despite structural changes in the health sector the need for expert advice to inform medicines funding decisions has remained constant.

In accordance with s50(4) of the NZPHD Act, “the members of the pharmacology and therapeutics advisory committee are appointed by the Director-General of Health”. The legislation recognises the important role that PTAC plays in providing the PHARMAC Board with high quality clinical advice to inform medicines funding decision-making and therefore requires that appointments are made “in consultation with the board of PHARMAC”.

Scope of the Review

This review specifically considers the PTAC Guidelines. A copy of the current Guidelines is available on PHARMAC’s website.

PHARMAC has drafted a revised version of the PTAC Guidelines, which it is proposing be called “*The Terms of Reference for PTAC and PTAC Subcommittees*” (attached). The key proposed changes are summarised in Appendix 1 at the end of this document. We would like to hear your feedback on both the changes that are proposed in the attached draft, and any

other amendments that you consider should be made to the draft Guidelines. PHARMAC is open to hearing any and all views on the specification of the draft Guidelines that would best support PTAC and PTAC Subcommittees in fulfilling their roles.

The process for appointing members to PTAC has been addressed in a separate review of the PTAC Appointment Protocol. This was led by the Ministry of Health and included a consultation process.

A broad description of the person specification for PTAC members is covered in the PTAC Guidelines (section 4.1.3). A more detailed current position description for PTAC members is available on the PHARMAC website at <http://www.pharmac.govt.nz/2008/05/14/PTAC%20Member%20Position%20Description.pdf>.

Nature of consultation

We have provided our proposed amendments to the Guidelines for comment to ensure that there is clarity about the changes we are proposing. We consider that interested stakeholders are then better placed to comment on our suggested changes, and to identify any other changes they think we should consider.

PHARMAC welcomes any and all views on the draft Guidelines. PHARMAC's role in considering consultation responses is not to 'count votes' but rather to ensure that it has taken into account all views on the draft Guidelines before reaching a decision about the final content.

Consultation process

We welcome your comments on this proposed draft of the PTAC Guidelines (named *The Terms of Reference for PTAC and PTAC Subcommittees*). To assist PHARMAC's consideration of submissions, submitters are encouraged to provide reasons supporting their views. In particular, we are seeking your views on:

- the proposed changes in the attached draft Guidelines
- any other issues and amendments that you consider are required to ensure optimal arrangements are in place for PTAC to provide free and frank advice to the PHARMAC Board
- any other points you wish to share relating to the PTAC Guidelines.

To provide comment, please submit an email, fax or letter by **5pm Friday 13 June 2008**:

Erin Murphy
PTAC Secretary
PHARMAC
PO Box 10-254
Wellington 6143

Email: ptac@pharmac.govt.nz

Fax: (04) 460 4995

We also invite interested stakeholders to meet with PHARMAC staff. Please advise Erin Murphy (erin.murphy@pharmac.govt.nz or (04) 916-7512) by **Friday 30 May** if you would like to meet with us to provide your views on the draft PTAC Guidelines. If a range of stakeholder groups are interested in meeting with us, we may organise larger meetings with groups of stakeholders to discuss the draft document with PHARMAC staff.

We encourage you to distribute these consultation documents to any other stakeholders who you consider may be interested.

Information requested under the Official Information Act

Note that your submission and all correspondence you have with PHARMAC may be the subject of requests under the Official Information Act 1982. If there is any part of your submission or correspondence that you consider could *properly* be withheld under the Act, please include comment to this effect along with reasons why you want the information withheld. The reasons for withholding information under the Official Information Act 1982 are contained in Appendix 2.

If you are making your contribution as an individual as opposed to an organisation, PHARMAC will omit your personal details from the submission if you include the following statement at the front of your submission and sign it:

'I do not give my permission for my personal details to be released to persons requesting my submission under the Official Information Act 1982.'

Review Process

After the consultation period has concluded, PHARMAC will consider all the recommended changes to the draft Guidelines. At this stage PHARMAC staff will also consider feedback it has received on the Guidelines during the Ministry of Health-led consultation process on the review of the PTAC Appointment Protocol. PHARMAC staff will then prepare a final version for approval by the PHARMAC Board. The Ministry of Health will be involved throughout this review.

We expect to provide you with a summary of all consultation response and the final version of the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees by October 2008.

Further Information

If you require further information about this review of the PTAC Guidelines you can contact Erin Murphy at ptac@pharmac.govt.nz or (04) 916-7512.

Appendix 1: The Guidelines – key proposed changes

The key proposed changes to the PTAC Guidelines and our rationale for these are provided in the table below.

Amendments to improve transparency and understanding	
Proposed change	Rationale where required
The revised draft makes it more explicit that the Decision Criteria are PHARMAC's, but that PTAC and Subcommittees should use these as the basis of recommendations to PHARMAC.	To clarify that PHARMAC is the decision maker but that it is appropriate that PTAC and Subcommittees use these criteria to inform their advice to PHARMAC.
The "Relationship with PHARMAC" section has been renamed "Relationship Management" and now covers all key relationships for PTAC & Subcommittees, including: <ul style="list-style-type: none"> • between PTAC/Subcommittees and PHARMAC; • between PTAC and Subcommittees (which now states that all PTAC minutes will be provided to the relevant Subcommittee once they are finalised, as is current practice); • between PTAC/Subcommittees and PHARMAC staff (including the roles of the PTAC Secretary and Subcommittee Secretary). 	To make it easier to access complete information about PTAC's and the Subcommittees' relationships.
The "Relationship with PHARMAC" section has also been updated to state that "nothing in these Terms of Reference is intended to restrict or fetter the ambit of the advice that PTAC provides to the PHARMAC Board".	To make explicit the fact that PTAC is not controlled by PHARMAC as to the content of its advice or views.
The 'Relationship with PHARMAC' section (section 3.1) was reworded to provide equal access for the Chair of the PHARMAC Board to attend PTAC meetings and the Chair of PTAC to attend PHARMAC Board meetings. That is, the Board Chair would require the approval of the PTAC Chair to attend a PTAC meeting as is currently the case with the Chair of PTAC attending PHARMAC Board meetings.	To reflect Medicines New Zealand principles of confidence and transparency by reinforcing that PTAC's advice is its own and is not influenced by PHARMAC.

Amendments to improve transparency and understanding	
Proposed change	Rationale where required
The responsibilities of the PTAC Chair and Subcommittee Chair are listed in section 6	To make it easier to access complete information about the Chairs' responsibilities.
The process for web publishing of PTAC minutes has been outlined (section 9.4).	<p>To makes it clearer that PHARMAC determines what information will be published on the web.</p> <p>We propose to continue publishing the full Minute (subject to review in accordance with the Official Information Act 1982) for Applications where PTAC has made a final recommendation.</p>
Section 9.14 outlining the publication of Minutes has been further updated to include publication of the recommendation where PTAC has deferred making a final recommendation to approve/decline (for example, pending further information or review by a Subcommittee).	To increase transparency by making available some information about PTAC deferrals. Currently no information is published regarding a deferral. We do not recommend publishing the whole deferral minute as they are a 'work in progress' and may be misleading given that PTAC's final view may alter following, for example, feedback from the applicant. Generally, copies of the whole deferral minute are provided to the applicant for review and comment.
<p>The Membership section (paragraph 4.1) has been updated to refer to the Protocol for the Appointment of Members of the Pharmacology and Therapeutics Advisory Committee (PTAC).</p> <p>This section also refers to the list of members for both PTAC and its Subcommittees on the PHARMAC website (paragraphs 4.1.4 and 4.2.4).</p>	<p>To ensure that the Guidelines would continue to refer to the correct process document once the PTAC Appointment Protocol is updated.</p> <p>Similarly, when PTAC or Subcommittee membership is updated on the PHARMAC website, the Guidelines would continue to refer to the correct and up-to-date information.</p>
Section 7 outlines the responsibilities of all Members of PTAC and PTAC Subcommittees. The content in paragraph 7.1.1, which details these responsibilities, has been added in this revised draft and is not in the current version of the PTAC Guidelines.	To clarify the responsibilities of PTAC and Subcommittee members, particularly in relation to the Crown Entities Act; this is not referred to in the current Guidelines.

PTAC membership	
Proposed change	Rationale
<p>The membership of PTAC (section 4.1) has been clarified and the proposed changes allow for non-medical health professionals to be appointed to PTAC (in line with the NZPHD Act, 2000). An equivalent change would need to be made in the PHARMAC Operating Policies and Procedures.</p>	<p>To respond to feedback provided by stakeholders that PTAC membership should be defined by the skills of candidates rather than their profession.</p> <p>There is a very limited pool of candidates for appointment to PTAC. This change would increase the number of suitably qualified people who could be appointed to PTAC.</p>

Administrative amendments and updates	
Proposed change	Rationale
<p>The Guidelines have been restructured to give a more logical flow from section to section.</p>	<p>These proposed changes are largely administrative and aim to make the document easier to read.</p> <p>Some of these changes are to provide more information on current practices (for example, remuneration) or to align the document with newly updated processes (such as conflicts of interest processes).</p>
<p>The glossary of terms has been updated and includes revised definitions for “Minute” and “Published Minute”. Other key terms are also now defined in this section.</p>	
<p>Where appropriate, the terms of reference for PTAC and PTAC Subcommittees have been combined.</p>	
<p>The remuneration of PTAC and Subcommittee members has been clarified (section 5) and includes a statement about PHARMAC paying for travel and accommodation expenses for Members and refers to the Conference and Travel Allowance for members to use for professional development.</p>	
<p>Details of the administration role of the PTAC secretary have been moved to the PTAC administration manual.</p>	
<p>Additional information has been attached as appendices to the PTAC Guidelines. This information includes the relevant statutory provisions and PHARMAC</p>	

Administrative amendments and updates

Proposed change	Rationale
guidance notes for conflicts of interest.	
The indemnity section (paragraph 3.4.1) has been updated to stipulate that “indemnity only applies to circumstances where a Member has acted in good faith, and with reasonable care in the provision of advice and in accordance with their appointment and these Terms of Reference”.	
The conflicts of interest section (section 7.2) has been updated to align it with the new PHARMAC process for managing conflicts of interest.	
The description of the process for reviewing new applications (section 9) has been simplified.	
Section 9.2.2 has been updated to better reflect current practice and to request that comments on pharmaceuticals from relevant medical groups and other interested parties relate to PHARMAC’s Decision Criteria.	

Appendix 2: Relevant Provisions of the Official Information Act 1982

9. Other reasons for withholding official information –

- (1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.
- (2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to –
 - (a) protect the privacy of natural persons, including that of deceased natural persons; or
 - (b) protect information where the making available of the information –
 - (i) would disclose a trade secret; or
 - (ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or
 - (ba) protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information –
 - (i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
 - (ii) would be likely otherwise to damage the public interest; or
 - (c) avoid prejudice to measures protecting the health or safety of members of the public; or
 - (d) avoid prejudice to the substantial economic interests of New Zealand; or
 - (e) avoid prejudice to measures that prevent or mitigate material loss to members of the public; or
 - (f) maintain the constitutional conventions for the time being which protect –
 - (i) the confidentiality of communications by or with the Sovereign or her representative;
 - (ii) collective and individual ministerial responsibility;
 - (iii) the political neutrality of officials;
 - (iv) the confidentiality of advice tendered by Ministers of the Crown and officials; or
 - (g) maintain the effective conduct of public affairs through –
 - (i) the free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or
 - (ii) the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or
 - (h) maintain legal professional privilege; or
 - (i) enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or
 - (j) enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or
 - (k) prevent the disclosure or use of official information for improper gain or improper advantage.