

Summary of all submissions to consultation on the draft *Terms of Reference for the Pharmacology & Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees* ("PTAC ToR")

PHARMAC has recently completed a review of the PTAC Guidelines (now known as PTAC ToR) to "ensure optimal arrangements are in place for PTAC to provide free and frank advice to the PHARMAC Board"¹.

PHARMAC began reviewing the PTAC ToR in 2006. During the development of the Government's medicine strategy, some stakeholders expressed concern about the ability of PTAC to provide PHARMAC with free and frank, objective advice in relation to medicines funding applications. Responding to submitters' concerns, *Medicines New Zealand* committed to PHARMAC consulting broadly on changes to PTAC's operational guidelines.

In May this year, the draft "*Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees*" and consultation letter were distributed to a broad range of stakeholders, including pharmaceutical suppliers, medical groups, consumer groups, DHBs, health-related academic groups, PHARMAC's "interested parties" fax list, PTAC, PTAC Subcommittees and the Consumer Advisory Committee (CAC).

PHARMAC and Ministry of Health staff met with key stakeholders who requested an opportunity to discuss their consultation submissions.

PHARMAC received 23 consultation submissions from a range of stakeholders. PTAC and the Ministry of Health also provided feedback. Submissions to this consultation formed part of the information that the PHARMAC Board considered when approving the PTAC ToR at its September 2008 meeting.

SUMMARY OF CONSULTATION SUBMISSIONS AND PROPOSED CHANGES

This *Summary of Submissions* document provides a summary of the submissions we received. The views that stakeholders expressed in their submissions are described in general terms. For the purposes of this summary table, PHARMAC staff paraphrased and shortened respondent's comments. PHARMAC also provides some response comments on the issues that submitters' raised. It is important to note that this summary is not intended as a replacement for the individual submissions themselves; all of which stand in their own right. All submissions were individually provided to and considered by the PHARMAC Board, as part of the decision making process. Copies of the individual submissions received are available from PHARMAC on request (via email to erin.murphy@pharmac.govt.nz).

¹ *Actioning Medicines New Zealand* is available at <http://www.moh.govt.nz/moh.nsf/indexmh/actioning-medicines-nz?Open>

PHARMAC received 23 consultation submissions on the draft PTAC Terms of Reference. The submissions were received from:

- Federation of Women's Health Councils Aotearoa
- Auckland Women's Health Action Council
- Women's Health Action Trust
- Leukaemia & Blood Foundation of New Zealand
- Breast Cancer Aotearoa Coalition
- Access to Medicines Coalition
- New Zealand AIDS Foundation
- National Heart Foundation
- Janssen-Cilag
- Researched Medicines Industry Association
- Sanofi Aventis
- Bayer Healthcare
- Pharmaceutical Society
- New Zealand Medical Association
- College of Psychiatrists
- Royal New Zealand College of General Practitioners
- Piki Te Ora Nursing Service
- Krishan Madhan
- Northern Region DHBs Regional Oncology Group
- Northland DHB, Hawkes Bay DHB
- Waitemata DHB
- PHARMAC Consumer Advisory Committee

FEEDBACK ON CHANGES

We note that some suggestions made in consultation were outside the scope of this review. We have identified these with comments in the PHARMAC response section of the table below. PHARMAC welcomes separate engagement on any other topic that falls outside the scope of this review.

If you have any feedback or queries about the revised PTAC ToR, please contact Erin Murphy (erin.murphy@pharmac.govt.nz). If you would like further information about PTAC and PTAC Subcommittees, please contact Susan Haniel, Advisory Committee Manager (susan.haniel@pharmac.govt.nz).

SUMMARY OF CONSULTATION SUBMISSIONS AND PHARMAC RATIONALE FOR CHANGES

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
1.1.1	<p>Some submitters considered that PTAC should not sit within PHARMAC’s structures and systems. However, they noted that <i>Medicines New Zealand</i> had “committed the Government only to working within the current framework to ensure optimal arrangements exist for PTAC to provide to the PHARMAC Board free and frank advice”. Submitters considered that this meant that the changes being proposed in PHARMAC’s consultation document were around the fringes, rather than substantial and perceptions of PHARMAC influence remain.</p>	<p>The question of PTAC’s optimal role and structure was explicitly considered as part of the Medicines New Zealand strategy development. Overall, the review found the current arrangements to be sound.</p> <p>Both PHARMAC and PTAC consider that the PHARMAC – PTAC relationship works well and that PHARMAC receives objective and independent advice from PTAC.</p> <p>PHARMAC will be doing work to increase transparency and public understanding of our processes, and PTAC’s relationship with PHARMAC. A number of changes to the ToR should, in PHARMAC’s view, increase stakeholder confidence in the PHARMAC-PTAC relationship and the overall quality of PTAC’s advice.</p>	No change to the PTAC ToR.
1.2.1	<p>One submitter considered that PTAC’s role and function could be undermined by the creation of a Subcommittee, in particular when PHARMAC finds PTAC’s advice unsatisfactory and wishes to navigate around PTAC.</p>	<p>The PTAC Chair (along with PHARMAC’s Medical Director) makes recommendations to the PHARMAC Board about the establishment of any PTAC Subcommittee, and selection of its members. In addition, a PTAC member must be appointed to every PTAC Subcommittee, usually as the Chair, and will report back to PTAC.</p> <p>All Subcommittee minutes are provided to PTAC for comment.</p> <p>The PTAC Chair attends Board meetings and is provided with any advice provided directly to the Board. If the PTAC Chair has any concerns, these can be raised at Board meetings.</p>	No change to the PTAC ToR.

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2.2.1	<p>Some submitters questioned whether clinical effectiveness and cost-effectiveness should be separated from funding decisions.</p> <p>There were a number of views on where this balance should sit, including:</p> <ul style="list-style-type: none"> • PTAC not considering financial Decision Criteria at all • PTAC considering all Decision Criteria but differentiating between the clinical and financial factors more explicitly in PTAC minutes • support for PTAC considering the same Decision Criteria as PHARMAC <p>Some submitters also expressed concern that, in considering financial Decision Criteria, PTAC is being asked to consider something which it has neither the statutory obligation nor the experience to consider.</p>	<p>PHARMAC has a statutory obligation to establish PTAC; however, there is no statutory restriction on what criteria PTAC must use in providing its advice. PTAC uses the same decision criteria as PHARMAC with PTAC “giving weight to each criterion as PTAC considers appropriate”. While the weight given to each criterion may differ between PTAC and the PHARMAC Board, use of the same criteria ensures PTAC’s recommendations are based on the same set of factors that the Board itself will consider.</p> <p>Were PTAC’s criteria different to PHARMAC’s, a further process of integrating PTAC’s advice into a different decision framework would be required. PHARMAC considers that such a process would be inefficient and lose the benefits of the current interactions between PTAC and PHARMAC when considering the same relevant factors.</p> <p>PTAC members possess a patient-based clinical focus, but are also aware of the opportunity cost of funding one drug over another. Thinking about trade-offs and use of resources is a routine part of every clinician’s day-to-day practice. It is preferable to have explicit consideration of all criteria, including cost-effectiveness, instead of risking implicit consideration of matters that members feel are important but are ruled off-limits.</p> <p>In the Judicial Review of the trastuzumab (Herceptin) funding decisions, Judge Gendall considered that it is within PTAC’s ambit to consider cost, cost-effectiveness and budgetary impact.</p>	No change to the PTAC ToR.
2.2.1	One submitter considered that weighting of decision criteria should be done <i>a priori</i> and then applied systematically to the case being	Decision making is not a purely mechanistic exercise in measuring and analysing data, ticking off boxes and assessing performance against specific criteria. PTAC	No change to the PTAC ToR.

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	discussed, with relevant discussion against each criterion recorded in the minute and summarised with a reasoned argument for a final recommendation. If not, PTAC would have the ability to downgrade or ignore any of the criteria, without any consistency from one Application to the next and without providing a reviewable reason for doing so.	<p>recommendations, and ultimately PHARMAC's decisions, require the exercise of professional judgement on a wide range of complex issues, and the balancing of competing interests and values in an ever-changing environment.</p> <p>As written in the ToR, PTAC must consider <i>all</i> nine Decision Criteria and must not ignore any criterion, although it may consider that a criterion is not particularly relevant to a given recommendation. PTAC may use its judgement to weight the Decision Criteria.</p>	
2.2.1	One submitter considered that PHARMAC's current 9 Decision Criteria did not reflect or incorporate the Principles in <i>Actioning Medicines New Zealand</i> and re-releasing the PTAC ToR without reviewing the Decision Criteria (accepted as a PHARMAC-level review) would signal that PHARMAC is not complying with <i>Medicines New Zealand</i> .	<p>This current process was not a review of PHARMAC's Decision Criteria. <i>Medicines New Zealand</i> states that a fair and functional system is guided by six Principles. Although some stakeholders consider that PHARMAC's Decision Criteria should be explicitly aligned with the Principles, PHARMAC and the Ministry of Health consider that the current PHARMAC Decision Criteria are compatible with these Principles.</p> <p>Decision Criteria do need to be periodically evaluated, but PHARMAC has not yet set a timeframe for the next review. The criteria, as part of a review of the Operating Policies and Procedures, were last reviewed in 2005-06.</p>	No change to the PTAC ToR.
2.2.2	<p>There were differing views among submitters about Decision Criterion (i), as follows:</p> <ul style="list-style-type: none"> Amend criterion (i) to "Any other factors that are relevant to the pharmaceutical under consideration and their benefits". 	<p>This current process was not a review of PHARMAC's Decision Criteria.</p> <p>As written in the ToR, PTAC must consider <i>all</i> nine Decision Criteria and must not ignore any criterion, although it may consider that a criterion is not particularly relevant to a given recommendation. PTAC may also use its judgement to weight the Decision Criteria.</p>	<p>Reword paragraph 2.2.3 (changes in italics) as follows:</p> <p>"If PTAC or a PTAC Subcommittee uses criteria other than as set out in (a) – (h) above, the specific criteria <i>and the reasoning for these criteria being used</i> must be recorded in</p>

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	<ul style="list-style-type: none"> Is too broad and completely undermines the committees' entire process as it means PTAC can completely ignore any of the other criteria, and therefore should be removed. 	<p>We consider that if Decision Criterion (i) was used by PTAC, the criteria and reasons should be explained in the Minutes.</p>	<p>its Minutes.”</p>
2.2.4	<p>One submitter supported provisions that PTAC and Subcommittees may consult with such parties as they consider necessary or appropriate but considered that such consultation must be clearly documented in order to ensure that PHARMAC and/or PTAC is not seen to be simply trying to avoid criticism of its decision.</p> <p>One submitter considered that this paragraph provided for PTAC to consult with, and seek evidence or information from, other parties. The submitter considered that, given PTAC has no direct consumer input, this section should explicitly specify that PTAC could seek the views of the Consumer Advisory Committee.</p>	<p>PHARMAC consults with an open mind and values public and expert input into its decisions.</p> <p>The most appropriate source of advice, be it from health professionals or from consumers, depends on the particular Application being assessed.</p>	<p>Add the following to paragraph 2.2.4:</p> <p>“The fact of any such consultation and the parties consulted with will generally be documented in the Minute(s).”</p> <p>Reword paragraph 2.2.4 (changes in italics) as follows:</p> <p>“Subject to the confidentiality provisions in part 7.3 of these Terms of Reference <i>and PHARMAC’s obligations under the Privacy Act 1993 and Health Information Privacy Code 1994</i>, PTAC and its Subcommittees may consult with, and seek evidence or information from, such parties as they consider necessary or appropriate, <i>including relevant medical and consumer groups.</i>”</p>
2.2.4	<p>Many submitters considered that we need to clarify what is meant by “persuasive rather than conclusive evidence” and proposed that</p>	<p>We agree that “persuasive rather than conclusive evidence” is open to interpretation. This paragraph was intended to convey that there are different grades of</p>	<p>Reword paragraph 2.2.5 as follows:</p> <p>“PTAC and PTAC</p>

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	PTAC should be using evidence-based decision-making. Some submitters suggested that PTAC use a scale for ranking evidence.	<p>evidence which may be presented to PHARMAC, PTAC and PTAC Subcommittees, and that PTAC needs to be able to make judgements on the quality and validity of this evidence. Depending on the specific circumstances, a different quality of evidence may be appropriate and this can be weighed up at the time.</p> <p>We note that paragraph 9.3 of the ToR states that “PTAC is to set out the matters and evidence that it has primarily relied on in making a recommendation”.</p>	<p>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.”</p> <p>Reword paragraph 2.2.6 as follows:</p> <p>“PTAC and PTAC Subcommittees may take into account scales for grading evidence.”</p>
n/a	One submitter considered that a separate independent committee of experts should be established to perform cost-utility analyses, rather than PHARMAC staff, and run in parallel with PTAC.	<p>This matter was not part of this review.</p> <p>PHARMAC cost-utility analyses use conventional methodology in common with analyses internationally, and are reviewed by external experts as required. PTAC was one of many national and international experts and bodies that reviewed the policies contained in the Prescription for Pharmacoeconomic Analysis (PFPA)² when it was revised two years ago; analyses by PHARMAC staff conform to these policies.</p> <p>Inputs/assumptions in cost-utility models are frequently informed by PTAC’s previous consideration of Applications. Also, PTAC frequently reviews the inputs/assumptions in cost-utility analysis models.</p>	No change to the PTAC ToR.

² Available at <http://www.pharmac.govt.nz/2007/06/19/PFPAFinal.pdf>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
3.1	One submitter considered that the PHARMAC Board Chair, PTAC Chair and Subcommittee Chairs should have equal rights to attend each committee's meetings.	<p>As proposed in the consultation documents, the PTAC ToR state that:</p> <ul style="list-style-type: none"> • The Board Chair (or delegate) may attend PTAC meetings with the PTAC Chair's permission. • The PTAC Chair (or delegate) may attend Board meetings with the Board Chair's permission. • Subcommittee Chairs are usually PTAC members and are represented at Board meetings by the PTAC Chair. 	No change to the PTAC ToR.
3.1.2	Some submitters considered that for value in ensuring minutes are made available, both a timeframe and requirement (not <i>usually</i>) need to be entrenched into the process to benefit the PHARMAC Board's awareness of PTAC process.	There was an error in the way this paragraph was drafted. PTAC minutes are always provided to the PHARMAC Board. Minutes are usually provided at the next Board meeting but sometimes timing of minute finalisation and Board meetings mean that minutes need to be provided at, not the next, but the following Board meeting.	<p>Reword paragraph 3.1.2 as follows:</p> <p>"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."</p>
3.1.4	Some submitters considered that PHARMAC should not bypass PTAC and seek advice directly from Subcommittees. Submitters considered that if this option was maintained, there should be a clear protocol for when and how PHARMAC may bypass PTAC for advice from Subcommittees or other experts and suggested that if time is of the essence PTAC should meet by teleconference.	<p>Sometimes it is beneficial to PTAC's considerations, and more timely, to seek a Subcommittee view first and provide this to PTAC – it is important to maintain the flexibility to do this. All Subcommittee minutes are always reported back to PTAC for consideration.</p> <p>PTAC members are busy and it can be difficult to find a teleconference time that is convenient for all (or most) members.</p>	No change to the PTAC ToR.

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3.3.1	<p>One submitter expressed a concern that the PHARMAC Board, PHARMAC Medical Director and staff may be present at PTAC meetings and perception that this will influence the activities of PTAC and its recommendations.</p> <p>One submitter suggested that any involvement of PHARMAC Board/staff in PTAC discussion be at the invitation of the PTAC Chair.</p>	<p>PTAC is an advisory committee to PHARMAC and it is very helpful for PHARMAC staff to hear PTAC discussions. PHARMAC staff attendance helps to ensure that all questions are addressed by PTAC, that staff have understood PTAC's discussions and recommendations and for staff to answer any questions PTAC may have. In practice, PHARMAC staff speak with the permission of the PTAC Chair.</p> <p>PHARMAC Board members require the permission of the PTAC Chair to attend PTAC meetings.</p> <p>It is common practice for members of an organisation to attend meetings of its advisory committee(s).</p>	<p>Reword paragraph 3.3.2 as follows:</p> <p>“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.”</p>
3.3.4 – 3.3.10	<p>One submitter considered that the PTAC Secretary should be jointly employed by Ministry of Health and PHARMAC and therefore the role would be as official and impartial minute recorder.</p> <p>The submitter also considered that the PTAC Secretary should draft minutes and not PHARMAC supply side staff.</p>	<p>PTAC is an advisory committee of PHARMAC and therefore we consider that it is appropriate for the PTAC secretary to be a PHARMAC staff member. We note that the MAAC Secretary and MARC Secretary are Medsafe staff members.</p> <p>Minute-taking and drafting in this setting is complex. In most circumstances, Funding and Procurement staff are in the best position to understand committee discussions and initially draft the minute given their role is focussed on understanding the details of a funding Application and issues relevant to its consideration. Minutes are scrutinised, amended and approved by the committee, which ensures that the minutes are a true record of the committee's discussion and recommendations.</p>	<p>No change to the PTAC ToR.</p>
3.3.7	<p>One submitter considered that the PTAC Chair should set meeting agendas in consultation with PHARMAC staff to be consistent with 6.1.1 and that this should be the same for</p>	<p>As PHARMAC is seeking advice from PTAC, it is appropriate that PHARMAC has the ability to set PTAC's agenda. In practice, this is a collaborative process involving the PTAC Chair and PHARMAC staff (usually</p>	<p>Reword paragraph 6.1.1 to reflect that the PTAC Chair, PHARMAC Medical Director and PTAC Secretary all have roles in setting</p>

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	Subcommittees.	PHARMAC's Medical Director and PTAC Secretary). PHARMAC is always interested in what the PTAC Chair considers should be on the agenda and seeks to accommodate these views as far as possible. If the PTAC Chair, or PTAC, had any concerns about agenda setting, these concerns could be raised with the PHARMAC Board. In practice, PHARMAC considers the agenda setting process works very well, and is not aware of any concerns held by PTAC about what is and is not on each agenda.	the agenda, as follows: "consulting with PHARMAC's Medical Director and the PTAC Secretary to set the agenda for PTAC meetings"
n/a	One submitter considered that the PHARMAC Board should only make decisions contrary to PTAC's advice for specified reasons that do not compromise clinical advice.	<p>As this question relates to PHARMAC's decision making and not PTAC's advice, it is outside the scope of this review and was therefore not part of this process.</p> <p>It is unusual for the PHARMAC Board to make a decision against a PTAC recommendation, although this is possible given PTAC's advice is only recommendatory in nature, and "PHARMAC is not bound to accept PTAC's advice or follow its recommendations" (paragraph 3.1.1). The PHARMAC Board may attach a different listing priority or may make a decision that differs from PTAC's recommendations. Any Board decision may also take into account information that was not available at the time PTAC considered the Application.</p> <p>The PTAC Chair attends Board meetings, as does PHARMAC's Medical Director, and can provide any further comment or clarification on PTAC minutes as required by the Board.</p> <p>The Board receives PTAC minutes for consideration.</p>	No change to the PTAC ToR.
n/a	Some submitters considered that fairness in geographical representation of PTAC	PTAC members are appointed for their expertise and are not representatives of any specialty or geographical	No change to the PTAC ToR.

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	membership is important.	<p>region. However, PHARMAC and the Ministry of Health endeavour to maintain a PTAC membership that reflects a wide range of perspectives.</p> <p>PTAC currently has one member who resides and works in Australia and this perspective is valuable.</p>	Will refer this feedback for consideration in the review of the PTAC Appointment Protocol.
4.1	One submitter appreciated the addition of a psychiatrist to PTAC and was keen that this be continued.	It is valuable to have members from a range of disciplines but PTAC membership is not intended to be representative. It is members' critical appraisal skills and broad knowledge of medicine that are key to PTAC.	No change to the PTAC ToR.
4.1	<p>Some submitters considered that the appointment of PTAC members should be independent of PHARMAC and in particular its supply side.</p> <p>One submitter considered that the PTAC appointments should be made by Director-General of Health in consultation with Ministry of Health and the PHARMAC Board.</p> <p>One submitter suggested that a panel of independent people appoint PTAC members rather than the Director-General of Health in consultation with PHARMAC.</p>	<p>This matter is outside the scope of this review and was therefore not part of this process.</p> <p>Separate to this process, the Ministry of Health has been reviewing the PTAC Appointment Protocol and we expect a new Protocol to be available in late 2008.</p> <p>The NZPHD Act (2000) states that PTAC members are to be appointed by the Director-General of Health in consultation with the PHARMAC Board.</p>	No change to the PTAC ToR.
4.1	One submitter considered that the maximum term of appointment for PTAC members should be three years.	<p>This matter is outside the scope of this review and was therefore not part of this process.</p> <p>As noted above, the Ministry of Health has been reviewing the PTAC Appointment Protocol.</p> <p>PHARMAC considers that it is valuable to maintain a balance between new membership and the knowledge</p>	<p>No change to the PTAC ToR.</p> <p>Will refer this feedback for consideration in the review of the PTAC Appointment Protocol.</p>

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		and experience of current members who stay on PTAC.	
4.1	One submitter considered that the PTAC Chair should have a finite term of 3 years and that it should be clear how the position of PTAC Chair is selected. The submitter proposed Ministry of Health and PHARMAC Board (not staff) in consultation select the Chair.	<p>This matter is outside the scope of this review.</p> <p>As noted above, the Ministry of Health has been reviewing the PTAC Appointment Protocol.</p> <p>As with the appointment of all PTAC members, the PTAC Chair and Deputy Chair are appointed by the Director-General of Health in consultation with the PHARMAC Board.</p>	<p>No change to the PTAC ToR.</p> <p>Will refer this feedback for consideration in the review of the PTAC Appointment Protocol.</p>
4.1.3	<p>Many submitters expressed support for widening membership to other professionals with suitable expertise.</p> <p>One submitter was concerned about the definition of “senior health practitioner” and whether this could include an epidemiologist.</p>	<p>It is valuable to have members from a range of disciplines and perspectives although it is members’ critical appraisal skills and broad knowledge of medicine that are key to PTAC.</p> <p>As proposed in the consultation document, the PTAC ToR state that “in general, PTAC comprises senior health practitioners from multiple specialties...” but that overall membership “will be weighted towards practising clinicians”.</p> <p>PHARMAC considers that senior clinicians, nurses, pharmacists and other health professionals would be eligible if they have expertise in critical appraisal as well as broad experiences and knowledge of pharmaceuticals and their therapeutic indications.</p>	No change to the PTAC ToR.
4.2	One submitter considered that the RNZCGP should have a representative on each PTAC Subcommittee, appointed by the College, and that a pharmacologist should be on each Subcommittee.	Subcommittee members are appointed by the PHARMAC Board (in line with the Crown Entities Act) and are not representatives of any professional group. Nominations are sought from relevant professional groups; however, Members are appointed as independent experts for their expertise in a particular	No change to the PTAC ToR.

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		<p>discipline and their critical appraisal skills.</p> <p>A general practitioner and pharmacologist are, with the appropriate skills and competencies, likely to be valuable members of most subcommittees.</p> <p>Currently, a general practitioner is appointed to most Subcommittees and all Subcommittee advice is considered by PTAC which currently includes two general practitioners and two clinical pharmacologists.</p>	
4.1 & 4.3	<p>One submitter considered that a community member/consumer should sit on PHARMAC Board, PTAC and Subcommittees.</p> <p>Another submitter considered that a consumer representative was not required on PTAC <u>at this time</u> but considered that wording in ToR should allow for this.</p>	<p>Appointments to the PHARMAC Board are outside the scope of this review. As noted above, the Ministry of Health has been reviewing the PTAC Appointment Protocol.</p> <p>PTAC and PTAC Subcommittee members are appointed as independent experts, for their expertise in a particular discipline and their critical appraisal skills.</p> <p>More generally, the most appropriate source of consumer advice depends on the particular Application being assessed and Applications for funding and correspondence to PTAC may be provided by patient and consumer groups.</p> <p>There is ongoing work to seek early feedback from consumers on funding Applications. Consumers and consumer groups also make submissions on proposed PHARMAC decisions, and these responses are considered by the PHARMAC Board.</p>	No change to the PTAC ToR.
4.3	One submitter considered that revised provisions seemed to allow a reduction in Subcommittee size from 5 to 3 members. The	The revised ToR were not intended to reduce the size of Subcommittees. We consider that Subcommittees should have at least 4 members and that the quorum	Reword paragraph 4.3.1 – 4.3.2 as follows:

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	<p>submitter questioned whether this was intentional, and if so, was it appropriate?</p> <p>One submitter considered that the Chair of a Subcommittee should be a non-PTAC member.</p> <p>One submitter considered that it was important to have a PTAC member on every Subcommittee for reporting back to PTAC, but considered that the PTAC member did not need to be the Chair.</p>	<p>should remain at 3 members (including 2 non-PTAC members and one PTAC member).</p> <p>The PTAC member is usually the Chair of the Subcommittee for reporting back to PTAC.</p> <p>A Deputy Chair will be appointed and be responsible for acting as Chair when the Chair is unavailable and will consider any interests declared by the Chair (under section 7.2)</p>	<p>“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.”</p> <p>“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.”</p> <p>The Subcommittee Chair and Deputy Chair will be appointed by the PHARMAC Board (paragraph 4.2.1).</p> <p>Reword paragraph 8.4.1 as follows:</p> <p>“The quorum for PTAC 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 PTAC Subcommittee).“</p>
n/a	One submitter considered that PHARMAC should widen the pool of experts that it seeks	PHARMAC is using ad-hoc subcommittees more often for seeking advice from experts for an individual	No change to the PTAC ToR.

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	<p>advice from, to bring new and relevant expertise to bear on each Application.</p> <p>Some submitters suggested that at least one or two relevant specialists be invited to attend PTAC meetings and discuss matters arising within the funding Applications. The submitters considered that this would reduce wait time (due to time between Subcommittee meetings) and avoid the need to maintain a variety of Subcommittees.</p>	<p>Application, particularly within a narrow discipline. In addition, PHARMAC and PTAC can seek expert comment, and do consider correspondence from experts who are aware that an Application has been made. Individual clinicians, medical groups and consumer groups may make Applications for funding.</p> <p>The observers section allows relevant specialists to be invited to attend PTAC; however, we consider this should not be common practice or required given the methods of accessing such information described above. Inviting different experts to each PTAC meeting would be difficult for practical reasons.</p> <p>It is PHARMAC's role to maintain subcommittees, rather than PTAC's role, as subcommittees are committees of PHARMAC appointed by the PHARMAC Board.</p>	
5.1.1	One submitter considered that the remuneration of PTAC and Subcommittee members should be available under OIA by request.	<p>The hourly rate for PTAC and Subcommittee members is available on the PHARMAC website in the PTAC position description.</p> <p>The total annual remuneration paid to each committee member is listed in PHARMAC's Annual Report.</p>	No change to the PTAC ToR.
5.1.4	One submitter queried whether Subcommittee members are eligible for a conference allowance.	<p>A conference and travel allowance for professional development has been introduced for PTAC members. The decision to introduce this allowance stemmed from the risk of PTAC members foregoing other opportunities for professional development and PHARMAC's reliance on PTAC remaining up-to-date across a broad range of therapeutic areas.</p> <p>Subcommittee members more commonly accept alternative funding for training and conferences and any such conflicts are disclosed and managed (including</p>	<p>Reword paragraph 5.1.4 (changes in italics) as follows:</p> <p>"PTAC Members are entitled to a Conference and Travel Allowance for professional development. <i>This entitlement does not apply to Subcommittee Members.</i>"</p>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
		through review of subcommittee advice by PTAC).	
5.1.4	One submitter considered that PHARMAC should provide training in epidemiology and ethics for PTAC members.	<p>All PTAC members are skilled in critical appraisal and some members have post-graduate qualifications in epidemiology.</p> <p>Many of the relevant professional organisations and registering bodies have codes of conduct, including guidance on ethics. In addition, ethics is generally part of any medical or health related qualification.</p> <p>PHARMAC supports training, in whatever areas are considered relevant for PTAC members.</p>	No change to the PTAC ToR.
7.1.1	Some submitters considered that the responsibilities of members should include reviewing the material provided related to the Application or issue under consideration.	We agree that all committee members should be responsible for reviewing material provided to them related to an Application or issue under consideration. It was an oversight that this was not included in the draft ToR document.	<p>Add the following to paragraph 7.1.1:</p> <p>“reviewing all material provided relating to items on meeting agendas”</p>
7.2	<p>Some submitters supported strengthening conflicts of interest processes.</p> <p>One submitter considered that this section should reference the Crown Entities Act (2004) and that Members should be required to avoid conflicts in accordance with the Act. In addition, the submitter considered that if the Chair considers that a member should continue to act “in the public interest” this should be clearly recorded in the minutes.</p>	The revised PTAC ToR require that PTAC and Subcommittee members comply with the Crown Entities Act (2004). The relevant sections of the Act are included in Appendix 3 of the PTAC ToR.	<p>Section 7.2 states that:</p> <p>“Members are to avoid, to the greatest extent possible, any conflict with the performance of their duties and obligations as Members.”</p> <p>Please see PTAC ToR for further requirements around conflicts of interest.</p>
7.3.3	One submitter considered that 7.3.3 should	The ToR indicate that confidentiality agreements apply	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
& 7.3.4	allow members to disclose any other agenda items and not just Applications listed on the PHARMAC website.	except where items are on PHARMAC's website. PHARMAC only lists Applications received on the website. Other agenda items may need to be kept confidential, usually for commercial reasons.	
7.4 (& 6.1.1)	<p>Some submitters noted that the PTAC Chair and members require permission of PHARMAC staff to the act of representation and speaking to media. The submitter considered that this could be perceived as PHARMAC "gagging" PTAC members and therefore members not able to provide free and frank advice.</p> <p>One submitter considered that PTAC should undertake these activities "after consultation with the PHARMAC Medical Director" as opposed to needing consent. The submitter also considered that this paragraph should specify the PHARMAC Medical Director rather than broad term of PHARMAC staff.</p>	<p>A perception of "gagging" is possible unfortunately, but not correct. PTAC Minutes are available on the PHARMAC website. These minutes are PTAC's free and frank advice which is unfettered by PHARMAC. Subcommittee minutes will also be published on the PHARMAC website in line with the ToR.</p> <p>PHARMAC makes funding decisions, taking into account PTAC's advice. It is therefore appropriate that PHARMAC speak to those decisions, with PTAC and Subcommittee advice to PHARMAC also publicly available.</p>	<p>Add the following to paragraph 7.4.1:</p> <p>"... if they have the prior agreement of the PTAC Chair and the PHARMAC Chief Executive (which will be communicated by the Medical Director)."</p>
8.1.2	One submitter considered that the frequency of PTAC meetings and timing for notification of	PTAC meets four times per year and the sector is notified of PTAC meeting dates and deadlines in late	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	dates/deadlines is appropriate.	September/early October of the preceding year.	
8.1.4	One submitter considered that the reference to an “alternate member” in ToR is inconsistent with the PTAC Appointment Protocol. The submitter also queried why this provision is necessary and when it might be used.	<p>The ToR specifies that any temporary appointments should be made in accordance with the Appointment Protocol.</p> <p>As an example, this provision may be required when a current member has serious injury or illness, or goes on sabbatical, and this prevents them from attending PTAC for a period of time. It may be necessary for this member to be covered by a temporary member to ensure that the workload remains manageable for other PTAC Members.</p>	Ensure that the language is consistent between revised PTAC Appointment Protocol and ToR around temporary PTAC members.
8.4.1	<p>One submitter commented on the frequency of Subcommittee meetings and recommended the following:</p> <ul style="list-style-type: none"> • Specify a minimum frequency of Subcommittee meetings if there is at least one item to be considered. • A Subcommittee should meet within 3 months of an agenda item being referred to it. • Supplier should receive adequate notice of Subcommittee meeting dates and be invited to submit further information. This process is likely to help ensure that there is sufficient agenda material for a regular meeting of each Subcommittee. <p>One submitter considered that PHARMAC</p>	<p>PHARMAC is always interested in getting matters on agendas as soon as possible, limited only by competing priorities for those agendas and practical constraints.</p> <p>Subcommittee meetings are generally held on an “as required” basis. PTAC may decide whether or not it wants further advice from a Subcommittee – this is not mandatory.</p>	<p>Add the following to paragraph 8.4.2:</p> <p>“PHARMAC staff will endeavour to organise a PTAC Subcommittee meeting as soon as possible after PTAC referring an Application to a PTAC Subcommittee for rapid review, subject to Member’s availability and other factors (see section 9.3). At other times PTAC Subcommittees will meet as required.”</p>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	should establish a clear and regular schedule of Subcommittee meetings.		
8.5	<p>One submitter considered that <i>all</i> observers should sign a confidentiality agreement.</p> <p>Submitters expressed a range of views on who should be able to observe, as follows:</p> <ul style="list-style-type: none"> • No RMI or industry representatives. • General concern about who might observe. • Applicants should be able to attend for discussion of their Applications. • Develop a policy that outlines processes around who might observe, granting of speaking rights and participation in meetings. • Permission to attend as observer should be granted by MOH, and not PHARMAC staff. 	<p>In practice, all observers do sign a confidentiality agreement and this will continue. Any observers at PTAC or Subcommittee meetings are also noted in the Minutes.</p> <p>There are a wide range of opinions about who may or may not observe a PTAC meeting.</p> <p>PHARMAC considers that it is optimal to keep the wording in the ToR general so any interested party may attend at the discretion of the PTAC Chair and PHARMAC’s Medical Director. In making these judgements, a principled approach would be required in order to be robust and fair to all parties.</p> <p>The matter of whether PHARMAC staff should attend PTAC meetings has been addressed above (paragraph 3.3.1).</p> <p>Applicants are now invited to meet with PHARMAC to discuss Applications when they are submitted.</p> <p>With respect to attendance of Applicants (particularly pharmaceutical suppliers) at PTAC meetings, PTAC itself noted in its submission on the development of a medicines strategy:</p> <p>“This raises the obvious issue of what other parties should be permitted to attend or present. ... we question what can be said by suppliers at a meeting, necessarily</p>	<p>Reword paragraph 8.5.2 as follows:</p> <p>“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.”</p>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
		time-limited, that cannot be communicated succinctly and cogently in a formal written submission – as is meant to occur now. Further, evidence that is robust – the fundamental focus of PTAC – invariably needs to be communicated in written form to be completely and appropriately documented with all relevant information, so that PTAC can critically examine this evidence with due consideration and sufficient time.”	
8.5.1	One submitter considered that the observers section should be reworded so that observers can attend PTAC “at the discretion of the PTAC Chair <i>who may consult with PHARMAC’s Medical Director...</i> ” and not, as it states currently “at the discretion of PHARMAC’s Medical Director”.	Observers can attend PTAC meetings at the discretion of both the PTAC Chair and the PHARMAC Medical Director. As a committee advising PHARMAC, it is appropriate that PHARMAC have a role in determining who may observe meetings.	No change to the PTAC ToR.
9.1.2	One submitter considered that paragraph 9.1.2 should be amended so that Applications seeking funding should ideally have gained registration and all consents for marketing <u>or registration should be imminent</u> , i.e. expected within the next 3 month time period (being the timeframe before the next PTAC deadline).	PHARMAC accepts Applications where registration is imminent (i.e. expected within the next 3 month time period) but Applications will generally not be considered by PTAC until the product has been registered by Medsafe. It can however be difficult to estimate when registration might be imminent. Sometimes applicants are expecting registration to be completed within a month but it takes 6-12 months to come through. Funding registered indications is PHARMAC’s preference, but it is not a definitive policy position. There may be situations where, for good reason, PHARMAC considers funding something pre-registration or even funds something that is not registered.	No change to the PTAC ToR.
9.2	One submitter considered that increased transparency was needed around the rules applying to the order in which PTAC Applications are assessed because the ToR give PHARMAC staff considerable power in	Applications are made to PHARMAC and deciding whether Applications will go to PTAC or Subcommittee first is the responsibility of the PHARMAC Medical Director in consultation with the PTAC Chair.	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	<p>determining whether an Application is first reviewed by PTAC or a Subcommittee. The submitter considered that PHARMAC staff seem to use this to stall Applications.</p>	<p>PHARMAC recognises the possible perception that PHARMAC staff could stall Applications. However, PHARMAC always has an interest in funding medicines as quickly as possible (and therefore getting the requisite advice in a timely way). Setting rules would reduce PHARMAC's appropriate discretion to prioritise consideration and progression of Applications that, if funded, would achieve the best health outcomes.</p> <p>If an Application is considered by PTAC first, the revised ToR will have a mechanism for PTAC to recommend that an Application undergo "rapid review" by a Subcommittee. In addition, all PTAC minutes are provided to the relevant Subcommittee for Members' information.</p> <p>If an Application is considered by a Subcommittee first, the Subcommittee minute will be provided to PTAC for comment.</p>	
9.2.2	<p>One submitter agreed with the process requirement that PHARMAC <u>must</u> consider consulting and PTAC <u>may</u> consult.</p>	<p>This comment has been noted.</p>	<p>No change to the PTAC ToR.</p>
9.2.2	<p>Some submitters queried what criteria would be used to precipitate consultation with "interested parties"? The submitters considered that PTAC needs to record reasons for consulting to ensure that there is consistency and accountability for when this action is used/not used.</p> <p>One submitter considered that the PTAC Chair should decide whether to invite relevant interested parties to comment and the ToR</p>	<p>It is difficult to make rules about when to consult or seek additional comments/advice that would be relevant and appropriate for all situations. It is also not clear that rules, as opposed to applying judgement, have any benefits. Seeking information is a judgement by PTAC that can be recorded in the minutes. However, there may be good reason, such as protecting the privacy of an individual or of specific information, for not recording such activity in the minutes. That said, a more general description could be recorded.</p>	<p>Add the following to paragraph 9.2.2 (c):</p> <p>"The parties invited to comment and the reasons for selecting these parties will generally be documented in the Minutes."</p>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	should clarify whether this includes members of the public.	PHARMAC staff are undertaking further work to examine options for further stakeholder input (including by members of the public) into the funding process.	
9.2.2	<p>One submitter made the following comments:</p> <ul style="list-style-type: none"> • ...believe that Applications relating to a therapeutic area for which a Subcommittee exists should be considered by the Subcommittee in the first instance. • If this was the case, then PHARMAC should have the right to act directly on that advice without seeking further advice from PTAC (3.1.4). • PHARMAC should be clear about whether/when PTAC would subsequently consider the full Application and/or the Subcommittees' minutes. • ...do not believe that clause 3.2.1 of the guidelines should be in place without the above additional guidelines as it could potentially result in specialist advice not being sought where an Application is first considered by PTAC. However, 3.2.1 is necessary to ensure that PTAC can seek specialist advice when considering Applications relating to a therapeutic area for which no Subcommittee exists. 	<p>It is a matter of judgement, including a consideration of meeting scheduling and agenda priorities, as to whether an Application is first considered by a subcommittee or PTAC or PTAC only. PTAC will usually be provided with copies of Applications when Applications have been sent to a Subcommittee first.</p> <p>All Subcommittee minutes are provided to PTAC for comments (paragraph 3.2.1). Subcommittees provide advice and recommend priorities within their therapeutic group whereas PTAC provides advice that takes into account funding Applications across therapeutic groups and is therefore able to weigh up the relative merit of one Application against others.</p> <p>PTAC minutes are always provided to Subcommittees (paragraph 3.2.3). Copies of entire Applications are provided to Subcommittees when PTAC is seeking advice.</p>	No change to the PTAC ToR.
9.3	One submitter considered that PTAC minutes	PTAC is required to consider all information provided to it. The ToR continue to state that: "PTAC is to set out the	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	should list the evidence that was reviewed.	<p>matters and evidence that it has primarily relied on in making a recommendation”.</p> <p>Complete lists of all evidence considered could be very long (several pages per Application) and require compilation depending on how much evidence was listed by the Applicant and how much sourced by PHARMAC.</p> <p>If there is particular interest in a decision and the evidence that was relied on, PHARMAC could be approached for detail of the information that was considered.</p>	This consultation response will be fed into the review of the Guidelines for Funding Applications.
9.3.2	One submitter considered that Decision Criteria of particular relevance to recommendation should continue to be listed in the minutes but they should also explain why a criterion is particularly relevant.	<p>We consider that PTAC’s discussion of information and advice relating to each particularly relevant Decision Criterion is already detailed in the body of the committee minutes. PTAC’s discussions are technical and complex and a simplified summary risks omitting important information and, in practical effect, being seen to rewrite the minute which would not be appropriate.</p> <p>We will ensure that the minutes are drafted so that it is more explicit which Decision Criterion is being discussed in PTAC’s consideration of an Application.</p>	No change to the PTAC ToR.
9.3.3 (& 6.1.1)	One submitter noted that the Chair can cast a deciding vote in the event of a tied vote and considered that the Chair should be given power to cast a deciding vote without being compelled to.	A casting vote from a Chair is widely used in decision making contexts as a means of reaching a majority view. In practice, a casting vote is very rarely used, but it is important that the ability to use it exists as a means of forming a PTAC view which is what the PHARMAC Board requires.	No change to the PTAC ToR.
3.3 & 9.4	One submitter considered that the timing of meetings, secretarial functions and the promulgation of minutes for both PTAC and Subcommittees should be independent of	This matter has been discussed above (Comments relating to section 3.3).	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	PHARMAC's supply side.		
10.1.1	<p>Some submitters expressed support for the proposal to publish the recommendation where PTAC has deferred making a final recommendation to approve/decline (for example, pending further information or review by a Subcommittee).</p> <p>One submitter would like applicants to have the right to respond to <i>draft</i> minutes prior to publication on the PHARMAC website similar to the Australian Pharmaceutical Benefits Advisory Committee (PBAC) process.</p>	<p>Minutes are a record of the PTAC discussion which could not be edited for accuracy by Applicants who had not attended the meeting. However, Applicants have the opportunity to request that parts of the minute be withheld from publication in accordance with section 9 of the OIA.</p> <p>Applicants can also respond to PTAC comments in the minutes by writing to PTAC and/or PHARMAC and by providing further information for PTAC's consideration.</p>	No change to the PTAC ToR.
10.1	<p>Submitters expressed a range of views on the publication of minutes, as follows.</p> <ul style="list-style-type: none"> • Not happening in a timely manner • Improvement in time taken to publish and is now good <p>One submitter considered that the names of observers and attendees at a PTAC or PTAC Subcommittee meeting should be published.</p> <p>One submitter considered that a more simplified summary of meeting minutes should be provided for consumers and health professionals.</p>	<p>PTAC minutes are generally published on PHARMAC's website within 3 months of the meeting, and within 4 weeks of finalisation (during which time applicants have 2 weeks to request that any part of the minute be withheld in accordance with the OIA).</p> <p>Unless there is good reason to the contrary, the names of all observers and attendees at PTAC and Subcommittee meetings are noted in the published minutes.</p> <p>PTAC's discussions are technical and complex and a simplified summary risks omitting important information and, in practical effect, being seen to rewrite the minute which would not be appropriate. However, PHARMAC staff are reviewing how PTAC minutes are published on the website and whether they can be written or presented in a more reader-friendly way.</p>	<p>Add the following to paragraph 8.5.2:</p> <p>“The attendance of an observer at a meeting will be documented in the Minutes.”</p> <p>Add the following to paragraph 10.1.3:</p> <p>“The names of all observers and attendees at a meeting will also be published.”</p>
10.1.2	One submitter considered that paragraph 10.15 of the 2002 PTAC Guidelines, which	PHARMAC will begin publishing Subcommittee minutes for meetings since 1 July 2008 on the PHARMAC	Add the following to paragraph

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	obligates PHARMAC to publish the minutes of Subcommittee minutes, should be reinstated in ToR (para 9.4.3) .	<p>website once the minutes have been reviewed by PTAC. Minutes of earlier meetings may be requested.</p> <p>PHARMAC is examining options for improving the navigation and linking of information relating to an Application on the PHARMAC website.</p>	<p>10.1.2:</p> <p>“Once the Minute of a Subcommittee meeting has been reviewed by PTAC, it will be published on the PHARMAC website, subject to paragraphs 10.1.3 and 10.1.4.”</p>
n/a	One submitter considered that the PTAC briefing paper prepared by PHARMAC staff should at least be available to the applicant and ideally the applicant should get the opportunity to provide feedback before the paper is sent to PTAC.	<p>Applicants have an opportunity to provide any written information on their Application, which is provided to PTAC in full. Applicants also have an opportunity to present to PHARMAC staff prior to the PTAC meeting.</p> <p>Applicant feedback on the PTAC briefing paper would delay Applications being considered by PTAC. Applicant material is provided to PTAC and PTAC Subcommittees unchanged by PHARMAC and it is appropriate that PHARMAC provide a briefing paper with questions for the committee and any additional information that PHARMAC would like the committee to consider when making its recommendation(s).</p>	No change to the PTAC ToR.
n/a	One submitter considered that DHBs need early engagement with PHARMAC as part of the evaluation and planning process for any drug, particularly for comment regarding operational and service capability.	This is outside the scope of this review. PHARMAC staff are currently undertaking work to seek comments from interested parties earlier in the Application assessment process, including DHBs, which may address this issue.	No change to the PTAC ToR.
n/a	One submitter noted that the ToR now make no reference to how long PTAC members will have to review Applications. The submitter was concerned that this could be reduced from the 3 weeks in the current Guidelines.	<p>PTAC members generally get four weeks to review material for consideration at a meeting.</p> <p>Subcommittees generally get 2-3 weeks depending on the size of the agenda and the amount of reading. Flexibility is important to deal with different</p>	Update paragraph 3.3.8 of the ToR to state that the agenda and related papers will be sent to Members of PTAC <i>generally four weeks</i> before the relevant meeting.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
		circumstances.	
n/a	Some submitters considered that there needs to be a process for seeking a review of PTAC's decisions or recommendation.	<p>PTAC is an advisory committee making recommendations to PHARMAC, but not decisions. It is not appropriate to have an appeals process related to advice. If any party does not agree with the contents of the PTAC minutes, these concerns may be raised with PHARMAC or by submitting a reapplication.</p> <p>We will ensure that the process for reapplications or providing further information is detailed more clearly in the revised Guidelines for Funding Applications which are likely to be consulted on in early 2009.</p> <p>Applicants and other interested parties are always welcome to write to PHARMAC and/or PTAC with any concerns about a recommendation and provide supporting rationale and evidence.</p>	<p>Add the following to paragraph 9.2.3:</p> <p>“PTAC may consider any correspondence, new information or reapplications that are provided by Applicants.”</p> <p>Will also feed this comment into the review of the Guidelines for Funding Applications.</p>
	Many submitters expressed general support for the proposed changes.	PHARMAC expects the revised PTAC ToR to increase transparency and understanding of PTAC and Subcommittee operations and, in so doing, build additional confidence in PTAC's recommendations and PHARMAC's decisions.	
	One submitter noted that while they had not commented specifically on all the proposed changes, they were concerned that, overall, there appears to be a dilution of the meaning and intention of the guidelines.	The intention of this review was to ensure that the PTAC ToR support PTAC and PTAC Subcommittees in providing free and frank, objective advice to the PHARMAC Board. In other words it was to ensure, if anything, that the guidelines were more meaningful and purposeful in terms of describing PTAC's role.	Proposed changes to the ToR are detailed above.
	One submitter questioned why PTAC appeared to have lost its link (ie exchange of minutes) with MARC.	The link with MARC has been maintained and PTAC minutes continue to be provided to MARC. This paragraph was removed from document as it is not relevant to the PTAC's ToR but it is documented in the	No change to the PTAC ToR.

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
		PTAC Administration Manual for PHARMAC staff.	
	<p>One submitter considered that the key changes needed to achieve an improved model involve:</p> <ul style="list-style-type: none"> • Separate cost effectiveness decisions from funding decisions • Separate medical and scientific decision from funding and procurement decisions • Create reliable metrics and reporting requirements • Improve decision-making processes 	<p>These changes – particularly the first two – were considered as part of the Medicines Strategy review and the Ministry of Health was satisfied that such changes were not desirable. PHARMAC agrees that such changes are not desirable and reconsideration of the matters was not part of this review. With respect to metrics or, more broadly, performance measures, PHARMAC will seek to continue to improve such measures over time. Simple metrics are often suggested but often not meaningful. PHARMAC is always open to improving decision-making processes, and considers that a number of the changes through this process will build additional confidence in PHARMAC’s decisions.</p>	<p>Proposed changes to the ToR are detailed above.</p>
	<p>One submitter welcomed ongoing evaluation of whether the amendments to the existing guidelines were successful in improving transparency and understanding of PHARMAC’s processes.</p>	<p>PHARMAC agrees that evaluation is important. It may be difficult to isolate the effects of any particular change, but future reviews of the ToR, and wider scrutiny of PHARMAC’s performance, will be instructive as to whether changes being made through this process have generated benefits.</p>	
	<p>One submitter questioned why particular products with high priority recommendations from PTAC are not listed at this time.</p>	<p>The PHARMAC Board may attach a different listing priority or may make a decision that differs from PTAC’s recommendations, including taking account of information not available at the time PTAC considered the Application. There are a number of factors involved in PHARMAC’s decisions to fund products, including budget availability and negotiating contracts with suppliers.</p>	<p>No change to the PTAC ToR.</p>

REF.	SUBMISSION COMMENT	PHARMAC RESPONSE	ACTION (with respect to <i>draft</i> ToR)
	One submitter recommended that for each funding Application there is a timeline on the PHARMAC website that can be viewed to ascertain where each Application is at in the process.	This suggestion is not related to this review process. PHARMAC is reviewing the provision of information on its website as part of the medicine strategy work.	No change to the PTAC ToR.
	One submitter noted that while there was some support for limiting access to some pharmaceuticals, it was considered by some that there was perhaps some overuse of the Special Authority process and that this needed to be reconsidered.	This matter is not related to this review process. PHARMAC carefully considers the application of access restrictions and use of Special Authorities – both when they are set and over time as additional information becomes available.	No change to the PTAC ToR.