

GUIDELINES
FOR THE
PHARMACOLOGY AND THERAPEUTICS
ADVISORY COMMITTEE (PTAC)
AND ITS SUB-COMMITTEES

2002

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GLOSSARY

The following words are used in the Guidelines and have the following meanings.

“Act” means the New Zealand Public Health and Disability Act 2000 and includes any regulations, amendments, re-enactments and replacements.

“Chairperson” means the Chairperson of PTAC (see section 15).

“Deputy Chairperson” means the Deputy Chairperson of PTAC (see section 5.2).

“Director-General” means the chief executive or acting chief executive of the Ministry of Health.

“Guidelines” means the Guidelines for PTAC.

“MARC” means the Medicines Adverse Reactions Committee.

“Medsafe” means the New Zealand Medicines and Medical Devices Safety Authority.

“Member”, “Members” or “PTAC Member” means a member of PTAC.

“Minute” means that part of the record of a PTAC or Sub-committee meeting (including meetings by teleconference and recommendations made by other means of communication) that contains a recommendation to accept or decline an application for a new investment or a clinical proposal to widen access and related discussion.

“PHARMAC” means the Pharmaceutical Management Agency.

“pharmaceutical(s)” means a medicine, therapeutic medical device or related product or related thing.

“Pharmaceutical Schedule” means the list of pharmaceuticals for the time being in force that states, in respect of each pharmaceutical, the subsidy that the Crown intends to provide for the supply of that pharmaceutical to a person who is eligible for the subsidy.

“PTAC” means the Pharmacology and Therapeutics Advisory Committee.

“PTAC Secretary” means the secretary of PTAC (see section 9).

“Sub-committee(s)” means a sub-committee of PTAC (see section 10).

“supplier” means the supplier of a pharmaceutical, usually a pharmaceutical company.

1. Primary Purpose

PTAC is a committee of vocationally registered medical practitioners with expertise in clinical pharmacology, internal medicine and general practice. The primary purpose of PTAC is to provide PHARMAC with objective advice on pharmaceuticals and their benefits (see section 50(1)(a) of the Act).

2. Functions

2.1 To perform its primary purpose, PTAC is to:

- (a) consider and make recommendations to PHARMAC on applications for the listing, de-listing, restricting and de-restricting of pharmaceuticals on the Pharmaceutical Schedule which have been referred to it by PHARMAC;
- (b) when requested by PHARMAC, consider and make recommendations to PHARMAC on proposals for defining, removing or amending a therapeutic group or sub-group of pharmaceuticals on the Pharmaceutical Schedule;
- (c) review, monitor and, from time to time, make recommendations to PHARMAC in relation to the management of the Pharmaceutical Schedule;
- (d) subject to the prior agreement of PHARMAC, initiate its own reviews of any policy adopted by PHARMAC in relation to the management of the Pharmaceutical Schedule and provide reports or make recommendations to PHARMAC arising from those reviews;
- (e) make recommendations to PHARMAC on the information that should be provided in support of applications for the listing of pharmaceuticals on the Pharmaceutical Schedule;
- (f) consider and report, or make recommendations, to PHARMAC on any other matters that may be referred to it by PHARMAC; and
- (g) give objective expert advice on pharmaceuticals and their benefits.

3. Powers of PTAC

3.1 PTAC is to have all such powers as may be reasonably necessary to enable it to perform its primary purpose including, without limitation, the power to:

- (a) consult with, and seek evidence or information from, such parties as it considers necessary or appropriate (subject to the confidentiality provisions in section 17); and
- (b) request further information or evidence from PHARMAC, or an applicant, or supplier in relation to a particular pharmaceutical, therapeutic group or sub-group or any other matter that has been referred to it for consideration or recommendation.

4. Criteria

- 4.1 In performing its functions and exercising its powers, PTAC is to take into account, where applicable and giving such weight to each criterion as PTAC considers appropriate, the following criteria (considering both the information provided to it and the information it has collated)¹:
- (a) the health needs of all eligible² people within New Zealand;
 - (b) the particular health needs of Maori and Pacific peoples;
 - (c) the availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
 - (d) the clinical benefits and risks of pharmaceuticals;
 - (e) the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
 - (f) the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule;
 - (g) the direct cost to health service users;
 - (h) the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
 - (i) such other criteria as PTAC thinks fit.
- 4.2 In using these criteria, PTAC may obtain such written or oral evidence or information as it considers necessary. PTAC may rely on persuasive rather than conclusive evidence, and may seek evidence or information from different sources to substantiate or refute any claims made in relation to a particular pharmaceutical or in relation to any other matter that it considers appropriate.
- 4.3 PTAC is to make every reasonable endeavour to advise PHARMAC of any "other criteria" that it may have taken into account in terms of paragraph (i) above in making its report or recommendation.

5. Relationship with PHARMAC

- 5.1 PTAC is an expert advisory committee to PHARMAC. It makes recommendations to PHARMAC regarding, in particular, the listing of pharmaceuticals on the Pharmaceutical Schedule. Any recommendation by PTAC, (including any listing priority) may vary ultimately from PHARMAC's view, in part because PTAC reviews Pharmaceutical Schedule applications at a different stage in the assessment process

¹ These criteria correspond with PHARMAC's Operating Policies and Procedures (OPPs) (Second Edition).

² As defined by the Government's then current rules of eligibility.

from PHARMAC. PHARMAC may have a wider range of relevant evidence and/or information before it, for example cost benefit data, when it makes decisions. Consequently, PHARMAC may attach a different listing priority or may make a decision that differs from PTAC's recommendations. PTAC is an advisory committee to PHARMAC whose advice PHARMAC includes in its decision-making process.

- 5.2 The Chairperson or, in his or her absence, the Deputy Chairperson or any other Member appointed by the PHARMAC Board, has the right to attend and participate in all meetings of the Board of PHARMAC while reports or recommendations of PTAC are discussed (but may not vote on any matter at that meeting) and is to report back to PTAC in that regard.
- 5.3 PHARMAC staff are entitled to attend each meeting of PTAC and, in particular, the relevant PHARMAC staff member(s) should be present at the meeting to discuss any topic(s) relevant to the therapeutic group or issue for which he or she is responsible. In general, PHARMAC staff may present information and provide, or seek, clarification of issues discussed as necessary

Similarly, PHARMAC's Board is entitled to be represented at each meeting of PTAC by such persons as the Board may appoint for that purpose. Neither PHARMAC staff nor PHARMAC's Board's representative(s) are, nor are deemed to be, Members. PHARMAC staff and PHARMAC's Board's representative(s) have the right to participate in all discussions at the meeting, but may not vote on any matter at that meeting.

- 5.4 PHARMAC is to indemnify PTAC Members and Sub-committee members against all costs, liabilities, expenses and claims that PTAC or Sub-committee members may incur as a direct or indirect result of advice given in their capacity as independent expert advisers to PHARMAC. This indemnity only applies to circumstances where a PTAC Member or Sub-committee member has acted in good faith and with reasonable care in pursuance of their functions and powers.

6. Process of Appointment

- 6.1 PTAC members are to be appointed by the Director-General in consultation with the Board of PHARMAC (in accordance with the Protocol for the Appointment of Members of the Pharmacology and Therapeutics Advisory Committee).

7. Removal of Members and Resignations

- 7.1 Members may resign at any time by notice in writing to the Director-General and to PHARMAC's Board.
- 7.2 The removal of Members is to be determined by the Director-General in consultation with the Board of PHARMAC.

8. Remuneration

- 8.1 Members are to be paid for their attendance at meetings and any time spent preparing for meetings and for performing any other work as requested by PHARMAC. The Board of PHARMAC will set the level of payment.

9. PTAC Secretary

- 9.1 A PTAC Secretary, who may be a PHARMAC staff member, is to be appointed by PHARMAC to support PTAC and assist the Chairperson in performing his or her role. In particular, PTAC's Secretary is to provide the services necessary for the smooth operation of PTAC including (without limitation):
- (a) determining a programme of meetings;
 - (b) providing a list of suggested agenda items; and
 - (c) ensuring that papers for meetings are sent to Members.
- 9.2 PTAC's Secretary will be responsible for keeping a record of each meeting of PTAC (including by teleconference). The process for finalising the record is to be as follows:
- (a) the record is to be prepared and sent to Members within one week of the meeting;
 - (b) Members are to peruse the record and return comments to PTAC's Secretary within one week of receiving them;
 - (c) PTAC's Secretary will produce a final draft of the record in light of the suggested changes. The final draft will then be sent to Members for review within one week of the PTAC Secretary receiving comments on the first draft. Once any further changes are included in the final draft, the Chairperson will sign the record as finalised;
 - (d) a copy of the signed record should be sent to each Member and will be included for ratification as part of the agenda of the next meeting of PTAC; and
 - (e) a copy of the signed record may also be forwarded to MARC.
- 9.3 The agenda for each meeting is to be set by the Chairperson, in liaison with PHARMAC's Medical Director and the PTAC Secretary. The agreed agenda and related papers are to be sent to Members by PTAC's Secretary, if possible, three weekends before the relevant meeting.
- 9.4 The PTAC Secretary is responsible for managing communications between Members and members of the general public or other interest groups.
- 9.5 In line with standard practice, the PTAC Secretary stands apart from PTAC recommendations and does not have voting rights at any PTAC meeting.

10. Sub-committees

Establishing Sub-Committees

- 10.1 PHARMAC, or the Chairperson in agreement with PHARMAC's Medical Director, may establish Sub-committees.
- 10.2 Sub-committees will generally report directly to PTAC. PTAC will, when it considers it appropriate, seek advice from Sub-committees on specific issues relating to applications to list pharmaceuticals on the Pharmaceutical Schedule. Sub-committees will give a written opinion to PTAC and PTAC will consider this opinion when it reviews a supplier's application at its next meeting.
- 10.3 Occasionally PHARMAC will seek advice directly from Sub-committees where, for example, time is of the essence. In these circumstances PHARMAC may directly rely on the advice of Sub-committees without it being considered by PTAC but shall notify the Chairperson before doing so.
- 10.4 PHARMAC, or the Chairperson in agreement with PHARMAC's Medical Director, may also establish ad hoc Sub-committees where PHARMAC or PTAC requires specialist advice on a specific topic.

Functions of Sub-committees

- 10.5 A Sub-committee may have the following functions:
 - (a) consider and make independent and objective recommendations to PTAC (and occasionally PHARMAC) on applications for the listing and de-listing, restricting and de-restricting of pharmaceuticals on the Pharmaceutical Schedule which have been referred to it by PTAC or PHARMAC;
 - (b) when requested by PTAC (or occasionally PHARMAC), consider and make independent and objective recommendations on proposals for defining, removing or amending a therapeutic group or sub-group of pharmaceuticals on the Pharmaceutical Schedule;
 - (c) advise on possible strategic directions in any given speciality;
 - (d) consider and report, or make independent and objective recommendations, to PTAC or PHARMAC on any matters that may be referred to it by PTAC or PHARMAC.
- 10.6 Section 4 of the Guidelines applies to Sub-committees. In particular, in performing its functions and exercising its powers, Sub-committees are to take into account, where applicable and giving such weight to each criterion as the Sub-Committee considers appropriate, the criteria outlined in section 4.1.

Powers of Sub-committees

- 10.7 A Sub-committee will have the powers that may be reasonably necessary to enable it to perform its functions, including without limitation, the power to:

- (a) consult with, and seek evidence or information from, such parties it considers necessary or appropriate (subject to Sub-committees' confidentiality obligations described below); and
- (b) request further information or evidence from PTAC or PHARMAC where applicable, or an applicant, or supplier in relation to a particular pharmaceutical, therapeutic group or sub-group or any other matter that has been referred to it for consideration or recommendation.

Sub-committee Secretary

- 10.8 To the extent applicable, section 9 of the Guidelines applies to Sub-committees. References to PTAC are to be read as references to a Sub-committee. References to the Chairperson are to be read as references to the Sub-committee's Chairperson. The Sub-committee's Secretary may be a relevant PHARMAC staff member.
- 10.9 The agenda for each Sub-committee meeting is to be set by the Sub-committee Chairperson, in liaison with PHARMAC's Medical Director and the relevant PHARMAC staff member.
- 10.10 A copy of the record of Sub-committee meetings is to be sent to PTAC members as soon as the record is signed and is to be included in the agenda for the next full meeting of PTAC and formally reviewed by Members at that meeting. A copy of the signed record of Sub-committee meetings may also be forwarded to MARC. The Sub-committee Secretary shall hold the original copy of the record.

Process for Reviewing Applications

- 10.11 Section 12.6 applies to Sub-committees. References to PTAC are to be read as references to a Sub-committee. To the extent applicable the remaining provisions of section 12 apply to Sub-committees.

Confidentiality in relation to Sub-committees

- 10.12 Subject to sections 10.14 to 10.17, and subject to any public law obligations of PHARMAC in relation to the disclosure of information (including under the Official Information Act 1982), all information, documents and other material relating to matters on the Sub-committee's agenda, as well as the proceedings of Sub-committees, are confidential to the Sub-committees, PTAC and PHARMAC. Sub-committee members must comply with any statements of confidentiality obligations issued by PHARMAC and will sign confidentiality undertakings in the form required by PHARMAC.
- 10.13 Sub-committee members are required to store all material relating to a pharmaceutical in a secure place until the matter has been considered by PHARMAC, after which time Sub-committee members must either destroy the material or return it to PHARMAC.
- 10.14 Sub-committee members may, if appropriate, disclose the fact that PHARMAC has received an application from a supplier in respect of one or more of its pharmaceuticals once the application has been placed on the Sub-committee's agenda.

This type of disclosure should be limited to circumstances where Sub-Committee members believe it would assist Sub-committee members to obtain information from colleagues on the use, efficacy, adverse effects etc of the pharmaceutical(s) in question.

- 10.15 Once the record of a Sub-committee meeting is finalised, and has been reviewed by PTAC Members, a Minute will be made publicly available by PHARMAC by publishing it on PHARMAC's website, provided that PHARMAC reserves the right to withhold any element(s) of a Minute that it considers appropriate on grounds of commercial confidentiality. In doing so PHARMAC will be guided by the principles and withholding grounds of the Official Information Act 1982.

Once the Minute is publicly available, Sub-committee members may then discuss with colleagues matters considered at the Sub-committee meeting, but only on a general basis and only to the extent of the contents of the finalised Minute. In particular Sub-committee members are bound by each decision of the Sub-committee, and will not take any steps outside a Sub-committee meeting to undermine the decision of the Sub-committee.

- 10.16 Sub-committee members are prohibited from speaking to the media in relation to the activities of their Subcommittee and PTAC and any matters discussed at or considered by the Sub-committee or PTAC at their respective meetings, unless Sub-committee members have the prior written agreement of the Chairperson of PTAC and PHARMAC's Medical Director.
- 10.17 Sub-committee members shall not report to their professional associations without the knowledge and agreement of the Chairperson of PTAC.

Conflicts of Interest in relation to Sub-committees

- 10.18 Sub-committee members are to be alert to potential conflicts of interest as they arise in their daily professional life or otherwise and declare any such conflicts at the next Sub-committee meeting.
- 10.19 Sub-committee members are to avoid, to the greatest extent possible, any conflict between the performance of their duties and obligations as Sub-committee members, and any obligations and interests they may have as a result of their professional duties and any agreement, arrangement, understanding or other connection or interaction (whether legally enforceable or not) with a supplier. In particular, if a Sub-committee member wishes to accept supplier-funded travel, accommodation or other benefits, including clinical trial sponsorship, that member must declare this at the next Sub-committee meeting.
- 10.20 A Sub-committee member who is directly or indirectly interested in any matter that is under consideration or review by the Sub-committee, is to disclose the nature of that interest to the Sub-committee immediately after he or she becomes aware of it. A member who discloses an interest to the Sub-committee in accordance with this section will not be disqualified from discussing or voting on the matter concerned and is to be counted in the quorum for that meeting, unless the Chairperson of that meeting, in his or her discretion, decides that the particular interest is likely to affect

the member's ability to properly discharge his or her duties. If, as a result of the disqualification of a member under this section, a quorum cannot be maintained, then the relevant matter is to be referred to the next meeting.

- 10.21 Where a Sub-committee member declares or discloses a conflict of interest, this shall be recorded in a Conflicts of Interest Register, which is to be attached to each Sub-committee meeting agenda.

Membership of Sub-committees

- 10.22 Sub-committee members will generally include at least 2 relevant specialists (specialists may include health professionals who are not medical practitioners), 1 general practitioner and 1 general physician. Sub-committees will also have at least one PTAC member, who will usually act as the Chairperson. The general practitioner and general physician on Sub-committees may also be PTAC Members.

Appointment and Vacancies of Sub-committees

- 10.23 Sub-committee members are to be appointed by the PHARMAC Board (on the recommendation of the PTAC Chairperson and PHARMAC's Medical Director) for a term of 3 years.
- 10.24 When there is a vacancy on a Sub-committee, the PTAC Secretary will request nominations for the vacant position(s) from the appropriate professional groups. In general, the PTAC Secretary will ensure that there are at least two nominations for every position. The Chairperson, in consultation with PHARMAC's Medical Director, will select the preferred nominees and recommend the appointment of these persons to a Sub-committee to the PHARMAC Board. The PHARMAC Board is not bound by the recommendations of the PTAC Chairperson and PHARMAC's Medical Director and may appoint such persons as it sees fit.

Temporary Members of Sub-committees

- 10.25 The PHARMAC Board (on the recommendation of PHARMAC or the Chairperson and PHARMAC's Medical Director) may appoint temporary members to Sub-committees for such terms and on such conditions as it determines appropriate in order to fill any casual vacancy.

Meetings of Sub-committees

- 10.26 Sub-committees may meet more frequently than full PTAC meetings. The quorum for Sub-committee meetings is 3 members and should ideally include at least one non-PTAC Sub-committee member.
- 10.27 To the extent they are applicable, Sub-committees will follow PTAC's meeting procedures as detailed in sections 11, 13 and 14 of the Guidelines.

Remuneration of Sub-committee members

- 10.28 Sub-committee members are to be paid for their attendance at Sub-committee meetings and any time spent preparing for meetings and for performing any other

work as requested by PHARMAC. The PHARMAC Board will set the level of payment.

Renewal and Cancellation of Sub-committee Appointments

- 10.29 A Sub-committee member's appointment may be:
- (a) renewed or extended by the PHARMAC Board; or
 - (b) terminated by the PHARMAC Board without any right of compensation.

Dissolving Sub-committees

- 10.30 Sub-committees established under sections 10.1 or 10.4 can be dissolved by the PHARMAC Board or PTAC (with the agreement of the PHARMAC Board) at any time. Sub-committee members may resign at any time by notice in writing to the Chairperson of PTAC. The PTAC Chairperson will notify the PHARMAC Board if a sub-committee member resigns.

Documentation for Sub-committees

- 10.31 The PTAC Secretary will provide new Sub-committee members with the following documentation, as a minimum:
- (a) PHARMAC's Operating Policies and Procedures;
 - (b) PTAC's Guidelines;
 - (c) a statement of confidentiality obligations;
 - (d) a payroll details form, to be signed and given to PHARMAC's office manager;
 - (e) an expense claim form and;
 - (f) a conflict of interest statement form.

11. Meetings of PTAC

- 11.1 PTAC is to meet as and when required by PHARMAC staff and no fewer than four times in each year. Meetings are to be held in Wellington at PHARMAC's offices, or as provided in sections 13 (teleconferences) or 14 (recommendations by other means of communication) unless the Chairperson, in agreement with PHARMAC, directs otherwise. The PTAC Secretary and Chairperson will select the dates for PTAC meetings, taking into account the dates of PHARMAC Board meetings and PHARMAC workflow. They will present the dates to Members, who will confirm the dates subject to their availability.
- 11.2 The quorum for meetings of PTAC is 6 Members, of whom one member (subject to section 11.5 below) must be either the Chairperson or Deputy Chairperson. In exceptional circumstances (for example, where time is of the essence) the Chairperson may direct that the quorum for a particular meeting is to be 5 Members.

- 11.3 Members can request leave of absence from any particular PTAC meeting, which may require the appointment of an alternate Member (for example, where the Member's absence will mean the meeting does not have a quorum). In respect of an alternate Member, the process of appointment will be identical to the process for the appointment of PTAC Members referred to in section 6 of the Guidelines. Alternate Members may be appointed in advance before they are specifically required for any particular meeting.
- 11.4 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 other written or electronic mail message.
- 11.5 The Chairperson is to preside at each meeting of PTAC unless he or she is absent or is unwilling or unable to preside. In this case the Deputy Chairperson (if present, willing and able), is to preside. If neither the Chairperson nor Deputy Chairperson can preside, then the Members present at the meeting must elect a Member who is present to be the Chairperson.
- 11.6 Members are to endeavour, at all times, to reach a consensus on reports and recommendations made to PHARMAC. However, if consensus cannot be achieved, then a report or 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 Chairperson of the meeting is to have a second or casting vote. Members who disagree with, or dissent from, a decision of PTAC are able to register their dissent or disagreement, and the grounds for it, in the report or recommendation to PHARMAC. However, Members are bound by each decision and will not take any steps outside the meeting to undermine a consensus or majority decision.
- 11.7 Subject to compliance with the above procedures, PTAC may regulate its internal procedures in such manner as it thinks fit.

12. Process for Reviewing Applications

- 12.1 Applications to list a pharmaceutical on the Pharmaceutical Schedule are expected to meet certain requirements (persons should contact PHARMAC staff for the appropriate information). PTAC expects to review good clinical evidence in support of applications, in particular, data on clinical outcomes, comparative studies with alternative medications and cost-effectiveness information.
- 12.2 When PTAC considers applications for new listings, the pharmaceutical should ideally have already gained registration and all consents for marketing in New Zealand from Medsafe.
- 12.3 On receipt of applications, PHARMAC staff will acknowledge receipt of the application. PHARMAC staff will make the existence of applications for new investments (including clinical proposals to widen access) (including the name of the body making the application) publicly known by publishing it on PHARMAC's website.

- 12.4 The Chairperson, PHARMAC's Medical Director (or their nominees), the PTAC Secretary and at least one other Member may meet (by teleconference or by other agreed means of communication) to consider, at their discretion:
- (a) whether a particular application(s) should be considered directly by PTAC; or
 - (b) whether a particular application(s) should be referred to a relevant Sub-committee 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. Where comments are sought, the main objective will be to enable interested parties to outline specific issues relating to the pharmaceutical (such as its role, its benefits over currently funded treatments, the quality of the evidence supporting those benefits and the definition of patients most likely to benefit from the pharmaceutical) early in the decision making process. These comments will be considered by PTAC or a Sub-committee when it considers the application.
- 12.5 PTAC may consider more complex applications in two stages at two separate meetings. The Chairperson and PHARMAC's Medical Director will establish which, if any, applications are appropriate for this two-step process. When PTAC decides to follow the two-step process, Members will receive a copy of the full application at the first meeting. The first meeting is primarily focussed on critical appraisal of the literature provided by suppliers or obtained from appropriate searches conducted by an independent research organisation. The PTAC Secretary will liaise with the relevant TGM to produce a brief paper with questions to be discussed at the first meeting. If PTAC considers the application worthy of further consideration, it will proceed to the second stage and will be considered at a second meeting of PTAC.
- 12.6 PTAC is to set out, in all recommendations it makes to PHARMAC, the matters and evidence that it has primarily relied on in making that recommendation. Where the application considered by PTAC is an application to list a particular pharmaceutical on the Pharmaceutical Schedule PTAC will make one of the following types of recommendations to PHARMAC. When making recommendations set out in paragraphs (a) and/or (c) below, PTAC will indicate which decision criteria it has given particular weight to in the course of making such recommendations:
- (a) recommend that the pharmaceutical be listed and the priority it gives to its listing;
 - (b) defer a final recommendation subject to further information being supplied;
 - (c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

13. Teleconferences

- 13.1 PTAC may, if the Chairperson agrees (and the meeting has a quorum, see section 11.2), have a meeting by contemporaneous linking together by telephone (teleconference). To the extent applicable, the rules and procedures relating to PTAC meetings set out in section 11 will apply to a teleconference held under this section. In addition, the following rules are to 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 teleconference must:
 - (i) at the start of the teleconference, acknowledge the Member's participation in the teleconference to the other Members taking part;
 - (ii) be able to hear the other Members taking part at all times throughout the teleconference; and
 - (iii) on any vote, individually express his or her vote at the teleconference.

13.2 A Member may not leave a meeting held under this section by disconnecting his or her telephone unless he or she has first obtained the permission of the Chairperson. A Member is to be presumed to have continued to be present, and to have formed part of the quorum, at all times during a teleconference unless he or she has been expressly permitted to leave.

14. Recommendations by other means of communication

- 14.1 In exceptional circumstances, for example where time is of the essence, PTAC and Sub-committees may make recommendations by facsimile, electronic mail or other means of communication without a meeting having to be held.
- 14.2 In such circumstances, any recommendation of PTAC or a Sub-committee must be unanimous. If a consensus cannot be achieved, then a meeting under section 11, or a teleconference under section 13, must be held.
- 14.3 If a unanimous recommendation is achieved, the PTAC Secretary or Sub-committee secretary must prepare a record of the recommendation, which is then signed by all PTAC Members or members of the particular Sub-committee.

15. Responsibilities of the Chairperson

- 15.1 Subject to the requirements set out in section 11, the Chairperson is generally free to conduct PTAC meetings as he or she sees fit. The Chairperson will endeavour to ensure all PTAC meetings start and finish on time and that where possible all agenda items are covered. The Chairperson is responsible for setting the agenda for the meetings, in liaison with PHARMAC's Medical Director and the PTAC Secretary. The Chairperson is also responsible for signing off the final version of the record of any meetings of PTAC.
- 15.2 The Chairperson should be aware of the range of perspectives across PTAC and PHARMAC and should manage discussion of those differing perspectives.
- 15.3 The PTAC Chairperson will, where possible, attend meetings of PHARMAC's Board to express the view of PTAC on issues considered by PHARMAC, but is not entitled to vote at the meetings. The Chairperson is also responsible for liaising with

PHARMAC's Board in regard to the resources to be allocated to PTAC and its Members.

- 15.4 Provided that he or she has first obtained the agreement of PHARMAC, the Chairperson will, as necessary, represent the interests and views of PTAC to relevant Government officials and departments and to the media.

16. Conflicts of Interest

- 16.1 Members are to be aware of potential conflicts of interest as they arise in their daily professional life or otherwise and declare any such conflicts at the next PTAC meeting.
- 16.2 Members are to avoid, to the greatest extent possible, any conflict between the performance of their duties and obligations as Members, and any obligations and interests they may have as a result of their professional duties and any obligations or interests they may have as a result of any agreement, arrangement, understanding or other connection or interaction (whether legally enforceable or not) with a supplier. In particular, if a Member wishes to accept supplier-funded travel, accommodation or other benefits, including clinical trial sponsorship, that Member must declare this conflict at the next PTAC meeting.
- 16.3 A Member who is directly or indirectly interested in any matter that is under consideration or review by PTAC, is to disclose the nature of that interest to PTAC immediately after he or she becomes aware of it. A Member who discloses an interest to PTAC in accordance with this section will not be disqualified from discussing or voting on the matter concerned and is to be counted in the quorum for that meeting, unless the Chairperson of that meeting, in his or her discretion, decides that the particular interest is likely to affect the Member's ability to properly discharge his or her duties. If, as a result of the disqualification of a Member under this section, a quorum cannot be maintained, then the relevant matter is to be referred to the next meeting.
- 16.4 Where a Member declares or discloses a conflict of interest, this shall be recorded in a Conflict of Interest Register, which is to be attached to each PTAC meeting agenda.

17. Confidentiality

- 17.1 Subject to sections 17.3 to 17.6, and subject to any public law obligations of PHARMAC in relation to the disclosure of information (including under the Official Information Act 1982), all information, documents and other material relating to matters on PTAC's agenda, as well as the proceedings of PTAC, are confidential to PTAC and PHARMAC. Members must comply with any statements of confidentiality obligations issued by PHARMAC and will, if required, sign confidentiality undertakings in the form required by PHARMAC.
- 17.2 Members are required to store all material relating to a pharmaceutical in a secure place until the matter has been considered by PHARMAC, after which time Members must either destroy the material or return it to PHARMAC.

- 17.3 Members may, if appropriate, disclose the fact that PHARMAC has received an application from a supplier in respect of one or more of its pharmaceuticals once the application has been placed on PTAC's agenda.

This type of disclosure should be limited to circumstances where Members believe it would assist to obtain information from colleagues on the use, efficacy, adverse effects etc of the pharmaceutical(s) in question.

- 17.4 Once the record of a PTAC meeting is finalised, a Minute will be made publicly available by PHARMAC by publishing it on PHARMAC's website, provided that PHARMAC reserves the right to withhold any element(s) of a Minute that it considers appropriate on grounds of commercial confidentiality. In doing so PHARMAC will be guided by the principles and withholding grounds of the Official Information Act 1982. Once the Minute is publicly available, Members can then discuss with colleagues matters considered at the meeting but only on a general basis and only to the extent of the contents of the finalised Minute (see also section 11.6 of the Guidelines).
- 17.5 Members are prohibited from speaking to the media in relation to the activities of PTAC and any matters discussed at or considered by PTAC at meetings of PTAC, unless they have the prior written agreement of the Chairperson and PHARMAC's Medical Director.
- 17.6 Members shall not report to their professional associations without the knowledge and agreement of the Chairperson.

18. **Observers**

- 18.1 At the discretion of the Chairperson and PHARMAC's Medical Director, observers may attend meetings of PTAC. These observers are not however, and are not to be deemed to be, PTAC Members and, unless the Chairperson of the particular meeting otherwise agrees, these observers will not have any right to speak at the meeting.
- 18.2 Observers will be required to sign confidentiality undertakings, prior to attending any meeting of PTAC, in the form required by PHARMAC.
- 18.3 Observers should not, in the view of the Chairperson by their presence, affect any recommendations of PTAC, either by influencing or constraining discussion at any PTAC meeting.

19. **Open Days**

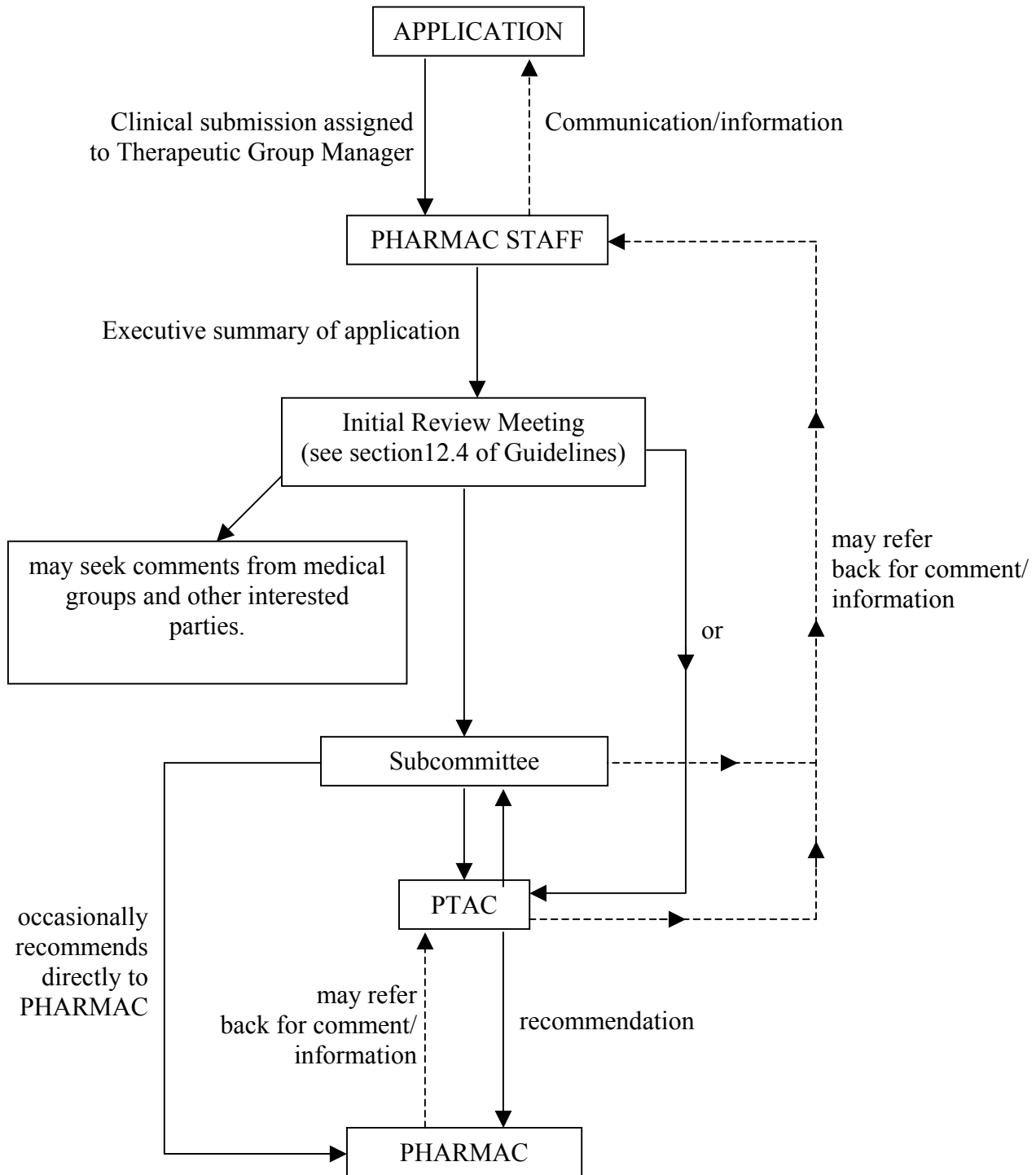
- 19.1 PTAC may, with PHARMAC's agreement, hold open days for general discussion. Members will not discuss past or current applications at any open days.

20. **Variation of Guidelines and Disputes**

- 20.1 These guidelines provide direction on PTAC's functions and processes, but are not intended to cover every eventuality. They are to be interpreted flexibly and pragmatically, to allow PTAC the scope to adapt its functions and processes as the

need arises. These guidelines may also be varied or revoked at any time (which may, where PHARMAC considers it appropriate, involve consultation) from time to time, by the PHARMAC Board.

- 20.2 Any dispute or disagreement as to the meaning or application of any section in these Guidelines (except for the appointment process referred to in section 6 and 7 of the Guidelines) is to be determined by the PHARMAC Board, whose decision is final.



Note: This diagram fits into the “PTAC or Sub-committee” part of the diagram in paragraph 4.5 of PHARMAC’s OPPs. This diagram provides a simplified, indicative guide to the process that PHARMAC and PTAC will usually follow when listing a pharmaceutical on the Schedule. PHARMAC and PTAC are not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate.