

23 December 2009

Guidelines for Funding Applications to PHARMAC

PHARMAC is pleased to announce the publication of updated *Guidelines for Funding Applications to PHARMAC* (the “*Guidelines*”). An earlier draft of the *Guidelines* was the subject of a consultation letter dated 14 May 2009.

The updated *Guidelines* are now available to download from the PHARMAC website: <http://www.pharmac.govt.nz/suppliers/DecisionMakingProcess>. The key changes include:

- an outline of the revised process for submitting a funding application, including a PHARMAC process for screening Applications for completeness;
- a request to disclose certain patent information;
- a request to provide information on the impact of funding the medicine on the health sector (i.e. costs and savings);
- a request to list, and declare, all known ongoing relevant clinical trials;
- a request for copies of all errata and journal correspondence relating to published trials that are provided;
- details of information required for follow-up applications (“Reapplications”); and
- less information requested in Applications for the funding of generic pharmaceuticals, where another brand of the pharmaceutical has previously been considered by PHARMAC for funding.

Applications submitted to PHARMAC after 9 March 2010 should be based on the information requested in the updated *Guidelines*. Applications submitted to PHARMAC before this date may be based on either the updated or previous version of the *Guidelines*.

Further details about the amendments to the *Guidelines*, and the reasons for the amendments, can be found on the following pages.

Purpose of the Guidelines for Funding Applications to PHARMAC

The *Guidelines* provide guidance on how to prepare applications to PHARMAC for the funding of new pharmaceuticals or to widen access to pharmaceuticals that are already funded.

The information requested in the updated *Guidelines* is not mandatory; however, it is the information that PHARMAC typically requires when assessing an Application. A thorough Application, including the information requested in the *Guidelines*, will assist us in assessment, and means we are less likely to have to seek further information during the assessment process.

Good quality Applications will include the following elements:

- critical appraisal of key clinical evidence;
- information relating to PHARMAC’s nine decision criteria;
- complete market and epidemiological information;

- information on cost-effectiveness (based on PHARMAC's methodology for cost-utility analysis as published in PHARMAC's Prescription for Pharmacoeconomic Analysis - PFPA); and
- disclosure of information on all known ongoing trials and patents.

Good quality Applications will be clear, cite all sources, explain all assumptions, and include all information of material importance.

Amendments to the Guidelines for Funding Applications to PHARMAC

The key amendments to the *Guidelines*, and reasons for these amendments, are outlined below:

Amendment	Reason for Amendment
Inclusion of a checklist outlining the information PHARMAC requests in an Application.	A quick reference guide to clarify the information requested.
Outline of a revised process for submitting an Application, including a PHARMAC process for screening for completeness.	An initial screening process for an Application is intended to save applicants time and money (printing and courier costs etc) so that PHARMAC can ensure that an Application is complete before it is accepted.
A clearer distinction between 'information required' and 'additional information'.	Not all information PHARMAC requests is critical, and some Applications can be progressed without it (or PHARMAC can source the information from elsewhere). For example, although it is desirable for suppliers to provide a cost-utility analysis (CUA), PHARMAC can undertake the analysis in-house.
A clearer outline of information to be included in the synopsis.	Clarification was considered necessary as the synopsis is an important part of an Application.
A requirement to disclose certain patent information.	This information is used to estimate the budget impact of an Application.
Further information requested on the impact on the health sector (costs and savings).	This information is used to estimate the budget impact of an Application to DHBs.
Further details on the clinical and epidemiological evidence (including presentation of clinical evidence and critical appraisals of trials).	This integrates key material currently suggested by the 'Recommended Methods to Derive Clinical Inputs'. This information is essential to PHARMAC's decision making in terms of patient numbers (potential budget impact), population need (including Maori/Pacific), and clinical effectiveness.
Details on acquiring epidemiological data and citing sources used for estimates and assumptions.	This integrates material described in the 'Recommended Methods to Derive Clinical Inputs'. Consistent provision and reporting of such information is necessary for PTAC and PHARMAC when assessing the robustness and comprehensiveness of the evidence in Applications.
A requirement for copies of all errata and journal correspondence relating to published trials.	These often contain key information/insights that are considered by PHARMAC when undertaking critical appraisal. Post-publication peer review can be just as important as review prior to publication.
A requirement to list, and declare, all known ongoing relevant trials.	This requirement aims to minimise any risk that key evidence is missed.

Amendment	Reason for Amendment
A requirement to declare that all known unpublished trials have been included.	The making of such a declaration, as occurs in Canada, reinforces the importance of providing all evidence relevant to the Application and will help ensure this happens.
Stronger emphasis on providing information on cost-effectiveness.	With this information it is more likely that the Application will be able to be assessed and prioritised more quickly.
Optional additional information, including information on public health significance and the health needs of Maori/Pacific people.	This integrates key material currently suggested by the 'Recommended Methods to Derive Clinical Inputs'. The provision of this information appreciably improves the quality of assessments for decisions.
Details of information required for 'Reapplications' to address concerns raised by PTAC.	Significantly less information is required in 'Reapplications' and this is intended to make the 'Reapplication' process less onerous for Applicants.
Significantly less information requested in Applications for the funding of generic pharmaceuticals .	If a pharmaceutical has been assessed by Medsafe as safe and effective, and PHARMAC has already assessed other brands of the pharmaceutical, then PHARMAC will already hold information on the clinical effectiveness of the pharmaceutical. This change is intended to make the Application process less onerous for pharmaceuticals that are already funded.

Feedback received

We appreciate all of the feedback that we received, and acknowledge the time people took to respond. Consultation occurred over a six week period ending 1 July 2009, and all consultation responses were considered in their entirety in making a decision on the proposed changes.

A key concern raised in consultation was that the updated *Guidelines* contained substantial increases in the information to be provided in Applications.

The additional information requested is largely due to the integration within the *Guidelines* of the '*Recommended methods to derive clinical inputs for proposals to PHARMAC*', and inclusion of information that PHARMAC staff have often needed to request after an Application is made. However a number of amendments were made, as a result of consultation feedback, which has reduced the quantity of information requested at the outset of an Application.

We have also ensured that the updated *Guidelines* clearly state that the information requested is not mandatory to include in all Applications. We note however that a thorough Application, including all the information requested, is likely to enable PHARMAC to progress it more efficiently.

The table below outlines a summary of the main issues raised in consultation, and PHARMAC's response. We note that several issues were raised during consultation that did not relate directly to the *Guidelines*. We will be contacting responders directly to address these and other comments not detailed in the table.

Theme	Comment
Some responders considered that Applicants should not be required to highlight confidential information, as all information in Applications should be treated as confidential.	This requirement has been removed. PHARMAC is bound to process requests for information in accordance with the Official Information Act (OIA), regardless of whether or not the information is marked as confidential by the Applicant.
Several responders considered that the request to provide information on 'other common unregistered indications' be removed.	This request has been removed. We consider that this information can be obtained by PHARMAC from other sources if required.
A number of respondents had concerns regarding the request for pipeline information for other presentations of the pharmaceutical.	This request has been clarified so that information is only requested on other presentations or formulations of the pharmaceutical that have been submitted or approved in other OECD countries.
Several responders considered that requesting information on pricing in all countries was excessive and not always obtainable, and therefore considered should be removed.	The Guidelines have been amended to only request information from OECD countries.
Some respondents felt that the request for information on marketing and impact on market penetration should be removed.	This request has been removed.
Several responders considered that there was duplication in information requested for presenting the clinical evidence.	Amendments have been made to the information requested when summarising a clinical trial. In addition, although PHARMAC still recommends the use of GATE and SIGN to critically appraise clinical trials and grade clinical evidence, this information is no longer requested.
Some responders questioned the rationale for requesting three copies of an Application in advance, and considered that this would result in a delay to consideration of an Application.	We ask for three copies in advance so that PHARMAC can undertake an initial screening of the Application. Previously 15 copies of an Application have been provided and the Application was either incomplete, inadequate or did not meet the criteria for PHARMAC to consider funding – thus resulting in delays to its consideration. This amendment is intended to reduce costs to the Applicant, and ensure that the Application (when received) is able to be progressed.
Several responders sought that the request to provide details of countries where registration/funding has been approved or declined be removed, as they considered the information to be difficult to obtain and irrelevant.	Information on registration and funding in other countries is useful when estimating uptake and obtaining market information. However, we acknowledge that this information may be difficult to obtain, and therefore this request has been amended to restrict it to information from OECD countries and to clarify that it only needs to be provided if readily available.
Several responders considered that more information should be requested on the safety of generic pharmaceuticals.	The Guidelines have been amended to explicitly state that if PHARMAC has not previously assessed a different brand of the pharmaceutical, a full Application is required.

More information

If you have any questions about the *Guidelines for Funding Applications to PHARMAC*, you can call our toll free number (9am to 5pm, Monday to Friday) on 0800 66 00 50.