PHARMAC
Pharmaceutical Management Agency

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To all Pharmaceutical Suppliers and Interested Parties

Consultation on Revised Funding Application Guidelines

We are now inviting submissions on the revised Funding Application Guidelines. We hope you will take the time to make a submission, and we look forward to receiving your views.

In June 2008 we wrote to inform you that PHARMAC was undertaking a review of the Guidelines for new chemical entities (pharmaceuticals), new indications and formulations, combination products and generic pharmaceuticals. The aims of the review included:

- aligning the Guidelines with version 2 of the Prescription for Pharmacoeconomic Analysis (PFPA) (http://www.pharmac.govt.nz/2007/06/19/PFPAFinal.pdf);
- improving the transparency and understanding of the application process; and
- further ensuring that the Guidelines specify all the information that PHARMAC requires in the application process.

The initial stage of the review is complete and we are now consulting on an updated draft. Once finalised, this new version of the Guidelines will replace the current version (version 1, on our website), including the 'Recommended Methods to Derive Clinical Inputs'.

The draft revised Funding Application Guidelines are available on the Consultation page of the PHARMAC website at http://www.pharmac.govt.nz/consultation, under the heading 'Draft version 2 of the Funding Application Guidelines. Closes 1 July 2009'.

The Application Guidelines are written for anyone wanting to make a funding Application. As Applications to PHARMAC must include all relevant information and may be deferred if incomplete or unclear, it is important to be aware of the changes proposed to the Guidelines.

Key proposed amendments include:

- a checklist outlining the information required in an Application;
- a detailed outline of the Application process;
- outline of a revised process for submitting an Application, including a PHARMAC process for screening for completeness;
- clearer distinction between 'information required' and 'optional information';
- a clearer outline of information to be included in the synopsis;
- a requirement to disclose patent information;
- further information requested on the impact on the health sector (costs and savings);
- further details on the clinical and epidemiological evidence required (including presentation of clinical evidence and critical appraisals of trials);
- details on acquiring epidemiological data and citing sources used for estimates and assumptions;

- a requirement for copies of all errata and journal correspondence relating to published trials;
- a requirement to list, and declare, all known ongoing relevant trials;
- a requirement to declare that all known unpublished trials have been included;
- stronger emphasis on providing information on cost-effectiveness;
- optional additional information, including information on public health significance and the health needs of Maori/Pacific people;
- details of information required for Reapplications;
- significantly less information requested in Applications for the funding of generic pharmaceuticals; and
- a detailed glossary of terms.

If you have any questions regarding these amendments, please email the PHARMAC Guidelines Project Team: guidelines@pharmac.govt.nz

We invite you to send a submission to PHARMAC regarding your views on the draft version 2 of the Funding Application Guidelines.

Please provide your comment by way of written submission to Rachel Grocott (Team Leader, Assessment) by **1 July 2009**:

Email:	guidelines@pharmac.govt.nz
Fax:	(64) 4 460 4995
Postal Address:	PHARMAC c/o Rachel Grocott PO Box 10-254 Wellington 6143

All consultation responses will be considered in detail. Subject to the views raised and further work required, we envisage releasing an updated version of the Funding Application Guidelines in late 2009.

Yours sincerely

Matthew Brougham
Chief Executive