

12 June 2008

Dear Pharmaceutical Suppliers and Interested Parties

### **Review of Application Guidelines**

PHARMAC is currently undertaking a review of the application guidelines for new chemical entities, new indications and formulations, combination products and generic pharmaceuticals. We plan on consulting on a revised version of the guidelines in early 2009.


In the interim, several minor amendments have been made to the application guidelines (previously referred to as submission guidelines), in order to align the guidelines with the revised version 2 of the Prescription for Pharmacoeconomic Analysis (PFPA). The PFPA was updated in 2007, and PHARMAC undertook extensive consultation on this document in mid-2006.

The key minor amendments to the application guidelines include:

- clarifying that the form of analysis PHARMAC requires is cost-utility analysis;
- discount rate – amending from 8% to 3.5% as specified in the revised PFPA;
- omission of request for information on disability-adjusted life years (DALYs); and
- applications for generic pharmaceuticals (Section B) where the chemical entity has previously been considered by PTAC – only one copy of the synopsis is required (not fourteen as previously stated); but a further fourteen copies may be required if the application needs to be discussed by PTAC.

If you have any questions regarding any of the information in this letter, please contact Rachel Grocott at PHARMAC ([rachel.grocott@pharmac.govt.nz](mailto:rachel.grocott@pharmac.govt.nz); 04-916-7535)

Yours sincerely



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