



The Royal Australasian
College of Physicians

From the President

13 June 2012

Ms Trisha Garrett
Office of Therapeutic Medicines
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Via Email: ocm@tga.gov.au

Dear Ms Garrett

Therapeutic Goods Association (TGA) Consultation on Evidence Required to Support Indications for Listed Medicines

Thank you for the opportunity to provide feedback on the draft document "*Evidence Required to Support Indications for Listed Medicines*" as published on the TGA Website. The Royal Australasian College of Physicians (RACP) is pleased to be involved in this initiative to ensure patient protection and quality use of medicines.

The RACP welcomes the revised draft document that now strengthens the detailed requirements for sponsors of 'Listed Medicines' including weight loss products. We agree that all listed medicines, including all conventional medicines and devices, must be backed by detailed evidence required to support the type of health benefit claimed. The medicine must be acceptable to the TGA for the relevant indication, and be accompanied by an expert report. Furthermore, the RACP agrees with the definitions of the expert report.

Should you wish to discuss further, then please contact Dr Judith Walker, Senior Policy Officer, by email Judith.Walker@racp.edu.au or telephone 02 9256 9627.

Yours sincerely

Dr Leslie E Bolitho AM