



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

FILE No:
DOC:
MARS/PRISM:

The General Manager
Adjudication Branch
Australian Competition and Consumer Commission
PO Box 1199
DICKSON ACT 2602

**RE: Applications for revocation and substitution A90994-A90996
Medicines Australia**

Dear Ms Arnaud

I am writing to you as National Manager of the Therapeutic Goods Administration (TGA) in relation to the authorisation of Edition 15 of the Medicines Australia Code of Conduct (the Code).

The TGA is the Australian Government body responsible for the regulation of therapeutic goods in Australia. The Prescription Medicines' industry, with the exception of generic manufacture, is largely represented in Australia by Medicines Australia.

The TGA regulates the therapeutic goods at various levels, including control over manufacturing standards, pre-market entry requirements, post-market monitoring and control of advertising.

For prescription medicines, there are restrictions in place against consumer advertising within the Therapeutic Goods legislation. These are important controls, but in order to fully protect the public health, the TGA and industry work together in a cooperative manner to enforce standards of truthfulness, transparency and accuracy of detailing to health professionals through application of the Code.

The TGA applies conditions to the registration approval of all prescription medicine products to require compliance with the principles of the Code. In this way, one standard is applied fairly and equally to all prescription medicine products creating a level playing field for advertising regulation.

The authorization of the Code is fully supported by the TGA and is seen as an essential component in improving the outcome of promotion of prescription medicines in Australia. The 15th edition of the Code has been updated and strengthened.

I am satisfied that the Code also contains provision for a complaint mechanism and for handling of appeals and enforcement of standards. I am aware that the Code Committee has broad and relevant representation outside of its membership in relation to enforcement of the code provisions. These review and enforcement arrangements are also supported by the TGA, which is represented on the Code Committee.

Yours sincerely

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Dr David Graham
National Manager

16 May 2006