



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: Application A90994-6 – Medicines Australia's Code of Conduct

Dear Mr Gregson

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

For your background information, 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 the latter there are restrictions in place against consumer advertising within the Therapeutic Goods legislation. These are important 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 through applications of the Code of Conduct.

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.

The code also contains provision for a complaint mechanism and for handling of appeals and enforcement of standards. The TGA notes that Medicines Australia has broad and relevant representation outside of its membership in relation to these provisions. These arrangements are also supported by the TGA.

I hope these comments are helpful.

Yours sincerely

Dr David Graham
National Manager
11 January 2006

