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**Queensland  
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Queensland **Health**

Enquiries to: Andrew Petrie, Director  
Medicines & Pharmacy Services  
Unit  
Telephone: 07 323 41167  
Facsimile: 07 323 40773  
File Ref: DG042744.doc

Ms I Arnaud  
Director  
Adjudication Branch  
Australian Competition &  
Consumer Commission  
PO Box 1199  
DICKSON ACT 2602

Dear Ms Arnaud

Thank you for your letter of 5 December 2005 to Ms U Schreiber, Director-General of the Department of Health regarding application for revocation and substitution (A90994-6) lodged by Medicines Australia Inc. I have been asked to respond to this.

The Medicines Australia Code forms an important part of a co-regulatory model with the Therapeutic Goods Administration to manage practices of pharmaceutical manufacturers associated with marketing and distribution of Medicines in Australia. Use of such an approach provides the opportunity of minimising the level of control applied by regulatory organisations, whilst seeking to maintain expected standards.

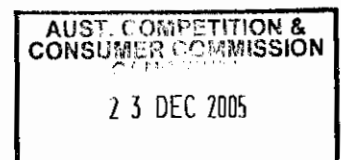
Whilst it is desirable in principle for such a document to continue to be available, I do not believe that negotiations between Medicines Australia and the National Coordinating Committee on Therapeutic Goods (NCCTG) have been finalised. This particularly relates to provisions associated with "starter packs". Although there have been significant changes to respond to requests which, it is hoped will allow repeal of some state legislation, I believe it would be premature to finally endorse the document at present. In spite of this updating of Edition 15 not being finalised, this version appears to improve accountability and standards around possession and handling of starter packs by company personnel and have a range of other enhancements in other parts of the document. I would not raise objection to some form of interim approval of the document, pending final agreement by NCCTG on the content.

Yours sincerely

Andrew Petrie

**Director  
Medicines & Pharmacy Services Unit**

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**Office**  
Queensland Health  
147-163 Charlotte Street  
BRISBANE QLD 4000

**Postal**  
GPO Box 48  
BRISBANE QLD 4001

**Phone**  
07 3234 1167

**Fax**  
07 3234 0773