



**Date** 15 March 2006

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~~Confidential Email~~ MS 16/3/06

Dear Ms Davis

### Medicines Australia - Application for Authorisation

Further to our letter of 24 January 2006, Medicines Australia (**MA**) has now received a response from the National Coordinating Committee for Therapeutic Goods (**NCCTG**) in respect of the NCCTG's consideration of the provisions of the Code relating to starter packs.

A copy of a letter from Dr David Graham, Chair of the NCCTG, dated 9 March 2006 is attached in which Dr Graham indicates that the NCCTG members support Edition 15 of the MA Code of Conduct.

Two issues have been raised by NCCTG members that they would like MA to consider when the Code is next revised, as set out in Dr Graham's letter of 9 March. MA intends to propose to its members that the minor revisions recommended by the NCCTG are adopted. These revisions are:

- amending the second sentence of section 5.1.10 by replacing the word 'lockable' with the word 'locked'; and
- amending section 5.1.1 to include the following wording at the end of the section ', or by authorised company representatives (including agents working under a contract to, but not directly employed by, the holder of a manufacturer's licence or wholesale dealer's licence)'.

**Our Ref** CYOS: EXMS:201287744

exms S0111682865v1 201287744 15.3.2006

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If you have any queries in relation to the above, please let us know.

Yours sincerely

**Carolyn Oddie**

Partner

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**Emma Marsh**

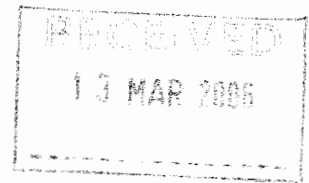
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**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**



Ms Deborah Monk  
Director  
Scientific and Technical Affairs  
Medicines Australia  
Level 1, 16 Napier Close  
Deakin ACT 2600

Dear Ms <sup>Deborah</sup> Monk

Further to telephone conversations and email correspondence with Sharyn McGregor, I am writing to confirm the outcome of the recent out-of-session consideration of the Medicines Australia Code for the Supply of Starter Packs by the National Coordinating Committee on Therapeutic Goods (NCCTG).

I am pleased to confirm that NCCTG members supported the Code in its revised form. However two issues were raised by members that should be considered at the earliest opportunity to revise the Code:

- Clause 5.1.10 [Security]  
The word 'lockable' should be changed to 'locked' in order to strengthen this clause with a view to improving compliance.

I understand that you spoke to the relevant NCCTG member about the intention of this particular provision, and that you indicated Medicines Australia would endeavour to enforce compliance in the implementation of the Code, and would consider strengthening this provision as the Code is refined.

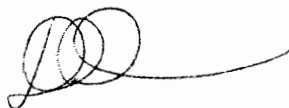
- Authorised representatives who are third party agents  
It was also suggested that the Code does not adequately cover representatives employed by a separate company which is contracted by the product sponsor.

Although Medicines Australia advised that representatives employed under these circumstances are included in supporting guidelines to the Code, as these guidelines are not adopted by State/Territory legislation, they cannot be enforced. NCCTG members have been asked to consider the implications for their respective jurisdictions, and some States and Territories may need to ensure that the relevant legislation provides for these circumstances, in addition to provisions which adopt the Code.

It is NCCTG members' strong preference that the Code be amended as soon as possible to cover representatives employed by product sponsors under these specific circumstances.

Should you wish to discuss this matter further, please call Ms McGregor on (02) 6232 8197.

Yours sincerely

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

Dr David Graham  
Chair  
National Coordinating Committee  
on Therapeutic Goods

9 March 2006