



Date 23 May 2006
From Fiona Crosbie / Emma Marsh
To **Brownwyn Davis**, Australian Competition and
Consumer Commission
Email bronwyn.davis@accc.gov.au

ABN 47 702 595 758

Deutsche Bank Place
Corner Hunter and Phillip Streets
Sydney NSW 2000
Australia
Tel 61 2 9230 4000
Fax 61 2 9230 5333

Correspondence
GPO Box 50
Sydney NSW 2001
Australia
DX 105 Sydney

www.aar.com.au

~~Confidential Email~~ *MS 23/5/06*

Dear Ms Davis

Medicines Australia - application for authorisation

As foreshadowed in our letter to you of 4 May 2006, Medicines Australia (**MA**) wishes to make a further submission in response to the Commission's Draft Determination in respect of Medicines Australia's applications for revocation and substitution A90994-A90996.

1. Sanctions


The Commission has commented in para 3.70 of the Draft Determination on the potential fine of up to \$200,000 that may be imposed on a complainant member in the event of a frivolous or vexatious complaint. MA would be grateful if the Commission could acknowledge in the Final Determination that this sanction may be imposed on any company complainant, not just on an MA member.

2. Appeals Committee

The inclusion of a consumer representative nominated by the Consumers' Health Forum of Australia as a member of the Appeals Committee is a new addition in Edition 15. MA would be grateful if the Commission could include a footnote to para 3.76 of the Final Determination to this effect (on the basis that other amendments to the Code have been referenced in footnotes in the Draft Determination).

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3. Advertising in electronic prescribing software

The Commission suggests that the restriction on advertising displayed in Medical Director is self-imposed (para 6.53). However, MA submits that restriction on advertising displayed in Medical Director is directly attributable to the amendments included in Section 3.9.1 of Edition 15 of the Code of Conduct (the **Code**) which prohibit the placement of advertisements in clinical tools or patient education materials which may be used by a prescriber during a consultation or discussion with a patient. MA would therefore be grateful if the Commission could acknowledge in the Final Determination that this as a benefit that is directly attributable to the Code.

4. Starter Packs

The Commission has commented in the Draft Determination on the amended provisions in the Code relating to Starter Packs, which have been included as a result of the Galbally Review (paras 6.90 to 6.95 and 6.160 to 6.161).

The Commission has commented in para 6.94 of the Draft Determination on AAR's letter of 15 March 2006 sent on behalf of MA in which a copy of a letter from the Therapeutic Goods Administration stating that members of the National Coordinating Committee on Therapeutic Goods supported the Code in its revised form. In that same letter, the Commission was advised that MA intends to propose to its members that minor revisions to the Code are adopted, as recommended by the NCCTG. 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)'.

MA would be grateful for the Commission's acknowledgment in the final Determination the intention to amend the Code in this way (in the same way as the Commission has acknowledged in para 6.151 of the Draft Determination the intention to amend the Explanatory Note to Section 9.4).

5. Consumer complaints

The Commission commented in the Draft Determination that there is limited information on the MA website about making a complaint (para 6.123) and thought that this could be improved (para 6.186).

MA would like to inform the Commission that it has recently launched a revised website which includes a pro forma complaint submission form. Further materials are in the process of being prepared that will include information directed to members of the general public about how to lodge a complaint, and how complaints are considered by the Code of Conduct and Appeals Committees. When Edition 15 of the Code comes into effect,

additional information will be included in relation to the new provisions of the Code providing access to an independent facilitator.

6. Proposed Condition C1

MA queries whether the penultimate paragraph of proposed Condition C1 should in fact be the final paragraph of the proposed Condition. This is because the report referred to in the penultimate paragraph appears to be the annual report to be prepared by the Monitoring Committee, so the sentence 'The report shall also' appears to flow more clearly after the paragraph that is currently the final paragraph, which discusses the obligation on the Monitoring Committee to prepare the annual report. If this amendment is made, the order of the paragraphs will mirror the order of the paragraphs of Condition C1 imposed in relation to Edition 14 of the Code.

MA looks forward to receiving the Commission's responses to the above comments in due course. In the meantime, please let us know if you have any comments or queries in relation to any of the above.

Yours sincerely

Fiona Crosbie
Partner
Fiona.Crosbie@aar.com.au
Tel 61 2 9230 4383

Emma Marsh
Senior Associate
Emma.Marsh@aar.com.au
Tel 61 2 9230 4136