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From Fiona Crosbie / Emma Marsh

To **Bronwyn 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 9/6/06

Dear Ms Davis

Medicines Australia - application for authorisation

Medicines Australia (***MA***) wishes to respond to the submissions made in response to the Commission's Draft Determination in respect of Medicines Australia's applications for revocation and substitution A90994-A90996.

As the submissions from the parties primarily reference the submission from the Australian Consumers' Association (***ACA***), MA's comments below mainly address the issues raised in the ACA submission. The ACA has raised precisely these issues before and MA has responded to them in previous submissions. The Commission has also commented on the issues raised by the ACA and its views are reflected in its Draft Determination. However, MA has responded to the ACA's most recent submission for the sake of completeness and to reiterate its position in relation to the issues raised.

1. Provisions to detect breaches are adequate

The ACA comments that the MA Code of Conduct (the ***Code***) does not contain adequate provisions to detect breaches in relation to the marketing of pharmaceuticals.

As noted in previous submissions to the Commission, MA submits that the Code includes substantial requirements for monitoring of activities of pharmaceutical companies to ensure compliance with the Code.

The Monitoring Committee is established under Section 14 of the Code and its membership has been expanded in Edition 15 of the Code to include a consumer representative nominated by the Consumers' Health Forum. As set out in our letter of 4

May 2006, MA's intention is that under Edition 15, the Monitoring Committee will undertake as a minimum:

- the review of one separate type of promotional material in three different therapeutic classes (for example, advertisements in one therapeutic class, printed promotional material in another therapeutic class and brand name reminders in a third therapeutic class);
- a review of three different promotional activities covered by the Code across all therapeutic classes, which would include the review of company sponsored educational meetings and symposia.

This proactive monitoring of company activities is in addition to the Code of Conduct Committee considering complaints that are submitted in relation to company materials and activities by industry and other non-industry complainants.

MA therefore submits that the Code of Conduct is effective in providing appropriate mechanisms to detect and deal with potential breaches of the Code.

2. Processes for determining breaches

The ACA comments that the Code process for adjudicating complaints is not transparent or balanced.

MA refers the Commission to MA's previous submissions that describe the impartiality and transparency of the complaints handling process, including:

- The Code of Conduct Committee that determines complaints is comprised of members, the majority of whom are independent of the pharmaceutical industry. These members are nominated by independent organisations including the AMA, RACGP, ADGP, RACP, CHF and TGA. Therefore it is unreasonable to claim that the process is unbalanced or weighted in favour of particular companies or the industry broadly.
- Edition 15 of the Code includes a new process to ensure that members of the Code of Conduct Committee hearing a complaint do not have a conflict of interest, as the Commission has noted in the Draft Determination.
- The different stages of the complaint handling process are set out in detail in Appendix 1 of the Code.
- The outcomes of the Committee's review of complaints will be published quarterly on the MA website under Edition 15. Complaints relating to activities directed to members of the general public are published on the MA website as soon as the complaint is finalised.
- To further enhance transparency of the Code processes, MA has now published on its website the names of the independent members of the Code of Conduct and Code Appeals Committees. This information may be viewed at: http://www.medicinesaustralia.com.au/pages/page96.asp

3. Penalties and other sanctions

The ACA comments that the penalties specified in the Code are inadequate to deter breaches.

MA reiterates its rejection of this comment. As previously advised, the level of fines provided for in Edition 15, the effect on companies and the cost to them of corrective advertising are comparable with penalties and sanctions imposed under State fair trading laws and the Trade Practices Act for misleading conduct and other Part V breaches.

MA wishes to reiterate that the fines under the Code are only one aspect of sanctions that can be imposed if a company is found to have breached the Code. Consideration of the adequacy of the penalties must take into account the cost of withdrawing and replacing materials found in breach, of issuing any corrective advertisement or letter, and the damage to a company's reputation, which is particularly important to companies.

A potential fine of $200,000, which is applicable for serious breaches where there is potential for patient harm as a result of promotional materials or activity found in breach, and for repeat breaches is, MA submits, a real deterrent.

MA therefore submits that the range of penalties and other sanctions are adequate to deter breaches of the Code.

4. Measures to monitor effectiveness and review and improve the Code

Contrary to the ACA's assertion that there are no measures to monitor the effectiveness of the Code or to consult with stakeholders to review and improve the Code, as the Commission is aware, MA undertook extensive and comprehensive consultations with internal and external organisations during the development of Edition 15 of the Code. The list of organisations that were invited to make submissions to MA in relation to the Code was included in our submission to the Commission of 30 November 2005.

MA also submits that through the authorisation process it has submitted the Code to further comprehensive review and has demonstrated its willingness to respond to valid comments made during this process, such as making further changes to the Code in relation to Starter Packs and the promotion of medical devices and publication of further information about the Code process on its website. MA has also promptly responded to the Commission's proposal in the Draft Determination for more detailed information to be published regarding the Monitoring Committee's review of company-sponsored educational meetings and symposia.

5. Advertisements in Prescribing Software

The ACA also commented that the Code does not adequately regulate advertisements appearing in prescribing software.

As noted in previous submissions to the Commission, Edition 14 of the Code already regulates advertising in prescribing software. These provisions have been strengthened in Edition 15 in order to avoid the placement of advertisements in clinical tools or patient education materials which a doctor may use in consultation or discussion with a patient.

6. The complaints process is simple and accessible

The ACA also commented that the complaints process should be simplified so that consumers can become more involved.

MA considers that the complaints process is sufficiently accessible to consumers. There is no expectation or requirement for a consumer complainant to engage in dialogue with a subject company prior to submitting a complaint, as there is for an industry complainant. As the Commission is aware, with the introduction of Edition 15, MA will provide access to independent facilitators to assist non-industry complainants to make complaints.

As advised to the Commission in our letter of 23 May 2006, MA has also revised its website and is providing more information through this portal to assist non-industry complainants to make complaints. In addition, MA has recently published a brochure for consumers about the Code of Conduct, a hard copy of which has been posted to the Commission today.

MA would also be pleased to engage with the ACA to discuss additional methods by which to inform consumers about the Code.

7. MA Continuing Education Program

MA submits that the ACA's assertion that members of the public cannot obtain any information about the MA Continuing Education Program (***CEP***) is incorrect. A course outline is available from the MA website, and from the University of Queensland website.

As explained previously, it is reasonable for MA to protect the intellectual property it has created in the course materials. It would therefore be unreasonable to expect MA to distribute the course materials to people who are not undertaking the course.

8. Issues raised in other submissions

MA notes with considerable concern the submission by Dr Mansfield of Healthy Skepticisim that several thousands of heart attacks and hundreds of deaths have been caused by misleading promotion of Vioxx. MA submits that this assertion is completely groundless and is not supported by any evidence. Whilst MA fully supports that promotional material must not be misleading, as is required by the Code, it would not be possible to make a link between promotional material directly resulting in such significant patient harm. MA rejects Dr Mansfield's assertion in the strongest terms.

Dr Mansfield proposes publication of greater details about the Monitoring Committee's review of promotional materials in order for independent parties to check the Committee's determinations. As noted previously by MA, in our letter of 7 April 2006, the Monitoring Committee already comprises members independent of MA, including representatives of the AMA, RACGP and consumers. MA does not, therefore, believe that such double checking of the Committee's findings is necessary or appropriate. In addition, were Dr Mansfield's suggestion adopted, this would result in inefficiency and delay in the monitoring process.

However, MA has undertaken to publish more detailed information about the outcomes of the Monitoring Committee's review of companies' support of educational meetings and symposia, as described in our letter to the Commission of 23 May 2006.

Dr Mansfield's comments in relation to the membership of the Code of Conduct Committee have been addressed in section 2 above.

Dr Mansfield's comments in relation to sanctions have been addressed in section 3 above.

MA looks forward to receiving the Commission's Final Determination 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