20 August 2009

Mr Richard Chadwick
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Australian Competition and Consumer Commission
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Dear Mr Chadwick

Applications for Revocation and Substitution - A91150 & A91155 & A91156 & A91183 & A91184

We act for Medicines Australia (***MA***) in respect of its application for authorisation of Edition 16 of the Medicines Australia Code of Conduct (***the Code***).

MA undertook an extensive consultation process when revising the Code and is pleased that the submissions received by the ACCC recognise the significant public benefits of the Code.

We comment further on the specific matters addressed in the submissions.

1. **Increasing fines**

   The submissions of the Royal Australasian College of Physicians (***RACP***) and Dr Ken Harvey of La Trobe University suggest increasing the level of fines payable for breaches of the Code. Edition 16 of the Code substantially increases fines for moderate, severe and repeat breaches of the Code by 50%, 100% and 100% respectively. MA does not consider any further increase is necessary at this time.

2. **Greater transparency about the allocation of fines**

   RACP requests greater transparency regarding the spending of fine revenue.

   On 28 June 2008 the MA Board resolved to establish a Special Purpose Fund (***the Fund***). The Fund will be financed by fines imposed under the Code and used to finance corporate social initiatives. The details of two proposed major projects valued together at over $1.1 million are currently being finalised with an indigenous health organisation. MA will publish the details of the projects in its annual report which will be available on MA's website.

3. **Application of the Code**

   A number of submissions propose that the Code apply to more industry participants.

   The submissions vary in their view of the appropriate ambit of the Code. RACP suggests the Code should apply to generic companies, NHMRC considers it should apply to non-members of MA and Dr Harvey proposes a review of the regulation of the promotion of therapeutic goods, with a single Code to govern all therapeutic goods and promotional practices.

   The following facts are relevant to the ambit of the MA Code:

   (a) **MA is the national association representing the innovative medicines industry in Australia.**

(b) Membership of MA is voluntary and members represent more than 80 percent of the prescription medicines industry. Adherence to the Code is a requirement of membership of MA.

(c) There are four categories of MA membership:

- Class one - for research based prescription pharmaceutical companies (innovators);
- Class two - for non-research based prescription pharmaceutical companies (generics);
- Class three - for companies significantly engaged in research into potential pharmaceutical products but which have yet to commence significant production; and
- Class four - being firms or companies ineligible for other classes of membership which are significantly engaged in the development, testing or registration of prescription pharmaceutical products or which are in the opinion of the Board of MA engaged with the research based pharmaceutical industry for a significant part of their business.

Further details, including the member companies in each class can be found on the MA website at www.medicinesaustralia.com.au and at page 35 of the submission lodged with the Commission on 30 June 2009.

(d) All prescription medicines must be registered on the Australian Register of Therapeutic Goods. As a condition of registration of prescription medicines, the Therapeutic Goods Administration (***TGA***) requires that promotional material relating to the registered good must comply with the MA Code.

Therefore:

- the Code applies to members of MA (whether they are innovators or generic companies); and
- the Code applies to non-member companies to the extent required by the TGA's marketing approval letter.

Dr Harvey is concerned that the different standards of behaviour required of innovators and generic companies has potentially anti-competitive consequences. As set out above, MA has four categories of membership, and class 2 includes generic companies.

MA appreciates the potential for the Code to create higher standards of conduct for its members, however, all voluntary schemes of industry self regulation will involve such a discrepancy developing and this of itself does not negate the benefit of the Code. In *Re Medicines Australia Inc* [2007] ACompT 4, the Tribunal found that as a general principle, voluntary codes were potentially of significant public benefit. The Tribunal was satisfied that there was no material anti-competitive detriment and no other public detriment that arose from the Code [333].

Implicit in Dr Harvey's concerns about the different standards of conduct imposed on members and non-members is a recognition that the Code is effective. MA is open to suggestions about how its Code might be made to apply to more industry participants but does not believe that this issue goes to the question whether the Code in its current form

should be authorised. MA has recently made submissions to the National Health and Hospitals Reform Commission and Productivity Commission's Annual Review of Regulatory Burdens on Business that the Code should apply more broadly.

4. **Generic industry representation on the Code Committee**

RACP suggests that if the entire Code applies to the generic industry, the Code Committee should include representatives from the generic industry. Edition 16 of the Code extends representation of MA member companies on the Code Committee to:

- two member company senior executive officers with full voting rights;
- two member company medical/scientific directors with full voting rights;
- one member company marketing director with full voting rights; and
- a maximum of two observing and non-voting employees of member companies.

The class of membership of a company is not relevant to representation on the Code Committee. Accordingly, the Code already provides the opportunity for a class two or generic member to be one of the representatives on the Code Committee.

5. **Clarify the head of power for the imposition of fines**

NHMRC suggests there should be an explanatory note in section 24 to clarify the head of power for the imposition of sanctions. The current section 24 provides:

> Pursuant to the Constitution of Medicines Australia, Section 5 Disciplining of Members, the Board is empowered to discipline a Member Company should the member company be found guilty of conduct contrary to the Code of Conduct.

The head of power is therefore section 5 of the Constitution.

MA is always open to suggestions that might clarify the Code, and is content to consider any particular wording proposed by the NHMRC.

6. **Minor suggested changes**

NHMRC has suggested a number of minor additional amendments. MA accepts these suggestions and responds to each as follows:

- the reference to NHMRC's National Statement (on page 72) can be updated to read *NHMRC National Statement on Ethical Conduct in Human Research*; and
- the title of the Code will be added to the front page of the published version of the Code.

Please contact us if you have any questions.

Yours sincerely

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