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13 September 2012

Mr Mark Basile Adjudication Branch Australian Competition and Consumer Commission 360 Elizabeth St Melbourne Melbourne VIC 3000

Dear Mr Basile

Medicines Australia: Application for Revocation and Substitution A91316, A91317, A91318, A91319 and A91320

We refer to our recent discussion regarding Medicines Australia's application for authorisation of Edition 17 of the Medicines Australia Code of Conduct (the **Code**). We provide below a response to questions raised by you during that discussion.

1. Generic Medicines Industry Association (GMiA) submission to ACCC

The GMiA proposes that Medicines Australia's amendment to section 2.6 of the Code, which prohibits the provision of brand name reminders to healthcare professionals, should either be rejected by the ACCC or that the prohibition should not apply to the generic medicines industry.

Medicines Australia does not consider that the prohibition against brand name reminders in Edition 17 of the Code should be removed or amended.

As the ACCC is aware, under Edition 17 of the Code member companies may no longer provide brand name reminders to healthcare professionals, although medical education items which enhance patient care can be provided subject to the provisions of section 9.13. Medicines Australia considers that this amendment:

- increases the existing public benefits associated with the Code's provisions regulating the provision of promotional material to healthcare professionals;¹
- results in no public detriment; and

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¹ These public benefits were recognised by the ACCC in authorising Edition 16 of the Code. The ACCC considered that one public benefit likely to result from the Code was the setting of consistent standards for medical and promotional claims: ACCC: Determination Medicines Australia Code of Conduct 16th edition, 3 December 2009 at [5.130].

 reflects a global trend in the pharmaceutical sector to prohibit or limit the provision of brand name reminders to healthcare professionals.²

Although brand name reminders are prohibited under Edition 17, the Code **does not prohibit** member companies from promoting their products to healthcare professionals generally, so long as promotional material complies with the requirements in the Code. In this respect, section 2 of the Code includes provisions governing advertising to healthcare professionals via (a) supply of printed promotional materials, (b) healthcare professional journals, (c) mailing of printed promotional material (d) audiovisual material and (e) the internet.

If Edition 17 of the Code is authorised all pharmaceutical companies (including generic manufacturers) will therefore continue to have available several avenues through which they can provide information on their products to healthcare professionals. Medicines Australia does not consider that prohibiting brand name reminders will reduce the level of competition between pharmaceutical companies or affect adversely generic medicine manufacturers specifically. The GMiA has not provided any evidence to support its view that the amendment in section 2.6 will have the effect of reducing the ability of generic manufacturers to compete.

2. Amendments to Edition 17 of the Code

In our letter of 24 August 2012 Medicines Australia agreed to make certain amendments to the Code following the submission provided to the ACCC by the Department of Health and Ageing. As requested, attached to this letter is a version of Edition 17 of the Code indicating in track changes where relevant amendments have been made.³

Yours sincerely

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² By way of example, jurisdictions such as the UK and the US prohibit the provision of brand name reminders (also called promotional aids) to healthcare professionals. The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals provides a rationale for the prohibition of such products as follows "Providing items for healthcare professionals' use that do not advance disease or treatment education – even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar "reminder" items with company or product logos) – may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff..." (section 10).

³ See amendments in sections 8.10, 10.5, 10.10, 10.11, 18(g) and the definition of 'advertisement' in the glossary. Medicines Australia has also removed the definition of 'ACSOM' from the glossary as that body is no longer referred to in the Code as a result of the amendments.