20 August 2010

Dr Richard Chadwick
General Manager
Adjudications Branch
Australian Competition and Consumer Commission
GPO Box 3131
Canberra ACT 2601

Dear Dr Chadwick

**Re: Generic Medicines Industry Association Pty Ltd applications for authorisation [A91218 & A91219]**

Thank you for providing the opportunity for Medicines Australia to make a submission in respect of the Draft Determination concerning the Generic Medicines Industry Association's (GMiA) application for authorisation of its Code of Practice, second edition.

**Scope of the competitive environment**

The GMiA has stated in its submissions to the ACCC and in its Code of Practice (clause 5.1) that its 5 members supply more than 90 percent of generic medicines prescribed through the PBS. The ACCC has further clarified that GMiA members supply approximately 33 percent of all prescriptions (by number of prescriptions) supplied through the PBS. Medicines Australia members and GMiA members are direct competitors in the out of patent market, which is why it is important for there to be equivalent standards of conduct and equally effective self-regulatory processes for all companies that supply prescription medicines in Australia.

The Federal Government pays a $1.53 dispensing incentive to pharmacists when a prescription is dispensed where the cost to the patient is no more than the co-payment fee. This incentive is paid if the originator product is dispensed and it is priced the same as the equivalent generic brand of the medicine i.e. there is no brand price premium associated with the product. The dispensing incentive is not only paid for dispensing a generic (non-originator) brand (paragraph 2.33 in the Draft Determination, 3 August 2010 refers). The Government, through its policy of providing the incentive for dispensing both off-patent originator brands and off-patent generic brands, has already recognised that both originator and generic suppliers compete in the same market. This serves to further illustrate that Medicines Australia members are directly competing with GMiA members.

**Transparency**

Medicines Australia supports the proposed conditions of authorisation which will require the extension of the educational event reporting requirements in clause 10 of the GMiA Code. This will provide an appropriate level of transparency about the relationships between members of GMiA and healthcare professionals, including pharmacists, which will provide greater confidence that the standards described in the Code are being met.

Medicines Australia also supports the condition requiring reporting of lump sum value of benefits provided to pharmacists (other than more favourable trading terms), including hospitality, entertainment, gifts, non-price incentives and loyalty rewards programs. Whilst we would prefer that these incentives were specifically prohibited by the GMiA Code, as they are under the Medicines Australia Code (Section 9.12), we accept that transparency about these benefits will act as a deterrent to conduct that cannot withstand public and professional scrutiny. However, Medicines Australia maintains that all companies that supply prescription medicines should be required to be subject to the Medicines Australia Code of Conduct.

**Sanctions**

Medicines Australia remains concerned that the financial sanctions for breaches found under the GMiA Code are inadequate. GMiA has advised the ACCC that the financial sanctions have been set relative to the amount its members spend on hospitality, which it claims is considerably less than that spent by Medicines Australia members. Whilst the ACCC made a comment in its authorisation of the Medicines Australia Code of Conduct 16$^{th}$ edition about the relativity between the level of fines and expenditure on hospitality by pharmaceutical companies (paragraph 5.110), we respectfully submit that this comment should not be interpreted to mean that the level of fines should be benchmarked against the expenditure by member companies, collectively or individually, on hospitality. Such an approach fails to acknowledge that the fines under the Code may be imposed for a breach of any provision of the Code, not only conduct related to provision of hospitality or other benefits to healthcare professionals.

To further illustrate why we consider that expenditure on hospitality is an inappropriate benchmark for establishing the appropriate level of monetary sanctions we offer the following comparison. Some Medicines Australia member companies hold between two and twenty educational events for healthcare professionals per annum. The expenditure by these companies on hospitality is minimal, probably less than any one of the GMiA member companies, and may only be provided in association with an educational event. However, as members of Medicines Australia these companies are still subject to the level of sanctions that may be imposed under the Medicines Australia Code for any conduct contrary to the Code. Further, the ACCC noted that some generic pharmaceutical companies offer reward programs that can be used to obtain benefits such as holidays, electronic equipment or tickets to sporting events. The

monetary value of these benefits provided to pharmacists by generic companies is currently undisclosed.. If one accepted GMiA's argument for establishing the appropriate level of fines, these benefits would also need to be taken into account. However, this is just one area of conduct regulated under the Code and should not be used as a benchmark for establishing effective sanctions for the whole scope of conduct regulated under the Code.

Medicines Australia does not consider that the level of sanctions available under the GMiA's Code should be benchmarked against an individual company's expenditure, or the whole association membership's expenditure on hospitality. We reiterate that we consider there should be equivalent sanctions under the GMiA Code as those available under the Medicines Australia Code. Again, the practice of applying differential standards to companies competing in the same market appears at odds with the principle of competitive neutrality. Whilst for one supplier to the off-patent market a breach of a code requires one level of fine (under the Medicines Australia Code), exactly the same breach made by a different supplier attracts a much lower fine (under the GMiA Code). This suggests to the community that a breach of ethical conduct is somehow not as bad when made by one company compared with another company operating in the same market.

The fines proposed under the GMiA Code are equivalent to those that applied under Edition 13 of the Medicines Australia Code, adopted in 2000. The level of fines has been increased over the last decade (and three editions of the Code) in response to the community, the ACCC, the Competition Tribunal and other stakeholders' comments about effective sanctions as a deterrent to breaching the Code. We do not believe that the levels of fines under the GMiA Code are likely to be sufficient to act as a deterrent to breaching the Code.

Medicines Australia therefore submits that the ACCC should decline to authorise the GMiA Code in its current form or, alternatively, should authorise the GMiA Code subject to conditions (under s 91(3) of the *Trade Practices Act 1974* (Cth)) that require the sanctions under the Code of Practice to be increased to be equivalent to those under Edition 16 of the Medicines Australia Code of Conduct.

**Complaints handling**

Medicines Australia commends the amendments that GMiA has made to the Code of Practice to address the concerns that Medicines Australia had expressed about the independence of the Code Complaint Committee (CCC). We also commend the inclusion of provisions that require declaration of conflicting interests by company representatives sitting on the CCC and the requirement for a quorum of the CCC which will ensure that the membership is made up primarily by members independent of GMiA company representatives.

**Period of authorisation**

Medicines Australia supports the ACCC's requirement that the authorisation should be reviewed in three years rather than five years, in consideration that this is the initial implementation of the new Code of Practice. We are particularly concerned that the effectiveness of the sanctions and complaints process is reviewed in the three year time frame if the level of fines remains as proposed by GMiA.

Thank you again for the opportunity to provide a submission on the application from GMiA for interim authorisation of its Code of Practice.

Yours sincerely

**Dr Brendan Shaw**
Chief Executive

Medicines Australia Limited ABN 23 126 990 001
16 Napier Close Deakin ACT 2600 Phone +61 2 6122 8500 Fax +61 2 6122 8555 www.medicinesaustralia.com.au