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16 July 2010

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

By email – richard.chadwick@accc.gov.au

Dear Dr Chadwick

Re: Generic Medicines Industry Association (GMiA) – proposed Code of Practice

Thank you for inviting GMiA to provide a response to the submissions from interested parties about its application for interim authorisation of the proposed Code of Practice.

GMiA believes that it has put forward relevant and legitimate reasons, as identified in the ACCC's *Guide to Authorisation,* to justify a decision by the ACCC to grant interim authorisation of the Code of Conduct, namely

- GMiA has received a complaint pertaining to the commercial operations of a member of GMiA;
- Members ofthe GMiA Code Complaint Committee could more confidently discharge their responsibilities in adjudicating on the current complaint with an interim authorisation in place; and
- the Code of Practice is not highly anticompetitive.

If fact, GMiA believes that the present case represents the ideal type of situation where the ACCC should grant an interim authorisation.

GMiA remains confident that the Code of Practice represents a sensible, effective and efficient system of best practice self-regulation in relation to the supply of generic medicines.

GMiA is confident that the grant of interim authorisation will not permanently alter the competitive dynamics of the market or prohibit the market from returning to its pre-interim state if the authorisation is denied.

GMiA notes some concerns raised by Medicines Australia and the Consumer Health Forum, in particular the adequacy of sanctions and the composition of the Code Complaint Committee. In general, members of GMiA have considered these issues and believe that the current Code achieves the right balance on both these issues. More specifically, GMiA notes that these issues do not present a valid reason for denying interim authorisation as the interim authorisation will not influence the ultimate determination of the ACCC.

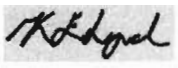
The proposed sanctions in the GMiA Code of Practice are appropriate when considered in the light of the total amounts spent by members of GMiA on promotional activities. The level of sanctions will be re-assessed to ensure that the sanctions are an effective deterrent in future revisions of the Code. It is noted that the level of sanctions proposed in the GMiA code are aligned with those of other sectors of suppliers of therapeutic goods, for example the Code of the Medical Technology Association of Australia. It is also noted that the sanctions in the Medicines Australia code have been substantially increased in recent editions as lower sanctions were historically found to be ineffective. It is appropriate to only increase sanctions in the event that the current level of sanctions proposed by GMiA are found to be ineffective.

The composition of the GMiA Code Complaints Committee provides a balance between ensuring the right skills and expertise are present on the committee and that the committee is manageable. Currently the committee comprises 57 per cent independent members (4 independent members of a total of 7 members). This is similar to the Medicines Australia committee composition of 58 per cent independent members (7 independent members of a total of 12 members).

GMiA welcomes the Position Paper released by the Parliamentary Secretary for Health, the Hon. Mark Butler MP on 30 June 2010 concerning the Promotion of Therapeutic Goods and is confident that the GMiA Code of Practice more than adequately meets the regulatory goals identified in the Position Paper.

Should you require any further information, please contact me on 0432 500 308.

Kind regards,



Kate Lynch
Chief Executive Officer
Generic Medicines Industry Association Pty Ltd