Generic Medicines Industry Association Pty Ltd

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Generic Medicines Industry Association

Submission to the Finance and Public Administration Legislation Committee: Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

19 April 2013

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1. Executive Summary

The Generic Medicines Industry Association (GMiA) seeks to develop good relationships with all constituencies involved in the continued delivery of pharmaceutical care to the Australian community and to contribute to the long-term sustainability of the Pharmaceutical Benefits Scheme through support of the principles of the National Medicines Policy.

Members of GMiA welcome any initiatives that increase public confidence in generic medicines and the activities of the generic medicines sector.

However, members of GMiA believe that the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 should not be passed as it would impose a significant administrative and cost burden on members that is inappropriate in the absence of a clear public benefit. GMiA has demonstrated that the provisions in the 2nd edition of the GMiA Code of Practice (Code) are sufficient to ensure appropriate interactions with the medical profession.

2. Submission

Members of the Generic Medicines Industry Association (GMiA) welcome any initiatives that increase public confidence in generic medicines and the activities of the generic medicines sector.

Members of GMiA believe that the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 is not necessary, should not be passed, and that the provisions in the 2nd edition of the GMiA Code of Practice (Code) are sufficient to ensure appropriate interactions with the medical profession and the ethical supply of generic medicines to the Australian community.

The additional conditions proposed in the Bill entail significant compliance costs, generating significant additional administrative burden on the industry. In contrast, the public benefit derived from the Bill is negligible. It is inappropriate to add administrative burden to industry in the absence of a clear net benefit.

GMiA notes the significant administrative and cost burden that event reporting of educational activities provided to pharmacists would place on its members. The cost of collecting this information would need to be passed onto patients by way of increased prices of generic medicines.

GMiA is pleased to report that as at April 2013, the GMiA Code of Practice has been in operation for three full years. On 1 March 2010, GMiA released the first edition of its Code. The second edition of the Code was authorised by the ACCC on 3 November 2010 for a period of three years.

The Code formalises the commitment of GMiA Members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards.

A copy of the Code can be found at our website at www.gmia.com.au/gmia-code-of-practice/. The GMiA website also includes information on how complaints can be made, and it posts details of Members' event and non-price benefit reporting and the detailed reports of the annual administration review of the Code.

The Code is principle based, providing guidance in a single document, on the different legislation, regulation and guidelines with which sponsors of generic medicines listed on the Australian Register of Therapeutic Goods (ARTG) comply. In particular, section 6 of the Code sets out the key legislation, regulation and guidelines applicable to suppliers of generic medicines.

During the three years that GMiA has administered the Code, GMiA has received five complaints. One complaint required the convening of the Code Complaint Committee and was satisfactory resolved. One complaint, which was subsequently deemed not to be a complaint by the Code Administration Committee, was satisfactory resolved without the need to convene the Code Complaint Committee. Three complaints pertained to the activities of non-members of GMiA. GMiA members have demonstrated that the current system of best practice self-regulation is appropriate in ensuring the ethical supply of generic medicines to the Australian community.

Details of the complaints can be found in the annual report of the Code Administration Committee. This report provides a comprehensive review of the administration of the Code and can be found on the GMiA website at:
http://gmia.com.au/gmia-code-of-practice/annual-review/annual-review-of-code-2012/
http://gmia.com.au/gmia-code-of-practice/annual-review/annual-review-of-code-2011/

Finally, GMiA would be pleased to provide further information during a public hearing of this Inquiry.

3. Generic Medicines Industry Association

The Generic Medicines Industry Association (GMiA) was established in 2001 to represent the interests of suppliers of generic medicines in Australia. GMiA has 18 members, including five full members who supply approximately 90% of the non-original generic medicines to the Australian market.

GMiA seeks to develop good relationships with all constituencies involved in the continued delivery of pharmaceutical care to the Australian community and to contribute to the long-term sustainability of the Pharmaceutical Benefits Scheme (PBS) through support of the principles of the National Medicines Policy.

The guiding principles of the Members of the GMiA are:

i. To support the long term sustainability of the PBS by ensuring the timely and cost effective provision of Generic Medicines to consumers.

ii. To support the quality use of medicines (QUM) in partnership with other stakeholders.

iii. To support the development of policies that facilitate timely access to Generic Medicines for all Australians.

iv. To support the development of policies that promote the continued viability of a local manufacturing base for Generic Medicines (for domestic and export markets).

v. To encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate interchangeability of Generic Medicines amongst Healthcare Professionals, Government and Consumers.

vi. To support balanced intellectual property rights in the pharmaceutical sector that enable timely, cost effective access to Generic Medicines.

vii. To enhance the accountability of Members by establishing a complaints handling mechanism that is both accessible and transparent.

viii. To reduce actual and potential conflicts of interest between Members and Healthcare Professionals responsible for prescribing prescription medicines by establishing an Educational Event reporting procedure with independent review.