GMiA Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540
PO Box 222
Pymble BC
NSW 2073

8 May 2013

Senate Finance and Public Administration Committees
PO Box 6100
Parliament House
Canberra ACT 2600
Australia
c/ email: fpa.sen@aph.gov.au

Dear Sir / Madam,

Re: Inquiry by the Finance and Public Administration Legislation Committee concerning the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

The Generic Medicines Industry Association (GMiA) is the national association representing companies that manufacture, supply and export generic medicines. The generic medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

GMiA was pleased to make a submission to the Finance and Public Administration Legislation Committee concerning the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013. GMiA notes that, although we had advised the Committee that we were available to provide evidence, we were advised that we were not required to give evidence at the inquiry's public hearing in Melbourne on Monday 29 April 2013. GMiA is concerned that a number of issues raised related to generic medicines, as noted in the Hansard from the public hearing, have not been fully addressed.

Therefore, in the interest of providing the Committee with information regarding generic medicines, this letter is intended to provide the committee with facts that would have been discussed if GMiA had appeared at the hearing. Specifically, GMiA would like to address:

- The GMiA and the importance of generic medicines;
- The unique operating environment for generic medicine manufacturers; and
- The GMiA Code of Practice.

<u>The Importance of Generic Medicines</u>

Full Members of GMiA are companies that predominantly manufacture and/or sell generic medicines in the Australian market and/or manufacture generic medicines for export. To correct misinformation given at the inquiry by Medicines Australia, GMiA has 18 members, including five full members who supply approximately 90% of the non-original generic medicines to the Australian market, making the association highly representative of the generic medicines sector. All GMiA members support the GMiA principles and GMiA Full Members adhere to the GMiA Code of Practice.

A generic medicine is an equivalent of the reference brand medicine (the original brand of the

medicine). It contains the same active ingredient as the original brand medicine, is expected to deliver the same health benefit and is therefore interchangeable with that product. Generic medicines must meet the same, strict, Australian standards - including the same manufacturing requirements - as original brand medicines. Generic medicines are high quality medicines delivering affordable health for all Australians. Every time a generic medicine is dispensed in Australia in place of the original brand, savings are delivered to the national economy.

In 2010, the Government introduced by legislation the Expanded and Accelerated Price Disclosure (EAPD) Policy. These reforms to the generic medicines sector are currently delivering savings of a minimum $1.9 billion over four years. These savings are in addition to savings to the PBS (Government contribution) of an estimated minimum $1.4 billion from April 2005 to April 2009 that have been driven by the generic medicines industry sector.

The Unique Generic Medicine Operating Environment

GMiA members operate in a unique commercial environment, which is different to that of the suppliers of original brand medicines and other suppliers of therapeutic goods and it is important that the committee note these differences.

There is typically lengthy market experience, understanding and knowledge of a medicine by the time a generic medicine enters the market, which can be 15- 20 years after the original brand was first launched. Doctors' prescribing habits regarding an off-patent medicine are usually well formed; and pharmacists are well informed as to the medicine's indications and effectiveness.

There is a commercial business to business interaction between generic medicine suppliers and pharmacy owners. The nature of these interactions is already transparent through Price Disclosure. Under this system, companies submit sales information to the Department of Health and Aging, and, based on this information, the price the Australian Government pays is adjusted to reflect more closely the price at which the medicines are supplied in the marketplace.

The major difference between the promotion of original brand medicines and generic medicines is that the marketing of generic medicines typically seeks to change behaviour at the point of dispensing not at the point of prescribing. Generic medicine manufacturers therefore do not seek to influence the prescribing habits of doctors through educational events or other activities. The decision to substitute a patient from one brand to another brand at the point of dispensing is unlikely to create any change to the health outcomes for the patient, and is likely to create a financial saving for the patient, potentially increasing patient compliance.

The GMiA Code of Practice

The GMiA Code of Practice 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. The Code provides for a Code Administration Committee established to ensure the successful implementation and ongoing effectiveness of the Code and a Code Complaint Committee established to hear Complaints brought under the Code by members, members of other associations, Healthcare Professionals or the public.

The GMiA Code is subject to an annual review by the GMiA Code Administration Committee. In 2012, the Code Administration Committee concluded, "*The Code has been effective in formalising the high standards of conduct adhered to by Members*".

GMiA rejects any suggestion that its Code is any less rigorous or capable of self-regulation than the Medicines Australia Code. The GMiA Code specifically reflects the unique operating environment of suppliers of generic medicines and sets out the best practice standards, aligned with that unique operating environment required of all members. As outlined in the GMiA submission to this inquiry, during the three years that GMiA has administered the Code, GMiA has received only five complaints. GMiA members have therefore demonstrated that the current system of best practice self-regulation is appropriate for this sector in ensuring the ethical supply of cost effective generic medicines to the Australian community.

GMiA suggests a meeting with the committee would be appropriate and is pleased to provide further clarification on any of the points raised in this letter.

Kind regards,

Kate Lynch
Chief Executive Officer
Generic Medicines Industry Association Pty Ltd