GMiA Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

Generic Medicines Industry Association

Submission to the Senate Standing Committee on Community Affairs: Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013

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For further details
Please contact
Kate Lynch, CEO

1. Executive Summary

The Generic Medicines Industry Association (GMiA) welcomes the opportunity to comment on the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013.

The GMiA supports in principle the technical amendments as outlined in the Bill and appreciates that these are intended to fill current gaps in the regulation of therapeutic goods. However, members of GMiA are concerned about the implications of this Bill on the cancellation of medicines from the Australian Register of Therapeutic Goods (ARTG) based on "presentation" and the follow on consequences that may follow as a result of the current Therapeutic Goods Administration (TGA) review of labelling and packaging.

2. Submission

The GMiA supports in principle the technical amendments as outlined in the Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013. GMiA appreciates that the main provisions of the bill:

- Make amendments to the definition of 'therapeutic goods' in subsection 3(1) of the Act to enable the Minister, by legislative instrument, to specify products that are taken not to be therapeutic goods for the purposes of the Act;
- Provide the Secretary power to remove products from the Australian Register of Therapeutic Goods (the Register) which are not, or are no longer, therapeutic goods within the definition in the Act;
- Clarify the source of the power for the Secretary to approve product information under section 25AA of the Act; and
- Include a number of other minor amendments designed to ensure consistency in the way the different classes of therapeutic goods are treated under the Therapeutic Goods Act 1989.

Of particular concern to GMiA members is the amendment providing power for the Secretary to suspend/cancel registered and listed goods where the "presentation" of that good is not acceptable. GMiA appreciates that the presentation of a medicine can influence the quality use of that medicine and supports the current TGA power to reject an application for inclusion on the ARTG any product deemed unsuitable. Therefore, GMiA requests clarification of what the Secretary would consider acceptable/unacceptable presentation to be, especially as it relates to labelling and packaging.

In 2012 the TGA initiated a review in relation to Therapeutic Goods Order 69 (TGO 69) *General requirements for labels for medicines* and has committed to reviewing *the Best Practice Guideline on prescription medicine labelling*.As part of the TGA's commitment to the National Medicines Policy and the quality use of medicines in the community, the GMiA recognises that the outcomes from this review will shape new comprehensive guidelines for how medicines can be labelled and packaged. It is understood that the TGA will propose a change to TGO 69 that will mandate requirements for medicine packaging and labelling, including specifications for the minimum font size of a medicine's active ingredient. This review is ongoing and GMiA continues to work with the TGA and other stakeholders to define these new requirements.

GMiA is concerned that an unintended consequence of the amendment in this Bill may be that the Secretary is able to suspend/cancel medicines from the ARTG that do not meet the, as yet

undetermined, requirements mandated as a result of the TGA labelling and packaging review. GMiA is concerned that this power could see a number of currently registered medicines removed from the ARTG for failing to meet for example, the minimum font size requirements. If this were to occur, GMiA members would be required to bear an unacceptable cost for recall and repackaging of medicines to prevent cancellation from the ARTG. The follow on consequence could be that medicines are removed from the ARTG and, following a cost-benefit analysis, not re-registered by the sponsor. This could affect the continuity of supply of medicines in Australia.

With this issue in mind, the GMiA therefore requests:

- the committee consider this amendment in the context of an ongoing labelling and packaging review; and
- "grandfathering" of currently registered medicines on the ARTG, effectively ring-fencing them from the need to implement changes to "presentation" to meet the as yet undetermined packaging and labelling requirements.

GMiA would be pleased to provide further information by correspondence or in any 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.