3 May 2013

Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

By email: Community.affairs.sen@aph.gov.au

To the Committee Secretary

Medicines Australia Submission to the Inquiry into the *Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013*

Medicines Australia welcomes the opportunity to comment on the *Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013* (**the Bill**) which seeks to amend the *Therapeutic Goods Act 1989* (**the Act**).

Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to the Australian market. In 2011-12, our industry generated more than $4 billion in exports for the third consecutive year and invested over $1 billion in research and development. Our members comprise over 80% of the prescription medicines market and play an integral role in delivering better health outcomes for Australians.

Summary

Medicines Australia acknowledges the Bill includes amendments dealing with a variety of issues under the Act, most of which are technical in nature. In general terms, Medicines Australia supports the various policy objectives of the amendments. Nevertheless, Medicines Australia seeks:

- to ensure no unintended consequences flow from the Bill;
- certainty regarding the new power to cancel registration of a medicine due to presentation in the context of the current labelling and packaging review; and
- further engagement on future reform.

General comments

Medicines Australia broadly supports the policy objectives of the Bill. Amongst other things, these objectives include:

- providing greater consistency of regulatory rules and processes across various classes of therapeutic goods;
- increasing clarity, including that compliance with advertising requirements includes compliance with the Therapeutic Goods Advertising Code;
- strengthening the Therapeutic Goods Administration's powers to obtain information from sponsors, acknowledging that the integrity of the regime depends upon the decision maker being able to make decisions on accurate information; and
- removal of inconsistencies, including inconsistencies relating to advertising offences.

As mentioned, Medicines Australia wishes to ensure no unintended consequences of the Bill. Further, Medicines Australia makes the following specific comments regarding the amendments in Schedules 3 and 7 of the Bill.

Goods that are not therapeutic goods

As identified in the Explanatory Memorandum, there is a range of products falling within current, broad definition of "therapeutic goods", which are not appropriately regulated by the Therapeutic Goods Administration (TGA). It is reasonable to exclude these products from the definition of a "therapeutic good" and from the remit of regulation by the TGA.

These reforms are unlikely to affect Medicines Australia members. Nevertheless, Medicines Australia seeks to ensure industry members are properly consulted prior to industry interests being affected. In this regard, Medicines Australia supports that sponsors must be informed, and have an opportunity to respond, before a product is removed from the register under the proposed s 9F(3) of the Act. However, there appears to be no comparable requirement for an affected party to be consulted prior to the Minister declaring a good not to be a therapeutic good under a determination in 7AA(1) or (2). Although this determination would be made via legislative instrument, the disallowance period does not amount to meaningful industry consultation. In the interests of a consultative approach to regulation, Medicines Australia supports industry consultation prior to determinations that affect members' interests.

Presentation

Medicines Australia acknowledges the significant safety concerns if the presentation of therapeutic goods is unacceptable. In addition, Medicines Australia supports the TGA having appropriate enforcement powers. However, as with any regulatory and enforcement powers, members seek to ensure that both the requirements and the enforcement powers are clear and predictable.

As the Committee will be aware, listed products will be subject to deregistration if there is "unacceptable presentation." Unacceptable presentation is defined in s3(5) of the Act. In contrast, registered products will be subject to deregistration if the presentation is "not acceptable." There is no statutory definition of "not acceptable."

Committee Members may be aware that the TGA is currently undertaking a Packaging and Labelling Review (the Review). Throughout the Review there has been a variety of reform proposals affecting all aspects of medicines packaging and labelling. Some proposals have been out of step with international best practice; would create inefficient, unique Australian requirements; and lack evidence demonstrating resultant decreased medication errors or increased quality use of medicines (QUM). Some proposals, despite having no evidence-basis, were supported by the TGA's External Reference Group (ERG). The TGA has not committed to any particular type of reform as yet. However, the TGA has not ruled out any proposals, nor made a commitment to harmonise with other leading markets, underpinned by international bestpractice. As such, future packaging and labelling requirements are uncertain.

It is unclear whether the outcomes of the Review could affect the interpretation of "acceptable presentation" under the Act. With this uncertainty, Medicines Australia is cautious about empowering the regulator to deregister products based on a potentially uncertain or changing requirement for presentation. This is particularly pertinent, as the provisions apply to goods already included in the register when the Bill commences.

In summary, industry supports presentation requirements that underpin QUM, and evidence-based labelling and packaging reform harmonized with other major markets and consistent with international best-practice. Further, industry supports the TGA having the appropriate enforcement powers and acknowledges the current lack of such powers. However, given the current uncertainty, industry requests

the Committee give greater consideration to this power, and its implications with the current Labelling and Packaging Review.

Consultation

Industry has consistently supported a transparent and consultative approach to regulatory reform. Industry welcomes advance notification or consultation prior to introduction of future legislation into the Parliament. Medicines Australia supports the decision to refer the Bill to inquiry and thanks the Senate Standing Committee on Community Affairs for the opportunity to provide a submission to the Inquiry.

Should you seek further information on this submission, please contact Kayla Calladine, Regulatory Manager

Yours sincerely,

Brendan Shaw
Chief Executive