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Senate Finance and Public Administration Committees
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

By email to: fpa.sen@aph.gov.au

Re: Inquiry into the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013*

Dear Sir / Madam,

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. ASMI is a strong advocate of the National Medicines Policy (NMP) and has consistently encouraged its members to align all aspects of their operations with the four arms of the NMP. ASMI and its members are also committed to the Quality Use of Medicines (QUM).

ASMI welcomes the opportunity to provide a submission in relation to the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* under examination by the Senate Finance and Public Administration Committee.

1. Summary

There has already been (and continues to be) a significant commitment by industry and Government to strengthen the self-regulatory controls in this area.

For this reason and the reasons outlined below, the proposed amendment to the *Therapeutic Goods Act* should not be passed.

2. Background

2.1 The Working Group on Promotion of Therapeutic Products (the Working Group)

In March 2011, the Working Group on Promotion of Therapeutic Products (the Working Group) presented their final report to the Parliamentary Secretary (Ms Catherine King). ASMI was represented on the Working Group and endorsed the Group's recommendations.

The Working Group agreed that the ethical promotion of therapeutic products is central to the trust-based framework within which healthcare professionals advise and treat patients. The therapeutic product industries necessarily work closely with healthcare professionals to develop evidence-based approaches to particular treatments, in the development of educational materials on the correct use of products, and to support hands-on learning in the correct use of certain products. However the fundamental trust, and the value of the relationship, can be undermined where the independence of decision-making by healthcare professionals may be seen to be compromised by inappropriate promotion which is not in the best interests of patients or consumers, and which can add to the cost of healthcare.

The Working Group also agreed that Therapeutic industry sector codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community. As a result, the therapeutic industry sectors committed to collaborating with relevant stakeholders in code creation, updating, education, monitoring and compliance.

The Working Group developed a high level statement of principles to be incorporated in each therapeutic industry sector code, together with a statement of the obligations on companies operating in the industry covered by the code. The high level statement of principles provides that the Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties. In this context the quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumers' needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

In addition to the high level statement of principles, the Working Group recommended that each therapeutic industry sector code include provisions which addressed a list of operational areas as well as provisions to address specified governance areas.

2.2 A level playing field

In Australia there are a number of industry associations which represent different therapeutic industry sectors. Many of the associations have codes of conduct which apply to members of the associations. However these codes do not have uniform coverage, nor are they enforceable to address the behaviour of non-members of the associations. The Working Group examined mechanisms to ensure a level playing field across the therapeutic sectors, and between members and non-members of industry associations. It also noted the need to ensure the standards for conduct of health care professionals align with the standards expected of the therapeutic products industries.

The Working Group addressed the need for adherence to industry codes by non-members as well as members by recommending that an applicant nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing/inclusion of a product on the ARTG. *This recommendation was not agreed to by the Government and remains to be implemented.*

2.3 The Governments Response to the Working Group's report

The Government's response to the Working Group's report was published as part of the TGA's Blueprint for reform. (T*GA Reforms: a blueprint for the TGA's future).*In that document, the Government re-affirms its "strong support"[1] for self regulation of the relationship between health care practitioners and the therapeutic goods industry.

2.4 The Codes of Conduct Advisory Group

Following on from the TGA Blueprint, The Government has recently established the Codes of Conduct Advisory Group, chaired by Emeritus Professor Lloyd Sansom, to oversee and guide the implementation of the Working Group's recommendations relating to self-regulation. $1.4m has been allocated to this work.

ASMI is also a member of this Advisory Group.

2.5 The ASMI Code of Practice

In response to the Working Group's report (and in consultation with members and with external stakeholders), ASMI has made a number of changes to our Code of Practice.

The revised Code was published in March 2013 and included changes to the high level principles, operational areas and governance provisions in order to give effect to the recommendations of the Working Group. Other changes were also made aimed at improving and clarifying the operation of the Code.

A copy of the revised Code has been published on our website[2] and has been included with this submission.

Of relevance to this inquiry, the revised Code includes a separate section on "Relationships with Stakeholders" which incorporates both general and specific controls on the behaviour of members.

Also, the revised Code now includes "hospitality" and "entertainment" among the promotional categories considered by our Promotional Monitoring Panel. The Panel publishes an annual report on the outcomes of its monitoring activities.

Furthermore, the Code already included provisions to allow non-members to be bound by the Code upon their agreement to be so bound. ASMI has developed procedures and forms to accept and document such agreement.

ASMI is now finalising a revised training program on the Code.

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[1] http://www.tga.gov.au/pdf/tga-reforms-blueprint.pdf (refer to page 15 of the PDF)
[2] http://www.asmi.com.au/about/ASMI-Code-of-Practice.aspx

2.6 Collaborative approach to reforms

It is ASMI's position that effective reform requires consultation with all affected stakeholders.

This is consistent with our position in relation to the the many other TGA reforms currently underway.

The proposed amendment is not the result of a consultative process and is flawed as a result.

2.7 The therapeutic products industry

The therapeutic products industry in Australia is a diverse collective, and there are considerable differences between the sectors, some of these differences relate to:

- The financial resources of the companies.
- The size of the companies and their geographical locations.
- Government controls over price.
- Intellectual property protections.
- The interactions with healthcare practitioners.
- The interactions with non-healthcare professionals.
- The ability to advertise products directly to consumers.
- The ability for consumers to self-select products.
- The risks associated with the products.

It is therefore crucial that any change in regulation should be risk-based and that the tendency to prescribe a "one-size-fits-all" solution must be resisted.

The costs of regulation are inevitably passed on to the consumers of non-prescription medicines, it is therefore essential that any compliance measures are proportionate to the risks and that they do not introduce unnecessary complexity. So for example, a complex and expensive compliance system set up to monitor something which rarely occurs in a particular industry sector would place an unnecessary burden on that sector and would result in increased costs to consumers, without any corresponding increase in their protection.

3. Concerns with the proposed amendment

Having read the proposed amendment and the explanatory memorandum (and in light of the above background), ASMI offers the following comments:

<u>The proposal covers all medicines (and only medicines).</u> The explanatory memorandum indicates that the bill seeks to regulate "the prescribing habits of doctors" and yet the definition of a "regulated pharmaceutical product" includes both listed and registered medicines. This means that the proposed amendment will have a far greater reach than apparently intended, and yet will not regulate devices. The amendment will regulate all those registered medicines available without a prescription (e.g. all those goods included in Schedules 2 and 3 of the SUSMP as well as all those goods excluded from scheduling).

The amendment will also regulate all listed and complementary medicines (e.g. vitamins, minerals, sunscreens, etc). This inconsistency between the stated aims and the actual reach demonstrate either an error in the drafting or a misunderstanding of the industry.

The proposal only regulates a specific set of professionals. The definition of "registered medical practitioner" is different to the definition of "healthcare professional" already included in the *Therapeutic Goods Act*. This inconsistency will create two distinct classes of professional covered under the act and ignores the roles played by other healthcare professionals and non-healthcare professionals in the delivery of therapeutic goods to the end user.

The proposal only regulates a specific set of activities. The proposed amendment only appears to cover two very specific activities, sponsorship of an overseas event and hospitality at any event. The proposed amendment is silent on all the other potential interactions between healthcare practitioners and the industry. In relation this, we again note that the revised ASMI Code of Practice includes a separate section on "Relationships with Stakeholders" which incorporates both general and specific controls on the behaviour of members. The self-regulation of our members already covers a wider field than the proposed amendment.

Marketing. The explanatory memorandum states that "currently the marketing of regulated pharmaceuticals to consumers is banned". The statement is false. Currently many registered medicines and all listed medicines can be advertised directly to consumers on TV, radio, the internet and in print. This statement indicates a misunderstanding of the industry.

Industry codes. The explanatory memorandum states that the proposed Act will replace "the industry code with legislation". This statement ignores the fact that the industry is covered by a number of codes, some of which are binding on all advertisers (e.g. the Therapeutic Goods Advertising Code), some of which are binding on members (e.g. the ASMI Code of Practice). There is no single "industry code" and since the various codes regulate a range of behaviors and since the proposed amendment only regulates a small set of activities, the proposal cannot meaningfully be said to "replace" a code.

Inconsistent with the Government's stated approach. As discussed above, the Government has expressed its commitment to strengthening self-regulation of the relationship between health care practitioners and the industry. Indeed an Advisory Group has been funded and established for this very purpose. In ASMI's view it would be premature to partly regulate an area that is already the subject of a government review, especially when that regulation is inconsistent with the Government's stated views on the matter.

Does not recognise the differences in industry sectors. As discussed above, ASMI have recently updated our Code of Practice to include "hospitality" and "entertainment" among the categories considered by our Promotional Monitoring Panel. This revision (and the other controls on relationships with stakeholders) have been introduced following stakeholder consultation. The controls that are in our Code are different to the controls in other Codes and this is a reflection of the differences between industry sectors. In ASMI's view it is inappropriate to apply a one-size-fits-all solution to a diverse industry. In ASMI's view it would be premature to partly regulate this area before the revisions to our Code have had a chance to take proper effect.

4. Summary

There has already been (and continues to be) a significant commitment by industry and Government to strengthen the self-regulatory controls in this area.

For this reason and the reasons outlined above, the proposed amendment to the *Therapeutic Goods Act* should not be passed.

Please do not hesitate to contact me if you would like to discuss any of the above in more detail.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director