Therapeutic Goods Amendment (Pharmaceuticals Transparency) Bill 2013

Senate Finance and Public Administration Committee

Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (+612) 9900 0650
F (+612) 9900 0655
E reception@mtaa.org.au

IVD
AUSTRALIA

1. Executive summary

The Medical Technology Association of Australia (MTAA) and IVD Australia (IVDA) welcome the opportunity to respond to the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* under examination by the Senate Finance and Public Administration Committee.

MTAA and IVDA share the view that the proposed legislation introduces a level of government intervention in industry self-regulation which is unwarranted and unnecessarily complex and expensive. All compliance processes bring with them an added cost which, in the case of companies working in the health sector, will result in additional burdens to sponsors of therapeutic products. These costs will be passed on to health product purchasers, thereby adding cost to the health system with no perceivable additional benefit.

MTAA and IVDA both have in place industry codes of practice which are mandatory for members of each association, and advisory for other companies within the medical device sector. The primary business of the company dictates which code a company must comply with.

MTAA and IVDA propose that current arrangements be strengthened in line with the unanimous recommendations of the Working Group on Promotion of Therapeutic Products (working group) which reported to the Government in March 2011. Specifically MTAA and IVDA propose that a requirement be introduced whereby each company which registers a product on the Australian Register of Therapeutic Goods (ARTG) be required to nominate a relevant industry code with which it agrees to adhere, as a condition of registration. The company then becomes subject to the jurisdiction of the code for compliance purposes, including independent monitoring and complaints processes.

2. About MTAA and IVDA

MTAA represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products listed on the ARTG and approximately 75% of the higher risk implantable medical devices products listed on the Prostheses List and used in the Australian marketplace. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small to medium sized Australian innovator companies.

IVD Australia represents manufacturers, exporters and distributors of *in vitro* diagnostics (IVDs) in Australia. IVDs are regulated by the TGA under the Medical Device regulations and are currently undergoing transition to new arrangements that will mean all IVDs are included on the ARTG. IVDA currently represents over 55 companies ranging from large multinational subsidiaries, independent distributors to start-up diagnostic innovator companies.

3. Coverage of the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* (Bill)

MTAA and IVDA note that the purpose of the Bill is to regulate "inducements" offered by a regulated corporation which is defined as:

- A corporation that imports regulated pharmaceutical products (defined as a medicine that is a listed good or a registered good) into Australia,
- A corporation that manufactures such products, or
- A corporation that supplies such products in Australia.

The companies represented by MTAA and IVDA are not covered by this definition as they all import, manufacture, or supply medical devices. A 'medical device' is defined under the *Therapeutic Goods Act 1989* as[1]:

> *any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*
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> *i. diagnosis, prevention, monitoring, treatment or alleviation of disease;*
> *ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;*
> *iii. investigation, replacement or modification of the anatomy or of a physiological process;*
> *iv. control of conception;*
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> *and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.*

As such the Bill does not presently impose requirements on medical device companies. However as the Bill covers all companies supplying medicines, both listed and registered, this leaves medical devices as the remaining unaffected

[1] Section 41BD

therapeutic sector. For this reason MTAA and IVDA wish to put on the public record their concerns with the proposed legislation.

4. Background

In response to concerns about practices by some companies in the therapeutic products industries, the Government released a Position Paper[2] in June 2010 with the objective of ensuring that decisions on management (including treatment options) for health needs are based on sound clinical evidence, not driven by incentives or other influences. The Government was also concerned to ensure that self-regulatory therapeutic industry codes of conduct are effective in minimising the potential for any promotional activities to compromise the quality use of medicines and to increase cost pressures on the health system.

The Position Paper sought 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 that the standards for conduct of health care professionals align with the standards expected of the therapeutic products industries.

Subsequent to the publication of the Position Paper the Government appointed the CEO of MTAA to chair a multi-stakeholder working group to review arrangements for regulation of the promotion of therapeutic products to healthcare professionals. The working group was industry-led and included all industry associations representing sectors of the therapeutic industries, as well as a cross-section of healthcare professionals, and consumers.

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 it was agreed that 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.[3]

The working group recognised the value of strong self-regulatory codes and developed a high level statement of the principles to be incorporated in each 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 provided 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.

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2 http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation%3A+Position+Paper+on+the+Promotion+of+Therapeutic+Goods

3 Report of working group on promotion of therapeutic products. March 2011. Executive summary. Page 1.

The working group recommended that each therapeutic industry sector code include provisions which address specific areas of interaction between companies and healthcare professionals:

- Gifts and offers
- Industry-sponsored educational events
- Conduct of company representatives
- Consulting arrangements with healthcare professionals
- Shareholdings and/or other financial interests by healthcare professionals in therapeutic product companies and/or products
- Hospitality and entertainment
- Research and education grants
- Promotional claims/advertisements to healthcare professionals
- Surrogate medical writing ('ghost' writing)
- Sponsorship of third party educational conferences
- Celebrity endorsements
- Direct to consumer advertising
- Funding of patient groups
- Product samples
- Disease awareness campaigns
- Use of social media in promotions directed to healthcare professionals.

The working group recommended that each therapeutic industry code include provisions which address governance areas for the effective implementation of the code by companies in each sector:

- Education on the code's operation
- Monitoring of compliance with the code
- Enforcement of the code in response to a complaint or a breach
- Sanctions to support the enforcement.

The working group recommended a set of obligations that each therapeutic industry code would require of companies under the relevant code.

Importantly 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 Government and remains to be implemented.

The working group considered the need for alignment of the codes which govern the behaviour of healthcare professionals with the industry codes, incorporating high level ethical principles and recognising the mutuality of these relationships.

In late 2012 a second body, the Codes of Conduct Advisory Group, was established by Government to oversee and guide implementation of the working group's recommendations relating to self regulation. That work is currently underway under the chairmanship of Professor Lloyd Sansom. Both MTAA and IVDA are represented on the Advisory Group.

5. MTAA and IVDA Codes of Practice

Both MTAA and IVDA have codes of practice that apply to member companies in their segment of the medical devices (medical technology) industry. Compliance with the codes is mandatory for members of each association under the relevant constitution. Compliance with the codes is advisory for non-members. Currently there are no mechanisms in place to compel compliance by non-members.

The codes contain provisions to enable the oversight of company behaviour including monitoring, complaints, and penalty provisions. These processes operate independently of the associations with independent panels of stakeholders (including healthcare professionals, consumers, healthcare bodies, and industry representatives).

MTAA is committed to ensuring that the code of practice which it administers on behalf of the industry, called the Medical Technology Code of Practice, is understood by all companies in the medical technology sector. During 2013, MTAA will be conducting a Code outreach program to a range of stakeholders including industry participants, healthcare professionals and consumers. The outreach program has been put in place to provide information on the Code and the benefits of compliance. The MTAA also offers various Code training modules. These modules are available to MTAA members as well as non-members

In addition MTAA offers a licence to those companies which not only sign on to support the Code but also demonstrate that they have undertaken a range of activities to embed the Code within the company. A licensed company is known as an MTAA Code licensee and is permitted to use a trade marked symbol in its collateral material to indicate its adherence to the Code.

IVD Australia is currently undertaking a review of its Code after three years of operation. IVDA has introduced training for members (and non-members) including an introductory e-learning program to promote compliance to the code.

6. MTAA and IVDA comments on the Bill

MTAA and IVDA are concerned that the reporting requirements proposed by the Bill introduce considerable complexity and cost with no perceivable additional benefit from the introduction of transparency requirements. As outlined above the MTAA and IVDA codes provide for monitoring of company engagement with healthcare professionals with random auditing. This is backed by a complaints process under which another company, or a healthcare professional or consumer, can bring a complaint about a company's activities.

Many companies in the medical technology sector are familiar with reporting requirements under the various US State 'Sunshine Act' provisions and the soon-to-commence provisions implementing Section 6002 of the Affordable Care Act (Sunshine Provisions). While the stated intent of the Sunshine Provisions is to provide patients with clear, meaningful information concerning industry relationships, the therapeutic industries in the US remain concerned that such a process not act to discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies.

MTAA and IVDA are concerned that the focus on reporting, rather than on the ethical nature of the transactions, diverts attention away from substantive issues and on to more peripheral issues. The Bill creates a civil penalty where:

- A company provides sponsorship for a conference, convention, or educational seminar which is to be held outside Australia and the majority of attendees are medical practitioners

- A company provides hospitality in the form of meals or entertainment where the value is more than $100 per registered medical practitioner.

Under the MTAA and IVDA codes the location of a third party educational conference or company-sponsored training and education is not restricted to facilities in Australia. The codes require that company-sponsored training and education is conducted in a clinical, educational, conference, or other setting that is conducive to the effective transmission of knowledge and is not selected because of its leisure or recreational facilities. Conducting company-sponsored training and education at resort locations is specifically prohibited. In addition, the Medical Technology Industry Code of Practice states that a company can only sponsor a conference if it is primarily dedicated to promoting objective medical, scientific and educational activities and discourse. Focusing on whether the venue and program are directed towards education seems a more appropriate consideration, rather than prohibiting all overseas venues.

The MTAA and IVDA codes do not prescribe a limit on hospitality however they mandate that any hospitality provided must be modest and appropriate for the event. Entertainment is specifically prohibited.

The Bill is also rather narrowly focussed on “medical practitioners”. It should be noted that there are other participants within the health sector than registered medical practitioners. Other healthcare practitioners such as theatre nurses, pharmacists and laboratory scientists are included with the scope of the current MTAA and IVDA codes.

In highlighting these examples under the Bill MTAA and IVDA point out that the Bill imposes restrictions which are less stringent than those already in place under the self-regulatory codes of these industry bodies.

Reporting to an independent Code Monitoring Committee is already required under the compliance programs administered by the associations, and backed up by complaints processes.

If there is any weakness in the current arrangements it is that non-member companies of the associations can operate outside the ethical restrictions imposed by the codes. This would be addressed if the outstanding recommendation from the working group on promotion of therapeutic products was implemented under a co-regulatory model (namely that all companies in the therapeutic industry signed on to compliance with a relevant code when registering a product on the ARTG). This would be a more effective solution than government-imposed compliance.