



— Dental Industry Review  
Therapeutic Goods Amendment  
(Pharmaceutical Transparency) Bill 2013

This submission reviews the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* that seeks to put in place statutory limitations on the interaction between healthcare professionals and the therapeutic products industry.

**ADIA**

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## Table of Contents

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Section 1	General commentary	Page 3
Section 2	Review of proposed legislation	Page 4
Appendix A	The Australian Dental Industry Association	Page 6
Appendix B	Abbreviations	Page 7

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## Section 1 – General commentary

The Australian Dental Industry Association (ADIA) represents the business that manufacture and supply more than ninety-five percent of the dental products used in Australia. As with many stakeholders associated with the sale of therapeutic products, ADIA understands that the ethical promotion of dental products is central to the trust-based framework within which healthcare professionals advise and treat patients.

The dental industry necessarily works 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 is recognised that this 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. For this reason, ADIA is working to strengthen its code of practice to reflect principles associated with the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties.

As it stands the Bill does not currently affect suppliers of medical devices as defined in the *Therapeutic Goods Act (Cth) 1989*, but only suppliers of medicines (both listed and registered) and thus will have negligible impact on the dental industry. However, given that the medical device sector is the only therapeutic product group excluded and therefore may be included at a later stage, it is appropriate that ADIA highlight the problems with the proposed legislation.

As the Australian Government is currently progressing a series of reforms to strengthen industry self-regulation and in so doing align all industry codes across the therapeutic products sector, and as this work is yet to be completed, ADIA submits that the timing of the Bill is premature and this it should be set aside by the Parliament.

Troy R Williams AFAIM MAICD  
Chief Executive Officer

2 May 2013

## Section 2 – Review of proposed legislation

The Bill states its purpose is to safeguard the integrity of prescribing medicines in Australia. It seeks to do this by replacing current industry codes with legislation that sets more stringent restrictions on the interactions between pharmaceutical companies and physicians that minimises the opportunity to provide inducements, and thereby unduly influence prescribing behaviours.

### Applicability to the dental industry

In its current form the legislation will not affect the supply of dental products as these are defined under Section 41BD of the *Therapeutic Goods Act (Cth) 1989* as medical devices. These are typically an appliance, apparatus, instrument, equipment or diagnosis tool that does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means.

Although the dental industry will be largely unaffected by the outcomes of the proposed legislation, it is important to highlight that the arguments in favour of the Bill are not strong given the current whole-of-industry moves to strengthen voluntary codes of practice associated with the promotion of therapeutic goods.

### Government mandated industry review

In June 2010 the Australian Government released a Position Paper 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 Australian 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.

A working group was established respond to the Position Paper and considered the public submissions received, the current coverage of the industry codes, and possible mechanisms to extend code compliance to non-members of associations. The working group developed a high level statement of the 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.

### Common industry principles

The major associations in the therapeutic product sector, including ADIA, have agreed upon a 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.

The industry associations are working towards development of industry codes that have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, with its effectiveness assessed through the eyes of the relevant community.

### **Revised dental industry code of practice**

The working group recommended that consistency of therapeutic sector industry codes of practice be facilitated by each therapeutic industry association incorporating in its code the high level principles, operational coverage areas and governance provisions developed by the working group. To this end, ADIA is currently reviewing its code of practice and it is anticipated that a new code will be in place within twelve months.

In developing its new code, the ADIA has written to its counterpart organisations representing dental and oral healthcare professionals with codes that govern the behaviour of healthcare professionals. The basis for this communication is that there are two parties to the relationship and that the ethical promotion of therapeutic products expected of industry should be mirrored or reflected in the healthcare professional codes.

### **Government response to industry action**

The Australian Government's preferred regulatory options were released in December 2011 as part of the *TGA Reforms – A blueprint for TGA's future* package. Its preference is to maintain an emphasis on self-regulation and strongly supports industry's initiative to harmonise their codes of conduct to incorporate the working group's high level principles. The inclusion of these level high- principles into industry specific codes of conduct is a continuing process and the Australian Government will consider the feasibility of establishing a committee to evaluate the work of industry bodies.

The Australian Government has stated that further changes to the framework for the promotion of therapeutic goods will be considered if it is found that there is a need to provide greater encouragement to non-members of industry associations to nominate and sign up to an appropriate industry code.

As the Australian Government is currently progressing a series of reforms to strengthen industry self regulation and in so doing align all industry codes across the therapeutic products sector, and as this work is yet to be completed, ADIA submits that the timing of the Bill is premature and this it should be set aside by the Parliament.

## Appendix A — ADIA Introduction

Formed in 1925, ADIA is the peak national association representing the suppliers of quality dental product and services to dentists and allied oral healthcare professionals. The ADIA membership represents businesses, including a growing number of dental laboratories, that supply around more than ninety-five percent of the nation's purchases of dental product and consumables which are valued at an estimated \$860 million per annum.

ADIA members have the opportunity to contribute to the development of not only the Association, but also the broader dental industry, through a number of national committees that address regulatory, technical, skills and industry promotional issues. A national board of seven leading professionals attends to governance matters and sets the strategic direction of the Association.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. The Association provides advice to agencies including the TGA and the National eHealth Transition Authority (NeHTA), often nominating industry representatives to government committees and working groups. The Association also supports its members in the development of technical standards for dental products and consumables, nominating industry representatives to committees of both Standards Australia and the International Standards Organisation (ISO).

ADIA builds partnerships between dentists and the suppliers of dental products and services. The Association is the organiser of the nation's premier dental trade show, the highly acclaimed *ADX Dental Exhibition*, which attracts more than four thousand dentists and allied oral healthcare professionals every year.

At an international level, ADIA is a founding member of the International Dental Manufacturers (IDM), the Geneva-based global confederation of national dental trade associations. ADIA is also a supporting member of the FDI - World Dental Federation.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports the development of both TAFE and university courses relevant to the dental industry and the Association delivers the widely acclaimed *ADIA Introduction To Dentistry Course*.

The ADIA national office is based in Sydney and the Association is active in all mainland states.

More information can be found online at [www.adia.org.au](http://www.adia.org.au)

## Appendix B — Abbreviations

The following definitions are provided for information only and do not form part of the Code for the purposes of interpretation, compliance or adjudication:

ADIA	Australian Dental Industry Association
ARTG	Australian Register of Therapeutic Goods
DBA	Dental Board of Australia
DoHA	Department of Health and Ageing
FDI	World Dental Federation ( <i>Fr. Fédération dentaire internationale</i> )
IDM	International Dental Manufacturers association
ISO	International Standards Organisation
NeHTA	National eHealth Transition Authority
TGA	Therapeutic Goods Administration



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