Australian Dental Industry Association | ADIA

— Dental Industry Review Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013

As the peak representative body for suppliers of quality dental products, the Australian Dental Industry Association (ADIA) supports the majority of proposed amendments to the *Therapeutic Goods Act (Cth) 1974.*

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The Australian Dental Industry Association (ADIA) tenders this submission to the Senate Community Affairs Legislation Committee to support its review of the *Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013*, legislation that proposes amendments to the *Therapeutic Goods Act (Cth) 1989.* On balance, these amendments are supported by ADIA.

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Executive Summary

ADIA has reviewed the *Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013* that proposes amendments to the *Therapeutic Goods Act (Cth) 1989,* the latter hereafter referred to simply as "the Act" for ease of reference. This submission has been prepared to allow the Senate Community Affairs Legislation Committee to take into account views of the businesses that manufacture and supply dental products.

On balance, ADIA supports the amendments as they make more clear and transparent a number of regulatory processes and requirements applying to the regulation of all classes of therapeutic goods by the Therapeutic Goods Administration (TGA).

ADIA does not support one proposed amendment, this being a change that allows the Secretary the option of publishing information about various regulatory decisions made under the Act (including suspension and cancellation of goods from the Register) on the Department's website rather than in the *Australian Government Gazette*.

In tendering this submission, ADIA takes the opportunity to highlight problems associated with enforcement of the Act, particularly with the importation of dental products via the internet. Although beyond the scope of the Amendments currently before the parliament, ADIA nonetheless believes they merit review and are outlined in Chapter 6 of this submission.

ADIA takes this opportunity to thank the Senate for this opportunity to tender advice on the Bill and we wish the Senators well in their endeavours.

Troy R Williams AFAIM MAICD
Chief Executive Officer
Australian Dental Industry Association

1 May 2013

Chapter 1: General commentary

ADIA broadly supports this package of amendments to the Act as they are of a minor, technical nature, designed to ensure, where appropriate, consistent regulatory treatment of the different types of therapeutic goods including prescription, over-the-counter and complementary medicines, therapeutic devices, biologicals and medical devices.

Stakeholder consultation

It is important to tender concern about the absence of consultation with industry and consumer stakeholders prior to the release of the Bill to the parliament. It is acknowledged that some matters are sensitive in nature thus consultation is either difficult or inappropriate prior to the matter going before parliament. However, these reforms are administrative in nature so this sensitivity does not apply.

The first opportunity that industry had to discuss the proposed legislative amendments was on 26 March 2013 when the TGA Therapeutic Industry Consultative Committee met in Canberra, some six days after the Bills were presented to parliament.

The TGA is implementing a comprehensive package of reforms drawn together by the Australian Government and announced in the document entitled *TGA Reforms – A blueprint for TGA's Future* released by the (former) Parliamentary Secretary for Health and Ageing, the Honourable Catherine King MP, on 8 December 2011. This document constitutes a response to several major reviews of therapeutic goods regulation that were undertaken in 2010 and 2011 and addresses matters from product regulatory standards, advertising, promotion and transparency. It would have been possible, and indeed desirable, to deal with the proposals before the parliament as part of, rather than separate from, that series of reforms. ADIA is confident that if this had been the case, proper industry consultation could have been undertaken.

ADIA notes that for more than a decade there has been broad agreement amongst Government, industry and consumer stakeholders that the role of the TGA has been to carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard while ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. The underpinning philosophy has been support for a regulatory framework that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. It is noted that in recent times the TGA has proposed a number of significant reforms to the regulatory standards for therapeutic products that depart from this underpinning philosophy. That said, over the course of the past six weeks the senior management of the TGA have discussed ADIA's concerns in this area and we are hopeful of a renewed focus that places renewed emphasis on the risk-management principle.

Chapter 2: Products not therapeutic goods

The Bill proposes to amend the Act allowing the Minister to make a legislative instrument determining that goods are not to be therapeutic goods for the purposes of the Act either generally or when used, advertised, or presented for supply in a particular way. ADIA supports this amendment although the context contained in the Bill's explanatory memorandum is questioned.

Like the Australian Government, ADIA has noted that health-related claims are increasingly being made about a range of products, many of which do not meet a conventional and accepted term of definition of "therapeutic products". These were referenced in the Parliamentary Secretary's second reading speech:

> *Some recent examples of goods for which therapeutic use claims have been made include mattresses which contain bacteria spores designed to reduce the effects of dust mites and 'power band' bracelets, which were claimed would boost a wearer's balance, strength and flexibility. Consumer protection may in fact be a more appropriate regulatory focus for these products than the more prescriptive therapeutic goods framework contained in the act.*
>
> Second Reading Speech – Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 – Parl. Sec. Health & Ageing. House of Representatives Hansard – 20 March 2013

ADIA concurs with this observation that such products are unlikely to fall within the definition of therapeutic product and thus the protections afforded to consumers within the *Competition and Consumer Act (Cth) 2010,* specifically the Australian Consumer Law (ACL), are more appropriate. ADIA also concurs with the Australian Government's view that it is important that there is as much clarity as possible about which goods are covered by the regulatory scheme, and for the Minister to consider whether particular goods which may come within the definition are appropriate for regulation under the Act. Furthermore, ADIA is confident in the fact that such a determination would be required to be tabled before Parliament and would be disallowable, providing an appropriate safeguard in the case of an egregious decision by the Minister.

Regulatory enforcement

The explanatory memorandum notes that the legislation imposes substantial criminal and civil penalties for persons importing or supplying goods that come within the definition of 'therapeutic goods' if those goods are not included in the Register or are not otherwise exempt or approved (sections 19B and 19D of the Act refer). ADIA contends that such representations give a false impression of the effectiveness of the current regulatory framework.

ADIA believes that the current legislative framework is both unenforced and unenforceable – the fault rests not with the TGA but the parliament which has failed to provide the necessary statutory authority for the TGA to be effective in this area. In practice, there are few instances of penalties being handed out, thus reform of the TGA's enforcement activities is warranted. This is further outlined in Chapter 6 of this submission.

Chapter 3: Removal of products from the register

The Bill proposes amendments to the Act to include power for the Secretary to remove a product from the Australian Register of Therapeutic Goods (ARGT) if the product does not meet, or no longer meets, the definition of a therapeutic good in subsection 3(1) of the Act. For reference purposes, the Act defines a "therapeutic good" as follows:

> *Therapeutic goods means goods:*
> *(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:*
> *(i) for therapeutic use; or*
> *(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or*
> *(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or*
> *(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);*
> *and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:*
> *(c) goods declared not to be therapeutic goods under an order in force under section 7; or*
> *(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or*
> *(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or*
> *(f) goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.*
>
> Therapeutic Goods Act (Cth) 1989
> Commonwealth of Australia

This will be important in particular for medicines listed in the Register under section 26A of the Act on the basis of certifications made by the applicant, where the electronic listing process does not involve pre-market scrutiny by the TGA. Here there is no opportunity to screen an application to establish that the relevant goods come within the definition before they are included in the Register.

The amendment will also allow the Secretary to remove a product that may have come within the definition when it was included but no longer does so, for instance where claims about its therapeutic use are no longer being made.

This amendment is supported by ADIA.

Chapter 4: Products information amendments goods

ADIA notes that the Bill proposes amendments clarifying that the Secretary may approve product information for medicines under subsection 25AA(1), and under new subsection 25AA(1A) is obliged to notify the sponsor of the medicine of the approved product information.

As these amendments relate the medicines and not medical devices thus are beyond ADIA's area of expertise, the Association has not formed a view on this section of the Bill.

Chapter 5: Other Amendments

The Bill contains a series of amendments associated with decisions to cancel the registration or listing of therapeutic goods and the publication of such decisions. To support the work of the committee, ADIA deals with this series of amendments separately.

Unacceptable presentation leading to deregistration / delisting

The Bill proposes amendments that allow the Secretary to suspend or cancel the registration or listing of therapeutic goods where the presentation of the goods is not acceptable or, in the case of listed goods, is unacceptable. This amendment is supported by ADIA.

Failure to provide information leading to deregistration / delisting

The Bill proposes amendments that allow the Secretary to cancel the registration or listing of therapeutic goods where a sponsor does not respond to a request from the Secretary under section 31 of the Act to provide specified information or documents about those goods. This amendment is supported by ADIA.

Publication of regulatory decisions on the website

The Bill proposes amendments that allow the Secretary the option of publishing information about various regulatory decisions made under the Act (including suspension and cancellation of goods from the Register) on the Department's website rather than in the *Australian Government Gazette*. This amendment is not supported by ADIA.

The Parliamentary Secretary's second reading speech and the Bill's explanatory memorandum present the option to publish regulatory decisions in the *Australian Government Gazette* or on the TGA website as an either / or option, that is if it is published on the TGA website it will not be published in the *Australian Government Gazette.* For example, the explanatory memorandum states that regulatory decisions would be published on the TGA website "rather than in the Gazette".

Although ADIA is supportive of the TGA publishing its decisions on its website, ADIA believes that in the interest of transparency and good regulatory process, such decisions should also be featured in the *Australian Government Gazette.*

Disclosure of recipient information

The proposed amendments give the Secretary power to require, in particular circumstances (for instance where therapeutic goods have been suspended or cancelled from the Register, or where the Secretary has come to the view that the safety, quality, efficacy/performance, or presentation of therapeutic goods, is unacceptable), the sponsor of those therapeutic goods to provide information about the goods to the public or to a class of persons such as health care professionals or

patients, and to give to the Secretary information about persons to whom the goods have been supplied. This is supported by ADIA.

Definition of kits containing therapeutic goods

The proposed amendment modifies the definition of a kit in section 7B of the Act to encompass kits containing (among other things) only one registered or listed therapeutic good, or a biological combined with other items (provided they are for use as a unit). This is supported by ADIA.

Provision of false information for a varied entry

The amendments introduce a new offence where a sponsor provides information that is false or misleading in a material particular in relation to a request under section 9D of the Act for a variation to an entry on the Register. This is supported by ADIA as it is consistent with requirements associated with a new entry.

The series of proposed amendments outlined above are supported with the exception of the proposal that allow the Secretary the option of publishing information about various regulatory decisions made under the Act (including suspension and cancellation of goods from the Register) on the Department's website rather than in the *Australian Government Gazette*.

Chapter 6: Further necessary reform

In tendering these amendments to the parliament for consideration, the Australian Government has missed the opportunity to strengthen the work of the TGA by enhancing its regulatory enforcement mechanisms. This is important in an environment where a growing volume of therapeutic products is imported directly by patients and individual healthcare professionals in a manner inconsistent with the Act.

Under the Act, medical devices imported, manufactured in Australia, supplied by a corporation, supplied interstate or to the Commonwealth, or exported must be included in the ARTG unless specifically exempted by the Act. When required by law, an importer is required to have the medical device entered onto the ARTG, even if that exact medical device already appears on the ARTG because another importer has arranged for the entry. As the TGA notes:

> *If someone wants to supply a device that is identical to a device that is already in the ARTG, even if both devices are made by the same manufacturer, an application to include the device in the ARTG must still be made to the TGA. This is because the ARTG is not only a record of the devices that can be supplied in Australia; it is also a record of all the sponsors who are legally responsible for the medical devices on the market.*
>
> Guide: Australian Regulatory Guidelines for Medical Devices
> Therapeutic Goods Administration (Canberra, 2011)

Despite this advice, there remains a common misconception that if a medical device manufactured overseas appears on the ARTG it can then be imported by any person or company. There is the inevitable risk that a healthcare professional, acting in good faith, may purchase a medical device via the internet from an overseas manufacturer that appears on the ARTG, thus negating the protection that the Act puts in place.

A cursory examination of online auction sites such as eBay demonstrates that it is possible to purchase a range of medical devices in Australia, including some relatively high risk devices such as autoclaves and tooth filling materials from markets including China and India. Similarly, there are many reputable companies operating in the European Union (EU) and the United States of America that offer their dental products for sale online and in full compliance with the regulatory arrangements that exist in those states. That said, the World Health Organisation (WHO) has sounded a note of warning:

> *Be cautious about buying medical products via the internet. In many countries, selling or buying medical products via the internet may at present be an illegal activity. You are strongly advised to obtain your medical products through legitimate distribution channels such as pharmacies.*
>
> Brochure: Medical Products And The Internet – A Guide To Finding Reliable Information
> World Health Organisation (Geneva, 1999)

The availability of these products online does not in any way infer substandard quality of product, nor any inappropriate conduct on the part of websites such as eBay, but it does highlight products readily purchased online and imported into Australia can circumvent safeguards.

Australian suppliers of medical devices (whether imported or locally manufactured) face increasing regulatory compliance costs. In October 2010 the TGA proposed changes to the medical devices regulatory framework which would have increased the costs of supplying dental equipment by at least two percent. This additional regulatory burden is not placed on overseas suppliers selling their product to Australia and operating outside the Act and thus these suppliers benefit from a considerable cost advantage compared to businesses operating within the established framework.

Devaluing a proven safety framework

The importation of medical devices via the internet establishes a supply chain that is outside the framework established by the Act. This bypasses normal safeguards that are put in place such as the premarket evaluation and approval of products, the certification of device manufacturer, mandated quality systems and post-market surveillance. The WHO has issued guidance on purchasing through legitimate channels and warned of buying product online:

> *When you buy a medical product through the appropriate channels, such as through your pharmacy, you can generally rely on the product meeting manufacturing requirements and you can count on its quality – in other words – the product contains the right active ingredients and has been manufactured, packaged, transported and properly stored before you buy it. By buying medical products through the internet, you may forfeit the quality assurance offered by authorised channels of medical product manufacturing, distribution and sales in your country.*
>
> Medical Products And The Internet – A Guide To Finding Reliable Information
> World Health Organisation (Geneva, 1999)

Although this information was primarily aimed at consumers of medicines, the information is entirely relevant to those importing medical devices via the internet. As with medicines, the regulatory regime administered by the TGA is effectively bypassed when medical devices are imported via the internet, significantly increasing risks to patients.

Bypassing recall

The purchase and importation of medical devices via the internet bypasses an important aspect of Australia's medical device regulatory framework, this being the framework to implement a recall of product.

As the TGA notes, a recall can occur because of simple problems, such as labelling or packaging errors, or for more serious problems such as an increase in unexpected side effects. In the event of a recall, a sponsor of a medical device has responsibilities

which may necessitate writing to distributors advising them of the recall, placing public notices (e.g. newspaper advertisements) and also notifying the TGA. In this way the product can be removed from use.

When a healthcare professional or consumer purchases medical devices from overseas, there is a very good chance that they will not be notified of a subsequent recall of the medical device.

The TGA has reported that in FY2009-10 there were 365 recalls of medical devices – equating to one per day. This i highlights the risks to patient safety when medical devices are imported and supplied in a manner that is outside the established framework for medical device recalls.

Problems associated with the supply of medical devices via the internet are likely to grow in both number and complexity as online purchasing continues to increase in acceptance. It is clear that a regulatory model adopted in the last two decades of the twentieth century is becoming increasingly irrelevant and inadequate in the twenty-first century. For this reason it is necessary for the Australian Government to safeguard patient safety by considering restrictions on the importation of medical devices via the internet.

Senate inquiry into the regulatory standards for medical devices

As a result of representations from ADIA, the Senate Community Affairs references committee considered this matter in its inquiry into the regulatory standards for the approval of medical devices that was conducted in 2011.

During the course of its inquiry, Senators stated that it is also concerned that the issue of unregulated importation of dental devices via the internet may indicate a much broader problem of inadequate regulation of other medical devices purchased through the internet. The committee is of the view that this requires further investigation and assessment by the TGA:

> *Recommendation 13 —*
> *The committee recommends that the Therapeutic Good Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated.*
>
> Report: The regulatory standards for the approval of medical devices in Australia
> Senate Community Affairs References Committee (11 November 2011)

In its response dated August 2012, the Australia Government stated that it agrees with this recommendation. It confirmed that the *Therapeutic Goods (Medical Devices) Regulations 2002*, therapeutic goods are required to be approved and included on the ARTG before they can be supplied unless there is an exemption.

Notwithstanding the acceptance of this recommendation, to date, the TGA has not acted to implement the recommendation.

It should be recognised that Australia has a system for the regulation of medical devices that is recognised internationally as the ideal standard. It escalates the regulatory barriers for

supplying medical devices in a manner that is commensurate with the risk, a principle supported by ADIA. On balance, the TGA is currently viewed as a competent regulator, discharging its responsibilities in the context of information known to it and the available resources. However, the work of the TGA needs to be strengthened by reviewing enforcement activities associated with the illegal supply of therapeutic products, particularly as far as those imported via the internet are concerned.

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

Appendix B: Abbreviations

ACCC	Australian Competition and Consumer Commission
ADIA	Australian Dental Industry Association
ARTG	Australian Register of Therapeutic Goods
DBA	Dental Board of Australia
DoHA	Department of Health and Ageing
EU	European Union
FDI	World Dental Federation (Fr. *Fédération dentaire internationale*)
IDM	International Dental Manufactures association
NeHTA	National eHealth Transition Authority
TAFE	Technical and Further Education
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

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