

**Australian Dental
Industry Association**

**Productive Commission Inquiry:
Economic Structure & Performance
of the Australian Retail Industry**

**Specific Issue:
Safety Concerns Associated With The
Importation of Dental Product
Via The Internet**

**Australian Dental Industry Association
— May 2011**

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This submission has been prepared by the Australian Dental Industry Association (ADIA) to provide an awareness of the safety problems associated with the importation of dental product via the internet. It is tendered to the Productivity Commission to support its inquiry into the economic structure and performance of the Australian retail industry.

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The Assistant Treasurer, the Honourable Bill Shorten MP, has advised ADIA the issues related to safety problems associated with the importation of dental product via the internet are a proper issue for the Commission to consider as part of this inquiry.^[1]

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ADIA Briefing Executive Summary

Many of the products used in contemporary dentistry are regulated by the Therapeutic Goods Administration (TGA) which is responsible for the *Therapeutic Goods Act (Cth) 1989* that establishes a regulatory framework for the importation, manufacture and supply of medical devices.

The current medical device regulatory framework was designed in the last two decades of the twentieth century and is becoming increasingly irrelevant in the twenty-first century. It is possible to purchase medical devices from overseas sources via the internet, a possibility simply not envisaged in the 1980s and early 1990s when the legislation was initially drafted and the supporting regulatory framework put into place. The outcome is that many high risk medical devices such as autoclaves, tooth filling materials and even bone grafting materials can be imported via the internet with no safeguards as to their fitness for use.

Although the problem of dental product being imported via the internet is not widespread, recent data suggests it accounts for between three to five percent of all dental product supplied into Australia. Of concern, dental products deemed to be intermediate and higher risk medical devices top the list of product purchased online from overseas in a manner inconsistent with the *Therapeutic Goods Act (Cth) 1989*.

A recent recall by an overseas manufacturer of a bone grafting material into Australia via the internet – and outside the regulatory framework administered by the TGA – demonstrates the very real risks that exist to patient safety.

The importation of dental product via the internet is a public health issue that will only grow in importance as the use of the internet as a procurement pathway grows, thus it merits investigation and an appropriate policy response by the Australian Government.

Troy R Williams MAICD AFAIM
ADIA Executive Officer

— 20 May 2011

Introduction

Australian Dental Industry Association

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 that supply around ninety-eight percent of the nation's purchases of dental product and consumables which are valued at an estimated \$860 million per annum.

The *2010-15 ADIA Strategic Plan* outlines a range of initiatives to assist the dental industry understand and influence the commercial, technical and regulatory environment in which the dental industry operates. The stated outcome of the strategic plan is to strengthen the membership by providing the dental industry with effective representation and support services necessary to ensure the supply of quality products that assist in the delivery of affordable dental care for ordinary Australians.

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. Through the *ADX Online* product database dentists and allied oral healthcare professionals are able to source quality dental product.

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 World Dental Federation (*Fédération Dentaire Internationale – FDI*).

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

Overview — Australia's dental industry

The Australian dental industry supplies equipment, product and services to dentists and allied oral healthcare professionals employed both in private practice and with government healthcare providers. In a broad sense, the dental industry is defined as the businesses in Australia that supply:

- Dental equipment and consumables;
- Consulting, legal and regulatory affairs services;
- Software used in dental surgeries and laboratories; and
- Dental surgery and laboratory design and fit-out services.

Under Australian law most types of dental equipment and consumables are classified as “medical devices” that need to be supplied in accordance with the framework established by the *Therapeutic Goods Act (Cth) 1989*. This legislation is administered by the TGA which regulates the quality, safety and performance of medical devices (e.g. dental equipment) that are manufactured, imported and / or supplied in Australia.

As with the general healthcare sector, fluctuations in economic conditions do not greatly affect the Australian dental industry which typically grows by six percent to eight percent per annum.

The estimated value of the Australian dental industry is \$860 million per year which includes the value-added component of dental product imported from overseas in addition to equipment servicing and dental practice management services including software and equipment financing.

Local manufacturing accounts for less than three percent of the dental product in Australia by volume and is largely limited to tooth filling material and dental equipment such as dentists' chairs. A review of the Australian Bureau of Statistics (ABS) data shows dental exports of approximately \$68 million in 2009. The top destinations for exported products were New Zealand, the United States of America, Germany, Brazil and Taiwan which represented approximately seventy-three percent of the market.

Imports of dental product were valued at approximately \$417 million in 2009 with the top five sources of imported product being the United States, Germany, Thailand, Switzerland and Ireland which accounted for sixty-two percent of total imports.

The products and services offered by Australia's dental industry are delivered by slightly more than two hundred businesses. Of these businesses, more than nine out of ten are ADIA members and they supply approximately ninety-eight percent of the product and services by value.

The Australian dental industry employs approximately 1,600 people in three prime functional areas, these being: Sales and marketing; warehousing and logistics in addition to finance and administration.

The Challenge — Importation of medical devices via the internet

By the nature of products used in contemporary dental practice the majority of dental product is classified as a “medical device” for the purposes of the *Therapeutic Goods Act (Cth) 1989*. One important outcome of this legislation is that most medical devices are required to be approved and included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied unless there is an exemption. The purpose of this legislation can be summarised as being:

The Therapeutic Goods Act, 1989 and associated regulations establishes a uniform, national system of regulatory controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods for human use. Responsibility for the regulatory controls lies with the Therapeutic Goods Administration (TGA) as the national regulatory authority for therapeutic goods. Overall control of the supply of therapeutic goods is exerted through three main processes:

- *The pre-market evaluation and approval of products intended for supply in Australia;*
- *The licensing of pharmaceutical manufacturers and certification of device manufacturer quality systems; and*
- *Post market surveillance.*

Under the Act, therapeutic goods for human use that are imported, manufactured in Australia, supplied by a corporation, supplied interstate or to the Commonwealth, or exported must be included in the Australian Register of Therapeutic Goods (ARTG) unless specifically exempted by the Act.^[2]

It should be recognised that Australia has a system for the regulation of medical devices that is recognised internationally as first-rate. 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.

A new component of the supply chain

Twenty years ago it was inherently difficult for healthcare professionals and consumers to purchase product from overseas sources without actually travelling overseas to arrange the purchase. Although the purchasing of medical devices from overseas sources was not unknown, with usual means being via mail order, it was not commonplace and often done in accordance with the prevailing legislation.

The emergence of the internet as a new component of the supply chain changed the established a new source of product. It is possible for virtually any medical device to be purchased online (reference Attachment 1) thus establishing a supply chain outside the regulatory framework established by the TGA.

Medical devices purchased via the internet may be sourced either through online stores or auction sites (e.g. eBay) or directly from overseas resellers of medical device that are either ignorant, or choose to ignore, the strict controls placed on the export of medical devices in many overseas jurisdictions. Medical devices purchased

online are then shipped to Australia via the postal service, presenting the TGA with an enforcement problem:

The TGA does not have a presence at Australia's border so we continue to work closely with Australian Customs and Border Control (Customs) and the Australian Quarantine Inspection Service (AQIS) to detect and prevent commercial shipments of unapproved therapeutic goods, or counterfeit goods, in any quantity from entering our domestic marketplace.

As part of this engagement, the TGA provides information and training programs to Customs and AQIS staff including practical examples of what therapeutic goods are, and how to ascertain the regulatory status of goods which have come to notice whether by way of containerised sea cargo, air freight or even parcel post. To this end, the TGA has a dedicated officer to promptly answer those enquiries from border staff at the barrier not only to detect illicit importation, but also not to delay the delivery of lawful importations.^[3]

ADIA takes this opportunity to commend the TGA for the proactive way it is addressing the safety issues associated with the importation of medical devices and its engagement with both the Australian Customs and Border Control Service and the Australian Quarantine Inspection Service (AQIS). However, it is clear that despite this commendable effort medical devices purchased via the internet from overseas sources continue to find their way to healthcare practitioners for use.

The regulatory framework designed more than twenty years ago has become outdated, unable to tackle the challenges put in place by the online sale of goods and services in the twenty-first century. The current model is largely based on the basis that product available within Australia is being distributed by businesses domiciled in Australia, and that the supply chain includes a Sponsor of therapeutic product.

Legitimate importation of medical devices

It is acknowledged that there are legitimate reasons to import medical devices via the internet. The current regulatory framework permits the importation for clinical trials and personal use amongst other reasons. As a general rule, importation with the intent of supplying the medical device to dentists or for delivering healthcare services to the general public will require that the medical device appear on the ARTG and meet the associated requirements.

The Australian Register of Therapeutic Goods

Under the *Therapeutic Goods Act (Cth) 1989*, 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.^[4]

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 very real risk that a healthcare professional, acting in good faith, may purchase via the internet from an overseas manufacturer a medical device that appears on the ARTG, thus negating the protection that the *Therapeutic Goods Act (Cth) 1989* puts in place.

Importation of medical devices via the internet

A cursory examination of online auction sites such as eBay demonstrates that it is possible to purchase in Australia a range of medical devices, including some relatively high-risk devices such as autoclaves and tooth filling materials from markets including China and India. [Refer: Attachment 1] 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.^[5]

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 that product can be readily purchased online and imported into Australia with no 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.^[6] This additional regulatory burden is not placed on overseas suppliers selling their product to Australia and operating outside the *Therapeutic Goods Act (Cth) 1989* 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 *Therapeutic Goods Act (Cth) 1989*. This bypasses normal safeguards that are put in place such as the pre-market 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.^[7]

Although this information was primarily aimed at consumers of medicines, the information is entirely relevant to those importing medical devices via the internet. The regulatory regime administered by the TGA is effectively by-passed 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. In the event of a recall, the Sponsor or a medical device has responsibility for the recovery of goods and corrective action.

A medical device may be recalled due to established deficiency in quality, efficacy or safety. As the TGA notes, a recall can occur because of simple problems, such as labeling or packaging errors, or for more serious problems such as an increase in unexpected side effects. A sponsor of medical device has responsibilities in the event of a recall 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 is not an insignificant number and 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.^[8]

Cautionary safety notices

From time to time the TGA and other bodies may issue advice concerning events that may adversely impact upon the safety of medical devices. A recent example is notification that the TGA provided to sponsors of product manufactured in Japan given the potential for medical devices manufactured in that country to be contaminated by radiation from the failure of the nuclear reactors as a result of the 11 March 2011 earthquake and tsunami. In this correspondence the TGA issued the following advice:

Given the unusual circumstances, the TGA is requesting that you seek an assurance from the applicable manufacturer/s (and submanufacturers, where relevant) that first, your products imported from Japan (and their ingredients / components and packaging) are safe for their intended purpose, and secondly, that there are suitable controls in place to ensure the recent events in Fukushima have not and will not compromise the safety and quality of the products or result in unintended harmful effects of consumers or other people handling them.^[9]

ADIA believes that the TGA's approach in issuing this cautionary note is entirely with merit and the Association has taken steps to rely this advice to suppliers of dental product within Australia. However, healthcare professionals and consumers who have purchased medical devices over the internet will, in all probability, be unaware of the risks that the TGA has identified as a result of the 11 March 2011 earthquake and tsunami in Japan.

International harmonisation of medical device regulation

A common misconception is that the international harmonisation of medical device regulation will address problems associated with the importation of medical devices via the internet, or even permit them without interference from local regulation. This is incorrect as this work is designed to address a different policy priority.

Australia supports the soon to be reformed Global Harmonisation Task Force (GHTF), an international group of representatives from medical device regulatory authorities and trade associations from the European Union (EU), the European Free Trade Association (EFTA), the United States of America, Canada, Japan and Australia. GHTF accomplishments include greater uniformity between national medical device regulatory systems. This is being done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world. It is noted that reviewing the GHTF work with a view to adoption is a standing work item for Asia Pacific Economic Cooperation (APEC) forum members.^[10]

Although there is a demonstrated intent of regulators to work toward the international harmonisation of medical device regulation, and the TGA's leadership in this area needs to be acknowledged, in practice this will have minimal impact on ensuring the quality of medical devices purchased via the internet when the country of origin and integrity of the supplier are unknown – the emerging international framework is designed to support the work of national regulators and reduce costs to business, not facilitate the sale of medical devices across national borders.

Promotion of unapproved therapeutic goods

The promotion of unapproved therapeutic goods is an offence under *Therapeutic Goods Act (Cth) 1989* and carries a financial penalty. Under the legislation a person must not intentionally or recklessly make a claim, by any means, that the person or another person can arrange the supply of unapproved therapeutic goods. These arrangements could be enforced in pre-internet times, but have proven quite unworkable in contemporary society – the Australian Government simply lacks the jurisdiction to police offerings of overseas websites.

For this reason, there is considerable benefit to be gained in terms of regulatory compliance by enhancing the knowledge of the safeguards that exist when buying product from organisations that have ensured that the regulatory requirements have been met.

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 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.

Affected Areas — Intermediate and high-risk items top the list

There has been a growing concern that the importation of medical devices by healthcare professionals bypasses established supply chains that provide a framework to ensure patient safety. However, until recently it was not difficult to quantify the extent of the area thus the potential risks to patient safety. To better understand the issue, ADIA surveyed its members with a view to quantifying three issues, these being:

- The product categories most likely to be sourced from overseas;
- The amount of product that is being sourced from overseas; and
- Responsible persons and regulatory awareness,

The survey respondents reflect the whole spectrum of the dental industry, from sole traders to multinational corporations and also sought the advice from individuals at different levels within the company. Importantly, the data also sought the views of front-line sales staff in addition to that from senior management given that front-line sales staff have a more intimate relationship with the customer and thus be able to observe discrete changes in buying patterns (e.g. continued purchases in one area but not in another), whereas management are able to assess sales levels at a whole of company level.

Once compiled and validated for statistical purposes the data demonstrated that the importation of product from overseas via the internet was consistent with broad expectations, both in terms of the product areas and overall impact. The data showed:

Category:	Disposables
Products:	These include bibs, gloves, cotton products, paper products and other consumables.
Regulation:	Many of these products will not appear on the ARTG and of those that do, typically are listed as a Class I medical device.
Assessment:	Industry advice is that these are not attractive item to buy online from overseas sources as although sold in high volumes, they have a relatively low unit cost. Further, as delivery is required in very short timeframes (often within one to three days) timeframes associated with overseas postage makes it undesirable.
Impact:	Survey data suggests that internet imports have resulted in a 2.5% drop in product sold through Australian supply chains (that include a Sponsor of medical devices)
Category:	Tools and accessories
Products:	burs, instrument trays, files, forceps, knives / scalpels, etcetera.
Assessment:	Industry advice is that these are attractive items to buy online as they are sold in intermediate volume levels and there is a significant price differential between product supplied by an Australian-based Sponsor and that supplied by a manufacturer in Asia (typically this price differential is not prevalent for products sourced online for Europe and North America).
Impact:	Survey data suggests that internet imports have resulted in a 4.4% drop in product sold through Australian supply chains (that include a Sponsor of medical devices)

.../cont.

Category:	Small equipment
Products:	Hand pieces, mix / dispensing machines, ultrasonic scalers, etcetera.
Assessment:	Industry advice is that these are highly attractive items to buy online as they have a moderately high unit cost. Such equipment is sold in relatively low-volume items and as replacement is often planned, thus postage delays are not a problem.
Regulation:	All equipment of this nature is listed on the ARTG as a ClassIIa medical device.
Impact:	Survey data suggests that internet imports have resulted in a 5.5% drop in product sold through Australian supply chains (that include a Sponsor of medical devices).
Category:	Large equipment
Products:	Autoclaves, imaging equipment, chairs, etcetera.
Assessment:	Industry advice is that the purchasing patterns from Australian healthcare practitioners is often to undertake a visual inspection first, thus purchasing online is inconsistent with this. These are high-value items purchased in intervals that span several years. Online purchases for autoclaves are not unknown however for large equipment it is problematical (a dental chair weighs approximately 150kg+)
Regulation:	All equipment of this nature is listed on the ARTG as a ClassIIa medical device.
Impact:	Survey data suggests that internet imports have resulted in a 0.4% drop in product sold through Australian supply chains (that include a Sponsor of medical devices). Further research is required to assess what specific product categories are affected.
Category:	Restorative
Products:	Teeth, filling materials, grafting materials, bonding agents and orthodontic appliances.
Assessment:	Industry advice is that these are that although these are attractive items to buy online given their intermediate unit cost and used in some volume, healthcare professionals are often reluctant to access this supply chain given the clearly identifiable patient risks.
Regulation:	Typically synthetic materials are listed on the ARTG as a ClassIIa medical device, however others are ClassIII biological.
Impact:	Survey data suggests that internet imports have resulted in a 4.7% drop in product sold through Australian supply chains (that include a Sponsor of medical devices).

ADIA is continuing the process of data collection to validate assumptions, however the information suggests that imports constitute approximately 3% to 5% of all dental product in this point in time. Significantly, the data suggests that the main products being imported are listed on the ARTG as a ClassIIa medical device, and the imports of ClassIII biological is noted with concern.

Reasons for imports — Insufficient regulatory awareness

The aforementioned survey also asked suppliers of dental equipment to tender advice on two issues that may motivate a healthcare professional to purchase medical devices via the internet, and also asked them to nominate who was the mostly likely person in the dental team to have made the purchase.

Who makes the online purchases?

The survey data concludes that Dentists (74%) were the mostly likely to have made the purchase, then the Practice Manager (19%), Dental Assistant (4%), Administrative staff (3%) which is consistent with the contemporary understanding of dental practice management where the primary practitioner is responsible for the selection of tools and equipment. It is important to note that this assessment is made by those with third-party knowledge of how dental practice operates, not by undertaking an assessment within the sector.

The extent of regulatory obligations of medical product importers

Survey respondents were also asked to identify the extent to which their clients have and understanding of the regulatory framework for the supply of medical devices. The data suggests that there is a limited understanding, probably not sufficient for healthcare practitioners to be aware that they have obligations associated with the importation of medical devices that are intended for use on patients. The following are the survey results.

Question —

With respect to an awareness of the medical device regulatory framework, in your experience what is the average awareness of the rules governing the supply of product amongst dentists and allied oral healthcare professionals?

Responses —

- 2% Excellent: Possesses a fully working knowledge of the legislation
- 17% Functional: Understands that importers have obligations to meet before supplying product
- 73% Limited: Understands that legislation exists but little knowledge of how it may apply to dental practice
- 8% None: No knowledge that there are rules for the supply of therapeutic product

It is important to note that these results are simply an assessment by industry professionals as a result of their dealings with dentists and allied oral healthcare professionals, however it does highlight that there is a significant amount of work to be done in increasing an awareness of the medical device regulatory framework amongst healthcare professionals.

The survey data suggests that dentists would be the primary audience for any campaign to increase awareness of the medical device regulatory framework. However, a question of funding this becomes a matter that cases a philosophical problem. In the lead-up to the 2011 Australian Government budget, ADIA recommended to The Treasury that a regulatory awareness campaign be funded in the 2011-12 Australian Government budget as opposed

to the TGA allocating funds. The need to fund these directly from the budget stems from the TGA's funding arrangements, which require all costs to be met from industry. As the TGA notes:

The TGA operates on a 100% cost recovery basis and collects its revenue primarily through annual charges, application, evaluation, audit and assessment fees.^[11]

This arrangement places the suppliers of medical devices in the untenable situation where they would be compelled to fund the TGA initiatives to address non-compliance by importers acting outside the established medical devices regulatory framework.

Case study — Risks associated with internet imports of dental product

A recent recall undertaken by a manufacturer in the United States of America highlighted problems associated with the importation of therapeutic goods via the internet.

In the latter part of 2010 a voluntary recall of a Class III Biological, a calcium sulphate based bone grafting material, was undertaken by a manufacturer in the United States of America, the ACE Surgical Supply Company of Massachusetts. It is understood that manufacturer undertook a voluntary recall of the product after there were adverse events associated with the product.

It is also understood that the manufacturer exported the goods following a breakdown in their quality assurance system (normally such goods would not be exported to Australia). ADIA has been advised by the TGA that the product was purchased by healthcare professionals in Australia and there is strong reason to believe that the product was purchased via the internet, although at the time of writing this is to be confirmed.

At face value the manufacturer has acted in accordance with proper processes and notified the responsible authorities concerning the adverse impact and then undertook a recall in accordance with established procedures. Assuming that the transaction took place in the United States of America (*i.e.* product manufacture, sales and dispatch) the manufacturer's actions fall outside the jurisdiction of the TGA. It is acknowledged that there may be issues for the US Food and Drug Administration (FDA) to review with respect to export of the product, but such issues are not strictly an issue for the TGA at this juncture.

Given that the customers who imported the product are based in Australia, under the *Therapeutic Goods Act (Cth) 1989* it is they who are legally responsible for the product once in Australia. Curiously, the TGA's focus in this matter was not the Australian-based importers of the product, but the manufacturer based in the United States of America that has, at face value, conducted its activities entirely outside the jurisdiction of the TGA.








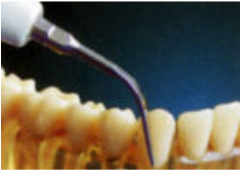








ADIA takes this opportunity to acknowledge that the TGA Office of Devices Authorisation was forthcoming when initially ADIA requested further information on this matter. However, ADIA has now twice sought advice from the TGA on a number of issues relating to this matter and has yet to receive a response. ADIA has sought advice on:

- The number of healthcare professionals who the TGA understands have, or are likely to have, imported the recalled material into Australia;
- If the recalled product was used by healthcare professionals in patients or if this is unknown to the TGA, whether the TGA has made any enquiries to determine this;
- If the TGA has established that the healthcare professionals imported the product in a manner that is contrary to the regulatory framework (*i.e.* for intended use on patients), or whether investigations have been undertaken to ascertain this;
- If it has been established that the healthcare professionals imported the product in a manner that is contrary to the regulatory framework (*i.e.* for intended use on patients), what further enforcement action has been undertaken; and
- If it has been established that the healthcare professionals imported the product in a manner that is contrary to the regulatory framework (*i.e.* for intended use on patients), has the matter been referred to the Director of Public Prosecutions (DPP) and if not, the legal basis for that decision?

This matter is viewed as one of considerable importance by ADIA as it tests the integrity of the regulatory framework in which therapeutic goods are manufactured, imported and supplied to the Australian marketplace.

The ACE Surgical Company recall highlights problems associated with the importation of medical devices via the internet. In this case the issue came to light as the overseas manufacturer followed all proper procedures and acted entirely appropriately, including forwarding a notification to the TGA. However, not all overseas suppliers who sell into Australia via the internet can be expected to behave in such a manner – in such circumstances what safeguards exists to protect patient safety.

Attachment 1 — Availability of medical devices online

	 <p>Three Colors For Choice</p>	<p>BRAND NEW Dental Medical Autoclave Sterilizer 12L Location: China Feedback: 1,857 99.4% Watch this item</p>	<p><i>Buy It Now or Best Offer</i> AU \$2,538.70 Free</p>
	 <p>Autoclave Sterilizer Electric</p>	<p>Dental Surgical Autoclave Portable - Electric type Autoclave , offer warranty, Low price.free SS drum Location: India Feedback: 39 80% Watch this item</p>	<p><i>Buy It Now</i> AU \$354.89 +AU \$11.83</p>
		<p>2-1 ROOT CANAL Brushless Endo Motor and Apex Locator CE Location: China Feedback: 8,153 99.2% Watch this item</p>	<p><i>Buy It Now or Best Offer</i> AU \$511.70 Free</p>
		<p>NEW Dental Scaler Scaling Tips 20pcs For EMS SALE Mixed Location: China Feedback: 3,934 99.7% Watch this item</p>	<p><i>Buy It Now</i> AU \$99.00 Free</p>
	 <p>2**Woodpecker LED.B Wireless Curing Light Dental</p>	<p>Location: China Feedback: 652 99.1% Watch this item</p>	<p><i>Buy It Now</i> AU \$199.00 Not specified</p>
		<p>5 DENTAL LATCH CONTRA ANGLE SLOW SPEED HANDPIECE AU Location: China Feedback: 3,265 98.4% Watch this item</p>	<p><i>Buy It Now or Best Offer</i> AU \$109.00 Free</p>
		<p>Dental Amalgamator Mixer For Amalgam 220V Location: China Feedback: 733 98.7% Watch this item</p>	<p><i>Buy It Now</i> AU \$118.29 +AU \$34.50</p>
		<p>Dental Light Curing Temporary Filling Materials 3g x 3 Location: Korea, South Feedback: 154 100% Watch this item</p>	<p>0 Bids AU \$0.94 +AU \$34.50</p>

Abbreviations

ABS	Australian Bureau of Statistics
AHPRA	Australian Health Practitioner Regulation Agency
ADIA	Australian Dental Industry Association
APEC	Asia-Pacific Economic Cooperation
AQIS	Australian Quarantine Inspection Service
ARTG	Australian Register of Therapeutic Goods
DBA	Dental Board of Australia
EU	European Union
FDI	Federation Dentaire Internationale (<i>Eng.</i> World Dental Federation)
GHTF	Global Harmonisation Task Force
IDM	International Dental Manufacturers
ISO	International Standards Organisation
NeHTA	National eHealth Transition Authority
TAFE	Technical And Further Education
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

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