Australian Dental Industry Association

Submission
— Senate Community Affairs Committee

Regulatory Standards
For The Approval Of Medical Devices

Australian Dental Industry Association
— 27 July 2011

Representing Dental Industry Excellence

Australian Dental Industry Association

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This submission has been prepared by the Australian Dental Industry Association (ADIA) to support the work of the Senate Community Affairs Committee as it conducts its inquiry into the regulatory standards for the approval of medical devices.

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Executive Summary

The majority of product used in contemporary dentistry constitutes a medical device for regulatory purposes, thus the Australian dental industry has considerable interests in the regulatory standards for the approval of medical devices. The dental industry's position is unique in the medical device sector given that the product is sold both to consumers and healthcare professionals, that differs from many other medical devices such as hip implants which are typically only supplied registered healthcare professionals such as surgeons.

ADIA believes that the framework that produces the regulatory standards for medical devices, as administered by the Therapeutic Goods Administration (ADIA), is recognised internationally as first-rate. It escalates the regulatory barriers for supplying medical devices in a manner that is commensurate with the risk. 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. That said, there is the need to review operations with a view to improving outcomes for patients, and the following summarises the key issues.

International harmonisation of medical device standards

The TGA's commitment to the international harmonisation of the medical device regulatory framework is exemplary, reflected in its commitment to the implementation of the Australia – New Zealand Therapeutic Products Agency (ANZTPA). However, in the past of the course year the TGA has proposed reforms that would have introduced Australian-only manufacturing requirements. There is also unease with the TGA's support for restructure of the Global Harmonisation Taskforce (GHTF) that disenfranchises industry participation in the decision making process.

Recommendation 1: That the Australian Government support further reform of the GHTF to develop a framework that mandates industry input at the highest levels.
Recommendation 2: That the Australian Government retain its commitment to the ANZTPA proposal, implementing a framework that mandates industry input at the highest levels.

Industry consultation on regulatory standards

As the framework for the development and administration of regulatory standards for the approval of medical devices has matured, so too has the consultative processes of the TGA. As part of its work as an advocate for the dental industry ADIA cooperates with a number of departments and agencies at a state and national level. Having reviewed the TGA's current processes and compared these with those employed by other departments and agencies, ADIA advises that in its view the TGA's consultative process are considered to serve as a model for others.

Recommendation 3: That options be considered for TGA staff to access industry expertise in a manner that is both open and transparent.

The cost of regulatory standards for medical devices

There is growing frustration in Australian dental industry because businesses that place their product on the Australian Register of Therapeutic Goods (ARTG) and meet the associated costs are placed at a commercial disadvantage compared to

businesses that supply dental product outside the regulatory framework and, in most cases, will remain unmolested by the TGA.

The TGA has shown itself unable to properly assess costs associated with amendments to the regulatory standards for medical devices, failing to identify the significant administrative and financial burden that would arise from its proposed reforms.

Recommendation 4: That a supplemental budget appropriation be made to fund the TGA's regulatory compliance and awareness activities.
Recommendation 5: That in developing proposals to amend regulatory standards for the approval of medical devices the TGA's current consultative mechanisms be used to assess potential costs.

Regulatory standards for the approval of custom-made medical devices

Custom-made medical devices include dental appliances such as crowns, bridges and dentures and a subject to less stringent regulatory approval standards as each device is a one-off with its own design requirements. The TGA has demonstrated a willingness to work with the dental industry to further strengthen the regulatory standards for the approval of medical devices that can be supported by industry.

There is a legitimate economic concern held by dental laboratories residing in Australia that their long-term viability is being adversely affected by imports of custom-made medical devices used in dentistry. This issue merits review, however the economic structure of Australia's dental industry is outside the terms of reference for the Senate inquiry.

Recommendation 6: As a matter of priority, the TGA continue to work with national stakeholders to strengthen the regulatory standards for custom-made medical devices.

Internet imports and standards for medical devices

Australian regulatory standards for the approval of medical devices can be readily circumvented when product is purchased online from overseas sources. It is possible to purchase from overseas sources (via websites such as eBay) most products that appear on the ARTG. There is evidence that healthcare professionals are buying dental product from overseas sources and using in their practices, thus circumventing the protections put in place by the *Therapeutic Goods Act (Cth) 1989.*

Recommendation 9: That the medical device personal importation provisions contained in the *Therapeutic Goods Act (Cth) 1989* be removed.
Recommendation 10: That the Australian Government provide a budget appropriation to the TGA to fund activities associated with awareness of, and compliance with, regulatory standards for the importation of medical devices.

Enforcement of medical standards for the approval of medical devices

The TGA's regulatory enforcement activities are focused on the businesses that have sought to comply with the regulatory standards for medical devices. Such businesses incur substantial regulatory compliance costs associated with both the initial process of placing a product on the ARTG and the TGA's subsequent post-

market surveillance activities. However, there is evidence to suggest that the TGA has a relaxed attitude when healthcare professionals import medical devices in a manner inconsistent with the regulatory framework.

Recommendation 11: That recommendation eighteen of the Pearce Review be implemented, this being that the TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.

The Australian dental industry supports the regulatory standards for the approval of medical devices and, with qualification, supports the work of the TGA in administering the legislation. That said, there are serious concerns with the TGA's regulatory enforcement activities that. given the lack of any proactive enforcement activities, allow substantial quantities of medical devices to be imported and used by healthcare professionals without penalty.

Troy R Williams MAICD AFAIM
ADIA Executive Officer

— 27 July 2011

Chapter 1 —
Introducing The 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 (*Fr.* Federation 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

Chapter 2 —
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.

Chapter 3 —
International Harmonisation Of Regulatory Standards For The Approval Of Medical Devices

Chapter Summary

Dentists and allied oral healthcare professionals rely heaving on the dental product supplied by the dental industry that is sourced from overseas. With around 95% of dental product imported, it is imperative that Australia has a regulatory framework 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. An effective way to realise this outcome is to ensure that Australian standards for the approval of medical devices are based upon those used overseas.

The TGA's commitment to the international harmonisation of the medical device regulatory framework is exemplary, reflected in its commitment to the implementation of ANZTPA. However, in the past of the course year the TGA has proposed reforms that would have introduced Australian-only manufacturing requirements. There is also unease with the TGA's support for restructure of the GHTF that disenfranchises industry engagement in the organisations decision making processes.

Chapter Commentary

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. The Industry Commission (predecessor of the Productivity Commission) noted in its report on the medical and scientific equipment industries:

> *The detailed requirements for devices in Australia differ markedly from those of its major trading partners. As a consequence, Australian exporters and imports have to conform to multiple regimes. This adds to their compliance costs and inhibits trade.*[1]

The Industry Commission's observation was made in a report dated December 1996 that contained a number of recommendations that sought to harmonise the Australian medical regulatory framework with those with key trading partners, primarily the European Union (EU) and the United States of America. The subsequent adoption of these recommendations by the TGA is to be commended as the changes have significantly reduced the regulatory differences between Australia's medical device regulatory framework and that of the European Economic Area (EEA), a framework that incorporates the EU plus Iceland, Liechtenstein and Norway. The differences with the framework that exists in the United States of America have also been reduced, albeit to a lesser extent.

Although there is an in-principle commitment by the Australian Government to medical device regulatory harmonisation at an international level, policy variations continue. In a discussion paper dated 25 October 2010, the TGA proposed a number of changes to the medical devices regulatory framework which were peculiar to Australia. As part of its consultation process the TGA received a number of comments highlighting the proposed Australian-only regulatory requirements, with ADIA noting:

> *Given that the proposed changes require changes to manufacturing process for medical devices manufactured overseas and supplied to the Australian market, the proposed changes are inconsistent with the goals that the GHTF is working towards. The result of these proposals is a greater divergence between the Australian framework for the regulation of medical devices and its overseas counterparts, both in GHTF participating nations and others.*[2]

The negative impact of what were represented by the TGA as "minor" amendments to the regulatory standards for the approval of medical devices, particularly those peculiar to the Australian market, should not be underestimated. One of the regulatory amendments proposed by the TGA in its discussion paper concerned medical devices packaging and labeling, an issue viewed by many to be of less importance compared to standards conformity and assessment. The TGA was advised:

> *The strongest consideration needs to be given to any change that will mean Australian specific labeling as our market volume means that it is not commercially viable to produce small quantities of dental devices labeled specifically for our market. This would then jeopardise supply to the Australian market, with the potential to severely impact healthcare professionals and consumers through inability to access currently approved products. In the unlikely event that a manufacturer should agree to manufacture devices with Australian specific labeling in small production runs, then due to the small volumes manufactured, prices would be significantly increased. This has the potential to compromise the affordability of dental care in Australia, as price increases across the entire range of low risk dental devices are passed on to consumers.* [3]

For these reasons ADIA supports the commitment by the Australian Government that sees the TGA work towards the international harmonisation of the regulatory standards for the approval of medical devices. The importance of internationally harmonised medical devices regulatory frameworks has been noted by the World Health Organisation (WHO):

> *In essence, governments are encouraged to follow the growing movement towards harmonized regulatory systems because a proliferation of different national regulations increases costs, hinders access to healthcare technologies, and can even unwittingly jeopardize the safety of the patient.* [4]

There is, however, still work to be done. By general consensus within Australia's dental industry, the EEA framework for the regulation of medical devices is more robust than that administered by the US Food and Drug Administration (FDA). The EEA framework also closely aligns with the current Australian framework administered by the TGA.

Global Harmonisation Task Force

The GHTF was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This was done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world. The GHTF is an international group of representatives from medical device regulatory authorities and trade associations from the EU, the European Free Trade Association (EFTA), the United States of America, Canada, Japan and Australia. It is noted that the GHTF work is a standing work item for the Asia Pacific Economic Cooperation (APEC) forum members, with a current priority being to:

> *Align domestic regulations for medical devices with the principles of the Global Harmonisation Task Force (GHTF). Progressively adopt and implement GHTF guidance documents.*[5]

In early 2011 it was announced, without reference to industry in Australia or overseas, that the GHTF was being restructured to remove industry input and opt for a "regulator driven" model. A GHTF report noted:

> *The regulator's group was of the view that achieving harmonised regulatory requirements remains a highly desirable objective, particularly in view of the pressures of a globalised manufacturing market for medical devices and increasing demands to streamline regulatory processes in order to deliver high quality products to the marketplace with minimal delays. The regulator's group considered that the best way to achieve such an outcome was to develop a regulator-led harmonisation and collaboration group that would allow for more detailed discussion between members on the optimum ways to achieve harmonisation at an operational level. Collaboration would be fostered by such an arrangement in areas such as new science and technologies, information and resource sharing and increased opportunities for technical expert interchanges.* [6]

ADIA finds this approach objectionable, based on the flawed premise that regulators have a detailed understanding of the needs of industry and the effects of their decisions on the cost of supplying medical devices. As is demonstrated in Chapter Four, the TGA lacks the expertise to properly assess the impacts of its proposals for regulatory reform. There is much to fear from a "regulator driven" model that deliberately seeks to reduce the input from industry and it is not a course of action that the Australian Government should support.

Although the TGA has not acted in the interests of either the dental industry or patients in supporting destructive changes to the GHTF, the TGA's leadership in other areas does need to be acknowledged, particularly in fostering Trans-Tasman regulatory convergence of the regulatory standards for the approval of medical devices.

Australia – New Zealand Therapeutic Products Agency Proposal

A renewed commitment to the proposed establishment of ANZTPA was announced by the Prime Ministers of Australia and New Zealand on 20 June 2011, is welcomed by ADIA. The association was a supporter of ANZTPA when it was first proposed several years ago, and the Association has maintained that its establishment is in the best interests of both patients and the Australian dental industry.

The agreement signed between the Prime Ministers signals the intent of both governments to progressively implement the joint agency over a period of up to five years. A staged approach focused on medicines, medical devices and biologicals will be adopted in order to establish the requisite building blocks for one regulatory system.

The Australian dental industry shares the view of the Australian Government that the creation of a joint regulatory scheme across both countries, that includes common regulatory standards for the approval of medical devices, will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries.

ADIA has received advice that the dental industry will be consulted throughout the process of working towards ANZTPA, and the Association takes this opportunity of highlighting the importance of the TGA fully engaging in the dental industry on this matter.

As a small market that is heavily reliant upon imports, the Australian dental industry benefits greatly from international harmonisation of regulatory standards for the approval of medical devices associated with the manufacture, export, import and supply of dental product. Tis ultimately produces lower costs for dental care than would be the case if Australia had its own, unique regulatory standards for medical devices. For this reason ADIA views the international harmonisation of the medical devices regulatory framework to be a highly desirable outcome.

Recommendation 1: That the Australian Government support further reform of the GHTF to develop a framework that mandates industry dental input at the highest levels.

Recommendation 2: That the Australian Government retain its commitment to the ANZTPA proposal, implementing a framework that mandates dental industry input at the highest levels.

Chapter 4 — Industry Consultation On Regulatory Standards

Chapter Summary

As the framework for the development and administration of regulatory standards for the approval of medical devices has has matured, so too has the consultative processes of the TGA. As part of its work as an advocate for the dental industry ADIA cooperates with a number of departments and agencies at a state and national level. Having reviewed the TGA's current processes and compared these with those employed by other departments and agencies, ADIA advises that in its view the TGA's consultative process are considered to serve as a model for others.

Chapter Commentary

ADIA notes the 2004 review of the TGA's consultative arrangements undertaken by Strategic Consulting Services Proprietary Limited, and the more recent review Chaired by Professor Dennis Pearce. ADIA takes this opportunity to acknowledge the work of the TGA in adopting many of the recommendations arising from the 2004 review – the resulting transparency is welcomed by ADIA as representative of the dental industry.

Effectiveness of current consultative arrangements

There are three primary points of engagement between ADIA and the TGA, these being: The TGA Therapeutic Industry Consultative Committee (TICC), the TGA Therapeutic Industry Consultative Committee Bilateral Meeting and the TGA Regulatory and Technical Forum for the Devices Sector. ADIA appreciates the ability to represent the dental industry in these forums and acknowledges the diligent work of TGA officers to ensure that ADIA has the opportunity to have issues placed on the agenda at this meeting. The process of securing comment from industry is a proactive one, with TGA officers contacting the membership of these committees requesting that stakeholders such as ADIA suggest items for discussion and provide supporting papers.

In its submission to the Pearce review, ADIA advised that, on balance, these forums work well. It was, acknowledged that there is a residual feeling that the full benefit is not being drawn from these meetings. ADIA advised the Pearce review that the current structure should be retained, however it is timely that an independent facilitator be brought in to work with TGA officers, industry stakeholders and consumer representatives (where appropriate) to draw the full benefit from these meetings.

Recognising industry expertise

Advice to ADIA from its membership highlights the importance of the TGA drawing upon the expertise that can be found in industry when the TGA is proposing changes to the regulatory standards for the approval of medical devices. The benefits to the TGA become particularly relevant when considering issues associated with specific product groups and industry issues. The 2004 review of the TGA's consultative arrangements noted:

> *Suppliers considered that the TGA did not take enough account of the fact that Australia is a small market and was overly conservative and cautious in its*

approach to issues. They also believed that the TGA did not take enough account of the expertise residing within industry and also had a negative view to some of the advice emanating from industry. Given that many from industry consider themselves to be professionals first and foremost, they felt that such an attitude by TGA officers impugned their professional integrity.[7]

In commenting on this point it should be stated that ADIA has found TGA officers to be entirely approachable and willing to engage with industry as the need arises. However, it is clear that the TGA would benefit from further engagement with industry when staff are in need of technical expertise as the following example highlights.

In October 2010 the TGA proposed changes to the medical devices regulatory framework which were poorly crafted from a technical viewpoint. The discussion paper stated that "The TGA is proposing to require sponsors to itemize the devices and / or various models that are supplied under the same ARTG entry" and later states "If approved, this list of devices identified by model number or trade name will appear as a list of devices under the ARTG entry". However, in developing the proposal the TGA failed to recognise that "devices", "model", "model number" and "trade name" are not the same thing from a sponsor's perspective thus there was confusion as to what the TGA was trying to achieve and almost impossible to properly calculate the cost. The purpose of raising the issue here is not to debate the merits of the proposal, but to highlight the fact that TGA staff would benefit from seeking advice from industry in industry practice and / or technical matters when considering proposals to amend regulatory standards for the approval of medical devices.

The TGA convenes the TGA Regulatory & Technical Forum for the Devices Sector and ADIA is supportive of, and a participant in, this forum. It currently does not serve as a platform for TGA officers to seek advice on technical matters specific to individual product areas, however as the TGA would benefit from access to the technical expertise that resides in industry this is an issue that needs to be considered.

TGA Website Redevelopment

The recent project to review the TGA's website is an important initiative that was supported by ADIA which was represented on the industry reference group assembled to provide advice and guidance on the website's structure and content. ADIA applauds this level of industry engagement that was proactively sought by TGA officers.

On balance, the TGA is perceived to be proactively engaging with industry and consumer stakeholders and has the necessary infrastructure in place to facilitate industry consultation on matters associated with the regulatory standards for the approval of medical devices. However, current arrangements could be strengthened once the TGA accepts the need to draw upon the technical expertise within industry that does not exist within the TGA.

Recommendation 3: That options be considered for TGA staff to access industry expertise in a manner that is both open and transparent.

Chapter 5 —
The Cost Of Regulatory Standards For Medical Devices

Chapter Summary

The Australian dental industry understands and accepts the principle of cost-recovery insofar as the TGA's approval processes are concerned, consistent as it is with the Australian Government's approach to regulation of other industry sectors. However, there is growing frustration amongst individuals within the Australian dental industry that businesses that place their product on the ARTG and meet the associated costs are placed at a commercial disadvantage compared to businesses that supply dental product outside the regulatory framework and, in most cases, will remain unmolested by the TGA.

The TGA has also shown itself unable to properly assess costs associated with amendments to the regulatory standards for medical devices. In late 2010 the TGA proposed changes that would have necessitated changes to manufacturing processes that the TGA claimed should not adversely impact upon regulatory costs when advice from industry was diametrically different.

Chapter Commentary

The supply of medical devices in Australia is heavily regulated and, on balance, ADIA supports the current framework for the manufacture, importation and supply of medical devices. The support of the dental industry is underpinned by the TGA's stated commitment to balance regulatory burden with costs to business, whilst fulfilling its role as a regulator effectively. The TGA has described its role and approach as being:

> *The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.*
>
> *The regulatory framework 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.*[8]

The Australian dental industry is becoming increasingly disenchanted with the TGA and confidence in the regulatory framework is falling. The underpinning concern is that the TGA aggressively enforces the regulations on Sponsors of therapeutic product but has a lackadaisical approach to enforcement when others supply product outside the regulatory framework. As some ADIA member noted "Why do I bother paying all the fees and charges and filling in endless paper? Many businesses supply dental goods without getting approval and what does the TGA do – nothing! Even worse, they might propose an awareness campaign that I'm meant to fund through higher TGA fees and charges". Regrettably, this view is broadly representative of the dental industry's views of the TGA's funding mechanisms.

Funding Compliance Activities

The Australian dental industry is not comfortable with the TGA's cost recovery arrangements which sees suppliers of therapeutic products through proper channels

(*i.e.* by listing product on the ARTG) funding enforcement activities directed at those companies that are supplying product through illegitimate means (*i.e.* by not listing product on the ARTG). As the TGA notes, all of its funding comes from the legitimate suppliers of dental product:

> *The TGA recovers the full cost of its regulatory activities within the scope of the Act through fees and charges for services provided to product introducers (sponsors) and manufacturers. Fees and charges are prescribed in regulations made under the Therapeutic Goods Act 1990, Therapeutic Goods (Medical Devices) Act 2001 and the Therapeutic Goods (Charges) Act 1990. Certain activities undertaken for Government have been funded from departmental allocations.*[9]

This approach provides an effective financial penalty on the businesses complying with the regulatory standards, transversely it provides a commercial advantage to the businesses that neglect their statutory responsibilities. ADIA recommends that the Australian Government provide a supplemental appropriation to the TGA that funds regulatory awareness and enforcement activities.

Current arrangements place 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.

Proposed Regulatory Standards To Increase Costs

In October 2010 the TGA proposed changes to the medical device regulatory framework that were published in a discussion document so as to facilitate public comment on the proposed reforms. ADIA tendered a response in December 2010 which provided positive recommendations to strengthen the regulatory framework without increasing the regulatory burden on business. The purpose of raising the matter as part of the review to improve the transparency of the TGA is not to revisit the proposed reforms, but highlight problems associated with the preparation of the discussion paper proposing regulatory reform and opportunities to improve processes going forward.

The following comment relates to proposal 3(ii) in the TGA's discussion paper of October 2010 proposing changes to the medical device regulatory framework. The specific nature of what the TGA is trying to achieve was ambiguous as the paper suggested several versions of the same proposal, however it can be broadly summarised as:

> *Sponsors will be required to label all devices with the ARTG number in accordance with Regulation 10.2 (amended) and essential principle 13.2 Information to be provided with medical devices – location.*[10]

In proposing this new regulatory standard for the approval of medical devices, the TGA made a unilateral assessment of the associated costs. The discussion paper contained the following reference by the TGA to this specific proposal:

> *This change should not adversely impact upon regulatory costs as sponsors are already required to publish their contact details on the information that*

> *accompanies a medical device. This amendment would only require sponsors to add the ARTG number to their contact details.* [11]

The TGA received advice from ADIA and other stakeholders that far from "not adversely impacting upon regulatory costs" the proposal significantly increased the regulatory burden for business which would directly increase costs to business which would be passed on to both healthcare professionals and the community. As one supplier of dental product noted:

> *If the ARTG number has to be on the device itself in many, or even some cases, this change substantially alters the existing regulatory arrangement for businesses and will result in a very large one-off cost to business, as well as significant ongoing costs.*
>
> *Most dental devices sold in Australia are imported and the compliance costs of having special product runs with ARTG numbers on devices destined for Australia will significantly and detrimentally impact upon the cost of health care in Australia. This is quite different to simply having something printed on packaging, such as a sponsor's details.* [12]

The advice from industry was that the TGA's proposed new regulatory standards for the approval of medical devices would significantly increase regulatory compliance costs, something that is diametrically opposed to the TGA's conclusions on this matter. In this environment there are questions concerning the reliability of data and / or base assumptions used by the TGA

The continued support by the dental industry for the medical device regulatory framework administered by the TGA is entirely dependent upon maintenance of the principle that regulatory framework 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.

Recommendation 4: That a supplemental budget appropriation be made to fund the TGA's regulatory compliance and awareness activities.
Recommendation 5: That in developing proposals to amend regulatory standards for the approval of medical devices the TGA's current consultative mechanisms be used to assess potential costs.

Chapter 6 —
Regulatory Standards For The Approval Of Custom-made Medical Devices

Chapter Summary

Custom-made medical devices include dental appliances such as crowns, bridges and dentures and a subject to less stringent regulatory approval standards as each device is a one-off with its own design requirements. The TGA has demonstrated a willingness to work with the dental industry to further strengthen the regulatory standards for the approval of medical devices, something welcomed by ADIA.

There is a legitimate economic concern held by dental laboratories residing in Australia that their long-term viability is being adversely affected by imports of custom-made medical devices used in dentistry. This issue merits review, however the economic structure of Australia's dental industry is outside the terms of reference for the Senate inquiry.

Chapter Commentary

Over the course of the past decade there has been a recurring public debate amongst professionals in the dental industry, dental professions and public concerning the regulatory standards for the approval of custom-made medical devices. In the context of contemporary dentistry, custom-made medical devices include dental appliances such as crowns, bridges and dentures. A series of inaccurate television news stories appearing in June 2011 once again ignited this debate.

The regulatory compliance framework

Throughout the early part of 2011 this issue has been revisited by the TGA, supported by key national stakeholders including ADIA and the Medical Technology of Australia (MTAA). A consensus has been established that the current regulatory standards for the approval of custom-made medical devices provides an adequate degree of patient safety, however some clarification of requirements is appropriate.

In some quarters there have been questions concerning the regulatory obligations resting with importers of medical devices, including custom-made medical devices. The TGA has confirmed that the importer of a custom-made medical device (*e.g.* a business, dentist or other healthcare professional) has the legal responsibilities of a sponsor of product insofar as they apply to custom-made medical devices. From ADIA's perspective, this largely settles the debate on the regulatory standards for the approval of custom-made medical devices imported from overseas. The onus is clearly on the importer (whether they be a business or individual healthcare professional) to supply a custom-made medical device in accordance with the prevailing regulatory standards.

ADIA notes that awareness of the regulatory framework that pertains to the importation custom-made medical devices is not high, even amongst healthcare professionals. For this reason, ADIA recommends the TGA embark upon an awareness campaign undertaken in partnership with key national stakeholders such as ADIA and the Australian Dental Association (ADA).

Alternative regulatory approaches

There has been debate in some quarters for further regulation of custom-made medical devices. Although ADIA welcomes debate on such proposals and the opportunity to review the same, the Association's preference is to strengthen awareness of the existing regulatory standards for the approval of medical devices rather than creation of further regulation. ADIA takes this opportunity to briefly review some options that have been canvassed:

- Country Of Origin Labelling: Notwithstanding the inherent problem in labelling a custom-made medical device, ADIA does not support such an additional regulatory requirement as it does nothing to improve patient safety. Country of origin labelling provides no assurance on the quality of the device, its composition and attributes. This proposal seems to be based on a commercial imperative to promote Australian-made product, supported by the inferred and false premise that all product imported from overseas is deficient in some way. It is noted that given that the importer of a custom-made medical device has the responsibilities of a Sponsor, the importer of the product (whether a business of healthcare professional) will have this information available for review by patients if it is requested.
- Materials Listing: It has been proposed that the materials within a custom-made medical device be provided to patients. ADIA has no philosophical problem with this proposal, however it dies little to provide patients with useful information. Many of the constituent materials of a custom-made medical device have complex chemical names not readily understood by the layperson (by way of example, most consumers struggle to identify the chemicals listed on a regular hair shampoo bottle). Again, it is noted that given that the importer of a custom-made medical device has the responsibilities of a Sponsor, the importer of the product (whether a business of healthcare professional) will have the relevant information available for review by patients if it is requested.
- Mandatory Choice: It has been proposed that a healthcare professional present the patient with a choice between a custom-made medical device manufactured in Australia and one made overseas. Given that this proposal interferes in the relationship between the healthcare professional and the patient, this proposal is not supported. It is important that patients have available to them the highest standards of care, provided under the professional guidance of healthcare professionals, which mandates the use of the most appropriate medical device irrespective of country of origin.

In considering reform to the regulatory standards for the approval of custom-made medical devices, ADIA highlights the need to reform the current 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.

ADIA takes this opportunity to acknowledge the commitment of the TGA to work with ADIA to strengthen the regulatory standards for the approval of custom-made regulatory devices, primarily through the TGA Regulatory And Technical Forum For The Devices Sector. During the course of the past year, the TGA has been responsive to requests for information and regulatory guidance. ADIA has raised the need for a campaign to increase compliance and the TGA has also been receptive to suggestions in this area. That said, ADIA takes the view

that it is entirely appropriate that this needs to be funded from a parliamentary appropriation whereas the TGA has expressed no view on the funding mechanism.

Problems associated with custom-made medical devices used in dentistry has arguably been the recipient of unwarranted public concern. As with any medical device there are inherent risks, augmented by genuine concern about product introduced to Australia outside the medical device regulatory framework. That said, at this stage no evidence has been produced to suggest anything other than a few isolated examples of adverse patient effects associated with custom-made medical devices used in dentistry. Such examples are regrettable and merit review, however do not warrant wholesale reform of the regulatory standards for the approval of medical devices.

Recommendation 6: As a matter of priority, the TGA continue to work with the TGA Regulatory and Technical Forum for the Devices Sector to review options to strengthen the regulatory standards for custom-made medical devices.

Chapter 7 —
Internet Imports & Regulatory Standards For Medical Devices

Chapter Summary

Australian regulatory standards for the approval of medical devices can be readily circumvented when product is purchased online from overseas sources. It is possible to purchase from overseas sources (via websites such as eBay) most products that appear on the ARTG. There is evidence that healthcare professionals are buying dental product from overseas sources and using in their practices, thus circumventing the protections put in place by the *Therapeutic Goods Act (Cth) 1989.*

Chapter Commentary

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.*[13]

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) 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.*[14]

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 standards for the approval of medical devices were first designed more than twenty years ago. The framework 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.*[15]

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.

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] 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.*[16]

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. 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.*[18]

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.[19]

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.*[20]

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.

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.

Internet imports and areas of greatest risk

There is broad agreement that the regulatory standards for the approval of medical devices are bypassed as a result of internet imports. 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 ClassI 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:	**b**urs, 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)

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.

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.

Under the *Therapeutic Goods Act (Clth) 1989* it is possible for a healthcare professionals to import medicines from overseas without becoming a Sponsor. Personal importation occurs when: an individual brings a therapeutic good into Australia on their person or arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier; and the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

Under the Personal Importation Scheme an individual may import a three month supply (at the maximum dose recommended by the manufacturer) of unapproved therapeutic goods into Australia in any one importation without any approval required by the TGA provided that:

- the goods are for the importer's own treatment or the treatment of their immediate family; and
- they do not supply (sell or give) the medicine to any other person; and
- where possible, they keep the medicines or medical devices in their original packaging with any dispensing labels intact; and
- the goods are not restricted under Australian Customs controls or quarantine rules and the goods do not contain a controlled substance; and
- the goods are not injections that contain material of human or animal origin (except insulin); and
- the total quantity of the goods imported within a twelve month period does not exceed fifteen months supply of the goods (for medicines, at the maximum dose recommended by the manufacturer); and
- if the goods are medicines in Schedule 4 or 8 of the Poisons Standard a prescription from a registered medical practitioner is held for the medicines.

In these circumstances, individuals can legally import most therapeutic goods for personal use under the Personal Importation Scheme. This arrangement in nonsensical, it infers that the Australian public needs protection when purchasing a product from an Australian supplier but needs no protection when purchasing product from overseas, even though in the latter scenario there are guarantees about the safety or quality of medical devices imported from overseas.

Recommendation 8: That the medical device personal importation provisions contained in the *Therapeutic Goods Act (Cth) 1989* be removed.

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

Chapter 8 —
Enforcement Of Regulatory Standards For the Approval Of Medical Devices

Chapter Summary

The TGA's regulatory enforcement activities are focused on the businesses that have sought to comply with the regulatory standards for medical devices. Such businesses incur substantial regulatory compliance costs associated with both the initial process of placing a product on the ARTG and the TGA's subsequent post-market surveillance activities. However, there is evidence to suggest that the TGA has a relaxed attitude when healthcare professionals import medical devices in a manner inconsistent with the regulatory framework.

Chapter Commentary

The Australian dental industry's confidence in the ability of the TGA to both adequately and fairly enforce regulatory standards for the medical devices is falling. This is due to the fact that the TGA had demonstrated a lack of capacity to proactively monitor and address the supply of medical devices outside the regulatory framework. Of concern, this view is not unique to the dental industry as the *Report of the Review to improve the transparency of the Therapeutic Goods Administration* (also referred to as the Pearce Review) from the committee Chaired by Professor Dennis Pearce AO noted:

> *There is a public perception that the TGA's investigations and compliance actions are ineffectual and rarely applied.*
>
> *The point was made that knowledge of the surveillance work undertaken by the TGA, and the outcomes achieved, are central to public confidence in the quality, safety and efficacy of therapeutic goods on the Australian market.* [21]

ADIA endorses these comments without reserve. In the experience of the Australian dental industry, it appears as the focus of the TGA's activities are dedicated to ensuring that existing Sponsors of medical devices comply with regulatory standards for the approval of medical devices whilst companies supplying product outside this framework can go about their business with apparent impunity. The TGA does not proactively enforce its legislation, relying upon complaints to be lodged, and there is little confidence in the TGA's activities in progressing a complaint as the TGA rarely reports on its activities or indeed provides follow-up information to the party who lodged the complaint. Further, as the example below highlights, the TGA often focuses its activities on the wrong party.

TGA compliance failure example

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, perhaps with the understanding that the TGA has bungled this investigation, further information has not been forthcoming. 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?

The TGA's advice on this matter has been inconsistent. It first reported that investigations had been discontinued and subsequently advised ADIA that it doesn't

comment on any matter which *may* be subject to review by the courts – in this scenario the public may never know the risks to which they may be exposed.

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.

At its most fundamental level, there is a lack of confidence that the TGA can adequately enforce the regulatory standards for the approval of medical devices.

The ACE Surgical Company recall highlights problems associated with the importation of medical devices via the internet, and also the enforcement mechanisms associated with the standards for the approval of medical devices. 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.

Recommendation 11: That recommendation eighteen of the Pearce Review be implemented, this being that the TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.

Abbreviations

Abbreviations

ABS	Australian Bureau of Statistics
ADA	Australian Dental Association
ADIA	Australian Dental Industry Association
AHPRA	Australian Health Practitioner Regulation Agency
AIMD	Active Implantable Medical Device
ANZTPA	Australia New Zealand Therapeutic Products Agency
APEC	Asia-Pacific Economic Cooperation
ARTG	Australian Register of Therapeutic Goods
DFAT	Department of Foreign Affairs & Trade
EEA	European Economic Area
EFTA	European Free Trade Association
EU	European Union
FDI	Federation Dentaire Internationale (*Eng.* World Dental Federation)
GHTF	Global Harmonisation Task Force
GMDN	Global Medical Device Nomenclature
IDM	International Dental Manufacturers
ISO	International Standards Organisation
MTAA	Medical Technology Association of Australia
NeHTA	National eHealth Transition Authority
RIS	Regulatory Impact Statement
TAFE	Technical And Further Education
TGA	Therapeutic Goods Administration
TICC	Therapeutic Industry Consultative Committee
TPP	Trans Pacific Partnership
US	United States (of America)
WHO	World Health Organisation

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