Australian Dental Industry Association

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Trans Pacific Partnership Agreement

Submission To The
Department of Foreign Affairs & Trade

From The
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Representing Dental Industry Excellence

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Trans Pacific Partnership Agreement

This submission from the Australian Dental Industry Association (ADIA) to the Department of Foreign Affairs and Trade (DFAT) provides commentary on negotiations associated with development of the Trans Pacific Partnership (TPP) free trade agreement.

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ADIA Submission
Executive Summary

The Australian Dental Industry Association (ADIA) welcomes the negotiations associated with the developing Trans Pacific Partnership (TPP) and takes this opportunity to highlight the importance of trade liberalisation to the Australian dental industry.

From a regulatory perspective most types of dental product are categorised as “medical devices” for regulatory purposes. Of the medical devices used by Australian dentists and allied oral healthcare professionals, it is estimated that some ninety-eight percent (by value), are imported from overseas. Despite this extraordinarily high proportion of imports, Australia maintains a number of regulatory requirements associated with the manufacture, importation and supply of medical devices which are peculiar to Australia. It is therefore beneficial for Australia to support initiatives that seek to harmonise, at an international level, regulatory arrangements for the supply of medical devices.

With respect to medical devices and specifically those used in dentistry, Australians stand to benefit on two fronts from the trade liberalisation, encapsulated by regulatory harmonisation, that the TPP agreement will deliver. The first benefit is access to cheaper products which will be an outcome of lower regulatory compliance costs. The second benefit will be faster access to new and innovative products which will be facilitated by internationally consistent product testing and conformance requirements.

In bringing the TPP agreement to fruition, there is considerable benefit in incorporating existing work to harmonise medical device regulation, specifically the work undertaken by the Global Harmonisation Task Force (GHTF). The GHTF is working towards a regulatory system seeks to encourage convergence of regulatory practices amongst nations which is important given that Australia constitutes around two percent of the global market for medical devices. The work of the GHTF is supported by the Asia Pacific Economic Cooperation (APEC) forum.

Australia relies heavily on imported dental product due to the relatively small domestic manufacturing base. In this context the potential for the TPP agreement to have an adverse impact on the dental industry is limited and counterbalanced by the potential to enhance export opportunities.

ADIA supports the inclusion of a medical devices sector chapter within the TPP agreement and looks forward to participating in its development.

Troy R Williams MAICD AFAIM
ADIA Executive Officer

— 27 January 2011

Introduction
Australian Dental Industry Association

ADIA is the national organisation representing the interests of companies that supply products and services to dentists and allied oral healthcare professionals. It represents businesses that supply more than ninety-five percent of the nation's purchases of dental product and consumables.

The Association was formed in 1925 when representatives from the various dental trade houses in Sydney, Melbourne and Adelaide met to safeguard the interests of the nascent dental industry. Harmed by the unethical practices, poor standards and suspect salesmanship of the time, it was agreed that there was a mutual benefit in coming together to self-regulate and improve business practices – as a result of ADIA's work the reputation and integrity of the dental industry have markedly improved over the decades.

Over the years the services provided by ADIA to support the dental industry have evolved. 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 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.

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. At a local level, ADIA State Branches allow the industry to come together to share experiences and cooperate on projects that advance the interests of the dental industry.

ADIA provides advice to agencies including the Therapeutic Goods Administration (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).

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

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 that supply:

- Dental equipment and consumables;
- Tooth filling materials, restorative materials and false teeth;
- 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 product 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 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 Australian Bureau of Statistics (ABS) shows dental exports of approximately $68 million in 2009, however that figure includes exports from Australia of goods manufactured outside Australia (*i.e.* forwarded to a third country via Australia). 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 export market by value.

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 by value.

The products and services offered by Australia's dental industry are offered 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.

TPP Framework & Strengthening Regulatory Coherence

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. However, the regulatory framework contains some requirements that are peculiar to Australia, thus the potential to address this through the TPP agreement is welcomed. 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 impact of minor regulatory amendments 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 TPP agreement with the qualification that a key outcome will be the harmonisation of regulatory frameworks, with particular reference to the medical devices sector. 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]

ADIA takes this opportunity to note that the ideal regulatory model, including underpinning standards and compliance monitoring frameworks, may not currently be found within a TPP member nation. 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.

GHTF & The TPP Agreement

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. The purpose of the GHTF is achieve 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 the GHTF work is a standing work item for 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]

ADIA welcomes initiatives that seek to harmonise the regulation of products and services and in pursuit of this goal advises that it is highly desirable that this be undertaken in the context of existing international agreements and negotiations. A considerable investment has been made by government and industry to date on the harmonisation of regulatory frameworks and it is incumbent on Australia, and other TPP member nations, to build upon work in this area rather than "reinventing the wheel" and either revisiting or recreating policies that have already been addressed.

As the TPP agreement matures, ADIA encourages TPP member nations that are in the process of enhancing their medical device regulatory framework to do so in the context of the GHTF principles.

Industry Codes of Conduct

The current regulatory framework for the manufacture, importation and supply of medical devices is augmented by industry codes of practice. The Australian Government initiated a project in 2010 to strengthen and standardise self-regulation through developing an industry framework for universal adherence to consistent

industry-wide codes for the promotion of therapeutic goods based on a common set of high level principles. The Australian Government's stated preference is for a model of self-regulation and working group of industry and consumer stakeholders has made considerable progress to achieve this outcome, a process expected to conclude in late 2011.

There is broad consensus amongst the various industry associations in the medicines and medical devices sector that the Australian therapeutic products industry should promote the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer need and supported by the ethical conduct of all parties. The quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

The various industry codes of conduct are different and some, such as ADIA's code, will need to undergo significant revision to fully comply with the Australian Government's proposed framework. It is pleasing to note there is work towards incorporating a common underpinning principle amongst all of the industry code of conduct. This is that therapeutic products companies have, as their primary objective, the maintenance of the trust and confidence of all communities with which they engage.

The various stakeholders within the therapeutic products sector have committed to collaborating with relevant stakeholders in code creation, updating, education, monitoring and compliance with their codes of conduct. ADIA believes that as negotiations continue in the development of the TPP framework, stakeholders within TPP member companies should be consulted so as to ensure that, as far as is practicable, industry codes of conduct can be harmonised internationally.

As a small market that is heavily reliant upon imports, the Australian dental industry benefits greatly from international harmonisation of regulatory requirements associated with the manufacture, export, import and supply of medical devices. For this reason ADIA views the harmonisation of the medical devices regulatory framework to be a highly desirable outcome of the TPP agreement.

TPP Member Nations & Australia's Dental Product Exports

The relatively low value of current dental exports [see table below] is such that the TPP agreement will not have a significant impact on Australia's dental product manufacturing capacity at this point in time. However, given that advice from Australian-based manufacturers is that regulatory compliance in overseas exports markets is the greatest inhibitor to the export of dental product, the TPP agreement can only be of value to the sector. The current dental product export data to TPP member companies is as follows:

TPP Participants – Dental Exports*

New Zealand	2007: $16.96M	2008: $28.30M	2009: $25.66M
United States of America	2007: $4.76M	2008: $8.07M	2009: $6.18M
Malaysia	2007: $0.60M	2008: $0.99M	2009: $0.93M
Singapore	2007: $0.55M	2008: $0.86M	2009: $0.81M
Vietnam	2007: $0.16M	2008: $0.19M	2009: $0.43M
Other (Non-TPP Participants)	2007: $26.12M	2008: $27.78M	2009: $25.29M

As the medical devices sector is highly regulated there are significant additional costs associated in getting a product to market compared to goods manufactured for other purposes (*e.g.* consumer electronics, clothing, agricultural machinery, etcetera). After discussions with its members, ADIA estimates that for every dollar spent on research, development and production to get a locally-manufactured medical device to market in Australia, the regulatory compliance costs add an extra seventy percent, a figure that increases for each additional export market.

Although considerable work has been undertaken on medical devices regulatory harmonisation through the GHTF, sadly regulatory divergence remains in the medical devices sector at an international level. It is therefore hoped that the TPP agreement will lead to the harmonisation of the medical devices regulatory framework amongst TPP member nations.

* This data excludes high-value imports and exports such as x-ray and digital imaging equipment and also furniture such as dental chairs as it is not possible to identity values relative to the dental industry from the data that also includes figures general healthcare and veterinary sectors. The data is drawn from Australian Bureau of Statistics (ABS) data which is based upon six-digit Combined Australian Customs Tariff and Statistical Nomenclature, itself based upon the harmonised system used by most nations as the system for describing and classifying goods.

TPP Member Nations & Australia's Dental Product Imports

The outcomes of TPP negotiations are of considerable focus to the Australian dental industry given its dependence on imported products. Presently Australia relies upon overseas manufacturers for some ninety-eight percent of dental equipment and consumables (by value).

As with any industry sector heavily dependent upon imports, the Australian dental industry experiences high overhead costs associated with freight and is also vulnerable to exchange rate fluctuations. The current dental product import data from TPP member companies is as follows:

TPP Participants – Dental Imports*

United States of America	2007: $42.53M	2008: $44.96M	2009: $49.12M
Singapore	2007: $4.36M	2008: $5.51M	2009: $6.95M
New Zealand	2007: $1.54M	2008: $1.62M	2009: $1.70M
Other (Non-TPP Participants)	2007: $150.27M	2008: $174.96M	2009: $189.51M

A significant additional cost for importers of medical devices is the current regulatory framework, particularly as it contains requirements specific to the Australian market. ADIA therefore consider that the TPP agreement be utilised as a tool to harmonise regulatory requirements for medical devices.

* This data excludes high-value imports and exports such as x-ray and digital imaging equipment and also furniture such as dental chairs as it is not possible to identity values relative to the dental industry from the data that also includes figures general healthcare and veterinary sectors. The data is drawn from Australian Bureau of Statistics (ABS) data which is based upon six-digit Combined Australian Customs Tariff and Statistical Nomenclature, itself based upon the harmonised system used by most nations as the system for describing and classifying goods.

TPP Framework & Government Procurement Processes

Other than individual dentists in private practice, the largest customer group for dental products and services is government. For this reason ADIA believes that the TPP agreement should evolve in a way that supports existing initiatives to streamline government procurement processes.

Government procurement has become unnecessarily complex as business is required to meet tender processes and contractual conditions which are sometimes excessive for the goods and / or services being purchased. As a result, tender writing for government can be difficult, is almost always resource intensive and often leads to failure if the company does not prepare for its tender writing task properly.

Many small to medium businesses often decide against participating in a government tender process as the investment of time and resources required to prepare a compliant tender are excessive. The result is often that government pays a higher price than necessary and for this reason effort is being directed at streamlining public sector procurement practices and streamlining them amongst Australian states and territories. ADIA recommends that harmonisation of government procurement practices becomes a feature of the TPP agreement.

Australian and New Zealand Government Procurement Agreement

The Australian Government, Australian state / territory governments and the New Zealand Government have entered into the Australia and New Zealand Government Procurement Agreement (ANZGPA). The objective of the ANZGPA is to:

> *create and maintain a single trans-Tasman government procurement market in order to maximise opportunities for competitive suppliers and reduce costs of doing business for both government and industry.*[6]

One aspect of the ANZGPA that should be incorporated within the TPP agreement is the development of a mechanism for co-operation by TPP member countries to work towards achieving the greatest possible consistency in contractual, technical and performance standards and specifications, and simplicity and consistency in the application of procurement policies, practices and procedures.

Australia's National Medicines Policy

ADIA is not representative of Australia's medicines industry, however the Association takes this opportunity to affirm support for Australia's national medicines policy that seeks to improve positive health outcomes for all Australians through their access to and wise use of medicines. ADIA's support extends to the Australian Government funded Pharmaceutical Benefits Scheme (PBS) that provides timely, reliable and affordable access to subsidised medicines for Australians.

ADIA submits that the development of harmonised government processes, underpinned by contractual, technical and performance standards and specifications, will greatly increase competition in each TPP member country's market and reduce the cost to government of procuring dental products.

Abbreviations

ABS	Australian Bureau of Statistics
ADIA	Australian Dental Industry Association
ANZGPA	Australian – New Zealand Government Purchasing Agreement
APEC	Asia-Pacific Economic Cooperation
DFAT	Department of Foreign Affairs and Trade
EEA	European Economic Agreement
EFTA	European Free Trade Association
EU	European Union
FDA	Food & Drug Administration (USA)
FDI	Federation Dentaire Internationale (*Eng.* World Dental Federation.
GHTF	Global Harmonisation Task Force
IDM	International Dental Manufacturers
ISO	International Standards Organisation
NeHTA	National eHealth Transition Authority
TGA	Therapeutic Goods Administration
TPP	Trans Pacific Partnership
WHO	World Health Organisation

References

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4 *Medical Devices Regulations – Global overview and guiding principles*
World Health Organisation (Geneva, 2003)

5 APEC's Second Trade Facilitation Action Plan
Asia-Pacific Economic Cooperation Secretariat (Singapore, 2007)

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