Australian Dental Industry Association | ADIA

— ADIA Submission
Competition Policy Review

This submission to the Australian Government's review of competition policy seeks to identify opportunities to allow businesses across the dental industry to grow, create jobs and operate sustainably by creating an environment where government supports business innovation whilst removing excessive and sometimes redundant regulation.

ADIA
Australian Dental Industry Association
ABN 32 003 314 396

National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601
e: national.office@adia.org.au twitter: @AusDental
t: 1300 943 094 f: 1300 943 794
www.adia.org.au

idm Association of International Dental Manufacturers MEMBER

ACCI AUSTRALIAN CHAMBER OF COMMERCE AND INDUSTRY MEMBER

Australian Dental Industry Association Ltd.
ABN 32 003 314 396

ADIA National Office —
GPO Box 960, Sydney, NSW, 2001

Government Affairs —
GPO Box 1, Canberra, ACT, 2601

t: 1300 943 094 f: +1300 943 794
e: national.office@adia.org.au

This work is provided under the terms of a *Creative Commons Attribution 3.0 Australia* licence, with the exception of the ADIA logo, other images and where otherwise stated. The work is protected by the *Copyright Act (Cth) 1968* and / or other applicable law. Any use of this work other than as authorised under the license and the aforementioned Act, is prohibited. The Australian Government is granted license to use this work without constraint. For further information review the license at: www.adia.org.au/legals/CopyrightAttribution

Index

This submission from the Australian Dental Industry (ADIA) to the Australian Government's review of competition policy seeks to identify opportunities to allow businesses across the dental industry to grow, create jobs and operate sustainably by creating an environment where government supports business innovation whilst removing excessive and sometimes redundant regulation.

ADIA Reference: 4.9.10B – 10 June 2014

This Page Intentionally Blank

Executive Summary

The dental industry comprises businesses that range in size from small family entities through to local operations of large, multinational therapeutic product suppliers. They share common aspirations for the growth of their business, the creation of jobs and the financial sustainability of the dental industry. Naturally, they are bound by a universal commitment to the supply of quality dental products and services.

To excel, these businesses will benefit by increasing competition as a result of a reduction in red tape and lifting restrictions which limit flexibility and innovation. To this end, ADIA recommends the following:

Improving competition by third-party conformity assessment acceptance —

Improving access to new and innovative therapeutic products by removing unnecessary review processes in Australia for medical devices which duplicate the work done internationally.

Improving competition by removing regulatory duplication —

Reduce additional red tape by removing the ability of the ACCC to rely upon the *Competition and Consumer Act (Cth) 2010* to create regulatory controls on the supply of product which contradict prevailing state / territory government legislation.

Improving competition in public sector procurement —

That competition in healthcare procurement be strengthened by reviewing the centralised purchasing framework supported by the NPC and developed by NEHTA with a view to maximising the involvement of all businesses that previously supplied to the sector but which are now effectively disenfranchised.

The intervention of the Australian Government in these areas is inconsistent with the principle that the activities of government should not reduce competition unless the benefits to the community as a whole outweigh the costs and that the policy objectives can only be achieved by restricting competition.

As the peak business organisation representing manufacturers and suppliers of quality dental products, ADIA looks forward to further engagement with the review taskforce on these matters.

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

10 June 2014

Part 1 – Therapeutic Product Regulation & Competition

The Therapeutic Goods Administration (TGA) is responsible for administering the regulatory standards for the approval of medical devices. The TGA's regulatory requirements constitute a technical barrier to trade, imposing requirements and approval processes that are either different from, or duplicate, those which exist overseas. This additional regulatory burden:

- Reduces competition by retarding the dental industry's ability to introduce new products to the Australian market in a timely manner; and
- Increases prices as business seeks to off-set the costs associated with meeting an ever-increasing red-tape burden imposed by the TGA.

There is an opportunity for the Australian Government to improve competition in the supply of medical devices whilst that the goods available in Australia are of an acceptable standard.

Current regulatory framework —

The TGA regulates all medical devices that are manufactured within Australia or imported and supplied in Australia pursuant to provisions within the *Therapeutic Goods Act 1989* and subordinate legislation.

The TGA regulates therapeutic goods through: pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Since October 2002 the fundamental principles of the testing and assessment of medical devices in Australia have been based on similar principles developed for the European Union (EU) which are part of a global harmonisation approach steered through the Global Harmonization Task Force (GHTF) and the GHTF's successor, the international Medical Device Regulators Forum (IMDRF).

TGA assesses products to confirm that the medical device is safe and efficacious in accordance with the intended use as declared by the manufacturer of the medical device. This assessment is done on an application by application basis.

Under the Act, the TGA is required to examine and certify the conformity assessment procedures undertaken by Australian manufacturers supplying medical devices in Australia as well as manufacturers producing medical devices containing particular designated materials, irrespective of where the manufacture occurs.

One of the areas of additional burden for the dental industry in supplying their products in Australia is that while the TGA accepts CE certification (CE marking indicates the compliance with EU legislation of a product, wherever in the world manufactured, and enables its free movement within the EU) for medical devices manufactured overseas, inspections by the TGA are required for Australian manufacturers of equivalent technology.

Because of the restriction on choice of conformity assessment certification options for the Australian manufacturers, coupled with longer timeframes and costs in obtaining the TGA certification, the manufacturers have felt compelled to also obtain CE certification from Notified Bodies (which are the are the only recognised third-party bodies that can carry out a conformity assessments laid down in the relevant harmonised European standards or European Technical Assessment) in the EU in order to supply their products in the EU earlier than if the TGA issued CE certification under the mutual recognition agreement between Australia and the EU.

This regulatory burden imposed by TGA processes has been recognised on several occasions by Government reviews including *the Report of the Taskforce on Reducing Regulatory Burdens on Business – Rethinking Regulation* which reported in January 2006.

Reform that enhances competition —

The *Report of the Taskforce on Reducing Regulatory Burdens on Business – Rethinking Regulation* recommended that the Australian Government should consider allowing Australian manufacturers to chose a certification body (acceptable to the TGA), based in Australia or overseas, to verify and certify their conformity assessment procedures.

An option that enjoys widespread support from all industry stakeholders for the TGA to utilise regulatory approvals from other jurisdictions. In addition to the generally accepted European CE certification, ADIA recommends that the TGA allow the use of other equivalent regulatory approvals from recognised competent regulators. Relevant tools include the US Food and Drug Administration Pre-Market Approval (PMA), which is considered to be comparable to the European and Australian design examination review, or the Health Canada product licence.

The *Therapeutic Goods Act (Cth) 1989* and subordinate legislation already allow TGA to accept certificates from different jurisdictions as it sees fit, so this improvement would not require any further change to the regulatory framework for the supply of medical devices.

The ability of businesses across the dental industry to grow, create jobs and operate sustainably is dependent upon a regulatory framework for therapeutic products 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. This can be achieved without the TGA duplicating and replicating conformity assessment work undertaken by notified bodies.

Part 2 – Poisons & Chemicals Regulation & Competition

Competition in several product sectors is jeopardised by the work of the Australian Competition and Consumer Commission (ACCC) and its interpretation of the *Competition and Consumer Act (Cth) 2010* to create a regulatory framework that duplicates existing laws. By way of example, the amount of red tape faced by Australian manufacturers of teeth whitening products has unnecessarily escalated, jeopardising business profitability and jobs. This is a result of the Australian ACCC seeking to control teeth whitening products by imposing its own framework which conflicts with established and widely accepted state / territory legislation that are recognised as effective standards specific to this type of product

Current Regulatory Framework —

The regulatory standards for teeth whitening products are set out in the Poisons Standard which is the legal title for the *Standard for the Uniform Scheduling of Medicines and Poisons*. This is a legislative instrument for the purposes of the *Legislative Instruments Act (Cth) 2003*.

The Poisons Standard consists of decisions regarding the classification of medicines and poisons (including teeth whitening products) into Schedules for inclusion in the relevant state / territory government legislation. The Schedules within the Poisons Standard provides a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety.

New regulatory standards for teeth whitening products came into force on 1 May 2013 as a result of amendments to the Schedules within Poisons Standard.

The amendments to the poisons standard made no change to the current regulatory standards for low-strength teeth whitening products containing 6% or less hydrogen peroxide and / or 18% or less carbamide peroxide which allow these to be supplied as over-the-counter products. The amendments, supported by ADIA, provide a high level of consumer protection by only allowing the lawful supply of take-home teeth whitening products containing concentrations of greater than 6% hydrogen peroxide and / or greater than 18% carbamide peroxide through registered dental practitioners as part of their dental practice. Such professionals are bound by the registration standards set by the Dental Board of Australia (DBA), which states that teeth whitening products should only be used by a registered dental practitioner with education, training and competence in teeth whitening.

The amendments to the Poisons Standard resulted from an expert committee's determination which considered the published reports regarding the attributes of teeth whitening products, the relative safety of the products and the treatment of the product group by overseas jurisdictions.

There is widespread support amongst consumer groups for the regulatory framework provided for in the Poisons Standard that is administered by state / territory governments.

The ACCC's ability to intervene and reduce competition through additional red tape arises through its interpretation of the *Competition and Consumer Act (Cth) 2010* which defines the act of "supply" of consumer goods as any act that includes the sale, exchange, lease, hire or hire purchase. As this legislation makes no distinction between types of suppliers, the ACCC argues that the legislation affords it the power to control the supply of any consumer product whether or not already regulated, including medicines, poisons and chemicals – some of the most regulated products in the country.

With respect to teeth whitening product, the ACCC has formed its own regulatory approach that is inconsistent with state / territory government regulatory standards (which reference the Poisons Standard). This is based, in part, on incomplete records from selected state / territory Poisons Information Centres in a manner that uses information out of the originally intended context and doing so with deliberate selectiveness.

The ACCC is suggesting it will use mandatory recall provisions within the Act to create in effect its own regulatory standard, and has threatened to use this instrument against all teeth whitening products that are lawfully supplied in accordance with established state / territory legislation, but in a manner inconsistent with ACCC policy.

Reform that enhances competition —

The ability of the ACCC to rely upon the *Competition and Consumer Act (Cth)* to create additional red tape in the form of regulatory controls that contradict prevailing state / territory government legislation be discontinued.

Earlier competition reforms in the medicines, poisons and chemicals area produced a national regulatory framework in which the eight states and territories rely on the *Standard for the Uniform Scheduling of Medicines and Poisons* to provide commonality to their regulatory functions. It is therefore disappointing that the ACCC seeks to set aside such good work that has served the economy so well.

ACCC's actions with respect to this matter highlight the risks to competition that arise when a regulator is given broad powers that allow it to act independently of existing regulations.

.

Part 3 – Government Procurement & Competition

The National E-Health Transition Authority (NEHTA) is working to reduce competition in the procurement of healthcare products by restricting the supply chain. With the support of the Australian Government and its state / territory counterparts, it is standardising supply chain management so that only those businesses with the time, expertise and financial resources can sell products to the health system via a centralised product catalogue.

Standardised government procurement goals —

With support of the Australian Government and its state / territory government counterparts, NEHTA has created a National Product Catalogue (NPC). The NPC records important supply chain and clinical information such as: Price; Product components; Pack sizes; TGA risk classification; and Pharmaceutical Benefits Scheme (PBS) or RPBS notification and Prostheses Rebate Code. The NPC uses GS1's standard identifier, the Global Trade Item Number (GTIN), as the globally unique primary product identifier for every NPC record.

The NPC was developed in 2006 by NEHTA as the single source of master data for Australian healthcare organisations when purchasing medicines, medical devices and other medical consumables.

To allow purchasing officers to use this identification information, NEHTA has developed an eProcurement platform designed to streamline the eProcurement process. This facilitates business-to-business electronic transactions, instead of manual and paper processes, with the stated aim of streamlining the procurement process. However, this eProcurement platform effectively eliminates purchasers from selecting anything other than the businesses that have entered their products on the NPC.

According to NEHTA, there are less than five hundred suppliers listed on the NPC which is thought to be a small sample of the several thousand businesses that supply to the healthcare system.

State, territory and Commonwealth health departments now require suppliers to populate the NPC with item master data for the purposes of tenders and contracts and to ensure this information is maintained up to date. Significantly, as the NPC includes price data the benefits that typically flow to clients as a result of volume pricing, periodic discounts (*e.g.* end of financial year), discounts for historical prompt-payment of accounts and strong competition amongst a number of suppliers may not be available.

The cost for a business associated with entering onto the NPC the full range of products currently supplied to the health system is cost-prohibitive for businesses of any size, with the outcome that many elect not to do so. The cost manifest itself in data collection, data entry, entry maintenance as well as the fees directly incurred for product entry.

Of the business in the dental industry that have entered products onto the NPC, ADIA is advised that this has only been the case for high-value product lines, thus substantially reducing competition across many product categories.

Reform that enhances competition —

That competition in healthcare procurement be strengthened by reviewing the centralised purchasing framework supported by the NPC and developed by NEHTA with a view to maximising the involvement of all businesses that previously supplied to the sector but which are now effectively disenfranchised.

ADIA welcomes the improvement to public sector procurement which have arisen from NEHTA's work; however, the creation of the NPC and the cost to business of making and maintaining entries serve only limit competition. Businesses both large and small are refraining from placing products on the NPC as they lack the time, expertise and financial resources to place the full range of products typically purchased by the healthcare system. Thus, the NPC serves only to limit selection and reduce competition insofar as procurement of healthcare products is concerned.

An Introduction – Australian Dental Industry Association

The Australian Dental Industry Association (ADIA) brings together the manufacturers and suppliers of quality products and services used in dentistry.

Since its formation in 1925, ADIA has provided leadership, strategy, advocacy and support to allow businesses across the dental industry understand and positively influence the commercial, technical and regulatory environment in which they work.

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 is recognised by the Australian Government as an authoritative voice on policy issues concerning the manufacture and supply of dental products.

Australia's most authoritative assessment on the market for dental products is the *ADIA Australian Dental Industry Intelligence Report* which is published annually. This is augmented by the *ADIA Australian Dental Industry Business Conditions Survey* which provides a quarterly assessment of key indices measuring sales prices, sales volumes, business input costs, staff levels and staff employment costs. The latter survey also provides the data that underpins the *ADIA Australian Dental Industry Red Tape Index*.

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).

Recognising the need for business across the dental industry to attract and retain skilled staff, the *ADIA Strategic Plan* includes a strong focus on workforce development. Through a ground-breaking alliance with MEGT Recruitment and Employment Services, ADIA assists businesses to employ apprentices and trainees across a range of occupations. In partnership with Charles Sturt University, a graduate-level program is offered to small business operators.

ADIA brings suppliers of dental products and services closer to dentists and allied oral healthcare professionals through initiatives such as the highly popular *ADX Sydney* dental exhibition, the nation's premier dental trade show which attracts more than 8,000 stakeholders from the dental community on a biennial basis.

In working towards an environment where member businesses can grow, operate sustainably and create jobs, ADIA is affiliated with the Australian Chamber of Commerce and Industry (ACCI), the nation's foremost grouping of employer organisations. This link ensures the views of the dental industry are taken into account as the Australian Government considers reform across high-level policy issues such as business taxation, international trade, environmental policy, workplace relations, workplace health and safety in addition to vocational education and training. At an international level ADIA works with the association of International Dental Manufacturers (IDM).

For further information visit:
www.adia.org.au

Acronyms

ACCC	Australian Competition and Consumer Commission
ACCI	Australian Chamber of Commerce and Industry
ADIA	Australian Dental Industry Association
DBA	Dental Board of Australia
EU	European Union
FDA	Food & Drug Administration (United States of America)
GHTF	Global Harmonisation Task Force
GTIN	Global Trade Item Number
IDM	Association of International Dental Manufacturers
IMDRF	International Medical Device Regulators Forum
NEHTA	National E-Health Transition Authority
NPC	National Product Catalogue
PBS	Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration

■ ADIA MEMBER BUSINESSES ■

3M ESPE A.R. Medicom AB Dental Employment Agency Accentu8 Novotecnica Acteon Australia / New Zealand Active Change for Life A-dec Australia AHP Dental & Medical Ainsworth Dental Airport Function Centre AJ Barber Alldent Alphabond Dental Amalgadent Dental Supplies Ampac Dental Anthos in Australia AP Design AR Instrumed Argibond Dental Supplies Ark Health Auspharm Australasian Academy of Dento-Facial Aesthetics Australasian Dental Practice Australasian Dentist Australian College of Dental Education Australian Imaging Australian Medical Suction Systems Bien Air Australasia Biodental Technologies BioHorizons Australia Biomedex Biomet 3i Bite Magazine Body Logic Resources Borg Dental Bourke Dental Supply Bova Compounding Carestream Dental Carl Zeiss Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates Clark Jacobs Clisby Engineering Colgate Oral Care Coltene-Whaledent International Commodore Joinery Critical Dental Curaden Swiss Dental Axess Dental Burs Australia Dental Concepts Dental Depot (QLD) Dental Fitout Projects Dental Innovations Dental Installations Dentalife Dentaurum Australia Dentavision Dentequip Dentiform Australia Dentist's Choice Dentpro Dentsply (Australia) Designer Project Group Designer Surgeries Designs for Vision Digital Dental DPL Australia Dürr Dental AG East Coast Dental Services Ecocycle Australia Elite Fitout Solutions Empire Dental Devices EMS Erskine Dental Essology Finlease (Aust) First Dental GC Australasia Dental Glamsmile GlaxoSmithKline Gritter Dental Gulmohar Dental Gunz Dental Hayes Handpiece Australia Heine Australia Henry Schein Halas Heraeus Dental Australia HICAPS High Tech Laser Australia Hogies Australia Horseley Dental Supplies Hu-Friedy Mfg Co Inc ID Health IDOZ Medical iMixwell Impulsedent Australia Independent Dental Supplies Inline Medical & Dental Innovatio Dental Supplies Investec Specialist Bank Ivoclar Vivadent Johnson and Johnson Pacific Kerr Corporation Leading Dental Levitch Design Australia Lizard Software Lomax Financial Group Lorchant Dental Marda Investments Med & Dent (WA) Medfin Australia Medi-Dent Medical Dental Solutions NQ Medical Equipment Services Medifit Medilend Melbourne Dental Miele Australia Miniflam Australia Minimax Implant (Dentium Australia) Mobile Clinics Australia [Kuipers] Mocom Australia Momentum Management Myofunctional Research Co NAOL Australia Neoss Australia Nobel Biocare NSK Oceania One Dental Oral-B (Procter & Gamble) Osseo Dental Osstem Australia Pegasus Dental Services Philips Oral Healthcare Presidental Prime Practice Priority Dental Supplies Trust Professional Dentist Supplies Profile Financial Services Purus Health and Medical Technologies RCR International Ridley Dental Supplies Right Time Business RJ Dental Sales & Service Roland DG Australia RutiniDent Dental Supplies RWD Dental Image SDI Ltd Sieverts Radiation Protection Consultancy Siltex (Australia) Sirona Dental Systems Software of Excellence South Austral Southern Implants Australia Specialites Septodont Stoneglass Industries Straumann Suntech Dental Equipment Services Supreme Orthodontic Supply (Aust) The Bambach Saddle Seat The Dental Solution Australia Tri-Dental Implants TrollDental Trustwater Australia Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Inc Veden Australia VOCO Australia W&H Wellsites West Coast Dental Depot Whiteley Corporation William Green Wisbey Dental Zeno Dental

ADIA
Australian Dental Industry Association Limited
ABN 32 003 0314 396

National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601
t: 1300 943 094 f: 1300 943 794
e: national.office@adia.org.au
www.adia.org.au