ORALHEALTH
PROFESSIONALS ASSOCIATION

SUBMISSION

INQUIRY INTO THE SUPPLY OF DENTAL PROSTHESIS

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This submission reviews the current market for the sourcing and supply of custom made medical devices for dentistry. The review also includes the current regulatory framework.

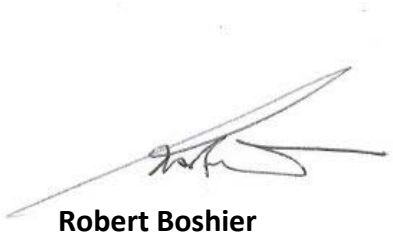
EXECUTIVE SUMMARY

For more than a decade the importation of custom-made medical devices (in dentistry) has been an issue for the dental laboratory sector globally, not just locally.

In its early adoption phase, there were cases of poor quality materials used and poor quality workmanship. Over time there has been significant improvement in the regulations and regulators, the capabilities of the international laboratories and local sponsors.

The Oral Health Professionals Association (OHPA) represents Dental Technicians, Laboratories and related fields of practice. In this paper we highlight gaps between the current regulations, their application and reporting transparency. There is also the continued issue of data collection within the federal framework, and that much of the industry data available is collected by sector associations, such as ours.

As we look to the future and the reported increasing demands that our aging population will place on the sector, the Association is advocating for a domestic dental laboratory sector and workforce that have the capabilities and skills to adapt to globalisation challenges. We support continued government reforms that assist the competitive capabilities of our local laboratories, those that streamline red tape, and those that increase our workforce capabilities.



Robert Boshier

National President

30 October 2014

CUSTOM-MADE MEDICAL DEVICES[1]

THE AUSTRALIAN DENTAL LABORATORY MARKET

"Custom made medical devices are defined in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) as medical devices that are:

- *made specifically in accordance with a request by a health professional specifying its design characteristics or construction,*
- *intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice."*

Examples include:

- *dental appliances such as crowns, bridges and dentures*
- *prosthetic or glass eyes*
- *orthopaedic or pedorthic footwear*
- *prosthetic limbs*
- *prescription glasses."*

Source: Therapeutic Goods Administration, Fact Sheet

In Australia there are two business types that manufacture and supply dental prosthetics, they are:

DENTAL LABORATORIES

The principals of Laboratories are generally Dental Technicians, or other Dental Practitioners (eg. Dentist). Laboratories make a range of prosthesis eg. crowns and bridges, dentures, acrylics, etc. Dental laboratories do not see patients, rather they work under instruction from Dentist, Dental Prosthetists and other referring dental practitioners

There is no regulatory requirement for the Dental Technicians working in the Laboratory, or the Laboratory itself to be registered (outside of commercial registration).

DENTAL CLINICS

The principals are Dental Prosthetists and they manufacture removable prosthesis such as full and partial dentures, mouthguards, seeing patients as practitioners.

[1] Custom Made Medical Devices within Dentistry are known colloquially as Dental Prosthesis or Dental Prosthetics. Colloquial terms will be used for the remainder of this submission paper.

The Dental Prosthetists practicing in the Clinic must be registered with the Dental Board of Australia, but the Clinic is not required to be registered outside of commercial registration.

The dental laboratory sector[2] in Australia can be split into two groups:

LARGE LABORATORIES: employing > 10 technicians, usually deploying digital technology, supply nationally, may have missed-supply chain model[3],

SMALL LABORATORIES: sole practitioners or those with less than 10 technicians, tend not to have invested in digital technology, supply is generally state or regionally based (or perhaps dentist centric), could also include 'cottage industry' technician operating in a lab attached to home (this is reducing as the sector increases in professionalism and competition increases).

In 2007, in response to increased use of offshoring for the manufacture of prosthesis and the initiation of a national approach to practitioner practices by the federal government, the OHPA developed and implemented the **Dental Laboratory Accreditation Program.**

The Accreditation Program supports and promotes those Dental Laboratories that are registered in Australia in authority approved premises, having all their products made by qualified technicians and using Therapeutic Goods Administration (TGA) registered materials. An accredited dental laboratory must also manage dust and fumes responsibly, work within the framework of the WHS, and have infection control procedures and a quality control program in place. This is a self-regulating program, requiring annual review and renewal. Periodic Audits are made on premises around the country to validate submitted information.

The purpose of the program is three-fold:

1) to assist the Dental Laboratory Sector in establishing and maintaining laboratory benchmarks for WHS/ etc and to support the Sector through the digital revolution facing all of the Dental Market;
2) to assist Dentists and others in their procurement responsibilities, when choosing a manufacturing partner; and
3) to offer safety and quality assurances to the patient of prosthesis made for them by a local accredited laboratory.

[2] For the purposes of this inquiry, the manufacturing entity referred to will in most cases be the dental laboratory and technician, as they are the bulk of the Sector. However, where relevant, we will differentiate for clarity.

[3] Mixed-Supply Chains within the Laboratory Sector is where some of the prosthesis supplied is manufactured in the Australian Premises, and some is sourced from an international laboratory partner or subsidiary.

DENTAL PROSTHESIS – SOURCING AND SUPPLY

When discussing sourcing and supply we should be looking at:

- Market Size, units or dollars
- Percentage of market, across a range of attributes.

However, there is no central body/ies tasked with the responsibility of data collection/ analysis for the manufacture and/or importation of dental prosthesis in the Dental Industry. As such, all evidence to the growth or degrowth of the Sector is based on Industry Surveys and anecdotal evidence collated by member Associations, such as ours.

From ADIA Industry research there is evidence that the dental laboratory supply market fell by 5.4% in the 2012/13 period, the third year in succession[4]. There is also evidence the dental supply market, though strong, saw another year of degrowth, largely attributed to the significant Government Dental Program cuts. Couple this level of degrowth with the increase in (anecdotal) offshoring and the dental laboratory market size can confidently be reported as contracting.

Degrowth in the Sector is leading to a number of outcomes:

1) More aggressive price setting, leading to insolvency and/ or bankruptcy, especially in the small laboratory category,
2) Decreasing workforce participation, with a number of Dental Technicians choosing early retirement or career change,
3) Domestic Laboratory Market Consolidation, as larger laboratories use their scale and capacity (and price) to increase market share; adding momentum to small laboratory closures[5].
4) Supply-chain model variations, as laboratories use various mixed-sourcing models to remain competitive.

It is undeniable that the amount of procurement choice for the Dentist and Dental Prosthetists is increasing as overseas manufacturers market via email (SPAM as defined by Australian Communications and Media Authority) directly to the local market, yet we are seeing the choice of Australian supply is decreasing due to the contracting domestic market.

The OHPA has for some time been advocating that the continued contraction of a domestic market, and the adoption of offshoring within domestic laboratories will in the medium to long term negatively affect the quality of education and career opportunities of future dental technicians.

[4] Source, ADIA Statistics — FY2012-13 Australian Dental Industry Intelligence Report

[5] It was indicated to OHPA by a large supply house that in NSW alone an estimated 76 laboratories in the last 18mths closed

Identified in the National Oral Health Plan, 2015 – 2023 Foundation Area 5 Workforce Development is the strategic need to ensure appropriate workforce levels and skills across all areas of Australia. This Plan also recognises that there are a number of workforce challenges to deliver on this strategic plan. In NSW State funding cuts to education is already impacting the delivery of a number of courses, Dental Technology and Dental Prosthetics included. This has the potential to impact significantly on the capacity and capability of local laboratories in delivering future services as future graduates may not materialise in the numbers required.

MARKET IMPACT OF DENTAL PROSTHESIS IMPORTING

In 2012, the OHPA surveyed the Sector (both Members and Non-members) and identified that up to 60% of custom-made devices in the area of crowns and bridges, was imported. This is almost twice the level of imports as reported in the US, where the National Association of Dental Laboratories estimate (based of US Food and Drug Administration data) that 38% of their equivalent market is offshored (circ.2012). It has also been identified that many of the imported prosthesis are single-unit crowns or bridges, those that are of a single logistical movement during the supply process, and have historically been the cash-flow generators for laboratories.

SO WHY THE SHIFT TO IMPORTS?

The primary reason for the shift to imports was unit PRICE.

The principle purpose for most manufacturing shifts from Australia to other countries (mainly Asia) is production costs. Over 60% of the direct cost in the production of a dental prosthesis, mainly:

- Labour costs, by way of the National Awards, and
- Raw Materials.

Neither of these are competitive with overseas manufacturers, and therefore the unit prices offered locally, in general, cannot compete with those imported. Therefore the Dental Laboratory must look for other competitive elements, eg. delivery times, quality of work, maintenance, client relationships management through communication and education/ knowledge sharing.

It is becoming evident though, that the larger laboratories who have invested in digital technologies are closing the price gap with the importers, and coupled with the advantage of domestic supply, may be in a position to claw back market share.

FUTURE MARKET IMPACT

There are two significant market impacts that will materialise as Australia continues its offshoring:

1) As the market for Implants and other cosmetic dentistry grows, the Dentist will require the services of a qualified Technician to work closely with them in these service provisions. However, should the local sector consolidation to a limited number of Metro-based, nationally servicing dental laboratories, this service may not be available.

2) The Patient cost increases for complex prosthetic work could be materialised as laboratories lose their capacity to cross-subsidise services. Adding more cost pressure to patients, would support patients:

    - Choosing to go overseas for their dental work (as they have already been preconditioned that overseas prosthesis are comparable in safety and quality to local),
    - Choosing to not maintain their prosthesis leading to failures.

AUSTRALIAN REGULATORY FRAMEWORK FOR DENTAL PROSTHESIS

In Australia there is currently a multi-dimensional regulatory framework across federal and state legislature governing the manufacture and supply of custom-made medical devices (or dental prosthetics) within the Dental Sector. The primary areas for this submission are:

1) The Therapeutic Goods Administration whose remit is to:

   "ensure the quality, safety and performance of medical devices that are devices imported into, supplied in, or exported from, Australia."

   TGA correspondence to OHPA, Oct. 2011

2) The Australian Health Professionals Regulatory Authority (AHPRA) and the Dental Board of Australia (DBA) for the professional practice and registration of Practitioners; and
3) Various State and Federal bodies for business and manufacturing regulations. For example, State EPA regulations, Fair Work Ombudsman, Work, Health and Safety Regulation, etc.

THE THERAPEUTIC GOODS ADMINISTRATION

The Act as it is today, provides a robust structure for the provision of quality and appropriate medical devices within the Australian market. With a comprehensive and equal treatment of each individual manufacturing entity, whether they be importers, local manufacturers or exporters. It is our opinion that the current regulation is appropriate for its purpose.

The issue to date within the Australian Dental Laboratory Sector has been the communication of this structure. It has not been until recently that the TGA has provided clearer communication and education pieces to the Sector to engage them in the regulatory framework.

Additionally, compliance and transparency into The Incident Reporting and Investigation Scheme (IRIS) intended to log, investigate and report may be limited due to the above communication issues. Though there have not been a significant number of complaints, it can be questioned whether there is an understanding within the Sector of their responsibility to report.

The OHPA continues to advocate for increasing reports and transparency within the dental prosthesis category.

THE AUSTRALIAN HEALTH PROFESSIONALS REGULATORY AUTHORITY (AHPRA) AND THE DENTAL BOARD OF AUSTRALIA (DBA)

These two national bodies provide direction, standards, policies and guidelines for the registered practitioners, those relevant to this discussion are Dentists and Dental Prosthetists.

Through the registration process and other mechanisms, they are able to effectively manage and monitor:

- Workforce numbers and locations of operation,
- Codes and Scopes of Practice,
- Advertising and Patient Disclosure requirements.

In 2010, with the establishment of the Dental Board of Australia, the national registration requirement for Dental Technicians was not implemented, and all State requirements removed. The Dental Technician is now classified as an Unregistered Health Practitioner. There is no federal body overseeing their practice.

OTHER STATE AND FEDERAL BODIES

Within the States, there is varying regulatory environments for the oversight of Unregistered Health Practitioners.

In New South Wales, South Australian, and as recently as July 2014 now Queensland these states have regulated a Code of Conduct and Complaint Management for these Practitioners. Victoria, Tasmania, Western Australia, Australian Capital Territory and Northern Territory do not have any regulatory framework for these practitioners.

Key business regulations for Dental Laboratories are:

- Environmental Protection (EPAs) – for the management of fumes and dust from the manufacturing process
- Fair Work Ombudsman – for the application and management of the Award, MA000027 Health Professional and Support Services Award
- Work, Health and Safety Regulation
- Australian Consumer Law,
- Other Local, State and Federal Laws as they effect the operations of Commercial Businesses within Australia

PATIENT DISCLOSURE:

PROSTHETIC COMPOSITION AND COUNTRY OF ORIGIN LABELLING

Currently, no regulation exists requiring patient disclosure for Prosthetic Composition and / or Country of Origin statements. Some individual dental practitioners are choosing to disclose Country of Sourcing for their prosthesis as a marketing tools, using statements such as:

> *We partner with Australian Dental Laboratories, or*
>
> *All our prosthesis are from Australian Dental Laboratories.*

However, due to the complex nature of some supply-chain models, this may not be a correct statement of Origin.

> *For example, the Dentist may contract an Australian Dental Laboratory to supply a single crown for a patient. The Laboratory is in registered Australian Premises and has employees in Australia. However, this order is not manufactured in the Laboratory, rather it is sent to the Australian Labs offshore partner for manufacture and then returned through the chain.*

The Australian Made Campaign reports that over 50% of Australians prefer to buy Australian Made Products (survey 2013). Given complex supply models across all manufacturing, the Australian Competition and Consumer Commission (ACCC) has also seen fit to release new Country of Origin Labelling Guidelines (April 2014) to ensure that those making a Country of Origin claim are not acting in a misleading or deceptive manner.

In August 2012, the Government Response to the Senate Inquiry into The Regulatory Standards for the Approval of Medical Devices in Australian included a number of recommendations, recommendation 12 being:

Recommendation 12
The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit.

Response:

The Australian Government notes the recommendation.

Custom made dental devices are not required to be included on the Australian Register of Therapeutic Goods. However, there are a number of requirements that must be met.

The therapeutic goods legislation requires that the importers of custom made dental devices hold certain information about the device including information identifying the manufacturer, the device and any special characteristics of the device.

The Australian Government will consult with the Dental Board of Australia on this recommendation, as the governing body with the authority to regulate the dental profession.

The OHPA supports the recommendation to improve transparency to the patient in componentry and country of origin labelling and would encourage the responsible entities to progress this recommendation.

Evidence of the OHPA commitment to Patient Disclosure is the supply to those laboratories within our Accreditation Program of printed patient information cards. These cards identify:

- Place of manufacture and qualification of Dental Technician,
- Components registration with the TGA
- Country of Origin statement.

At OHPA we encourage the patient, other dental professionals and those in the supply sector to **Think Globally – Act Locally**.

We believe that our Dental Laboratories produce world class, safe prosthetics; and we hope that Patients and Dentists will make procurement choices supporting the local laboratory sector.

APPENDIX 1

INTERNATIONAL REGULATORY REQUIREMENTS

United States:

- US Department of Labour, Bureau of Labour Statistics – workforce data
- US Food and Drug Administration – customs data and device regulations

Canada

Dental Technicians are regulated and licensed by the College of Dental Technicians of BC.

United Kingdom:

- Manage Dental Practitioner Registration, including Dental Technicians (equivalent to Dental Board of Australia)
- Dental Council UK - require detailed record keeping when it comes to prostheses and appliances made overseas,
- the Council also has prosecutor powers for non-compliance to the regulation,
- there is a requirement to disclose to the patient country of origin and other material information.

Germany:

- a tax is levied on all appliances entering the country.

New Zealand

- Dental Council of New Zealand is the regulating and registration authority for Dental Practitioners, including Dental Technicians.