The Australian Dental Prosthetists Association Ltd

Response to the ACT Inquiry into the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas

Introduction

The Australian Dental Prosthetists Association Ltd (ADPA) is the peak professional association for Dental Prosthetists (DPs) in Australia. Our members are the various state bodies which represent dental prosthetists and as such, we represent over 90% of the Dental Prosthetists registered in Australia.

Dental Prosthetists treat patients requiring removable dental prostheses including full and partial dentures and mouth guards. Dental Prosthetists work independently and do not work under the supervision of dentists. Dental Prosthetists have been active members of the oral health workforce for many years, and members are engaged in the public and private sectors and in a range of educational and managerial capacities. Practitioners provide services for patients accessing benefits from The Department of Veterans Affairs, State Dental schemes and the former Medicare Chronic Diseases Dental Scheme, as well as through private billing arrangements supported by private health insurers.

Dental Prosthetists can follow either of two paths to obtain qualification:

- Masters Degree (eg the Master of Dental Technology in Prosthetics conducted by Griffith University)
- Advanced Diploma of Dental Prosthetics (eg as conducted by RMIT University and various TAFE institutions)

Each of these pathways has a pre-requisite qualification of a Diploma in Dental Technology. As such, all dental prosthetists are dual-qualified as dental technicians.

Scope of Current Inquiry

ADPA acknowledges that this current inquiry specifically relates to the Australian Capital Territory. However, ADPA believes that the issues addressed in this inquiry have relevance at the national level and not just at the individual state/territory level. We therefore welcome the opportunity to provide our submission to you, and have responded to your specific points below.

Specific Questions

1. **The role of dental practitioners, dental technicians and other health professionals in providing dental prostheses and appliances, including dental crowns, bridgework, dentures and implants to patients in Australia;**

Dental Prosthetists are regulated through the Dental Board of Australia (DBA) under the Australian Health Practitioner Regulation Agency (AHPRA). The regulatory framework covers all members of the dental team with the exclusion of dental technicians, who are now unregulated.

The regulatory provisions define the various 'roles' of the members of the dental team under the "Dental Scope of Practice Registration Standard" and the related Codes and Guidelines. These documents state, for example, that:

> **"Dental prosthetists** work as independent practitioners in the assessment, treatment, management and provision of removable dentures, and flexible, removable mouthguards used for sporting activities. The education requirement for a graduate dental prosthetist is a

minimum two year full time education program approved by the National Board. Prerequisite for entry is a Diploma of Dental Technology (or equivalent).

Dental prosthetists may take impressions and records required for the manufacture of various types of splints, sleep apnoea/anti-snoring devices, immediate dentures and immediate additions to existing dentures. These procedures require written referrals to and from dentists and any appliance or device manufactured under such arrangement must be planned, issued and managed by the treating dentist.

Dental prosthetists educated and trained in a program of study approved by the National Board to provide treatment for patients requiring implant retained overdentures must enter into a structured professional relationship with a dentist before providing such treatment" (Dental Board of Australia, Guidelines for Scope of Practice, June 2014)

Dental Prosthetists therefore do not provide dental crowns, bridgework or implants but can, when appropriately educated and trained as set out above, treat patients requiring implant retained overdentures when in a structured professional relation with a dentist.

Dentists are the only members of the 'dental team', other than dental prosthetists, qualified and skilled to provide dental prostheses and appliances.

Dental technicians, who are not regulated by the provisions of AHPRA or the DBA, construct and repair dentures (false teeth) and other dental appliances including crowns, bridges, partial dentures, pre and post oral and maxillofacial surgical devices and orthodontic appliances in a laboratory. As indicated above, all dental prosthetists have an underpinning qualification as a dental technician. However, not all dental technicians undertake the further study required to qualify as a dental prosthetist.

Dental technicians do not deal directly with members of the public (whereas dental prosthetists do). They provide services to either dentists, dental specialists or dental prosthetists, who are the only members of the dental team with 'independent status' in relation to the provision of dental prostheses and appliances within their defined Scope of Practice.

Prior to 2010, dental technicians were regulated through the *Dental Technicians Registration Act 1975).* This act was repealed on 1 July 2010 upon commencement of the national regulatory scheme under the *Health Practitioner Regulation National Law Act 2009*, and dental technicians were not included in the new national scheme.

2. **Sourcing of dental prostheses and appliances from overseas makers by Australian dental practitioners; and**
3. **Growth in sourcing supply of dental prostheses and appliances since 2009 and the reasons for growth in sourcing and supply; and**
4. **4. The current level and anticipated future of dental prostheses and appliances provided to dental practitioners in the ACT;**

We are not aware of any readily available empirical data (either current or historical) which details the source of dental prostheses and appliances, and believe that it would be difficult to obtain such evidence given the more recent availability of direct online procurement from overseas sources.

Anecdotally, our members advise us that, whilst the sourcing of prostheses and appliances from overseas makers by Australian dental practitioners has a long history, there has been a marked increase in this practice and in work being sent overseas since the introduction of the national regulation scheme and the consequent de-regulation of dental technicians.

Further, they advise that the local supply of prostheses and appliances has probably declined as the availability of overseas work and products has directly affected the market through easy internet access and very low prices.

The ACT body of ADPA noted that laboratory work from ACT Health has been outsourced interstate without consideration of local industry and without being tendered. Such work could also potentially be sent overseas, which would then raise the same issues outlined elsewhere in this submission.

We are aware that, with the closure of the Chronic Diseases Dental Scheme and the delayed introduction of the National Partnership Agreement on Adult Dental Services until 1 July 2015, the volume of business for many of our members has significantly declined.

Our members have also advised that the impact on dental technology laboratories has been particularly significant, and laboratories have either reduced significantly in size or closed completely. This is likely to be both a consequence of the cessation/deferment of government funded schemes for dental prosthetic work and the availability of a cheaper overseas supply.

5. **Adequacy of current Australian regulatory arrangements and requirements governing the sourcing and supply of dental prostheses and appliances from overseas; and**

6. **Whether appropriate standards and regulations governing the sourcing and supply of dental prostheses and appliances from overseas are in force in Australia;**

The supply of dental prostheses and appliances from overseas is covered by the Therapeutic Goods Administration, which has an overall purpose to "'protect public health and safety by regulating therapeutic goods that are supplied in, or exported from, Australia'".

In 2011, a Senate Inquiry was conducted: The regulatory standards for the approval of medical devices in Australia. Chapter 2 of the report of that Inquiry is of relevance in relation to the sourcing and supply of dental prostheses and appliances, as summarised below:

- In its submission to the Inquiry, the TGA outlined that:
    - "2.7 Therapeutic goods include medicines, medical devices and biological products. Any product for which therapeutic claims are made (unless exempt) must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The TGA carries out both pre-market assessment and post-market surveillance
    - 2.8 In order to regulate medical devices, the TGA administers the following legislation:

- Therapeutic Goods Act 1989 (the Act);
- Therapeutic Goods Regulations 1990;
- Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations); and
- Therapeutic Goods (Charges) Act 1990."

However, later in Chapter 2:

- "2.39 The TGA commented that there are limitations on the coverage of the Act, and the requirement to be included on the ARTG. These exceptions include clinical trial exemptions; the Authorised Prescriber Scheme; the Special Access Scheme (SAS); and personal importation." (Therapeutic Goods Administration, Submission 18)

The closing section of Chapter 2 of that report specifically addresses "The regulation of custom made dental prostheses". This section specifically mentioned the submissions made by the Australian Dental Industry Association (Australian Dental Industry Association, *Submission 30)* and Logic Appeal (Logic Appeal, *Submission 33),* noting that:

- "2.165 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[s] from overseas sources and using [these] in their practices... (ADIA submission)"
- 2.166 Similar concerns were expressed by Logic Appeal who informed the committee that up to 50 per cent of custom made dental prostheses such as crowns, bridges, dentures and some implants are sourced from overseas markets such as China, India and Vietnam. Logic Appeal stated that these medical devices are not validated by the TGA at the source of manufacture. (Logic Appeal submission)
- 2.167 Logic Appeal went on to explain that while 'the onus is on the practitioner using them to verify they that they are of an adequate standard', the practitioner is frequently unaware of the source of the prostheses, as they may have ordered the item from an Australian address. Logic Appeal also told the committee that 'Patients are similarly unaware of where their dental device is manufactured (Logic Appeal submission)".

The committee commented:

- "2.171 The committee notes that custom made dental devices appear to escape TGA scrutiny, with dental professionals and patients alike unaware that up to 50 per cent of custom made dental prostheses are manufactured overseas, with no validation at the source of manufacture. The model employed in the United Kingdom, whereby patients are offered a statement of manufacture, and practitioners are obliged to retain this statement for the lifetime of the prosthesis, and must record whether the statement was provided to the patient or not, appears to have merit."

Therefore, while there is a regulatory framework in place to govern the sourcing and supply of dental prostheses and appliances from overseas, there appears to be a lack of enforceability in relation to the provisions, with no effective control over what is imported or sourced directly via the internet.

The current approach thus places the onus on the practitioner to be the person responsible for making sure that the prostheses or appliance is of a high standard and uses safe materials. Under the former

dental technician registration arrangements (pre 2010), there was a greater emphasis on standards and governance of the industry. However, since de-regulation of that industry and without any requirement for registration for dental technicians, there are now no standards that can be enforced or areas where control can effectively be exercised.

ADPA is fully supportive of the philosophy that the ultimate responsibility of the quality of the appliance placed in the patient's mouth is always the responsibility of the practitioner. ADPA contends, however, that it is not always possible to guarantee the material or appliance's content and/or quality, given that the derivation of the product or the materials is not always known. Even if the practitioner is endeavouring to meet requirements, they may (as Logic Appeal pointed out in their submission) be unaware of where the products are sourced if they order through an Australian address.

7. Whether dental patients and consumers are aware, or are made aware by practitioners, of the source and supply details of dental prostheses and appliances provided in Australia;

Whilst there are some provisions that relate to this area (see following), ADPA believes that the practice of individual practitioners may vary.

The DBA Code of Conduct contains a number of provisions with relevance to this area:

"2.2 Good Care

h) providing treatment options based on the best available information and not influenced by financial gain or incentives

3.5 Informed Consent

Informed consent is a person's voluntary decision about healthcare that is made with knowledge and understanding of the benefits and risks involved.

e) being mindful of additional informed consent requirements when supplying or prescribing products not approved or made in Australia,

Fees and financial consent

a) Patients or clients should be made aware of all the fees and charges involved in a course of treatment, preferably before the health service is provided.

b) Discussion about fees should be in a manner appropriate to the professional relationship and should include discussion about the cost of all required services and general agreement about the level of treatment to be provided." (Dental Board of Australia, Code of Conduct, March 2014).

3.5(e) of the Code, in particular, implies that the practitioner should disclose to their patients the source of the products being used in the treatment program. The section in relation to Fees and Financial consent similarly implies that, should a product be chosen based primarily on cost considerations, the patient should be made aware of this.

The Code suggests that "useful guide to the information that practitioners need to give to patients is available in the National Health and Medical Research Council (NHMRC) publication *General guidelines for medical practitioners in providing information to patients*. That publication is based on "the general principle that patients are entitled to make their own decisions about medical treatments or procedures and should be given adequate information on which to base those decisions."

This Code of Conduct would therefore appear to include sufficient requirements to ensure that patients are made aware of the source and supply details of the products being provided to them. The Code places the responsibility clearly on practitioners:

> "Practitioners have a professional responsibility to be familiar with this code and to apply the guidance it contains"

and the Code can further be used:

> "to assist National Boards in their role of protecting the public by setting and maintaining standards of good practice – Boards will use this code when evaluating the professional conduct of practitioners. If professional conduct varies significantly from this code, practitioners should be prepared to explain and justify their decisions and actions and serious or repeated failure to meet this code may have consequences for registration".

However, what is not clear is how the Board would determine whether an individual practitioner has adhered to the code, or how they would determine whether the information provided has been adequate and based on the best interests of the patient.

8. Experiences and relevant regulatory arrangements for dental prostheses and appliances sourced and supplied from overseas in other jurisdictions, such as the UK, US, New Zealand and Canada; and,

We note the comments made in the Senate Inquiry report in relation to the practice in the UK, "whereby patients are offered a statement of manufacture, and practitioners are obliged to retain this statement for the lifetime of the prosthesis, and must record whether the statement was provided to the patient or not, appears to have merit."

At this stage, we are unaware of regulatory arrangements in other jurisdictions. We have heard anecdotally that the UK, USA and Canada are experiencing similar issues to prosthetists in Australia, in that there is an increasing supply of appliances made at a cheaper cost in the third world.

The ADPA President, Mr John Rogan, will shortly be attending the annual meeting of the International Federation of Denturists, and will endeavour to obtain some more concrete information from our international colleagues.

9. Any other related matter.

As indicated above, we believe that the primary objective in relation to this issue needs to be to ensure the health and safety of the patient. The onus is on the practitioner to make sure work is of an acceptable standard and that price is not the sole motivator.

As such, it is imperative that any prostheses or appliances manufactured and sourced overseas should pass the same requirements as those manufactured locally. Dental prostheses and appliances are increasingly being outsourced and on a large scale, and the products should pass a number of tests and requirements. This can sometimes be ascertained from the material safety data sheets (MSDS), as these MSDS sheets will help ensure that toxic materials are not used and that the practitioner is aware of exactly what materials have been used in the product. However, to police this in relation to overseas manufactured products would be extremely problematic.

This can be contrasted to the situation of products made locally. Whilst materials that are used by Australian manufacturers have almost all been made overseas, local fabrication ensures that the practitioner is aware of the materials used and the composition of the ultimate product. However, for the products to be used in Australia, they have to be passed as compliant by the TGA and this has an associated cost factor due to the level of regulation.

ADPA recognises that the de-regulation of the dental technicians, the subsequent impact on the dental laboratory profession and the issues surrounding the sourcing and supply of dental prostheses and appliances made overseas are consequences of operating within a global economy, and accepts that Australian laboratories simply cannot compete on a level playing field with overseas laboratories that can employ cheap labour. However, we also want to ensure that the products being placed into patient's mouths are safe and fit for purpose.

Whether the product is made locally or overseas is not as relevant or important as to whether the product itself is safe. The current market and regulatory environment provides no assurances that this is the case in relation to many materials and products sourced overseas, due to the ease of online procurement and the lack of sufficient information provided when that material or product enters the country.

The Australian Dental Industry Association (ADIA), in its Policy Priority 4: "Internationally harmonised regulatory standards" has set out what appears to be an appropriate approach to overcome these difficulties. This Policy Priority states:

"The regulatory framework for dental product (and other medical devices) should support the international distribution of products that are proven to be safe and effective by a competent jurisdiction. Inconsistency in medical device regulation at a global level involves significant costs for both manufacturers and suppliers and constitutes a technical barrier to trade."

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