INQUIRY INTO THE SOURCING AND SUPPLY OF DENTAL PROSTHESES AND APPLIANCES TO AUSTRALIAN DENTAL PRACTITIONERS FROM OVERSEAS

STANDING COMMITTEE ON HEALTH, AGEING, COMMUNITY AND SOCIAL SERVICES

MARCH 2015

REPORT 4
COMMITTEE MEMBERSHIP

Dr Chris Bourke MLA (Chair)
Mr Andrew Wall MLA (Deputy Chair)
Ms Nicole Lawder MLA
Ms Yvette Berry MLA [until 10 February 2015]
Ms Meegan Fitzharris MLA [from 10 February 2015]

SECRETARIAT

Mrs Nicola Kosseck Secretary
Mr Panduka Senanayake Administrative Assistant
Mr Waris Mughal Researcher*

*Mr Mughal assisted the Committee whist participating in the ‘Work in the Assembly Program’. He completed his placement on 12 December 2014.

CONTACT INFORMATION

Telephone 02 6205 0435
Facsimile 02 6205 0432
Post GPO Box 1020, CANBERRA ACT 2601
Email committees@parliament.act.gov.au
Website www.parliament.act.gov.au
RESOLUTION OF APPOINTMENT

On 27 November 2012 the Legislative Assembly for the ACT agreed by resolution to establish legislative and general purpose standing committees to inquire into and report on matters referred by the Assembly or matters that are considered by the committee to be of concern to the community, including:

c) a Standing Committee on Health, Ageing, Community and Social Services to examine matters related to hospitals, community, public and mental health, health promotion and disease prevention, disability matters, drug and substance misuse, targeted health programs and community services, including services for older persons and women, families, housing, poverty, and multicultural and indigenous affairs;

The Assembly agreed that each committee shall have power to consider and make use of the evidence and records of the relevant standing committee appointed during the previous Assembly.¹

 TERMS OF REFERENCE

That the Standing Committee on Health, Ageing, Community and Social Services inquire into and report on the following matter:

- The sourcing of dental prostheses and appliances from overseas makers by Australian dental practitioners;
- Growth in sourcing supply of dental prostheses and appliances since (say) 2009 and the reasons for growth in sourcing and supply;
- The current level and anticipated future of dental prostheses and appliances provided to dental practitioners in the ACT;
- Adequacy of current Australian regulatory arrangements and requirements governing the sourcing and supply of dental prostheses and appliances from overseas;
- Whether appropriate standards and regulations governing the sourcing and supply of dental prostheses and appliances from overseas are in force in Australia;
- 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;
- 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,
- Any other related matter.

Matter self referred for inquiry by the Committee on 31 July 2014.
## Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT</td>
<td>Australian Capital Territory</td>
</tr>
<tr>
<td>ADA</td>
<td>Australian Dental Association</td>
</tr>
<tr>
<td>ADIA</td>
<td>Australian Dental Industry Association</td>
</tr>
<tr>
<td>ADPA</td>
<td>Australian Dental Prosthetists Association</td>
</tr>
<tr>
<td>ARGMD</td>
<td>Australian Regulatory Guidelines for Medical Devices</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
<tr>
<td>DBA</td>
<td>Dental Board of Australia</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>OHPA</td>
<td>Oral Health Professionals Association</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
</tbody>
</table>

The Committee ACT Legislative Assembly Standing Committee on Health, Ageing, Community and Social Services
TABLE OF CONTENTS

Committee membership ........................................................................................................ i
Secretariat ................................................................................................................................. i
Contact information ................................................................................................................ i
Resolution of appointment ..................................................................................................... ii
Terms of reference .................................................................................................................. iii
Acronyms and abbreviations ................................................................................................. iv

RECOMMENDATIONS ........................................................................................................... VII

1 INTRODUCTION ................................................................................................................ 1
Conduct of inquiry .................................................................................................................. 1
Report focus and structure ................................................................................................. 2

2 CURRENT AUSTRALIAN REGULATORY ARRANGEMENTS ........................................... 3
Regulatory framework ........................................................................................................ 3
Custom-made medical devices ......................................................................................... 3
Post-market assessment .................................................................................................... 5
Responsibility for statutory compliance .......................................................................... 7
Federal, State and Territory regulation ............................................................................. 9
Other regulatory, peak and representative bodies ....................................................... 9

3 MARKET FOR IMPORTED DENTAL DEVICES .......................................................... 13
Overseas sourcing ............................................................................................................. 13
Reasons for the move to importation ............................................................................. 14
Improving the viability of the Australian market .......................................................... 16
ACT dental appliance market ....................................................................................... 17

4 KEY ISSUES ..................................................................................................................... 18
Quality and safety of imported dental devices .............................................................. 18
Regulatory requirements - awareness and compliance ............................................... 25
Country of origin information ....................................................................................... 31
Cost disclosure .................................................................................................................. 36
Registration of dental technicians and dental laboratories ........................................ 37

5 OVERSEAS EXPERIENCE .......................................................................................... 40
RECOMMENDATIONS

RECOMMENDATION 1

4.100 The Committee recommends that the ACT Government should request that the Therapeutic Goods Administration and the Dental Board of Australia consider amending the relevant regulations, codes and guidelines to require the details about the manufacturer of a custom-made dental device to be provided to the prescribing practitioner and the patient.
1 INTRODUCTION

CONDUCT OF INQUIRY

1.1 On 31 July 2014, the Standing Committee on Health, Ageing, Community and Social Services (the Committee) resolved to conduct an inquiry into the sourcing and supply of dental prostheses and appliances to Australian dental practitioners from overseas.

1.2 An invitation for public submissions was advertised by the Committee in the Canberra Times on 1 September 2014. The Committee also wrote directly to organisations likely to be interested in the inquiry, inviting them to provide a written submission. Submissions were to close on 19 September 2014.

1.3 On 20 October 2014 the call for submissions was extended until 3 November 2014.

1.4 In a media release issued on 20 October 2014 the Chair of the Committee, said:

   It is important that the Standing Committee take the opportunity to examine all aspects of the current regulatory and standards regime which applies to this area of dental health and treatment. The Committee intends assessing for itself a number of issues – which are set out in the Committee’s terms of reference, and provide recommendations about issues which it considers need assessment and action by authorities responsible for this area of health administration.

1.5 The Committee received eight submissions and five additional comments from a range of stakeholders. A list of submissions is available at Appendix A ‘Submissions’.

1.6 The Committee held one public hearing for the Inquiry on Wednesday 12 November 2014. Details of this hearing and witnesses that appeared are below (Table 1.1).

<table>
<thead>
<tr>
<th>ORGANISATION</th>
<th>WITNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Dental Association</td>
<td>Associate Professor Neil Hewson, Federal Executive Councillor and Ms Eithne Irving, Manager Policy and Regulation</td>
</tr>
<tr>
<td>Therapeutic Goods Administration</td>
<td>Andrea Kunca, Head of Office of Device Authorisation</td>
</tr>
<tr>
<td>Oral Health Professionals Association</td>
<td>Ms Chantelle Adams, Chief Executive Officer</td>
</tr>
<tr>
<td>Interested Individual</td>
<td>Dr John Clark, Dentist</td>
</tr>
</tbody>
</table>

REPORT FOCUS AND STRUCTURE

FOCUS

1.8 As the Australian Dental Industry Association (ADIA) noted in its submission, Australia is signatory to a number of free trade agreements, treaties and has international trade obligations to the World Trade Organisation. The Committee notes that these agreements preclude any changes to the current regulations which would protect the domestic market by creating a barrier to trade and importation of dental devices.

1.9 The Committee has therefore chosen to focus its report on the quality and safety of dental devices manufactured overseas and the associated transparency and accountability issues.

TERMINOLOGY

1.10 Dental prostheses and appliances include devices such as crowns, bridges and dentures.

1.11 For simplification, all dental prostheses and appliances will collectively be referred to as ‘dental devices’ throughout this report.

REPORT STRUCTURE

1.12 Chapter 2 provides an overview of the current regulatory framework in Australia including:

- Custom-made medical devices
- Post-market assessment
- Sponsor responsibilities
- Dental practitioner responsibilities

1.13 Chapter 3 considers the current Australian market for imported dental devices as well as how and why it is changing.

1.14 Chapter 4 discusses the main concerns raised in evidence to the Committee around the importation of dental devices, including the adequacy of the current regulatory framework.

1.15 Chapter 5 provides an overview of the regulatory arrangements in the United States, Canada, the United Kingdom and New Zealand.

---

2 Submission 3, ADIA, p.5.
2 CURRENT AUSTRALIAN REGULATORY ARRANGEMENTS

REGULATORY FRAMEWORK

2.1 The Commonwealth’s Therapeutic Goods Act 1989 (the Act) sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia. The Act is supported by Regulations, and various orders and determinations which provide further details of matters covered in the Act including the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). 3

2.2 Dental devices are considered to be therapeutic goods and most fall within the definition of a ‘medical devices’ under the Act. 4 Therapeutic goods, including medical devices, are regulated by the Therapeutic Goods Administration (TGA) which is part of the Australian Government’s Department of Health.

CUSTOM-MADE MEDICAL DEVICES

2.3 The Regulations define custom-made medical devices as medical devices that are:

- made specifically in accordance with a request by a health professional specifying its design characteristics or construction; and
- 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. 5

2.4 As the TGA advised in its submission to the Committee, dental devices are often (but not always) regulated as custom-made medical devices. Some examples of custom-made dental devices include dental crowns, bridges and dentures. 6

2.5 Custom-made devices are exempt from pre-market assessment and inclusion on the Australian Register of Therapeutic Goods (ARTG) because they are considered low risk and due to the impracticalities of assessing individual devices custom-made for particular patients. 7

---

4 Therapeutic Goods Act 1989 (Cth), s41BD.
6 Submission 3, ADIA p3; Transcript of Evidence, 12 November 2014, p.17.
2.6 However, all custom-made devices must meet the same regulatory standards for product design, performance and safety regardless of the country of manufacture. They must undergo conformity assessment procedures under Part 7, Schedule 3 of the Regulations that comply with the relevant Essential Principles.  

2.7 The TGA provides an Essential Principles Checklist to assist manufacturers of both custom-made and off-the-shelf products to demonstrate their compliance with the Essential Principles.

2.8 The TGA advised that ‘the easiest way to demonstrate compliance with essential principles is to demonstrate compliance with internationally accepted standards.’ With custom-made devices, the onus is on the manufacturer to comply.

2.9 Manufacturers of custom-made devices must have appropriate risk management processes in place as well as documented procedures and detailed manufacturing records. They must demonstrate that the relevant Essential Principles have been addressed by preparing a statement which includes details such:

- the name and business address of the manufacturer;
- information to identify the device and the individual it is made for;
- details of the health professional who provided the specification;
- design characteristics; and
- ‘a statement to the effect that the device complies with the applicable provisions of the Essential Principles or, if the device does not comply with all applicable provisions of the Essential Principles, a statement explaining which provisions of the Essential Principles the device does not comply with and the reasons for the non-compliance’.

2.10 The manufacturer must keep the statement and documentation for at least five years and it must be available, on request, to the TGA. It does not need to be sent to the TGA in each instance.

2.11 The TGA is currently drafting a chapter for the Australian Regulatory Guidelines for Medical Devices (ARGMD) on the regulatory requirements for custom-made devices. An early draft guidance document on custom-made devices is available on the TGA website.

---

7 Submission 4, TGA, p5; Transcript of Evidence, 12 November 2014, p.16.
8 TGA, Custom Made Medical Devices; Transcript of Evidence, 12 November 2014, p.17.
10 Transcript of Evidence, 12 November 2014, p.20.
13 Therapeutic Goods (Medical Devices) Regulations 2002, Item 7.6 (2) Part 7 Schedule 3.
14 Transcript of Evidence, 12 November 2014, p.17.
15 Transcript of Evidence, 12 November 2014, p.22.
MANUFACTURING ACTIVITY

2.12 Despite not requiring listing on the ARTG, the TGA must be notified of the manufacture of custom-made devices. Section 10.3 (2) of the Regulations requires that:

The sponsor of a custom-made medical device that is imported into Australia must give the following information about the device to the [TGA] Secretary:

(a) the sponsor’s name and address;
(b) the manufacturer’s name and business address;
(c) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).17

POST-MARKET ASSESSMENT

2.13 The TGA post-market assessment processes include mandatory reporting of adverse events.

ADVERSE EVENTS - MANDATORY REPORTING

2.14 Sponsors and manufacturers share the same mandatory reporting obligations to notify the TGA of any adverse events associated with a medical device, whether it is off-the-shelf or custom-made.18

2.15 Adverse events are defined as events that ‘have led to or could have led to a death, serious illness or injury to a patient, person using the device or others.’ Mandatory reporting only applies to these types of events, not more minor incidents.

2.16 As the TGA advises, ‘adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.’ They include issues such as:

- mechanical or material failure;
- design issues;
- labelling, packaging or manufacturing deficiencies;
- device interactions; and
- user/systemic errors.21

---

17 Therapeutic Goods (Medical Devices) Regulations 2002, s10.3(2).
18 Submission 4, TGA, p5.
19 TGA, Medical device adverse event reports, ‘Statistics for 2013’, V1.0 June 2014, p.6; Therapeutic Goods Act 1989, 41MP.
20 TGA, Medical device adverse event reports, ‘Statistics for 2013’, V1.0 June 2014, p.7.
2.17 The adverse event reporting requirements are designed to ‘monitor information about medical devices so that appropriate action can be taken’. They also enable ‘systematic investigation of failures and/or deviations in the way a device performs, in an attempt to prevent an adverse event occurring again’.22

2.18 As the ADIA noted:

Investigations of reports of adverse events...or potential adverse events from medical device users (including patients and caregivers), sponsors and manufacturers, can lead to actions such as product recalls, safety alerts, product improvement, user education and compliance testing.23

2.19 Whilst reporting adverse events is mandatory for sponsors and manufacturers, the TGA encourages users and health professionals to report any adverse event that has caused, or could cause an injury to the patient or the device user. 24

2.20 The TGA stresses that ‘the act of reporting an event is not an admission of liability for the event or its consequences’. 25

ADVERSE EVENT REPORTING – PUBLICLY AVAILABLE INFORMATION

2.21 Some information about adverse event notifications for medical devices is released by the TGA on a publicly available database known as the Database of Adverse Event Notifications – Medical Devices (DAEN-MD). 26

2.22 The TGA notes on its website that:

The DAEN-MD Database does not include information about medical devices or therapeutic devices that have not or were not included on the ARTG (at the time the product was supplied); except where the adverse event report also includes a suspected device that was or is entered on the ARTG. 27

---

23 Submission 3, ADIA, p.7.
Responsibility for Statutory Compliance

Obligations of the Sponsor

2.23 Despite the seemingly complex supply chain models used for importing dental devices into Australia, the current regulatory framework clearly outlines that statutory compliance rests with the ‘sponsor’, as defined under the Therapeutic Goods Act 1989.

What is a Sponsor?

2.24 A TGA guide for sponsors, health professionals and manufacturers explains that:

- A sponsor is the person or organisation that imports or supplies medical devices in Australia, or exports medical devices from Australia. The sponsor can be the manufacturer, a health professional, or someone else.

- For example, where a manufacturer in Australia also supplies their custom-made devices directly to the market rather than through a third party, they will also be a sponsor under the Regulations.

- Or if a health professional obtains custom-made devices directly from the manufacturer for supply to his or her patients, then they will be a sponsor under the Regulations.

2.25 The TGA has jurisdiction over Australian manufacturers, Australian companies and Australian Sponsors. Sponsors must be Australian based and are the first point of call for liaison with the TGA about particular products, regardless of the manufacturer.

2.26 If a dentist or other dental practitioner imports directly, then they are considered to be a sponsor.

What are they responsible for?

2.27 The TGA advises that:

Sponsors have the primary responsibility for the safety of any therapeutic products they import into, supply in or export from Australia. Sponsors must comply with legislative requirements for therapeutic product vigilance under the Therapeutic Goods Act 1989.

---

28 Submission 3, ADIA, p.9; Transcript of Evidence, 12 November 2014, p.25.
29 Therapeutic Goods Act 1989, Section 3, Definitions.
30 TGA, Custom-made Medical Devices – Information for sponsors, health professionals and manufacturers, 2 July 2012.
31 Transcript of Evidence, 12 November 2014, p.18.
32 Transcript of Evidence, 12 November 2014, pp.1 & 7.
2.28 The ADA acknowledges that it is the sponsors’ responsibility for devices to be fit for purpose and to identify the manufacturer of the device.34

2.29 The Committee notes that the sponsor of a medical device must provide their name and address with the device ‘in such a way that a user of the device can readily identify the sponsor’.35 This information enables the user to make contact with the sponsor if further information about the device is required or to report an adverse event or reaction in using the device. In the case of custom-made dental devices, the user is the patient or wearer.36

OBLIGATIONS OF THE PRACTITIONER (DENTIST)

2.30 The Committee was advised that the onus is then on the practitioner to ensure the health, quality and safety of materials and dental appliances that they use.37

2.31 The TGA advises that health professionals prescribing custom-made devices are responsible for specifying the design characteristics or construction.38

2.32 The Australian Dental Association (ADA) notes that, ‘under the registration requirements dentists and dental prosthetists as independent practitioners are responsible for all treatment they provide to patients including the fitting of custom-made dental prostheses and appliances.’39 They must also ensure that imported devices have been manufactured in accordance with the regulations and standards.40

2.33 The ADA also notes that dental laboratories and suppliers of these devices are responsible for ensuring that labwork complies with the regulations and materials used must comply with relevant International Standards Organisation (ISO) standards.41

2.34 The Committee notes that dentists also have a general duty of care to ensure patient safety42 and are required to maintain an audit trail through their dental technician or sponsor regarding the origin of all laboratory work.43

---

33 TGA, Medical device adverse event reports, ‘Statistics for 2013’, V1.0 June 2014, p.10.
35 Therapeutic Goods (Medical Devices) Regulations 2002, s10.2
37 Submission 5, ADPA, p5&7-8; Submission 1, John Clark, Att B, P4.
38 TGA, Custom-made Medical Devices – Information for sponsors, health professionals and manufacturers, 2 July 2012.
39 Submission 8, ADA, p.1.
41 Submission 8, ADA, p.2.
2.35 The ADA notes that given these responsibilities, dentists should be confirming with their laboratory, or the sponsor (if they are not the sponsor) that TGA approved materials are being used in the manufacture of dental devices even if manufactured overseas.  

2.36 Dentists may also be sponsors if they are sourcing the device from an overseas manufacturer directly. If they are also the sponsor or manufacturer then they must additionally meet those relevant responsibilities.

**FEDERAL, STATE AND TERRITORY REGULATION**

2.37 As noted by the Oral Health Professionals Association (OHPA), the manufacture and supply of dental devices is also governed by various Federal, State and Territory business and manufacturing regulations such as those governing environment protection, fair work and work, health and safety.

**OTHER REGULATORY, PEAK AND REPRESENTATIVE BODIES**

**DENTAL BOARD OF AUSTRALIA**

2.38 The Dental Board of Australia (DBA) regulates the dental profession under the National Registration and Accreditation Scheme. The DBA regulates all dental-related practitioners (dentists, dental prosthetists, dental hygienists etc.), under the Australian Health Practitioner Regulation Agency (AHPRA) with the exception of dental technicians. Its role is to protect the public and it has established a regulatory framework of registration standards, codes and guidelines which all dental practitioners are expected to adhere to.

2.39 The Committee was advised that the DBA is able to manage and monitor workforce numbers and locations of operation, codes and scopes of practice, advertising and patient disclosure through the registration process.

2.40 The DBA advised the Committee that dental practitioners are expected to be mindful of the requirements of the TGA Regulations with respect to the sourcing and supply of dental devices. The DBA notes that ‘the Board [DBA] does have some considerations in how dental

---

42 Submission 2, Paul Hade, Att A (Guild Insurance), p.3.
43 Submission 1, John Clark, Att A, p.1.
45 TGA, Custom-made Medical Devices – Information for sponsors, health professionals and manufacturers, 2 July 2012.
46 Submission 6, OHPA, p.9.
47 Submission 7, DBA, p.1.
48 Submission 6, OHPA, p.10.
practitioners use appliances and prostheses in their practice.”

2.41 The DBA explained that:

When considering [any] dental treatment including that using dental appliances and prostheses, the Dental Board expects dental practitioners to be aware of the requirements of the Code of Conduct (the Code) including:

- the need to obtain informed consent for the care that the dental practitioner will provide to their patients, and
- facilitating the quality use of therapeutic products based on the best available evidence and the patient’s needs.

The Code has a specific reference at 3.5(e) for practitioners being mindful of additional informed consent requirements when supplying or prescribing products not approved or not made in Australia.

AUSTRALIAN DENTAL ASSOCIATION

2.42 The Australian Dental Association (ADA) is the peak body representing dentists in Australia. It aims to encourage the health of the public and the promotion of the art and science of dentistry. The ADA has branches in all States and Territories and membership is voluntary. Over 90 per cent of dentists in Australia are members, with membership implying an obligation for members to practise their profession in accordance with the standards laid down by the ADA.

2.43 The ADA ‘provides advice to members about their responsibilities in relation to the importation of medical devices’ through mechanisms like the ADA news bulletin.

2.44 The ADA has its own policy on custom-made dental devices (Policy Statement 6.12), recognising that some custom-made dental devices are sourced overseas. The statement notes that ‘the constraints that apply to Australian dental laboratories may not apply to overseas laboratories.’

2.45 The ADA policy requires that:

- Dentists and dental prosthethists have a responsibility to be aware that all materials used in custom-made dental prostheses and appliances should

---

49 Submission 7, DBA, p.1.
comply with *Therapeutics Goods (Medical Devices) Regulations 2002* and its amendments.

- Dental laboratories and suppliers of custom-made dental prostheses and appliances have a responsibility to ensure and guarantee that laboratory work complies with *TGR 2002* [the Regulations].
- The origins of all dental prostheses and appliances should be identified.
- All materials used in custom-made dental prostheses and appliances, wherever sourced, must comply with ISO standards.56

**Australian Dental Prosthetists Association**

2.46 The Australian Dental Prosthetists Association (ADPA) is a peak professional association for dental prosthetists in Australia. Its membership includes all the State and Territory bodies which represent dental prosthetists.

2.47 As the ADPA explains, ‘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.’57 The education pathways to becoming a dental prosthetist, mean that all dental prosthetists are dual-qualified as dental technicians.58

**Oral Health Professionals Association**

2.48 The Oral Health Professionals Association (OHPA) represents dental technicians and other related fields of practice nationally. Membership is voluntary and the majority of its members are dental laboratory owners.59

2.49 The OHPA states that it provides:

...public education and promotion, advocacy initiatives to promote the profession’s future, and offers a strong unified voice for the profession whenever called upon. As the national body representing Oral Health Professionals in Australia, the OHPA promotes the highest standards of professionalism and is guided by an Ethics Statement—ensuring everyone can have confidence in an OHPA member.60

---

57 Submission 5, ADPA, p.2.
58 Submission 5, ADPA, p.2.
2.50 The Australian Dental Industry Association (ADIA) is ‘the peak national association representing the suppliers of quality dental product and services to dentists and allied oral healthcare professionals.’\textsuperscript{61} It represents businesses including Australian dental laboratories. The ADIA provides advice to the TGA and nominates representatives for government committees, working groups and the committees of Standards Australia and the International Standards Organisation (ISO).\textsuperscript{62}

\textsuperscript{61} Submission 3, ADIA, p.23.
\textsuperscript{62} Submission 3, ADIA, p.23.
3  MARKET FOR IMPORTED DENTAL DEVICES

3.1 The Committee considered the practice of Australian dental practitioners sourcing dental devices from overseas manufacturers, the apparent growth in that market, reasons for overseas purchase as well as the market for imported dental devices in the ACT.

OVERSEAS SOURCING

3.2 The ADA highlighted that nearly all dental instruments, materials and equipment are imported with TGA approval.63 As a subset of this trend, there is strong anecdotal evidence to indicate that Australian dental practitioners are increasingly sourcing dental devices from overseas laboratories,64 particularly Asian laboratories.

3.3 Some of the evidence provided to the Committee suggests that around 50 to 60 per cent of the market for custom-made dental devices is likely to be sourced from overseas manufacturers.65 In comparison, the ADIA advised that twenty years ago most custom-made dental devices used in Australia were manufactured in Australia.66

3.4 The Senate’s Community Affairs References Committee noted, from evidence it received to its 2011 inquiry into the regulatory standards for the approval of medical devices in Australia, that ‘up to 50 per cent of custom-made dental prostheses are manufactured overseas’.67 Similarly a 2012 OHPA survey of the sector (including members and non-members) found that some estimated their loss of business to be between five and 50 per cent since July 2010.68 The OHPA survey also found that around 60 per cent of custom-made devices in the area of crown and bridges were imported’.69

3.5 ADIA research also indicates the Australian dental laboratory supply market fell in the 2012-13 period by around 5.4 per cent, the third year in a row.70

3.6 The increase in overseas sourcing of dental devices is not unique to Australia71, with practitioners and technicians in the US also reporting challenges for their domestic market.72
The US National Association of Dental Laboratories estimates that 38 per cent of their equivalent market is imported.\textsuperscript{73} The ADIA highlighted to the Committee that this trend mirrors increased importation across the dental sector, estimating that more than 95 per cent of the dental product used in Australia, by value, is imported.\textsuperscript{74}

3.7 The ADPA noted that European members of the International Federation of Denturists (IFD) are anticipating an approach to the EU to stop the practice of importation of dental devices from Asia but are not confident this will achieve any change in the current practice.\textsuperscript{75}

**Reasons for the Move to Importation**

**Cost**

3.8 Whilst the Committee heard that there are some custom-made dental prostheses options only available from overseas laboratories and manufacturers,\textsuperscript{76} the primary reason for the apparent increase in overseas sourcing of dental devices appears to be cost savings.\textsuperscript{77}

3.9 The Committee heard that price variations can be significant, with overseas sourced dental devices often being significantly cheaper than those produced in Australia.\textsuperscript{78} One submission noted that an Australian made crown could cost in order of $400 to $450. An imported crown from an Asian laboratory could cost between $60 and $80 from the intermediary importer who may be paying around $15 to the manufacturer.\textsuperscript{79}

3.10 The Committee notes that the cost of materials is one of the biggest factors in the overall cost of a device. The OHPA advised that the price difference between locally sourced components and internationally sourced components is large and usually due to ‘global pricing’ from suppliers.\textsuperscript{80}

3.11 The OHPA notes that production costs including labour costs (to meet National Awards) and raw materials are not competitive with overseas manufacturers.\textsuperscript{81}

3.12 Corporate dentistry models are apparently also a driver to importing dental devices, requiring certain revenue goals to be met by a dental practice.\textsuperscript{82}

\textsuperscript{71} Submission 3, ADIA, pp.4-5; Submission 5, ADPA, p.7; Submission 5b, ADPA, p.1; Submission 6, OHPA, p.3.
\textsuperscript{72} Submission 3, ADIA, pp.4-5; Submission 6, OHPA, p.7.
\textsuperscript{73} Submission 6, OHPA, p.7.
\textsuperscript{74} Submission 3, ADIA, p.5.
\textsuperscript{75} Submission 5b, ADPA, p.1.
\textsuperscript{76} Submission 8, ADA, p.1; Transcript of Evidence, 12 November 2014, p.6.
\textsuperscript{77} Submission 1, John Clark, Att B, p.1; Submission 6, OHPA, p.7; Transcript of Evidence, 12 November 2014, p.33.
\textsuperscript{78} Transcript of Evidence, 12 November 2014, p.26.
\textsuperscript{79} Submission 1, John Clark, Att B, p.1; Transcript of Evidence, 12 November 2014, p.33.
\textsuperscript{80} Transcript of Evidence, 12 November 2014, p.26.
\textsuperscript{81} Submission 6, OHPA, p.7.
3.13 The ADA highlights that the move towards importation is unlikely to be driven by profiteering. They note that their practice survey and ATO data indicate dental practice overheads are around 70 per cent and dental fees have not increased with the rate of the Consumer Price Index (CPI) over the last few years. They advised that the ADA is not allowed to have scale of fees like that of the AMA.

3.14 The ADA also noted that under schemes like the Chronic Diseases Dental Scheme and Veterans’ Affairs work was often done for a very low fee, and in some cases laboratory costs were greater than the dentist fee. Overseas dental devices may have been selected in these cases in order for the dentist to cover their overhead costs.

OUTCOMES FROM DECLINING LOCAL SECTOR

3.15 The OHPA advised the Committee that the trend towards importation has resulted in a range of outcomes for the local sector including:

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

3.16 They also warn that the change will negatively affect the quality of education and career opportunities for future dental technicians. They note that there are likely to be fewer local technicians to work closely with dentists to service the increasing market for implants and cosmetic dentistry.

3.17 OHPA also note that increasing importation reduces the ability for laboratories to cross subsidise for complex prosthetic work which is likely to add to cost pressures and may result in more patients choosing to travel overseas for dental work or not maintaining their prostheses.

---

82 Submission 1, John Clark, Att B, p.5; Transcript of Evidence, 12 November 2014, pp.34-35.
84 Transcript of Evidence, 12 November 2014, p.9.
86 Submission 6, OHPA, p.6.
87 Submission 6, OHPA, p.6.
88 Submission 6, OHPA, p.8.
89 Submission 6, OHPA, p.8.
3.18 However, the Committee was advised by the ADIA that ‘there is no authoritative source to provide specific data on the quantities and value of locally manufactured product and the product that is sourced overseas’.90 Similarly, the ADPA advises that it is not aware of any readily available empirical data detailing the manufacturing source of dental devices.91 Data issues are discussed further under ‘Reporting Requirements’ at Section 4.46 of this report.

**IMPROVING THE VIABILITY OF THE AUSTRALIAN MARKET**

3.19 The OHPA advised the Committee there are a number of areas that could be reviewed to help the local market reclaim some of the dental device market including better collaboration between dentist and technicians as well as country of origin labelling to inform patients and support patient choice for Australian manufacturing where applicable (discussed further in Section 4.83 of this report).92

3.20 The Committee notes the ADPA and OHPA advise that declining business for Australian dental laboratories may also be attributed to the cessation of the government funded Chronic Diseases Dental Scheme and deferral of the National Partnership Agreement on Adult Dental Services, not just increased overseas sourcing.93

3.21 The Committee heard that some larger Australian laboratories are gaining back some custom-made device market and closing the price gap with investment in digital technologies and fully digitised fabrication processes.94 The ADA advised that significant developments in dentistry relating to ‘intra-oral digital scanning and 3-D printing techniques’ will significantly impact on types of services supplied by dental laboratories.95 They note that:

> A dentist can now take a digital impression and directly send it to a laboratory for production of the crown or use in-house milling can make prostheses such as ceramic inlays or crowns in their practice.96

3.22 The ADA notes, however, that these changes may also ‘result in dentists producing appliances in their own practices and reduce the demand for services from both Australian and overseas laboratories’.97

---

90 Submission 3, ADIA, p.4.
91 Submission 5, ADPA, p.4.
92 Transcript of Evidence, 12 November 2014, p.27.
93 Submission 5, APDA, p.4; Submission 6, OHPA, p.6.
94 Submission 6, OHPA, p.7; Transcript of Evidence, 12 November 2014, pp.26-27.
3.23 The OHPA advocates ‘for a domestic dental laboratory sector and workforce that have the capabilities and skills to adapt to globalisation challenges’. It noted that Australian dental technicians and laboratories look for other ways to attract business and distinguish themselves from the overseas importation market including ‘delivery times, quality of work, maintenance, client relationship management’. However, the OHPA noted that students locally are not receiving the necessary education and digital skills to support these changes on a wide scale.

Local Education Standards and Courses

3.24 The OHPA also raised concerns that funding cuts for education in New South Wales and Victoria have already impacted on the delivery of courses including Dental Technology and Dental Prosthetics. The funding cuts increase costs to the student significantly resulting in dropping student numbers. The changes are likely to negatively impact on the number of graduates in these fields and potentially affect the capacity and capability of local laboratories.

ACT Dental Appliance Market

3.25 The DBA advised the Committee that, as of June 2014, there were 285 dentists and 15 dental prosthetists registered to practice in the ACT.

3.26 Additionally, the OHPA database indicates that there are 16 dental laboratories operating in the ACT, however there may be additional laboratories that do not have a relationship with OHPA.

3.27 The ADPA’s ACT body advises that ACT Health outsources work interstate ‘without consideration of local industry’ and that work may also be sent overseas.

3.28 The Committee notes that there is no authoritative data to measure the size of the dental device market in the ACT or to assess how much of that market is captured by the apparent trend towards overseas sourcing. Dental technicians and laboratories in the ACT are likely to be affected by the trend towards importation of dental devices from overseas manufacturers to the same degree as other Australian laboratories.

---

98 Submission 6, OHPA, p.7.
99 Submission 6, OHPA, p.7.
100 Transcript of Evidence, 12 November 2014, p.28.
101 Transcript of Evidence, 12 November 2014, p.28.
102 Submission 6, OHPA, p.7; Transcript of Evidence, 12 November 2014, p.28.
103 Submission 8, ADA, p.1.
104 Correspondence from OHPA to the Committee, 16 December 2014.
105 Submission 5, ADPA, p.4.
4 KEY ISSUES

4.1 In its Terms of Reference, the Committee set out to consider the adequacy and appropriateness of current Australian regulatory arrangements governing the sourcing and supply of dental devices for overseas.

4.2 From submissions and evidence presented to the inquiry, the Committee has identified four areas of concern:

1. Quality and safety of imported dental devices;
2. Awareness of the regulatory regime and reporting requirements;
3. Availability of information on the country of manufacture; and
4. Regulation and registration of dental technicians.

4.3 The Committee notes that the majority of concerns raised with the Committee relate only to custom-made dental devices, not off-the-shelf products. The Committee has therefore focused its discussion on custom-made devices.

QUALITY AND SAFETY OF IMPORTED DENTAL DEVICES

4.4 Some of the evidence provided to the Committee suggests that the current regulatory arrangements do not adequately ensure that imported dental devices meet minimum Australian safety and quality standards. Other submissions noted the common misperception that imported custom-made devices are completely unregulated.

4.5 Concerns raised about dental devices manufactured overseas included safety of the material composition, false claims of quality and meeting ISO standards, skill level of overseas manufacturers, inability to audit overseas manufacturers and difficulty enforcing the regulations. The Committee also heard concerns about potential liability issues and ethical concerns with purchase reward schemes. These concerns are discussed in more detail below.

THE CONCERNS

4.6 Isolated cases of inferior products and anecdotal evidence suggest a high level of public concern about the safety and quality of imported dental devices. This perception is bolstered by strong media reporting of those isolated cases.

---

106 Submission 1, Att B; Submission 2, Att A (Guild Insurance), p.1; Submission 3, ADIA p.6; Submission 5, ADPA, p.8.
107 Submission 3, ADIA, p11.
108 Submission 1, Att B; Submission 2, Att A (Guild Insurance), p1; Submission 3, ADIA, p11.
4.7 The ADPA believes that the current market and regulatory environment do not provide assurance that products sourced overseas are safe ‘due to the ease of online procurement and the lack of sufficient information provided when that material or product enters the country.’

4.8 Submissions noted that there have been cases of ‘aesthetic deterioration’ including discolouration of gold crowns and ceramics as well as ‘problems with fit, shade, shape and finish’. The Committee was also advised that these problems can lead to longer term oral health issues such as periodontal disease and tooth loss. There have also been ‘reports of incidents of injuries suffered by members of the public when such devices and materials have failed in one form or another.’

4.9 Another safety concern was that imported dental devices are more likely to (or regularly) contain harmful substances such as heavy metals. The Committee heard of overseas cases where unapproved and unsafe materials were being used in crowns. One submission advised that importing dental devices as ‘custom-made devices’ under the current TGA regulatory framework does not adequately ensure that quality and safety of the devices are to Australian standard because they are ‘effectively bypassing any requirement for verification of materials as being ‘TGA approved’.

4.10 The Committee was advised that the very low prices charged for devices from some overseas manufacturers raises legitimate concerns about the quality of work and materials being used. One submission noted that:

A typical overseas-made crown may vary in cost from $20 to $30 dollars if purchased directly from the overseas laboratory rather than a middle man in Australia. If the mark-up from that laboratory was, say $10, then you would have the cost of manufacture of the crown, including labour, at $10-$20.

The submission highlighted that an Australian laboratory could not produce a crowns for such low prices, given the cost of materials alone.

4.11 One submission also suggested that claims by some Asian manufacturers, and the relevant sponsors, that their products meet International Quality Standards (ISOs) and/or TGA material

---

110 Submission 1, John Clark, Att B, p.2.
111 Submission 1, John Clark, Att B, p.3.
113 Submission 1, John Clark, Att B, p.2; Submission 3, ADIA p.9.
115 Submission 1, Att B
116 Submission 1, John Clark, Att C, p.2.
117 Submission 1, John Clark, Att C, p.2.
118 Submission 1, John Clark, Att C, p.2.
requirement are false. The submission further states that ‘quality cannot be assured by the issuing of certification from notified bodies’ whose auditing does not consider Australian requirements. ISO 3285:2003 does not guarantee a quality product for Australia’ unless the TGA issues the certification.

4.12 The Committee was advised that the unknown skill of overseas manufacturers adds to the risk that imported devices do not meet Australian safety and quality standards. The submission noted that ‘the majority of factory workers are not skilled technicians’ but rather they are ‘trained to complete a small process in the production line’.

4.13 The Committee was also advised that TGA does not have the authority to audit overseas manufacturers and therefore the regulations, including the requirement for custom-made devices to comply with Essential Principles, are impossible to enforce. One submission advocated that a TGA audit process ‘which stipulates and checks that the correct materials and processes are utilised’ would be the only way to ensure that imported devices comply with the relevant standards.

4.14 The Committee notes that some submissions proposed restricting the importation of custom-made dental devices from overseas manufacturers to address safety and quality concerns.

LIABILITY/LITIGATION

4.15 The Committee was also advised that there are significant risks of future litigation given the anecdotal safety and quality risks of imported dental devices.

4.16 One submission provided an extract from a Guild insurance article on Importation of Dental Appliances and Equipment which notes that ‘the use of imported devices and equipment can give rise to complex legal and insurance considerations’. The Guild insurance article advises that there is ‘potential for a patient who suffers injury as a result of the use of an imported appliance or device to pursue legal redress against the practitioner as well as the manufacturer’.

---

119 Submission 1, John Clark, Att B, p.2 & Att C, p.3.
120 Notified Bodies are third party assessors notified by regulatory authorities of the member countries. They undertake assessments for compliance with relevant directives and regulations for high risk products where self declaration is not acceptable.
121 Submission 1, John Clark, Att B, p.2.
122 Submission 1, John Clark, Att B, p.3.
124 Submission 5, ADPA, p.5.
125 Submission 1, John Clark, Att B, p.4.
126 Submission 1, John Clark; Submission 2, Paul Hade.
127 Submission 2, Paul Hade, Att A (Guild Insurance), p.3.
128 Submission 2, Paul Hade, Att A (Guild Insurance), p.3.
4.17 The Committee was advised that the Medical Protection Indemnity Society (MIPS) dental insurance cover ‘would not apply in respect of claims and incidents relating to the use of any dental products, materials and/or devices not approved by the TGA’. 129 Similarly NIB apparently will not indemnify practitioners using non-TGA approved material.130

4.18 It is unclear whether custom-made devices would fall within the bounds of the MIPS exclusions as each device is not individually approved, however the current regulatory regime still requires custom-made devices to comply with the TGA’s Essential Principles and undergo conformity assessment procedures.131

ETHICS – REWARD SCHEMES

4.19 One submission to the inquiry also raised concerns about reward-type schemes implemented by some overseas dental laboratories whereby dentists earn rewards or points based on expenditure with that laboratory.132 The submission notes that all dentists participating in the program are acting contrary to Section 8.11 (b, c, d, e and h) of the Dental Board of Australia Code of Conduct for Registered Health Practitioners as may give rise to a potential or perceived conflict of interest, by being seen as a form of inducement.133

4.20 The submission advised that the US introduced law to prevent financial incentives driving practitioner purchases. The Committee notes that the US Physician Payments Sunshine Act 2009134 aims to promote transparency in relationships between medical industry and medical professionals in an effort to control the increasing costs of healthcare in the US.135 It does this by requiring manufacturers of medicines and devices to report any payments or other transfers of value (such as payments for research, travel, honoraria, speaking fees, meals, and textbooks or journal reprints) made to physicians.136

THE REGULATIONS

4.21 The Committee notes the above concerns and notes that some of the perceptions around quality and safety issues appear to be unfounded. Other evidence provided to the Committee disputed the above claims and indicated that the current regulatory framework is appropriate.

---

129 Submission 1. Att B, p.5.
130 Transcript of Evidence, 12 November 2014, p.37.
131 TGA, Custom-made medical devices.
132 Submission 1, John Clark, Att B, p.1; Submission 1b, John Clark.
133 Submission 1, John Clark, Att F, p.1.
134 Commonly referred to as the ‘Affordable Care Act’ or ‘Obamacare’ and which later on became part of the Patient Protection and Affordable Care Act 2010 (US).
4.22 In regards to overseas purchasing, the OHPA noted that ‘in its early adoption phase, there were cases of poor quality materials used and poor quality workmanship.’\textsuperscript{137} It noted that over time significant improvement has been made to regulations, as well as the capabilities of the international laboratories and local sponsors.\textsuperscript{138} The OHPA advised that:

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.\textsuperscript{139}

4.23 The ADIA believes that the current ‘regulatory standards governing design, performance and manufacturing of custom-made medical devices are appropriate to the currently identified level of risk’ and therefore do not need revision.\textsuperscript{140}

4.24 The ADA similarly believes that the current regulatory requirements, combined with the accreditation of dentists ‘provides an appropriate safety and quality framework for the sourcing and supply of dental prostheses from overseas’.\textsuperscript{141}

PRACTITIONER AND SPONSOR RESPONSIBILITIES

4.25 As discussed in Chapter 2, the onus is 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.\textsuperscript{142}

4.26 The Committee heard however that ‘increasing numbers of Australian dental schools have closed their dental laboratories, resulting in the undergrads at these schools having minimal exposure to lab work’ which is necessary for them to understand ‘production procedures and parameters’.\textsuperscript{143}

4.27 The Committee was advised that these skills, such as setting teeth and understanding impressions, help dentists to identify good and bad laboratory work, assess the quality and safety of the device before use on the patient and confirm the device meets the prescription design parameters that the dentist requested.\textsuperscript{144}

4.28 The Committee also notes that the sponsor is required to maintain the necessary information about custom-made dental devices including information identifying the manufacturer, the

\textsuperscript{137} Submission 6, OHPA, p.3.
\textsuperscript{138} Submission 6, OHPA, p.3.
\textsuperscript{139} Submission 6, OHPA, p.9.
\textsuperscript{140} Submission 3, ADIA, p.9.
\textsuperscript{141} Transcript of Evidence, 12 November 2014, p.2.
\textsuperscript{142} Submission 5, ADPA, p.5.
\textsuperscript{143} Submission 1, John Clark, Att B, p.4.
\textsuperscript{144} Submission 1, John Clark, Att B, pp.3-4; Transcript of Evidence, 12 November 2014, pp.35-36.

**MATERIALS**

4.29 The Committee notes that, regardless of the country of manufacture of custom-made devices, the current regulatory arrangements specify requirements around the choice of materials:

> In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:

  (a) the chemical and physical properties of the materials used in the device; and
  
  (b) the compatibility between the materials used and biological tissues, cells, body fluids and specimens;

> having regard to the intended purpose of the device.\footnote{Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1, Part 2.}

4.30 The Committee notes that the materials used within the device must be listed on the ARTG and comply with ISO standards,\footnote{Transcript of Evidence, 12 November 2014, p.6.} even if individual devices are not listed on the ARTG.

4.31 The ADPA highlights that manufacturing in Australia may provide more confidence in the safety and quality of the materials being used, but it comes at a cost:

> 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.\footnote{Submission 5, ADPA, p.8.}

**EVIDENCE**

4.32 The Committee notes from submissions and advice from witnesses that there is a lack of evidence to justify regulatory changes at this point in time.

4.33 The ADIA considered evidence from the USA, an OHPA survey and the level of reporting to the TGA of adverse events; coming to the conclusion that there is limited documented evidence that dental devices sourced from overseas are any less safe or are of inferior quality to those manufactured within Australia.\footnote{Submission 3, ADIA pp.6-7.}
4.34 The ADA notes that it is not aware of any reported evidence suggesting ‘the quality of products used in dental prostheses and appliances differs depending on whether or not it was supplied in Australia or sourced from an overseas supplier.’\textsuperscript{150} They note that there is no evidence that increased sourcing of prostheses from overseas has resulted in increased risks for patients and there have not been significant numbers of recorded complaints from patients.\textsuperscript{151}

4.35 The ADA also advised that, whilst there has likely been a growth in outsourcing, there is only anecdotal evidence to support that assumption.\textsuperscript{152} It suggests that a survey of practices may help to indicate the changes in the local and overseas market shares.\textsuperscript{153}

4.36 Similarly the OHPA advised the Committee that there is no data on which an assessment of quality can be made because the individual products can’t be assessed, regardless of the country of manufacture.\textsuperscript{154}

4.37 Dentist Dr John Clark also noted that ‘there has not yet been a documented case of unsafe Asian labwork in Australia’ although there have been in other countries.\textsuperscript{155}

4.38 The OHPA summed up the situation, stating:

> If under the TGA regulations, as they stand today, 100 per cent of all prostheses were actually recorded and then 100 per cent of all faults were then recorded, then you would be able to get some empirical data. But we do not have any central reporting system in which to gather that data.\textsuperscript{156}

4.39 The Committee notes that the TGA relies on the post-market reporting to identify difficulties in the custom-made devices market, most importantly adverse events reporting.\textsuperscript{157} The Committee discusses compliance with reporting requirements further from Section 4.44 ‘Regulatory Requirements – Awareness and Compliance’.

**COMMITTEE COMMENT**

4.40 The Committee acknowledges that, regardless of where dental devices are manufactured, they need to be fit for purpose and meet minimum safety and quality standards.

4.41 The Committee believes, on the weight of evidence provided to the inquiry and its analysis of the current Australian regulatory arrangements, that there is not enough evidence to support

---

\textsuperscript{150} Submission 8, ADA, p.2.
\textsuperscript{151} Transcript of Evidence, 12 November 2014, p.2, pp.4-5.
\textsuperscript{152} Transcript of Evidence, 12 November 2014, p.2.
\textsuperscript{153} Transcript of Evidence, 12 November 2014, p.3.
\textsuperscript{154} Transcript of Evidence, 12 November 2014, p.27.
\textsuperscript{155} Submission 1, John Clark, Att B, p.2.
\textsuperscript{156} Transcript of Evidence, 12 November 2014, p.27.
\textsuperscript{157} Transcript of Evidence, 12 November 2014, p.19.
a change to custom-made devices regulation at this point in time. The current regulatory regime addresses design, performance, quality and safety concerns without placing unnecessary regulatory burden on practitioners, manufacturers and sponsors.

4.42 The Committee also notes that there is little empirical evidence to support the seemingly widespread public perception that imported dental devices have systemic safety and quality issues.

4.43 The Committee further notes that engaging Australian dental laboratories to manufacture dental devices may be beneficial to the practitioner and patient because of the ability for dentists and technicians to form long term working relationships and greater opportunities for direct communication between the two parties. However importation continues to be a legitimate supply option available to practitioners and laboratories.

REGULATORY REQUIREMENTS - AWARENESS AND COMPLIANCE

4.44 Whilst the Committee believes that the current regulatory regime appears to adequately address quality and safety issues, it notes that awareness of the regulations around custom-made devices and compliance with some of the relevant regulatory requirements appears to be inadequate.

4.45 The TGA advised the Committee that there is probably a lack of understanding about the regulatory requirements for custom-made devices across all health professionals, not just the dental sector.

REPORTING REQUIREMENTS

4.46 There are two key reporting requirements under the current regulatory framework that appear to be poorly understood and applied:

- reporting of manufacturing activities; and
- reporting adverse events.

---

158 Submission 1, John Clark, Att B, p.2.
159 Submission 3, ADIA, p.7; Submission 6, OHPA, p.3; Transcript of Evidence, 12 November 2014, pp.19 & 21; Transcript of Evidence, 12 November 2014, p.36.
MANUFACTURING ACTIVITIES

4.47 As outlined in Chapter 2, the Regulations require sponsors and Australian manufacturers to notify the TGA of all manufacturing activities in relation to custom-made devices. 161

4.48 The Committee notes that under the current regulations, sponsors must provide the TGA with advice on the sponsor’s name and address, the manufacturer’s name and business address and ‘a description of the ‘kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).’ 162

4.49 The TGA reinforced this to the Committee, advising that, for every custom-made device, sponsors are required to notify the TGA of manufacturers details ‘and a description of the device so that it is actually apparent where the device was made’ and what the device was. 163 However, the TGA noted its concern that awareness of this regulatory responsibility is limited and sponsors may not be notifying the TGA about all manufacturing activities. 164

ADVERSE EVENTS REPORTING

4.50 Sponsors and manufacturers are also required to report adverse events. The adverse event reporting requirements aim to pick up difficulties once a product has been supplied and used, investigating complaints and compliance with the Essential Principles. 165

4.51 The ADIA notes that the TGA does not appear to have received a large number of reports concerning custom-made dental devices that warrant review, however they also note that awareness of the reporting and investigation scheme does not appear to be very high, nor fully understood by practitioners, sponsors and manufacturers. 166

4.52 Similarly, the OHPA advised that lack of awareness of the Incident Reporting and Investigation Scheme (IRIS) intended to log, investigate and report adverse events may be contributing to limited compliance and transparency. They note that:

Though there have not been a significant number of complaints, it can be questioned whether there is an understanding within the [dental] sector of their responsibility to report. 167

161 Therapeutic Goods (Medical Devices) Regulations 2002, S10.3.
162 Therapeutic Goods (Medical Devices) Regulations 2002, s10.3(2).
163 Transcript of Evidence, 12 November 2014, p.18.
164 Transcript of Evidence, 12 November 2014, pp.19, 21 & 23.
165 Transcript of Evidence, 12 November 2014, pp.18-19.
166 Submission 3, ADIA, p.7.
167 Submission 6, OHPA, p.9.
4.53 The Committee heard that the TGA has received a total of 14 complaints around custom-made devices out of ‘one million-plus devices’. The TGA investigated these complaints and nothing was found that required regulatory action against the sponsors or manufacturers.\(^{168}\)

**OTHER COMPLAINTS PROCESSES**

4.54 The Committee notes that there are also a number of avenues for patients to raise concerns or complaints if they are unhappy about the safety or quality of a dental device.

4.55 The ADA advised that most patients would first approach their dentist but there are also health service commissioners and some ADA branches that can provide conciliatory help and a consumer information/complaint telephone line.\(^{169}\) Dentists may let the ADA know if there were consistent problems with the product from a manufacturer or sponsor. If the complaint is about a practitioner, it can also be directed to the DBA.\(^ {170}\)

**EDUCATION**

4.56 Whilst the TGA acknowledged that those sponsors and manufacturers not implementing the regulatory reporting requirements are in breach of TGA legislation, the TGA advised that it prefers to focus on increasing education and awareness. They note that applying penalties and ‘prosecuting people for breaches is a last and least preferred option’.\(^ {171}\)

4.57 The ADA, DBA and OHPA all endeavour to inform their members of regulatory obligations around the importation and supply of dental devices.\(^ {172}\)

4.58 The ADA notes that they have an ongoing process to educate their members about their regulatory responsibilities including numerous articles, bulletins and newsletters.\(^ {173}\) It has also started a member forum on particular issues and a voluntary system of practice accreditation.\(^ {174}\)

4.59 The TGA highlighted that it is working with peak bodies, including the ADA and ADIA, to educate their members about the regulatory requirements.\(^ {175}\) They noted that some issues relate to practice which is outside of the TGA’s jurisdiction.\(^ {176}\) The TGA also advised that the

---

\(^ {168}\) Transcript of Evidence, 12 November 2014, p.19.
\(^ {169}\) Transcript of Evidence, 12 November 2014, pp.6-7.
\(^ {170}\) Transcript of Evidence, 12 November 2014, pp.21-22.
\(^ {171}\) Transcript of Evidence, 12 November 2014, pp.21-22.
\(^ {172}\) Transcript of Evidence, 12 November 2014, pp.5, 12, 21-22 & 25.
\(^ {173}\) Transcript of Evidence, 12 November 2014, p.12.
\(^ {174}\) Transcript of Evidence, 12 November 2014, p.12.
\(^ {175}\) Transcript of Evidence, 12 November 2014, pp.21-22.
\(^ {176}\) Transcript of Evidence, 12 November 2014, pp.21-22.
DBA and ADA have ‘undertaken to remind dentists of their legal obligations in relation to custom-made dental appliances’. 177

4.60 The OHPA notes that the TGA has only recently provided clearer communication and education material to the Australian dental laboratory sector about the structure of the regulatory framework. 178 The OHPA also continues to advocate for increased reporting and transparency within the dental prosthesis category. 179

4.61 The TGA notes that it is up to the ADIA or the ADA to talk with universities and ensure dental students are educated about the regulatory requirements. However, the TGA endeavours to communicate any regulatory changes to the relevant dental colleges as well as updating the TGA website. 180

EDUCATIONAL MATERIAL

4.62 Despite the efforts discussed above, the Committee notes that there appears to be a need for more simplified guidance from the TGA on what the regulatory requirements are for custom-made devices, particularly the reporting requirements. The Committee is aware that some work is underway to provide better educational materials.

4.63 As noted earlier in this report, the TGA is currently drafting a chapter for the Australian Regulatory Guidelines for Medical Devices (ARGMD) on the regulatory requirements for custom-made devices. 181

4.64 The TGA also advises it has updated information on its website (such as a fact sheet on custom-made medical devices for sponsors, health professionals and manufacturers) and it reviews training materials drafted by the ADIA or other bodies. 182

4.65 One submission also recommended that the ADA consider conducting courses for its members to provide them with a comprehensive overview of the whole regulatory framework. 183

COMMITTEE COMMENT

4.66 The Committee believes a chapter of the ARGMD on custom-made devices should further assist practitioners and sponsors to better understand their regulatory responsibilities, including reporting manufacturing activities and adverse events.

---

177 Submission 4, TGA, p.1.
178 Submission 6, OHPA, p.9; Transcript of Evidence, 12 November 2014, p.25.
179 Submission 6, OHPA, p.9.
180 Transcript of Evidence, 12 November 2014, p.22.
181 Transcript of Evidence, 12 November 2014, p.22.
182 TGA, Custom-Made Medical Devices – Information for sponsors, health professionals and manufacturers, 2 July 2012.
183 Submission 1, John Clark, Att C, p.3.
The Committee also believes there are opportunities for the TGA to create simple checklists for sponsors and manufacturers, including reference to the regulations, on what must be reported to the TGA, when to report and how to report.

**REPORTING MECHANISMS**

The Committee notes that, even if a sponsor is aware of the current regulatory reporting requirements, the apparent lack of a formal reporting mechanism to advise the TGA of manufacturing activities may also be contributing to low rates of reporting on manufacturing activities for custom-made-devices.

The TGA advised the Committee that there is no formal register to record manufacturing activities, with manufacturing information usually received at the TGA via email.\(^\text{184}\)

Similarly, the ADIA advised the Committee that whilst ‘sponsors of custom-made medical devices are required to notify the TGA that they are supplying such products to the Australian market’,\(^\text{185}\) there is no established process for this reporting.\(^\text{186}\)

The TGA highlighted that it is developing a form so that standard reporting information will be provided by sponsors.\(^\text{187}\) In the longer term, compliance with reporting should provide a reliable data set that would enable follow-ups if post-market issues are identified with custom-made-devices.\(^\text{188}\)

The ADIA further advised the Committee that:

> ADIA and the TGA have identified a pathway to improve the process by improving the ARTG’s online eBusiness portal to allow Sponsors to register that they are supplying custom-made medical devices.\(^\text{189}\)

The ADIA was concerned, however, that despite TGA assurances that such changes are being considered, they don’t believe there have been signs of progress. The ADIA therefore recommended that the ‘TGA expedite the required ARTG eBusiness upgrades’ to support compliance with reporting obligations.\(^\text{190}\)

---

\(^\text{184}\) Transcript of Evidence, 12 November 2014, pp.18 &23.
\(^\text{185}\) Submission 3, ADIA, pp.15-16.
\(^\text{186}\) Submission 3, ADIA, pp.15-16.
\(^\text{187}\) Transcript of Evidence, 12 November 2014, p.23.
\(^\text{188}\) Transcript of Evidence, 12 November 2014, p.23.
\(^\text{189}\) Submission 3, ADIA, pp.15-16.
\(^\text{190}\) Submission 3, ADIA, pp.15-16.
4.74 The Committee notes that a standard reporting form will assist the TGA to increase consistency in the information reported by sponsors and manufacturers. Additionally, the use of an online reporting portal would appear to simplify and streamline reporting processes. Combined, these mechanisms are likely to reduce the reporting burden on sponsors and manufacturers and may result in a more complete and accurate data set for the TGA on importation of custom-made devices as well as data on device safety and quality problems.

4.75 The Committee supports the implementation of tools and educational material that will assist sponsors and manufacturers to comply with the current regulatory requirements and which could result in increased reporting of manufacturing activities and adverse events to the TGA.

DENTIST REGISTRATION REQUIREMENTS

4.76 The ADIA advised the Committee that the Dental Board of Australia (DBA) should also clearly articulate ‘that compliance with regulatory standards is a mandatory requirement for registration as a dentist’, in a similar way to the UK’s General Dental Council (GDC). The GDC states:

All GDC registrations must comply with the GDC standards guidance. With regards to the commissioning and manufacturing of dental appliances, the following principle has particular relevance:

‘Find out about laws and regulations which affect your work, premises, equipment and businesses, and follow them’ (Principle 5.4L Standards for dental professionals).

When commissioning and manufacturing dental appliances this includes compliance with the Medical Devices Directive 93/42/EC.\(^{191}\)

4.77 The Committee notes that the Code of Conduct for Registered Health Professionals already includes similar guidance. It requires that:

- Practitioners must always act in accordance with the law.\(^{192}\)
- Practitioners need to be aware of, and comply with, the standards, guidelines and policies of their board.\(^{193}\)

---

\(^{191}\) Submission 3, ADIA, p.14.
\(^{192}\) DBA Code of Conduct for Registered Health Practitioners, p.2.
\(^{193}\) DBA Code of Conduct for Registered Health Practitioners, p.2.
EMPIRICAL DATA

4.78 The Committee notes that the lack of compliance with the reporting requirements results in a shortage of reliable data on the size of the market for imported custom-made medical devices as well as limiting scrutiny or oversight of custom-made dental devices by the TGA.

4.79 The OHPA also notes ongoing issues with data collection within the federal framework, advising that most of the available data is collected by sector associations like the OHPA.\(^{194}\)

4.80 The TGA advised the Committee that it does not believe it has ‘a full and accurate dataset’.\(^{195}\) It is therefore very difficult to draw conclusions from the data that TGA does have.\(^{196}\) The TGA further noted that ‘we are unlikely to be getting all the data that we need to have meaningful statistics’.\(^{197}\) The Committee notes that as a result there are substantial confidence intervals about the accuracy of the data.\(^{198}\)

4.81 As discussed in Sections 4.32 to 4.38 of this report, concerns about the quality, safety and quantity of imported custom-made devices can only be confirmed or debunked with a complete and accurate data set on manufacturing and adverse events.

COMMITTEE COMMENT

4.82 The Committee notes that the lack of empirical data on the numbers of imported devices and apparent lack of compliance with manufacturing and adverse event reporting requirements seriously impede the ability to develop a detailed understanding of the nature of this market and whether safety and quality issues are pervasive. Without adequate data the public perception and concerns with safety and quality are impossible to prove or disprove.

COUNTRY OF ORIGIN INFORMATION

4.83 The Committee also set out to establish whether dental patients and consumers are aware, or are made aware by practitioners, of the source and supply details of dental devices provided in Australia.

\(^{194}\) Submission 6, OHPA, p.3; Transcript of Evidence, 12 November 2014, p.26.

\(^{195}\) Transcript of Evidence, 12 November 2014, p.19.

\(^{196}\) Transcript of Evidence, 12 November 2014, p.21.

\(^{197}\) Transcript of Evidence, 12 November 2014, p.23.

\(^{198}\) Transcript of Evidence, 12 November 2014, p.23.
PATIENT AWARENESS

4.84 The Committee notes that one of the main areas of concern presented in submissions and by witnesses to the Committee was that dental devices imported from overseas manufacturers are being used without patient consent or awareness of the product’s country of origin and material composition.199

4.85 The OHPA advised that there is no regulation requiring disclosure to patients (although some practitioners disclose local manufacturing as a marketing tool), noting that the complex supply chain models that can exist make the accuracy of some statements debatable.200 They advise that some marketing promotes the location of the Australian sponsor, importer or ‘clearing house’, not necessarily the physical country of manufacture.201

CURRENT REQUIREMENTS

4.86 There is currently an implied requirement to inform patients but not a regulatory one. As noted in Section 2.41 of this report, the DBA Code of Conduct includes requirements for informed consent from patients for the care and treatment they will receive.202

4.87 The ADPA notes that the DBA Code of Conduct promotes the General Guidelines for Medical Practitioners on Providing Information to Patients, published by the National Health and Medical Research Council (NHMRC). The guidelines outline the types of information medical practitioners should give to patients ‘to help them make informed decisions about proposed investigations or treatment.’203 It 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.’ 204

4.88 The ADPA advises that these provisions ‘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.’205 However, it also notes that monitoring and enforcing adherence to the Code appears difficult.206

---

199 Submission 1, John Clark, Att B, pp.1-2 & 5; Submission 3, ADIA, p.15; Submission 5, ADPA, pp.6-7; Submission 6, OHPA, pp.11-12.
200 Submission 6, OHPA, p.11.
201 Submission 6, OHPA, p.11.
202 DBA, Code of Conduct for Registered Health Practitioners, s3.5.
203 NHMRC, General Guidelines for Medical Practitioners on Providing Information to Patients, p.3.
204 NHMRC, General Guidelines for Medical Practitioners on Providing Information to Patients, p.3; Submission 5, ADPA, p.7.
205 Submission 5, ADPA, p.7.
206 Submission 5, ADPA, p.7.
4.89 The Committee was advised that the ACT Dental Health Program supports the principle that ‘patients have the right to be fully informed in relation to the prosthetic being used and should be informed if the appliance is manufactured overseas.’

**STATEMENT OF MANUFACTURE**

4.90 In response to concerns, submissions to the Committee strongly supported the introduction of a regulatory requirement to inform patients of the country of manufacture of the dental devices being used as part of their treatment, in order to improve transparency.

4.91 In the United Kingdom, patients receiving a custom-made dental device are made aware that they can request a statement of manufacture, which is also required to be retained by the practitioner for the lifetime of the device, including a note on whether the information was provided to the patient.

4.92 The Senate’s Community Affairs References Committee inquiry into the regulatory standards for the approval of medical devices in Australia recommended:

    That the Therapeutic Goods Administration consider whether the 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.

4.93 As the ADIA notes, the Senate Committee’s recommendation recognises that there is a public perception issue with the safety of custom-made dental devices and proposes a reasonable course of action. The ADIA supports a change to the regulations governing the supply of custom-made devices in order to require a statement of manufacture be offered to the patient.

4.94 The Australian Government, in its response to the Senate Committee’s report, noted the recommendation and highlighted the current information required to be held by sponsors about a device and its manufacturer. The Australian Government also agreed to further consult with the DBA about the recommendation.

4.95 The TGA advises that its role does not include regulating clinical practices, therefore any

---

207 Director-General, ACT Health Directorate, Correspondence, 22 Sep 2014.
208 Submission 1, John Clark, Att C, p.3; Submission 7, DBA, p.1; Submission 5, ADPA, pp.6-7. Submission 3, ADIA, p.15; Submission 6, OHPA, p.12; Submission 8, ADA, p.2.
209 Submission 3, ADIA, p.12.
211 Submission 3, ADIA, p.13.
212 Submission 3, ADIA, p.15.
requirement for practitioners to provide patients with information on the country of manufacture for custom-made devices is a matter for the health professional. However the TGA notes that it works closely with the DBA and the ADA, and those organisations have ‘undertaken to consider adopting the United Kingdom approach of requiring a statement of manufacture be provided to patients’.

4.96 The OHPA is committed to patient disclosure and, within its accreditation program, already requires printed information cards to be provided to dentists with each prostheses supplied. The cards identify to the practitioner the place of manufacture, the qualifications of the dental technician, county of origin and note that the manufacturing used only TGA approved materials. The dentist can choose to disclose that information to the patient or not.

4.97 The ADA remains concerned that any requirement for disclosure to patients would be very hard to regulate or monitor. They advised that it is more important for the dentist to be aware of the manufacturing information and be in a position to ‘assure the patient that the materials and the processes used are to the correct standard.’

COMMITTEE COMMENT

4.98 The Committee considers that providing a statement of manufacture to patients would address calls for country of origin labelling. It is consistent with ‘good practice’ and the intent of the DBA Code of Conduct to obtain informed consent from patients for care and ‘facilitating the quality use of therapeutic products based on the best available evidence and the patient’s needs.’

4.99 As with the United Kingdom’s approach, the Committee also believes such statements should be retained by the dental practitioner to provide an audit trail in the case of future problems.

Recommendation 1

4.100 The Committee recommends that the ACT Government should request that the Therapeutic Goods Administration and the Dental Board of Australia consider amending the relevant regulations, codes and guidelines to require the details about the manufacturer of a custom-made dental device to be provided to the prescribing practitioner and the patient.

---

214 Submission 4, TGA, p.5.
216 Transcript of Evidence, 12 November 2014, p.29.
217 Submission 6, OPHA, p.12
218 Transcript of Evidence, 12 November 2014, p.29.
219 Transcript of Evidence, 12 November 2014, p.3.
221 Submission 7, DBA, P1; Submission 5, ADPA, pp.6-7; DBA, Code of Conduct for Registered Health Practitioners.
PRACTITIONER AWARENESS

4.101 The Committee also notes concerns raised in submissions about Australian laboratories or intermediaries outsourcing device manufacturing without awareness of the practitioner.

4.102 The ADA advised of situations where a dentist may send a job request to a local laboratory which then sends the prescription overseas for manufacture without the dentist’s knowledge or agreement.222

4.103 The ADPA makes a similar observation, noting ‘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.’223 They advised that a practitioner may be unaware of where a product has been sourced, even if they order through an Australian address.224

4.104 As noted in Section 2.45 of this report, the ADA policy statement 6.12 requires that ‘The origins of all dental prostheses and appliances should be identified.’225 It is unclear from this statement to whom the origins should be identified, but the Committee assumes this refers to the dental practitioner rather than the patient.226

4.105 The ADA would support a requirement for laboratories to declare to a dentist if a prosthesis was made overseas, but warns that any additional requirement should not increase the cost for consumers, particularly ‘where there is no firm evidence to indicate the current system is not protecting patients’.227

4.106 The Committee notes that labelling and record keeping requirements under the regulations already require this information to be provided with a device in many instances. Essential Principle 13 of the Regulations outlines that:

The following information must be provided with a medical device:

- information identifying the device;
- information identifying the manufacturer of the device;
- information explaining how to use the device safely;

having regard to the training and knowledge of potential users of the device.228

---

222 Transcript of Evidence, 12 November 2014, p.2.
223 Submission 5, ADPA, p.6.
224 Submission 5, ADPA, p.6.
226 Transcript of Evidence, 12 November 2014, pp.11-12.
227 Submission 8, ADA, p.2.
228 Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1, Part 2, s13.
Committee Comment

4.107 Application of Essential Principle 13 should result in practitioners receiving adequate information about a device to enable identification of the manufacturing company including name, or trading name, and address. 229

4.108 The Committee notes the ADA and ADPA’s comments about practitioners being unaware of the origin of dental devices and is concerned that compliance with Essential Principle 13 appears to be poor.

Cost Disclosure

4.109 As discussed earlier, some evidence provided to the Committee suggested that the chief motivation for dentists to import dental devices from cheaper overseas manufacturers is to save money on laboratory fees. 230 Submissions further suggested that some dentists also aim to make a profit by not passing on those laboratory fee savings to patients. 231

4.110 The ADPA notes that the DBA Code of Conduct requires that practitioners make clients or patients ‘aware of all the fees and charges involved in a course of treatment, preferably before the health service is provided’. 232 They advise that the Code implies patients should be made aware if a product has been chosen primarily for cost considerations. 233

Committee Comment

4.111 The Committee believes that providing patients with the option to request a statement of manufacture also provides an opportunity to discuss the related costs with their practitioner.

---

229 Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1, Part 2, s13.3.
230 Submission 1 John Clark, Att B, p.1.
231 Submission 1, John Clark, Att B, p.1; Transcript of Evidence, 12 November 2014, p.33.
232 Submission 5, ADPA, p.6.
233Submission 5, ADPA, pp.6-7.
REGISTRATION OF DENTAL TECHNICIANS AND DENTAL LABORATORIES

REGISTRATION OF DENTAL TECHNICIANS

4.112 Until the introduction of the regulatory scheme for dental practitioners under the Health Practitioner Regulation National Law Act 2009, dental technicians were regulated through the Dental Technicians Registration Act 1975. Dental technicians are not regulated under the new Act, with no requirement for them to be registered with any regulatory body.

4.113 Dental technicians are now classified as 'Unregistered Health Practitioners' and there is no federal body overseeing their practice or monitoring qualifications.

4.114 The ADIA advised that the rationale for the change is that ‘dental technicians are considered to be product fabricators, manufacturing to the requirements of a dental professional registered under the DBA.’

4.115 The Committee notes that the regulatory environment and oversight of Unregistered Health Practitioners varies across each State and Territory but in many cases does not extend beyond standard business/company registrations. The OHPA advised that:

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,

---

234 Submission 5, ADPA, p.3.
235 Transcript of Evidence, 12 November 2014, p.29.
236 Submission 6, OHPA, p10; Transcript of Evidence, 12 November 2014, p.29.
237 Submission 3, ADIA pp.3-4.
238 Submission 6, OHPA, p.10.
239 Submission 3, ADIA p.3.
TYPES OF DENTAL TECHNICIAN BUSINESSES

4.116 The OHPA explained to the Committee two business models that manufacture and supply dental devices.

4.117 The first are dental laboratories, headed by dental technicians or other dental practitioners like dentists. Dental laboratories fabricate crowns, bridges, dentures etc. under instruction from a dentist, dental prosthetists or other referring dental practitioner but do not see patients. Neither individual dental technicians nor laboratories themselves are registered as health service providers.241

4.118 Dental prosthetists on the other hand see patients as practitioners and manufacture removable prostheses such as full and partial dentures and mouthguards. Dental prosthetists are registered with the DBA.242

DEREGULATION AND QUALITY

4.119 The ADPA believes that deregulation of dental technicians makes quality and safety standards impossible to enforce:

Under the former dental technician registration arrangements (pre 2010), there was a greater emphasis on standards and governance of the industry. However, since deregulation 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.243

4.120 In contrast the ADIA believes that the role of dental technicians does not involve treating a patient or design specification so is clearly a manufacturing rather than health provider role, therefore ‘there is not a strong rationale for dental technicians to be registered.’244

COMMITTEE COMMENT

4.121 The Committee does not believe that there is strong evidence to reinstate registration of dental technicians.

240 Submission 6, OHPA, p.10.
241 Submission 6, OHPA, p.4.
242 Submission 6, OHPA, pp.4-5.
243 Submission 5, ADPA, p.6.
244 Submission 3, ADIA pp.3-4.
OHPA- Dental Laboratory Accreditation Program

4.122 The Committee notes that the OHPA has established an accreditation program to help maintain dental technician standards.

4.123 The OHPA represents dental technicians and other related fields of practice nationally. The majority of its members are dental laboratory owners.245

4.124 In 2007 the OHPA developed the accreditation program to support and promote dental laboratories that are registered in Australia in authority approved premises. In order to be accredited, laboratories must have qualified technicians fabricating all of their products using TGA registered materials. They must also 'manage dust and fumes responsibly, work within the framework of the WHS [workplace health and safety], and have infection control procedures and a quality control program in place.'246

4.125 The program aims to assist the sector to:

- establish and maintain laboratory benchmarks;
- support the sector through the digital revolution;
- assist practitioners in their procurement responsibilities when selecting manufacturers; and
- offer assurances of safety and quality to patients.247

4.126 The program is a self-regulating, requiring annual review and renewal. OHPA conducts periodic audits on premises around the country to validate the information submitted.248

Committee Comment

4.127 The Committee believes that the OHPA accreditation program is a sensible approach for the now deregulated industry to maintain benchmarks in quality of service and product. It enables dentists and other dental practitioners to identify quality Australian-based technicians and laboratories.

245 Transcript of Evidence, 12 November 2014, p.25.
246 Submission 6, OHPA, p.5.
247 Submission 6, OHPA, p.5.
248 Submission 6, OHPA, p.5.
5 OVERSEAS EXPERIENCE

5.1 The Committee also chose to review the experiences and relevant regulatory arrangements for dental prostheses and appliances sourced and supplied from overseas in other jurisdictions.

5.2 Regulatory arrangements in international jurisdictions such as the United States (US), Canada, the United Kingdom (UK) and New Zealand appear to be similar to the current regulatory regime in Australia, with devices classified and monitored on the basis of their potential risk to the user.

UNITED STATES

5.3 In the United States, the Center for Devices and Radiological Health (CDRH), a division of the Food and Drug Administration (FDA) has responsibility for regulating and monitoring the development, marketing, and distribution of all medical devices. FDA is an agency within the US Department of Health and Human Services and draws its regulatory authority and powers from the Federal Food, Drug and Cosmetic Act 1938 (the FFDC Act). Chapter V of the FFDC Act deals with drugs and devices.

5.4 FDA classifies devices in three classes: Class I, II, and III. Class I devices are low risk with Class III devices being high risk. 249 Almost all Class I and a small number of Class II devices are low risk and do not require any pre-market assessment and/or approval by FDA. Most Class II and all Class III devices are classified high risk and require approval from FDA. Custom-made devices as defined in Section 360j(b) of the FFDC Act, for any particular patient are exempt from Performance standards and Pre-market approval. 250 However, custom-made devices and their manufacturers are required to follow good manufacturing practices (GMPs). 251 GMPs require that facilities, processes and controls for the pre-manufacture design, manufacture, packing, storage and handling of devices meet FDA quality control requirements to assure device safety and effectiveness. 252

5.5 Dental laboratories with overseas operations, or those serving as the initial importer for an overseas laboratory, repackaging or manufacturing dental devices, are required to be

---

249 Food and Drug Administration, Medical Devices, Device Regulation and Guidance Overview http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
251 Woodlee, D., 2011, Understanding the US FDA’s Custom Device Exemption: Practical Solutions for Handling the Sale of Patient-Specific Devices in the USA, Journal of Medical Device Regulation, August 2011
registered with FDA. The FDA has inspection powers, however inspections are not common.\textsuperscript{253} There are claims that less than one percent of foreign restorations are inspected by the FDA.\textsuperscript{254}

5.6 Overseas prosthetics can be sourced into the US in two ways. Dentists are able to outsource directly to an overseas laboratory through a broker laboratory and therefore know the point of origin of dental devices. Dentists may also send work orders to a local laboratory which then sources devices from an overseas laboratory with or without the knowledge of the dentist.\textsuperscript{255} It is an FDA requirement to advise dentists if the laboratory has outsourced prosthetics manufacturing to an overseas laboratory.\textsuperscript{256} A 2009 dental laboratory survey indicated that the information on outsourcing from an overseas laboratory is provided only upon request by dentists. Further, dentists receiving the information are not required to disclose the information on overseas manufacturing of prostheses to patients.\textsuperscript{257}

5.7 In terms of material or components used by overseas laboratories manufacturing prosthetics, there is no FDA regulation or any other law in the US requiring the disclosure of material to the dentist.\textsuperscript{258} However, foreign laboratories are required to use FDA approved materials for manufacturing dental devices or prostheses and provide a declaration in this regard to FDA for their devices to be allowed for sale in the US.\textsuperscript{259}

5.8 The National Association of Dental Laboratories (NADL) conservatively estimated in June 2009 that 20 percent of work is outsourced but expected it to actually be in the range of 35 to 40 percent.\textsuperscript{260}

5.9 Like Australia there is very little hard evidence that outsourcing dental devices and prostheses from overseas results in a lower quality product beyond the anecdotal evidence and except for a small number of reported cases.

\textsuperscript{256} Pfister, R.L. and Winings, J.R., 2012, Outsourcing dentistry: Questions remain about the quality of ‘foreign’ dental prosthesis, RDHMag (Registered Dental Hygienist Magazine), Volume 30, Issue 12,
\textsuperscript{257} Pfister, R.L. and Winings, J.R., 2012, Outsourcing dentistry: Questions remain about the quality of ‘foreign’ dental prosthesis, RDHMag (Registered Dental Hygienist Magazine), Volume 30, Issue 12,
\textsuperscript{260} Pfister, R.L. and Winings, J.R., 2012, Outsourcing dentistry: Questions remain about the quality of ‘foreign’ dental prosthesis, RDHMag (Registered Dental Hygienist Magazine), Volume 30, Issue 12,
5.10 Therapeutic Products Directorate (TPD) of Health Canada is the regulator of health products and medical devices. The legal instruments enabling the regulation are *Food and Drug Acts 1985* and *Medical Devices Regulations 1998*.

5.11 TPD classifies medical devices into four classes: I, II, III and IV. Class I devices are potentially the lowest risk devices. Class I medical devices require an Establishment Licence to track in case of any adverse events. Manufacture and sale of medical devices in classes II to IV requires a valid Medical Device License. Further, class II to IV devices must be designed and manufactured according to *CAN/CSA ISO 13485:2003* Standard.\(^{261}\)

5.12 Appliances, devices and materials developed by dental laboratories are classified as either class II or III devices. Removable dentures and orthodontic appliances are class II and fixed dental prostheses (such as crowns and bridges) are class III medical devices. Manufacture of these devices requires a valid Medical Device Licence.\(^{262}\)

5.13 Dental professionals can source dental prostheses including custom-made devices from overseas laboratories without any licensing requirements. However, the overseas dental laboratories are required to have relevant class II or III Medical Device Licence. In addition, foreign and domestic laboratories are required to use the materials licensed under the *Medical Devices Regulations 1998*.\(^{263}\) Medical licences for general medical devices are issued after an assessment of evidence of their safety, effectiveness and quality submitted by the manufacturer.

5.14 In Canada, dental technicians are regulated and licensed by the College of Dental Technicians of British Colombia.\(^{264}\)

**UNITED KINGDOM**

5.15 Medicines and Healthcare products Regulatory Agency (MHRA) is the regulator of medical devices including dental appliances and prostheses in the UK. The European Union law, *Medical Devices Directive 93/42/EEC* (the Directive) in relation to general medical devices applies in the UK. The Directive is implemented in the UK through the UK’s *Medical Devices Regulations* (the Regulations) to ensure devices are safe and effective for the intended

---

\(^{261}\) Canadian Dental Association 2010, *Guidance Document Pertaining to Devices for Use in Dental Health Care*.

\(^{262}\) Canadian Dental Association 2010, *Guidance Document Pertaining to Devices for Use in Dental Health Care*.

\(^{263}\) Canadian Dental Association 2010, *Guidance Document Pertaining to Devices for Use in Dental Health Care*.

\(^{264}\) Submission 6, OHPA, p.13.
Devices are classified on the basis of the perceived or potential risk posed by their use to the user. Like Australia, general medical devices are categorised into classes (Class I, IIa, IIb and III) based on the level of risk, with class I devices being low risk and class III high risk devices.

The Directive defines the classification criteria using a rules based system. Devices are classified by manufacturers using an 18-rules system. All devices are required to meet conformity assessment and CE (Conformité Européenne in French) marking requirements. Conformity assessment is the process of ensuring the device conforms to the relevant laws and regulations such as the Directive and the Regulations. For the low risk devices in Class I, manufacturers can undertake self assessment and issue declaration of conformity and place the CE label on the device. As the level of risk increases for higher classes of devices, independent conformity assessments by third parties, designated as Notified Bodies by the Competent Authorities (regulatory authorities such as the MHRA), are required for the clearance of class IIa, IIb and III devices before their marketing for sale or use for service.

Dental appliances manufactured by dental laboratories on the prescription of dentists for a particular patient are custom-made medical devices. Manufacturers of custom-made medical devices are required to meet the conformity requirements of the Directive/Regulations and prepare a statement of compliance for their responsibility of custom-made devices. However, custom-made devices are exempt from third party conformity assessments and CE marking but are subject to the following labelling requirements:

- the name and address of the manufacturer or their representative in the European Union
- identification information on the device, description of the device and the patient’s name
- words ‘custom-made device’ on the packing of the device.

Despite exemption of custom-made dental devices from third party conformity assessment and CE labelling, the British Dental Association (BDA) recommends that ‘the dentist should check that the dental appliance has been manufactured in accordance with the Regulations and that the manufacturer of the appliance has registered with the Competent Authority (the MHRA in the UK).’

269 British Dental Association, 2012, Medical Devices, BDA advice, p.4.
Custom-made medical devices (including dental devices classified as Class IIa, IIb and III) require a statement of manufacture to be prepared and provided to the professional prescribing the device. The professional is required to inform the patient that a statement of manufacture is available for the patient. If the patient takes a copy, this information should be noted on the patient’s file. According to MHRA and BDA, the statement must contain the following information:

- Device identification information: description, serial and order numbers, generic name
- A statement to the effect of exclusive use by a particular patient and patients’ information
- Name and address of the prescribing professional
- Particular features of the device as specified in the prescription
- A statement on compliance with conformity requirement of the Directive
- Name and address (origin) of the manufacture or their authorised representative if outside the European Union.

MHRA further recommends that manufactures must retain and, if requested, provide documentation on the design, production and performance including expected performance of the custom-made device to the Competent Authority for assessment against conformity requirements of the Regulations.

The Directive and Regulations require manufactures, or their authorised representatives, of custom-made devices to register with a Competent Authority in any EU country before their devices can be allowed for use and service in the UK or the EU. Manufacturers based outside EU are required to appoint an authorised representative. There is no specific advice from MHRA in relation to the registration of foreign dental laboratories in the UK or EU. However, on the basis of information on registration requirements of custom-made devices, it appears that overseas dental laboratories manufacturing custom-made dental appliances and prosthesis must be registered with MHRA or another Competent Authority in the EU.

In 2011, the UK’s General Dental Council (the regulatory authority for dental professionals) issued advice on standards for commissioned dental appliances. The standard does not restrict UK’s dental professionals from commissioning dental appliances from foreign manufacturers.

---

270 British Dental Association, 2012, Medical Devices, BDA advice, page 3
but holds the dental professional accountable for the quality, safety and effectiveness of the custom-made appliance. The Standards were updated in September 2013 and the current standards do not provide any advice on foreign sourcing of custom-made dental appliances.

NEW ZEALAND

5.24 Medsafe is the regulatory authority in New Zealand and regulates medical devices under the *Medicines Act 1981* and *Medicines Regulations 1984.*

5.25 Medical devices classification system is similar to the system used in the UK and Australia. Medical devices are classified on the basis of the perceived risk to the user. Class I are low risk. Classes IIa, IIb, and III are medium to high risk devices. Manufacturers or sponsors/importers of devices into New Zealand determine the class of medical devices applying a system of 22 rules through an elimination process.

5.26 Medical devices (or dental devices) can be imported from overseas manufacturers. However their import is subject to having a New Zealand based sponsor. In addition, there are strict statutory requirements in relation to labelling of devices. Regulation 12(4) of the *Medicines Regulations 1984* prohibits the sale of any medical device whose label does not provide information on the name of the manufacturer, or their distributor if an overseas manufacturer. Sponsors are required to keep records of supplies to the patients to manage the recall process efficiently.

5.27 There are also statutory requirements of notifying/entering the details of devices into an electronic database, referred to as the Web Assisted Notification of Devices (WAND) Database. The database is not an approval system rather a post-market monitoring or safety system like Australia’s DAEN-MD. However, custom-made devices for a particular patient are exempt from reporting to the Database.

5.28 The Dental Council of New Zealand registers and regulates dental practitioners including dental technicians.

---


276 Medsafe, Medical Devices: Risk Classification of Medical Devices, [http://medsafe.govt.nz/regulatory/devicesnew/3-RiskClassification.asp](http://medsafe.govt.nz/regulatory/devicesnew/3-RiskClassification.asp)


281 Submission 6, OHPA, p13.
5.29 No reports of adverse effects of overseas custom-made dental devices were found in New Zealand.

INTERNATIONALLY HARMONISED REGULATORY STANDARDS

5.30 The ADPA highlighted to the Committee that it supports internationally harmonised regulatory standards as outlined in the ADIA Policy Priority four. The 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. 282
6 CONCLUSION

6.1 The Committee notes the apparent growth in the Australian market towards the sourcing and supply of dental appliances from overseas and notes that the trend appears to be global.

6.2 The Committee acknowledges concerns about the quality and safety of imported custom-made dental devices and notes that purchasing decisions may be a cost-driven shift. The Committee notes, however that custom-made devices are regulated under the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Medical Devices) Regulations 2002*.

6.3 The evidence presented to the Committee suggests that awareness of the regulatory requirements, particularly reporting requirements, is limited and as a result there is not reliable empirical data to support or dispute safety and quality concerns or to ascertain shifts in the dental devices market. The Committee supports increased education and awareness activities to improve regulatory the compliance of manufacturers, sponsors and dental practitioners.

6.4 The Committee believes that it is important for dental practitioners to know the manufacturing origin of the dental devices they are prescribing and supports increased patient awareness through the introduction of a statement of manufacture.

6.5 On the basis of current evidence the Committee does not believe that it is necessary to reinstate registration of dental technicians.

REVIEW OF THE REGULATION OF THERAPEUTIC GOODS

6.6 The Committee heard that a TGA expert panel will be conducting a review of the TGA’s regulation of therapeutic good, including medical devices. Stakeholder engagement sessions will be run by the panel which is due to report by 31 March 2015. 283

6.7 The Committee notes this is an opportunity for those seeking changes to the regulations for custom-made devices or other sections of the regulatory framework to get involved.

---

283 *Transcript of Evidence, 12 November 2014, p.16.*
ACKNOWLEDGEMENTS

6.8 The Committee would like to acknowledge and thank all individuals and key interest and stakeholder groups who made submissions to the Inquiry and appeared as witnesses at the public hearing for this inquiry.

Dr Chris Bourke MLA

Chair

5 March 2015
Appendix A  Submissions and QTONs

Submissions

<table>
<thead>
<tr>
<th>#</th>
<th>NAME/ORGANISATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr John Clark, Dentist</td>
</tr>
<tr>
<td>1b</td>
<td>Dr John Clark, Dentist</td>
</tr>
<tr>
<td>1c</td>
<td>Dr John Clark, Dentist</td>
</tr>
<tr>
<td>1d</td>
<td>Dr John Clark, Dentist</td>
</tr>
<tr>
<td>2</td>
<td>Mr Paul Hade, Dental Technician/laboratory owner</td>
</tr>
<tr>
<td>3</td>
<td>Australian Dental Industry Association</td>
</tr>
<tr>
<td>4</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>5</td>
<td>Australian Dental Prosthetists Association</td>
</tr>
<tr>
<td>5b</td>
<td>Australian Dental Prosthetists Association</td>
</tr>
<tr>
<td>6</td>
<td>Oral Health Professionals Association</td>
</tr>
<tr>
<td>6b</td>
<td>Oral Health Professionals Association</td>
</tr>
<tr>
<td>7</td>
<td>Dental Board of Australia</td>
</tr>
<tr>
<td>8</td>
<td>Australian Dental Association</td>
</tr>
</tbody>
</table>

Questions Taken on Notice

Some witnesses at the public hearing on 12 November 2014 chose to take questions from the Committee on notice in order to provide more detailed answers or confirm information.

Appendix B Conformity Assessment Procedures

There are several stages involved in the conformity assessment of a medical device: 284

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
<th>WHO IS RESPONSIBLE?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformity assessment procedures</td>
<td>• How a manufacturer demonstrates that they have met the Essential Principles for a particular medical devices</td>
<td>Manufacturer</td>
</tr>
<tr>
<td></td>
<td>• Manufacturers can choose the appropriate procedures to use, depending on the classification of the device</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involves assessment of the:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Technical documentation for the design of the devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Manufacturing processes used to make the devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Risk analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Clinical evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Ongoing monitoring and vigilance procedures that will be in place once the device is available for supply</td>
<td></td>
</tr>
<tr>
<td>Issuing conformity assessment evidence</td>
<td>Conformity assessment evidence is the certificate issued by a regulatory body to demonstrate a manufacturer has been assessed and has the appropriate systems in place to manufacture the devices. Assessment includes:</td>
<td>the TGA or an European Union (EU) Notified Body</td>
</tr>
<tr>
<td></td>
<td>• confirming that the conformity assessment procedures are appropriate for the classification of the device and have been applied correctly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• systematic examination of the</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation provided and procedures undertaken by the manufacturer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• may include an on-site audit of the manufacturing premises</td>
<td></td>
</tr>
<tr>
<td>• assessment processes will vary according to the conformity assessment procedures selected by the manufacturer</td>
<td></td>
</tr>
<tr>
<td>• re-certification of conformity assessment evidence that is due to expire</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Australian Declaration of Conformity (DoC)

Once the manufacturer has obtained conformity assessment evidence, they must make an Australian DoC.

The DoC declares that the device complies with:

- the applicable provisions of the Essential Principles
- the classification rules
- an appropriate conformity assessment procedure
- if requested, the TGA must be provided with a copy of the DoC
- the DoC must be maintained and updated when appropriate

| Manufacturer |  |

### Ongoing conformity assessment responsibilities

Maintain appropriate records, including:

- technical documentation
- evidence that an appropriate conformity assessment procedure has been applied

| Manufacturer |  |