Australian Dental Industry Association | ADIA

— Submission
Inquiry in the Therapeutic Goods Amendment Bills 2017

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products.

idm Association of International Dental Manufacturers MEMBER

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Australian Chamber of Commerce and Industry Member

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Content —

This submission is made with respect to the Senate Standing Committee on Community Affairs' inquiry into the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth).* It has been prepared following extensive engagement with the membership of the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of more than 95% of products used in Australian dentistry.

ADIA Reference: 11-11.18L – 8 January 2018

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Submission

Executive Summary

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Senate Standing Committee on Community Affairs' inquiry into the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth).*

These Bills make a number of amendments to the *Therapeutic Goods Act 1989 (Cth)* that allows the Therapeutic Goods Administration (TGA) to implement the commitments outlined in the Australian Government's response to the '*Expert review of medicines and medical devices regulation'* (MMDR). The Review identifies ways to improve access to therapeutic goods for consumers and respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

It is within this context that ADIA strongly supports the reforms in the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth*), hereafter simply referred to as "the Bills" for ease of reference.

Recommendations —

- The Bill should be passed by the parliament without amendment.
- The Senate Committee encourage the TGA make use of the strengthened monitoring and enforcement powers granted to it by the Bill.

Contained in the Bills are three key reforms which are of relevance to the dental industry in Australia. These include strengthening the TGA's powers to address illegal supply of therapeutic goods, designation of third-party conformity assessment bodies, and improved formal recognition of comparable overseas regulators.

ADIA is confident that the reforms contained therein represent a long-overdue positive step in improving Australia's regulatory framework for dental products so that public health and safety is secured while at the same time freeing industry from unnecessary regulatory burden.

ADIA looks forward to further engagement with the Committee concerning the legislation.

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8 January 2018

Section 1 Addressing illegal supply of therapeutic goods

Issue Summary:

Existing monitoring and punishment provisions in the *Therapeutic Goods Act 1989 (Cth)* do not allow the TGA to sufficiently address the illegal supply of therapeutic goods and the public is thereby exposed to unacceptable risk. As a result of the gaps in the TGA's statutory powers, the public is placed at harm, and these bills will fill these gaps. The provisions in the Bills that strengthen the TGA's ability to monitor and respond to instances of illegal supply will enable the TGA to better protect the public from illegal goods and more effectively deter non-compliance.

ADIA Advocacy Position:

- ADIA supports the amendments in the Bill as they will improve the TGA's ability to police the illegal supply of dental products in the Australian market.
- While the Bills will grant the TGA more powers to deal with illegal supply, these powers must be coupled with a commitment by the TGA to use them consistently to their full extent. Otherwise, non-compliance will not be appropriately deterred.

Detailed Analysis:

The *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth*) and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth)* together would amend existing legislation to strengthen the Therapeutic Goods Administration's (TGA) statutory powers to address the illegal supply of therapeutic goods in Australia. This will be achieved through a significant and necessary expansion of the TGA's enforcement and investigation powers. The result of these amendments is a strengthening of the product safety outcomes that are the policy objective of the regulatory framework for the supply of therapeutic goods in Australia.

Adoption of standard regulatory powers —

The Bills will amend the Act to include the provisions of the *Regulatory Powers (Standard Provisions) Act 2014 (Cth)* in relation to: monitoring; investigation; infringement notices; and injunctions. Furthermore, it is understood that there will be consequential amendments to the *Therapeutic Goods Regulations 1990 (Cth).*

While the dental industry supports the adoption of standard regulatory powers, it also supports necessary deviations. For example, to adequately enforce the Act, the TGA currently has powers for monitoring compliance and investigations that includes powers of entry, search and seizure of evidence, whether by consent or with warrant. This allows the TGA to take samples of any therapeutic goods on the premises or any 'thing' (with 'thing' defined in the Act) on the premises that relates to any therapeutic goods. Such provisions are not contained within *Regulatory Powers (Standard Provisions) Act 2014 (Cth)* provisions.

Accordingly, although the Act will be amended to adopt the *Regulatory Powers (Standard Provisions) Act 2014 (Cth)*, the Bills modify the standard monitoring powers to preserve the current power in the Act to allow authorised persons on reasonable grounds to enter any premises without warrant and seize therapeutic goods to avoid an imminent risk of death, serious illness or serious injury. This is supported by the dental industry.

Strengthening infringement notice provisions —

For a number of years ADIA has maintained that the provisions in the current regulatory framework for the approval of medical devices that address instances of illegal supply are largely unenforced and unenforceable.

Under the Act, infringement notices are restricted to use in relation to alleged breaches where strict liability applies or where the office is associated with a civil penalty. An infringement notice gives a person, to whom the notice is issued, the option of either paying the penalty set out in the notice to expiate the offence or contravention of a civil penalty provision, or electing to have the matter dealt with by a court.

The Australian Government has previously stated that the current arrangements associated with the issuance of an infringement notice are commensurate with the civil penalty provisions under the Act, the legal test being proof beyond reasonable doubt that the use of the therapeutic goods would be likely to result in harm or injury to a person.

Therefore, in circumstances where illegal supply can be proven but, by the nature of the medical devices supplied, no harm or injury to a person is likely the Act offers no effective deterrent to illegal supply. The TGA has therefore been powerless insofar as low-level infractions of the illegal supply provisions are concerned.

Similarly, instances where low level illegal supply can be proven action may not be taken as the cost to the TGA of being able to prove proof beyond reasonable doubt that the use of the therapeutic goods would be likely to result in harm or injury to a person.

It is there opinion of ADIA that these reforms will act to enhance confidence in the Australian market for medical devices, something achieved as a result of the TGA's ability to more effectively enforce the illegal supply provisions within the legislation.

ADIA therefore supports, without qualification, the provision in the Bills that would remove the requirement of likelihood of harm or injury to any person from each strict liability offence in the Act. This means that insofar as illegal supply is concerned, the offence would need only be proven to provide a trigger for an infringement notice to be issued. While is a significant improvement over the existing scheme which left many instances of illegal supply unaddressed, ADIA stresses the need for the TGA to act fairly, transparently and consistently. While the Bills will provide the TGA with broader statutory powers to issue infringement notices, the TGA must use these powers to penalise illegal supply and should not exercise discretion in in such instances. Requiring parties that have contravened the Act to undergo additional compliance training should therefore only be considered as an additional requirement in addition to a penalty rather than an alternative.

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Strengthening aggravated criminal offences —

ADIA is supportive of reforms that provide for graduated penalties that would allow the TGA to respond appropriately to the full range of non-compliance from repeated minor breaches through to serious non-compliance.

The bills include an additional circumstance of aggravation of likelihood of harm or injury to any person (removed from strict liability offences) to complement and strengthen current aggravating circumstances for top tier criminal offences throughout the Act, thereby capturing culpable activity or behaviour which has the potential to result in a public health risk. This approach is supported by ADIA.

Recommendation:

- This aspect of the Bill should be passed by the parliament without amendment.

Section 2 Designation of third-party conformity assessment bodies

Issue Summary:

Existing monitoring and punishment provisions in the *Therapeutic Goods Act 1989 (Cth)* do not allow the TGA to sufficiently address the illegal supply of therapeutic goods and the public is thereby exposed to unacceptable risk. The provisions in the Bills that strengthen the TGA's ability to monitor and respond to instances of illegal supply will enable the TGA to better protect the public from illegal goods and more effectively deter non-compliance.

ADIA Advocacy Position:

- ADIA supports the amendments in the Bills to allow the TGA to designate third-party conformity assessment bodies as doing so will create efficient competitive conformity assessment pathways that will lower assessment costs and times.
- In developing the criteria for third-party conformity assessment body designation, the TGA must consult with industry and prospective third-party conformity assessment bodies. The TGA should proactively engage the latter.

Detailed Analysis:

Under the current arrangements in the *Therapeutic Goods Act 1989 (Cth)* mean conformity assessments can only be conducted by the Therapeutic Goods Administration (TGA). The Bills would amend the Act to provide the TGA with the power to designate a body or bodies located in Australia to undertake conformity assessments of medical devices for the Australian market. Such bodies would need to meet specific criteria established by the TGA following consultation with patient groups and industry as well as undergo ongoing compliance monitoring. The TGA would also retain the ability and capacity to

There are multiple benefits associated with this amendment for patients, healthcare professionals, and industry. The presence of multiple third-party conformity assessment bodies would create competition in the delivery of prompt and high-quality product assessments in Australia and reduce the cost of assessment. These reduced compliance costs will reduce cost inputs in the supply of medical devices by the dental industry and as a result, patients will have access to more affordable oral healthcare. Likewise, patients, dental healthcare professionals, and industry alike will benefit from a more efficient product approval framework for medical devices that will broaden the range of medical devices, and therefore clinical options, that are available in Australia.

ADIA is of the opinion that, over time, this reform will provide a pathway for the dental industry, and medical devices sector more broadly, to introduce new and innovative patient diagnostic and patient treatment options more quickly and cheaply than would otherwise be the case.

As the Commonwealth does not provide significant funding to oral healthcare, compared to that which it provides to other healthcare sectors, the ability to rationalise and reduce the costs of product assessment and certification is an important mechanism by which it can improve oral healthcare affordability for Australians.

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Delegated Legislation Making —

The reform provides considerable delegated decision making that will allow the creation of regulations associated with this provision of the *Therapeutic Goods Act 1989 (Cth)* when amended. ADIA believes that this is necessary in order to provide a regulatory framework for the creation and ongoing operation of third-party conformity assessment bodies that is responsive and able to adapt as required.

In the Australian context, credentialing by the TGA of new third-party conformity assessment bodies is a new aspect to Australia's medical device regulatory framework. The ability to create and amend the legal obligations of third party conformity assessment bodies, via regulation which can typically be introduced more quickly than via an Act of Parliament, is thought to be desirable.

Recommendation:

- This aspect of the Bills should be passed by the parliament without amendment.

Section 3 Recognition of comparable overseas regulators

Issue Summary:

Existing monitoring and punishment provisions in the *Therapeutic Goods Act 1989 (Cth) do* not allow the TGA to sufficiently address the illegal supply of therapeutic goods and the public is thereby exposed to unacceptable risk. The provisions in the Bills that strengthen the TGA's ability to monitor and respond to instances of illegal supply will enable the TGA to better protect the public from illegal goods and more effectively deter non-compliance.

ADIA Advocacy Position:

- ADIA supports the amendments in the Bill to recognise comparable overseas regulators.
- These provisions in the Bills will cut the unnecessary red tape that Australian suppliers are subjected to by needing to have their goods approved in multiple comparable jurisdictions and reduce healthcare costs and improve access to quality therapeutic goods while ensuring public safety.

Detailed Analysis:

The *Therapeutic Goods Act 1989 (Cth)* in its current form already allows for the use of work of comparable overseas regulators in evaluating the safety and efficacy of medicines. Likewise, the Act in its current form also allows for the TGA to utilise the work of comparable overseas regulators in evaluating medical devices, however to a limited extent compared to that of medicines.

The Bills will allow for the TGA to identify appropriate designating authorise responsible in jurisdictions (primarily in the European Union (EU)) that are comparable to its own standards that are applied to the conduct of conformity assessments and have effective systems and process in place to ensure that these standards are upheld by 'notified' bodies that undertake assessments. Conformity assessments produced by these designated authorities that have met appropriate criteria (such as technical competence, quality management systems, track record, and transparency) could then be accepted by the TGA.

ADIA supports these amendments which would product assessments conducted by overseas comparable regulators recognised by the TGA. This would remove the need for onerous and costly duplication of conformity assessments and reduce delays in supplying safe and effective products in the market. Dental patients would therefore benefit from increased access to safe and effective treatment as well as reduced healthcare costs. The TGA's identification of overseas designated authorities based on strict criteria will ensure that that these assessments are conducted to an appropriate standard comparable to that of the TGA's own assessments and thereby maintain public safety.

Recommendation:

- This aspect of the Bill should be passed by the parliament without amendment.

Introduction Australian Dental Industry Association

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of ninety-five percent of the products used in Australian dentistry. The ADIA membership ranges in size from the local operations of multi-billion dollar corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. To this end, ADIA is a strong advocate for reforms that cut red-tape and allow businesses in the dental industry to grow, create jobs and operate sustainably.

Australia's largest healthcare trade show, *ADX* Sydney, is convened biennially by ADIA and attracts nearly ten thousand stakeholders from across the Asia-Pacific's dental and oral healthcare community. ADIA also convenes regional trade shows in Adelaide, Brisbane, Melbourne and Perth that provide a platform for the growth of member businesses.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports skills development across the dental industry. An pioneering partnership with MEGT sees the group training model used to employ apprentices and trainees across the industry and the *CSU – ADIA Graduate Certificate in Small Business Management* provides support for mid-career professionals.

Consistent with ADIA's role as the peak body for manufacturers and suppliers, ADIA is a member of the Australian Chamber of Commerce & Industry (AusChamber), the nation's foremost grouping of employer organisations. Amongst other affiliations is ADIA's membership of the association of International Dental Manufacturers (IDM), the Swiss-based global body for the dental industry.

In 2017 ADIA was named 'Association of the Year' by Associations Forum, a body committed to assisting associations and charities in governance, operations, membership and finances.

The ADIA national office is based in Sydney and the Association is active in all mainland states.
More information can be found online at:

www.adia.org.au

Abbreviations —

ADIA	Australian Dental Industry Association
ARTG	Australian Register of Therapeutic Goods
IDM	(Association of) International Dental Manufacturers
TGA	Therapeutic Goods Administration

ADIA MEMBER BUSINESSES

3M Oral Care A. R. Medicom Acteon Australia/New Zealand A-dec Australia ADR Dental AHP Dental & Medical Ainsworth Dental Airport Function Centre AJ Barber Alldent Alphabond Dental Amalgadent Dental Supplies Ampac Dental Andent Anthos in Australia ANZ Banking Group Ark Health Auspharm Australasian Dental Practice Australasian Dentist Australian College of Dental Education Australian Imaging Australian Medical Suction Systems Babich Maintenance and Steriliser Services Bambach Saddle Seat Biodegree Bite Magazine Body Logic Resources BOQ Specialist Borg Dental Bourke Dental Supply Carestream Dental Carl Zeiss Cassin & Sons Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates CMA Ecocycle Colgate Oral Care Coltene-Whaledent International Commodore Joinery Critical Dental Curaden Swiss Data Vision Australia Dentacast Australia Dental Axess Dental Business Brokers Dental Concepts Dental Depot (QLD) Dental Fitout Projects Dental Innovations Dental Installations Dentalife Dentaurum Australia Dentavision Dentequip Dentplex Dentpro Dentsply Sirona Designer Surgeries Designs for Vision DPL Australia Dunedin Dental Attachments Durodent Dental Supplies DURR DENTAL AG East Coast Dental Services ECOVIS Clark Jacobs Elite Fitout Solutions Empire Dental Devices EMS Erskine Dental First Dental GC Australasia Dental Geistlich Pharma Australia Glamsmile GlaxoSmithKline Gritter Dental Gulmohar Dental Gunz Dental Hayes Handpiece Australia Heine Australia Henry Schein Halas Heraeus Kulzer Australia HICAPS Hogies Australia Horseley Dental Supplies Hu-Friedy Mfg Co. Inc. Impulsedent Australia Independent Dental Supplies Inline Medical & Dental Ivoclar Vivadent Johnson and Johnson Pacific Kavo Kerr Leading Dental Levitch Design Australia Lorchant Dental Macono Orthodontic Laboratories Marda Investments McLaren Dental Med & Dent (WA) Medfin Australia Medical Dental Solutions NQ Medical Equipment Services Medi-Dent Medifit MediGrow Melbourne Dental Miniflam Australia Minimax Implant (Dentium Australia) Mocom Australia Momentum Management Myofunctional Research Co. NAOL Australia Neoss Australia Nobel Biocare NOVA iT Group NSK Oceania Odontex Dental Labs One Dental Optima Healthcare Group Orien Dental Supplies Osseo Dental Osstem Australia Osteon Medical Ozdent Dental Products Australia Pacific Dental Specialties Pegasus Dental Services Philips Oral Healthcare Practice Sale Search Praktika Presidental Prime Practice Professional Dentist Supplies Profile Financial Services Purus Health and Medical Technologies RCR International Ridley Dental Supplies Right Time Business RJ Dental Sales & Service Roland DG Australia RutiniDent Dental Supplies SDI Ltd Sieverts Radiation Protection Consultancy Smile Marketing Software of Excellence South Austral Southern Implants Australia Stoneglass Industries Straumann Supreme Orthodontic Supply (Aust) Surgery Plus Solutions Surgical Images TrollDental Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Urban IT VOCO Australia W&H Wellsites West Coast Dental Depot Westpac Whiteley Corporation William Green Wisbey Dental Xcellent Dental World XYZ Dental Zimmer Biomet

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