



— Submission
Therapeutic Goods Exposure Drafts Consultation

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

It addresses proposed reforms on the exposure draft Bills amending the
Therapeutic Goods Act 1989 and the *Therapeutics Goods (Charges) Act 1989*

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Content —

This submission provides commentary on the consultation draft of the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* published by the Therapeutic Goods Administration (TGA). 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.

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Executive Summary —

Over the course of the past decade the Australian Dental Industry Association (ADIA) has been a strong advocate for amendments to the *Therapeutic Goods Act (Cth) 1989*, hereafter simply referred to as "the Act" for ease of reference, in order to provide the Therapeutic Goods Administration (TGA) with a range of tools to more effectively enforce its legislation. In this context, ADIA is supportive of the overall direction of the proposed bill.

Having consulted with its membership and the broader dental community, ADIA takes this opportunity to offer the following observations with respect the proposed amendments to sanctions and penalties in the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017*.

Strengthening Aggravated Criminal Offences —

ADIA supports amendments to the Act to 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.

Transparency in infringement notice supply —

ADIA supports amendments to the Act to remove the requirement for strict liability offences when the prohibited action would be likely to result in harm or injury. ADIA contends that it is inappropriate that the TGA have any discretion not to issue an infringement notice in circumstances where illegal supply of medical devices can be proven; however, should the TGA continue to have the discretion whether or not to issue an infringement in cases where illegal supply can be demonstrated, it must exercise this discretion in the context of clearly defined and published guidelines. It must also ensure that there is transparency in actions that are taken in lieu of an infringement notice being issued.

Examples to better assess the impact of legislative reform —

ADIA has outlined a number of scenarios where it seeks the TGA's view as to how it would respond given the proposed changes. This will enable ADIA, and the broader medical devices sector, to better assess the impact of the proposed legislative reforms and provide valuable feedback to the TGA. ADIA regrets that TGA neglected to address these scenarios in its enforcement consultation despite requests to do so in the early stages of consultation; however, it has a second opportunity to do so in response in this round of consultation.

As to the matter of process, it is noted that the period between the release of the exposure draft and the closing date for comments was less than one week, and also less than one day after the TGA conducted stakeholder consultations on the proposed legislation. ADIA values the opportunity to engage with the TGA on this matter but the consultation timeframes are insufficient to fully consider the impact of the proposed legislation.

Section 1 – Strengthening Existing 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 draft exposure bill includes 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 including include this culpable activity or behaviour which has the potential to result in a public health risk.

ADIA supports the amendment to 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.

Section 2 – Transparency In Infringement Notice Application

In managing its compliance and enforcement decisions the TGA needs to act fairly, transparently and consistently. ADIA submits that this is particularly important insofar as illegal supply is concerned.

ADIA in its submission to the consultation paper entitled *TGA - enhancing sanctions and penalties in the Therapeutic Goods Act 1989* (released 3 May 2017) brought to the TGA's attention the high degree of concern as to the level of discretion that the TGA may exercise when dealing with instances of illegal supply. This is based upon the following statement in the TGA's consultation document that states:

In deciding how to deal with a non-compliance matter, we first consider education, guidance material or additional training for those who show a willingness to comply with the regulatory scheme.

The consultation paper then states that in deciding how to deal with a non-compliance matter, the TGA will first consider education, guidance material or additional training for those who show a willingness to comply with the regulatory scheme. This suggests that in instances where illegal supply can be proven, the TGA still may fail to take enforcement action. In response, ADIA submitted that it is inappropriate for the TGA to exercise discretion in instances where illegal supply can be demonstrated. Put simply, if illegal supply can be proven a penalty should apply. ADIA maintains this view.

Should the TGA continue to have the discretion whether or not to issue an infringement in cases where illegal supply can be demonstrated, it must exercise this discretion in the context of clearly defined and published guidelines.

Between its consultation with industry and the release of the exposure draft bill for public comment, the TGA has not addressed this concern.

While ADIA acknowledges that the bill is designed to provide the TGA with the tools and mechanisms necessary to enforce compliance it is not sufficient for the TGA to wait until the bill is legislated before providing clear guidance as to how it intends to use the powers that the bill grants.

ADIA has been consistent in its position that the TGA should not forgo the issuing of an infringement notice in favour of a warning, education requirement, or other measure in circumstances where illegal supply of medical devices can be proven. However, if the TGA is to exercise this kind of discretion it must at a minimum produce and make publicly available clear guidelines and principles that will inform its decision.

Likewise, if the TGA is to utilise another mechanism to punish non-compliance instead of an infringement notice it must ensure that the public be notified. This is not only a matter of sound transparency but will also serve to strengthen the action insofar as it acts as a disincentive to not comply to regulations. The TGA may wish to refer to the Australian Securities & Investments Commission's (ASIC) public warning notice listing on its website as an example of transparent enforcement.

Section 3 – Examples To Better Assess The Impact Of Legislative Reform

In consulting with the ADIA membership and the broader dental community, what became apparent was a strong interest in how the proposed amendments to the Act are likely to affect the TGA's regulatory enforcement and compliance activities insofar as illegal supply is concerned. This is best addressed by the TGA providing guidance on what it believes the outcomes of the reform will be.

As part of the TGA's ongoing engagement with ADIA on this series of reforms, ADIA in its submission to the TGA consultation on Regulatory Enforcement Reform, outlined a number of scenarios where it sought the TGA's view as to how it would respond given the proposed changes.

As the TGA failed to provide guidance with respect to these examples during its reform consultation in May 2017, ADIA would appreciate it if the TGA could take this second opportunity to outline what it believes its response would be.

Example A1 – Class I Importation & Use By A Healthcare Professional

A healthcare professional buys dental instruments (Class I medical device) either online from an overseas store or buys them at an overseas trade show. These dental instruments are then used on patients in the general community (*i.e.* the personal importation provisions do not apply).

Example B1 – Class 2A Importation & Use By A Healthcare Professional

A healthcare professional buys tooth restorative materials (Class 2A medical device) either online from an overseas store or buys them at an overseas trade show. These materials are then used on patients in the general community (*i.e.* the personal importation provisions do not apply).

Example C1 – Class 2B Importation & Use By A Healthcare Professional

A healthcare professional buys an autoclave / steriliser (Class 2B medical device) either online from an overseas store. This autoclave / steriliser is then put into use in the healthcare professionals practice.

Example A2 – Class I Importation & Sale By An Incorporated Business

A business imports from overseas dental instruments (Class I medical device). These dental instruments are then supplied to a healthcare professional.

Example B2 – Class 2A Importation & Sale By An Incorporated Business

A business imports from overseas tooth restorative materials (Class 2A medical device). These materials are then supplied to a healthcare professional.

Example C2 – Class 2B Importation & Sale By A Healthcare Professional

A business imports from overseas an autoclave / steriliser (Class 2B medical device). This autoclave / steriliser is then supplied to a healthcare professional.

.../cont.

For the purposes of providing a response it is assumed that the Sponsor (*i.e.* the individual / business supplying the product) has not arranged the appropriate entry on the Australian Register of Therapeutic Goods (ARTG). The TGA's response to each of these scenarios will allow the dental industry to fully appreciate the extent to which the bill will address the dental industry's concerns with the illegal supply of medical devices.

If the TGA's intended approach is to use infringement notices infrequently, perhaps as a tool of last resort, the legislation can be reasonably said to have failed in achieving its intended outcome. Within the community there is the perception that the TGA's legislation, insofar as illegal supply of medical devices is concerned, is both unenforced and unenforceable, the infrequent use of infringement notices will do nothing to address this outcome.

ADIA An Introduction —

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 national body dedicated to supporting not-for-profit organisations on matters of governance, financial sustainability, policy advocacy and member engagement.

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
ASIC	Australian Securities & Investments Commission
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 Presidential 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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