



— Submission Regulatory changes to personalised devices

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 regulatory changes related to personalised
and 3D printed medical devices.

Content —

This submission reviews the proposed regulatory changes related to personalised and 3D printed medical devices issued 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

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 Therapeutic Goods Administration's (TGA) consultation for proposed regulatory changes related to personalised and 3D printed medical devices.

ADIA is a strong supporter for regulatory framework for dental products, and medical devices more broadly, that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden.

The TGA has proposed reforms to the current medical device regulatory framework in Australia to respond to changes in the manufacture of personalised medical devices that are being enabled by new technological advances including '3D printing'. ADIA is entirely supportive of reform in this area, recognising the limitations of the current medical device framework. ADIA's intent is to support the TGA in the development of a new regulatory framework that provides the appropriate degree of patient safety in a way that does not impede the development and uptake of new emerging technology nor impose on business unnecessary regulatory compliance burden.

ADIA takes this opportunity to address the TGA's proposals as well as raise issues that require further refinement and consideration by the TGA. Broadly speaking, it is the view of the dental industry that the TGA is headed in the right direction, insofar as its proposals seek to address the limitations of the current framework. ADIA will therefore continue to work collaboratively with the TGA as it seeks to undertake regulatory reform in this area.

Based on advice received from its member organisations, ADIA tenders the following recommendations with respect to the TGA's proposed changes to the medical device regulatory framework.

Recommendations —

1. The proposed definitions should be clarified to remove overlapping features and the should be used in a regulatory framework based on risk-classifications so as to avoid impose an unnecessary, or an unintended, regulatory compliance burden on business.
2. The proposed definition of a 'personalised medical device' should be adopted.
3. Given the lack of a definition of 'runs or batches' there is a lack of clarity with respect to what would be captured in the proposed definition of 'mass-produced medical devices.' Further consultation on this is therefore required.
4. The TGA should revise its proposed definition of 'medical device production systems' so as to enable a degree of interoperability between the devices of different manufacturers.
5. The TGA should increase the minimum retention period for documentation held by custom-made medical device manufacturers.
6. The TGA should have the power to enter and inspect the facilities of custom-made medical device manufacturers.

7. The proposal to require manufacturers to provide documentation to patients for all medical devices should be limited to devices with a risk classification of Class IIa and only in a way that integrates this into a patient's *MyHealth* record. If necessary, this requirement should be held in abeyance until the *MyHealth* record infrastructure can accommodate this.
8. The TGA should provide further details with respect to the proposed annual reporting requirements for custom made medical device manufacturers so that ADIA is advise the TGA as to its potential costs and benefits.
9. The TGA should clarify whether the producer of dental crowns and bridges using ARTG-listed materials would considered a manufacturer under the new definition.
10. The TGA should clarify how it intends to define healthcare professionals and hospitals with respect to the manufacturer exclusion.
11. While the TGA should classify devices used to capture digital image files as Class IIa medical devices, the classification of image files themselves should remain unchanged.
12. Anatomical models produced using digital image files should not be classified as Class IIa medical devices so long as they are produced using a medical device production system that is on the ARTG (see Section 2 for further recommendations regarding this)
13. The TGA should adopt its proposal for 3D printed devices containing materials of human origin to be regulated as Class III medical devices within the medical devices regulatory framework.

From a regulatory perspective, and in the context of undertaking conformity assessment of medical devices, there is little to differentiate medical devices that are manufactured using additive manufacturing processes (e.g. 3D printing) from subtractive manufacturing processes (e.g. milling). For this reason ADIA is of the strong opinion that regulatory reform in this area should be agnostic as to the technology that's being used.

Many of the issues associated with reform in this area hinge on the definitions that are used and how these may be interpreted by different stakeholders. ADIA strongly recommends that the amendments to the *Therapeutic Goods Medical Devices Regulations 2002 (Cth)* be issued as an exposure draft, and subjected to lengthy industry consultation, before they be presented to the Minister for consideration.

It is understood that this is a complex area, one that seeks to ensure that today's regulatory framework supports the development of an emerging technology, this being 3D printing, for which the application and manufacturing processes are a continually evolving dynamic. ADIA, as the representative of a sector that is a proven early-adopter of this technology, looks forward to further engagement with the TGA on this matter.

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Section 1

New definitions for personalised devices

Issue Summary —

While the dental industry supports the overall direction of the TGA's proposals for reform, further development of the proposed definitions is required. In creating new definitions to support the personalised medical device regulatory framework, the TGA should ensure that a framework is developed that is readily understood by manufacturers, healthcare professionals and patients.

Recommendation/s:

1. The proposed definitions should be clarified to remove overlapping features and the should be used in a regulatory framework based on risk-classifications so as to avoid impose an unnecessary, or an unintended, regulatory compliance burden on business.
2. The proposed definition of a 'personalised medical device' should be adopted.
3. Given the lack of a definition of 'runs or batches' there is a lack of clarity with respect to what would be captured in the proposed definition of 'mass-produced medical devices.' Further consultation on this is therefore required.
4. The TGA should revise its proposed definition of 'medical device production systems' so as to enable a degree of interoperability between the devices of different manufacturers.

Detailed Analysis:

Taken as a whole, ADIA is confident that the TGA is heading in the right direction with respect to its proposed changes to definitions and other regulations in the context of personalised and 3D printed medical devices. While the proposals require further development by the TGA, ADIA understands that the TGA views these proposals as the beginning of a process through which improvements to the regulatory framework will be developed in consultation with industry. It is in this context that ADIA offers the following advice and requests for further clarification with respect to the TGA's proposals.

ADIA recognises the need for the TGA to create new definitions for personalised devices to ensure that the regulatory framework contains the appropriate vocabulary required to administer the regulation of personalised medical devices. However, in some cases the impact of the proposed definitions on the classification of dental crowns, bridges, surgical guides – products that feature prominently in the current roll-out of 3D printed medical devices – and medical devices that often feature a degree of personalisation is not entirely clear.

Given the proposed definitions of 'custom made medical devices', 'customised medical devices' and 'patient-specific medical devices', it is unclear how the manufacturers of dental crowns and bridges will be defined. This is because there appears to be a degree of overlap between these definitions.

The dental industry supports the development of new definitions insofar as they do not result in the imposition of unnecessary regulatory burden on manufacturers of dental crowns, bridges and related medical devices as they would not be viewed as "manufacturers" in the context of the *Therapeutic Goods Act 1989 (Cth)* and subordinate regulations. This is consistent with the approach taken in the regulations which have framed these definitions within the context of a risk-based approach to regulation.

ADIA, like the TGA, is of the view that low to medium risk medical devices such as dental crowns and bridges produced for an individual patient should not require the same regulatory oversight as high-risk medical devices. In this context it is understood that there is agreement between the dental industry and TGA that a risk classification of the medical device should determine the degree of regulatory oversight, as is the case in mass-produced medical device.

Following industry consultation, the following views are offered with respect the proposed definitions:

Personalised medical device

ADIA supports the proposed definition of a 'personalised medical device' as 'a device indented for a particular patient which could be a custom made, customised, or patient specific medical device.'

Mass-produced medical devices

ADIA supports in principle the creation of an additional definition of 'mass-produced medical devices'. However, depending on the TGA's definition of production 'runs or batches', manufacturers of dental crowns and bridges may be subject to unintended regulatory burden. For example, multiple dental crowns created for different patients may be sintered in a furnace together for efficiency. ADIA therefore requests that the TGA provide further clarification with respect to what activity it intends to capture in this definition.

Medical device production system

While ADIA supports the development of a definition of 'medical device production systems' an initial assessment of the TGA's initial approach that recognises a 'system' from design to production from a single manufacturer is problematic for a number of reasons.

In practical terms, the majority of equipment systems used in the dental industry including digital scanners, software, and an additive or subtractive manufacturing machine, consist of component devices from two or more different manufacturers. This is possible given the high degree of interoperability between devices facilitated by common industry software protocols and standards.

The TGA's proposal to limit its definition of 'medical device production system' to those systems comprising only of devices from a single manufacturer would therefore exclude the majority of equipment systems.

Further, if the TGA sought to lock in industry to a vendor-restricted model (i.e. a system where manufacturing inputs, design software and production equipment could only be used from a single supplier) may be inconsistent with the provisions of the *Competition and Consumer Act 2010 (Cth)* insofar as it was limiting the operation of equipment from different manufacturers that was designed to have a high degree of interoperability. Further, the TGA's current proposal may have the unintended

consequence of making it effectively impossible for a manufacturer that produces one type of device exclusively (i.e. a furnace) to sell their product as it would not form part of a self-contained 'system'. This is not to say that ADIA is not supportive of the TGA's approach in this area; however, it is an issue that merits review.

In the interest of competition and an open marketplace, ADIA's preference is for a high degree of interoperability so long as the essential principles can be achieved. Rather than prescribe specific collections of devices that together are classified as a system, the TGA should instead require that the manufacturers of these devices provide information with respect to their interoperability. Therefore, a 'medical device production system' may be appropriately designated if each individual device is listed on the ARTG and manufacturers' interoperability guidelines are followed.

As stated earlier, as there is little to differentiate medical devices that are manufactured using additive manufacturing processes (e.g. 3D printing) from subtractive manufacturing processes (e.g. milling) regulatory reform in this area should be agnostic as to the technology that's being used.

Given that many of the issues associated with reform in this area hinge on the definitions that are used and how these may be interpreted by different stakeholders. ADIA strongly recommends that the amendments to the *Therapeutic Goods Medical Devices Regulations 2002 (Cth)* be issued as an exposure draft, and subjected to lengthy industry consultation, before they be presented to the Minister for consideration.

Section 2

Changes to custom made conformity assessment procedure

Issue Summary —

The TGA has proposed changing the conformity assessment procedure for custom made devices to add additional requirements to strengthen its regulatory oversight over the production of these devices. ADIA supports some of these requirements as they would improve the regulatory framework without imposing unnecessary burden on industry. However, other proposals require further refinement from the TGA before ADIA can be in a position to lend its support.

Recommendation/s:

5. The TGA should increase the minimum retention period for documentation held by custom-made medical device manufacturers.
6. The TGA should have the power to enter and inspect the facilities of custom-made medical device manufacturers.
7. The proposal to require manufacturers to provide documentation to patients for all medical devices should be limited to devices with a risk classification of Class IIa and only in a way that integrates this into a patient's *MyHealth* record. If necessary, this requirement should be held in abeyance until the *MyHealth* record infrastructure can accommodate this.
8. The TGA should provide further details with respect to the proposed annual reporting requirements for custom made medical device manufacturers so that ADIA is advise the TGA as to its potential costs and benefits.

Detailed Analysis:

The TGA has proposed changing the conformity assessment procedure for custom made devices to add additional requirements to strengthen its regulatory oversight over the production of these devices. The TGA proposes to require:

- *that the manufacturer's statement about a custom made device is provided to the patient receiving the device. This is the current requirement in Europe.*
- *that the TGA be allowed to enter and inspect custom made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers.*
- *a manufacturer in Australia or sponsor of custom made devices to provide an annual report to the TGA of the custom made devices it has supplied.*
- *documentation about an implantable custom made device to be maintained for a minimum period of 15 years, the current specification of a 5 year retention period is inadequate.*

Proposed regulatory changes related to personalised and 3D printed medical devices
Therapeutic Goods Administration, 2017

ADIA supports in principle the proposal to increase the minimum retention period of documentation from five years to fifteen years and the provision of the power to the TGA to enter and inspect custom made device manufacturing sites. These two proposals would serve to strengthen the regulatory framework for custom made medical devices without imposing on business significant regulatory burden.

.../cont.

However, the proposal to require manufacturer's statements about custom made devices to be provided to patients should be reconsidered in the context of the TGA's risk-based regulatory approach, and in the context of the *MyHealth* recognition of the Australian Government. Imposing this requirement for all medical devices irrespective of risk would amount to a significant imposition of regulatory red tape on business. Rather, the TGA should instead consider limiting this requirement to Class IIa medical devices and above, and only in a way that such records can be integrated within a patient's *MyHealth* record. This approach will ensure that the proposal is more reflective of a risk-based approach. ADIA supports harmonisation of regulatory requirements with those of overseas jurisdictions only on the condition that they are considered within the Australian context in accordance with Australian regulatory standards and principles.

Further, the TGA would need to provide further information with respect to nature of the annual report that it is proposing requiring custom made medical device manufacturers to provide. ADIA is unable to support the requirement without a sound understanding of the regulatory burden that this requirement would place on dental suppliers who produce custom made medical devices.

Section 3

Changes to the definition of manufacturer

Issue Summary —

The TGA has proposed changes to the definition of manufacturer to clarify which entities would hold responsibilities of manufacturers. ADIA supports these changes in principle; however, further clarification is required so as to ascertain the precise outcomes on business.

Recommendation/s:

9. The TGA should clarify whether the producer of dental crowns and bridges using ARTG-listed materials would be considered a manufacturer under the new definition.
10. The TGA should clarify how it intends to define healthcare professionals and hospitals with respect to the manufacturer exclusion.

Detailed Analysis:

It is understood that the TGA proposes to amend the existing definition of a 'manufacturer' of a medical device to add further a further clarification to the provision that excludes from the definition of a manufacturer a person who assembles or adapts an ARTG-listed device or material for a specific patient. The proposed amendment would specify the following:

The assembly or adaptation must be in accordance with validated instructions provided by the manufacturer of the device to be adapted; and that, if an individual modifies a device already placed on the market or put into service in such a way that compliance with the essential principles may be affected, they shall assume the obligations incumbent on manufacturers.

Proposed regulatory changes related to personalised and 3D printed medical devices
Therapeutic Goods Administration, 2017

At face value, this proposal is not objectionable insofar as it is understood to mean that a producer of dental crowns, bridges and other prostheses would not be considered a manufacturer so long as they used ARTG-listed materials according to manufacturer instructions.

ADIA supports the TGA's proposal to add a new exclusion from the definition of manufacturer that would apply to healthcare professionals and hospitals that use ARTG-listed 'medical device production systems' to produce devices of risk classification Class IIa and lower for use in treating their own patients.

However, as previously stated, the TGA should consider in this context ADIA's recommendation that the definition of 'medical device production systems' should allow for the use of devices (*i.e.* design and manufacturing components) from different manufacturers so long as their interoperability is specified by the manufacturers. Further, given that the medical devices regulatory framework does not define or distinguish between persons other than sponsors and manufacturers, it is unclear how the TGA intends to exclude healthcare professionals and hospitals – as is understood to be the intended outcome – from the requirement.

Section 4

New classification for anatomical models and digital 3D print files

Issue Summary —

The TGA has proposed expanding the special classification rule that currently assigns Class IIa classification to X-ray diagnostic imaging devices to include anatomical models and devices that capture digital images. ADIA supports this proposal so long as exemptions related to medical device production systems are appropriately broadened.

Recommendation/s:

11. While the TGA should classify devices used to capture digital image files as Class IIa medical devices, the classification of image files themselves should remain unchanged.
12. Anatomical models produced using digital image files should not be classified as Class IIa medical devices so long as they are produced using a medical device production system that is on the ARTG (see Section 2 for further recommendations regarding this)

Detailed Analysis:

The TGA's intent with respect to its proposal to change the classification rules relating to anatomical models and diagnostic images, insofar as it is explained in the consultation paper, is somewhat unclear.

The proposal appears to refer to software used to create digital 3D print files, the digital image files, and the anatomical models produced by them somewhat interchangeably.

Below is the current formulation of the classification rule that the TGA has proposed the change;

5.4 Non-active medical devices intended to record X-ray diagnostic images.

A non-active medical device that is intended by the manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

Rule 5.4 of Schedule 2
Therapeutic Goods (Medical Devices) Regulations 2002

The TGA has proposed to amend this rule to the following;

5.4 Medical devices intended to record diagnostic images

A medical device that is intended by the manufacturer to be used to record diagnostic images is classified as Class IIa. This includes software and anatomical models intended for diagnosis or investigation of the anatomy.

Rule 5.4 of Schedule 2
Therapeutic Goods (Medical Devices) Regulations 2002

The proposal, insofar as it is understood based on the wording above, appears to be that software that records diagnostic images (including for use of additive or subtractive manufacturing processes) and the anatomical models that may be produced using these images should be classified as Class IIa as they are similar in risk profile to devices used to record X-ray diagnostic images.

.../cont.

Insofar as the proposal is understood to be the above, ADIA does not fully support this proposal. While ADIA supports the proposal that software used to capture or record a digital image would be classified as a Class IIa medical device, anatomical models that are produced using these files should not be up-classified. Anatomical models used for diagnosis, and for that matter 3D print image files, are more comparable to x-ray diagnostic images themselves and not the devices that capture them.

In this context, ADIA recommends that manufactures devices used to capture diagnostic images, whether they be x-ray based or not, be subject to the requirement to hold appropriate conformity evidence for a Class IIa medical device. Subsequently, the images that are produced using such equipment should not be classified as Class IIa devices. Further, if a digital image file is captured using an medical device production system that is included in the ARTG, anatomical models produced therefrom should not be classified as Class IIa medical devices.

As noted earlier, the definition for a 'medical device production system' should allow for the use of devices from different manufacturers so long as their interoperability is specified by the manufacturers in their ARTG entry.

Section 5

New arrangements for devices with human material

Issue Summary —

The TGA has proposed changing the regulatory framework under which 3D printed devices containing materials of human origin are regulated. ADIA supports changes to the classification of these devices in a manner that consistent with the approach of comparative overseas jurisdictions as it would allow for the possibility of abridged assessments.

Recommendation/s:

13. The TGA should adopt its proposal for 3D printed devices containing materials of human origin to be regulated as Class III medical devices within the medical devices regulatory framework.

Detailed Analysis:

The TGA in its discussion paper has proposed that 3D printed devices that contain materials of human origin, that are currently regulated under the biological regulatory framework, are instead classified as Class III medical devices and therefore assessed according to the medical devices regulatory framework. ADIA acknowledges that is consistent with the approach taken in comparative overseas jurisdictions and would therefore allow for the possibility of abridged assessment. ADIA therefore supports this proposal.

Appendix A

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.

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

Appendix B

Abbreviations used in this submission

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

■ ADIA MEMBER BUSINESSES ■

3M Oral Care 3Shape Australia A. R. Medicom Acteon Australia/New Zealand A-dec Australia ADR Dental AHP Dental & Medical Ainsworth Dental AJ Barber Ajax Dental Supplies Alldent Alphabond Dental Amalgadent Dental Supplies Ampac Dental Andent Anthos in Australia ANZ Banking Group Ark Health Auspharm Australasian Dentist Australian Imaging Australian Medical Suction Systems Babich Maintenance and Steriliser Services Biodegree Biomedex Bite Magazine 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 Dental and Medical Fitouts Core 3d Centres Create Dental Critical Dental Curaden Swiss Data Vision Australia Dentacast Australia Dental Axxess Dental Business Brokers Dental Concepts Dental Depot (QLD) Dental Education Centre Dental Fitout Projects Dental Innovations Dental Installations Dental Premium Engineering and Supplies Dental Protection Dental Wear Dentalife Dentaforum Australia Dentavision Dentequip Dentplex Dentpro Dentsply Sirona Designer Surgeries Designs for Vision Dunedin Dental Attachments Durodent Dental Supplies Durr Dental AG East Coast Dental Services Elite Fitout Solutions Empire Dental Experien Insurance Services GC Australasia Dental Geistlich GlaxoSmithKline Gritter Dental Hayes Handpiece Australia Halas HICAPS Hogies Australia Friedy Mfg Co. Inc. I Dental Independent Dental Supplies Vivadent Kavo Kerr Kulzer Levitch Design Australia Orthodontic Laboratories McLaren Dental Med & Dent (WA) Medfin Australia Medical Dental Solutions NQ Medical Equipment Services Medi-Dent Medifit MediGrow MegaGen Australia Miniflam Australia Minimax Implant (Dentium Australia) Mocom Australia Momentum Management My Dental Marketing Myofunctional Research Co. NAOL Australia Neoss Australia Nobel Biocare NOVA iT Group NSK Oceania NuMedical 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 Race Dental Ray Australia RCR International Ridley Dental Supplies 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) Surgical Images Teamwork Technology Tomident TrollDental Ultimate Dental Supplies Ultimo Dental Software Ultradent Products Australia Urban IT Vatech Medical VOCO Australia W&H West Coast Dental Depot Westpac Whiteley Corporation William Green Wisbey Dental XAND Innovations Xcellent Dental World XYZ Dental Zimmer Biomet



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