Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: members@mtaa.org.au

MTAA submission to TGA consultation paper:

Proposed Refinements to the Regulation of Personalised Medical Devices

July 2021

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Contents

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

1. Introduction and Background

This submission provides MTAA's feedback to the Therapeutic Goods Administration (TGA) public consultation: *Proposed Refinements to the Regulation of Personalised Medical Devices*, published on 21 June 2021.

As stated by the TGA, during the implementation phase of the new regulatory framework, numerous sectors advised the following:

- Previous changes were a duplication of existing regulation already provided by professional accrediting bodies or other regulatory bodies;
- The classification of certain requirements for some devices were excessive compared with the actual risk posed by the device; and/or
- The regulatory burden associated with compliance is unreasonable

MTAA notes that the current regulatory environment for Patient-Matched Medical Devices has been subject to multiple public consultations in recent years, including four by the TGA itself. There were also two consultations by the International Medical Device Regulators Forum (IMDRF), chaired by a TGA representative, which were also brought to the notice of Australian market participants:

1. TGA - Proposed Regulatory Changes Related to Personalised and 3D Printed Medical Devices (November 2017);
2. TGA - 3D Printing workshop (July 2018);
3. IMDRF - Definitions for Personalized Medical Devices (18 October 2018)
4. TGA - Proposed Regulatory Scheme for Personalised Medical Devices, Including 3D-Printed Medical Devices (February 2019); and
5. IMDRF - Personalized Medical Devices - Regulatory Pathways (24 July 2019)
6. TGA - Regulatory Changes for Personalised Medical Devices, Including 3D-Printed Medical Devices (August 2020)

MTAA welcomed the opportunity to provide comments to these six consultations over multiple years, and has been supportive of the new regulatory regime at each step of the consultative process. Over the last five years the TGA has, through the IMDRF, led the global response to mass personalisation of medical devices made possible by 3D printing, and helped create a first-rate regulatory system set to be adopted globally.

The Australian Government's own Regulation Impact Statement from December 2019 sets out the three core reasons that it was important to move the current regulatory arrangements:

1. Misalignment of regulatory oversight with level of risk;
2. Misalignment with international norms; and
3. Need to balance risk with regulatory burden

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

MTAA acknowledges the concerns of low volume artisanal device fabricators who make low-risk devices by hand, utilising traditional techniques and materials. Unfortunately, these proposed refinements are not well-targeted to assist this group of artisans and instead open the floodgates to a significant but inconsistent deregulation of medical devices in Australia which would put us out of step with the global regulatory trajectory.

Overall, MTAA is not supportive of the proposed refinements as outlined in this consultation and believes that taking thousands of medical devices and hundreds of device manufacturers and sponsors completely out of TGA oversight would be a highly retrograde step with long term adverse consequences for patients, clinicians and industry. It would also put Australia at odds with the approach of both the IMDRF and equivalent OECD countries.

Some examples that would create a number of inconsistencies across the Medical Device and broader health sector that would be difficult to reconcile are provided below if the proposed refinements at taken at face value:

- A 3D printed personalised mouthguard using novel materials would not need to meet the Essential Principles and would be regulated by either the ACCC or State and Territory consumer protection bodies (depending on the nature of the commercial entity which sold it), but a non-personalised adaptable mouthguard for sale in the chemist would be regulated by the TGA, would have to meet the Essential Principles and would require entry onto the ARTG.

- A set of dentures 3D printed utilising novel materials and technology by a dental prosthetist would be exempt from inclusion on the ARTG, but a traditionally fabricated pair of dentures manufactured by one of the largest dental laboratories in the world with ISO13485 accreditation would require ARTG inclusion.

- A personalised 3D printed plagiocephaly helmet designed to change the skull shape of a baby utilising novel materials and technology by an osteopath would be exempt from inclusion on the ARTG, but any plagiocephaly helmet fabricated by a chiropractor no matter the fabrication technique or whether they hold ISO13485 would require ARTG inclusion.

- Orthopaedic shoes 3D printed utilising novel materials and technology by a prosthetic orthotist (non-AHPRA regulated) would be exempt from inclusion on the ARTG but personalised orthopaedic shoes fabricated by chiropractor (AHPRA regulated), no matter the fabrication technique or whether they hold ISO13485, would require ARTG inclusion while all non-personalised mass-manufactured orthopaedic items would require ARTG inclusion, even if the manufacturer holds ISO13485.

- Orthodontic aligners manufactured in Australia would be Class 1 and require only self-certification of Essential Principles and Conformity Assessment, while orthodontic aligners manufactured in the United States regulated by the FDA are US Risk Class 2.

- A heart surgeon could 3D print an anatomical model of a heart for the first time to prepare for surgery and qualify for an alternative assessment pathway, but a specialist medical device manufacturer with ISO13485 would require traditional conformity assessment under Risk Class IIa.

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

- A personalised invasive splint which penetrates the skin, if made by a prosthetist, would be eligible for an alternate conformity assessment pathway effectively supervised by the professional requirements of a commercial peak body, whereas a mass-produced splint manufactured by a traditional device sponsor with ISO13485 would require traditional conformity assessment.

These examples highlight the kinds of inconsistencies make the health sector more difficult to navigate for both clinicians and patients and create more red tape burden than they alleviate.

Detailed responses to the questions in the consultation are provided below.

2. Responses to consultation questions

Exclusions

Question 1
Do you agree with the rationale for the proposed exclusion of products? If not, why not?

Response
No

In respect of products that do not meet the definition of a medical device, ipso facto these are already excluded from inclusion on the ARTG or TGA oversight.

For example, when it comes to physical impressions of a patient's anatomy and models cast (3D printed or otherwise), whether these are a medical device comes down to what they will be used for. If they are being used to plan a surgery, then clearly the models need to be regulated. Conversely if they are for "educational" use, they would not be. We do not think that extra regulation is required to stipulate that non-devices should not be regulated as medical devices when this is already the case.

We would note however that the misclassification of items as Class I include countless cases of up-classification, and it is these cases which are probably seeking to be "released" from a regulatory environment to which they were never actually subject. Up-classification is when very low risk items that fall outside the definition of a 'medical device' under the Therapeutic Goods Act 1989 (a non-device) are nonetheless certified in the ARTG as a Class I medical device. There are a number of ulterior reasons as to why a non-device may have been entered onto the ARTG, but none actually relate to whether an item is personalised or not. Accordingly, we do not see the "exclusion" from regulatory oversight category in this consultation as an appropriate solution.

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Question 2
Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.

Response
No

The risks posed by the proposed medical devices cannot be adequately managed if they are excluded from regulation by the TGA.

For those items which do meet the definition of a medical device, we do not believe that there has been sufficient reason given to exempt these devices from the Essential Principles and regulatory oversight, including adverse event reporting. The examples given of medical devices such as mouthguards, eyeball prosthesis and spectacle frames each have the capacity to be harmful or fail, and no rationale is provided as to why these devices are singled out to be exempted from the Essential Principles or safety reporting.

Further, to the extent that these refinements exclude a number of devices from TGA oversight and the Essential Principles completely, we submit that while the Competition and Consumer Commission (ACCC) as well as state or territory consumer protection laws, while all excellent, are in no way set up to deal with the complexities of these newly deregulated medical devices.

It should also be noted that in September 2019, the TGA had a consultative process entitled *Products Used for and by People with Disabilities* which canvassed the regulatory status of many of these devices and contemplated the possibility of removing them from TGA oversight. In that instance, it was widely recognised when considering the question through a patient lens - that TGA oversight against the Essential Principles is critical to ensuring safety, clinical efficacy and conformity. It would not be beneficial to now completely remove TGA oversight because a small number of manufacturers do not like regulatory oversight, which is possibly the primary motivation for representations supporting their exclusion.

Question 3
Are there further products that meet the principles proposed for exclusion?
What are they and why should they be excluded?
Please provide an explanation for why:

- the product represents no, or insignificant levels, of risk; or
- the product does not meet the definition of a medical device

Response

It is not clear precisely what the proposed principles for exclusion of medical devices from TGA oversight are.

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Exemptions

Question 4
Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

Response
No

The clinical judgement exercised by the prescribing health professional is a key factor in managing the risks associated with medical devices, but it is inappropriate risk management to require them to assume responsibility for ensuring the device is designed and manufactured appropriately.

Patient-matched medical devices are produced for a particular individual by a sponsor within validated parameters of a specified design envelope. The variables within the design envelope are predetermined by the sponsor and not the healthcare provider. As such, they can be considered to be mass-produced devices, with dimensional variations within a specified range. Clinical performance, compliance with safety and performance standards, material properties, manufacturing standards, the provision of labels and information, registration, and post market surveillance must all be conducted on such devices.

ARTG inclusion is not a particularly onerous obligation and serves to add transparency and consistency across the entire medical device ecosystem.

Question 5
Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.

Response

No

The proposed exemptions outlined in this consultation would omit or leave such assessment and regulation of the proposed devices solely to clinicians and, to a lesser extent, a series of clinical regulators and commercial peak bodies. AHPRA, ASCQHC and NDISQSC are excellent organisations but not well-equipped to ensure that clinicians they regulate are manufacturing safe medical devices. Similarly, the Oral Health Professional Association and the Australian Orthotic Prosthetic Association are both excellent organisations but are ill-equipped to ensure that their Members can utilise 3D Printing to manufacture safe and effective medical devices.

Neither these other organisations nor clinicians themselves necessarily have the technical capability or expertise necessary to assess the safety, efficacy and conformity of medical devices and products, or continuously regulate and monitor their use in the Australian market.

The increasing complexity and technology involved in producing these personalised devices is placing further limits on the capability of health professionals in this regard. While health professionals continue to be best placed to identify the specific clinical requirements for their individual patients, regulating the devices should remain the express purpose of the TGA.

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

While Class I medical devices pose the lowest risk to the public, this is not to say that they are without risks altogether. Numerous instances exist where patients have lost teeth with the improperly personalised and manufactured aligners, for example.

Indeed, patient-matched medical devices have more risks not fewer that their non-personalised counterparts. To amend the regulatory regime, such that they are not subject to any formal regulatory oversight means Australia, would have weaker regulation than all comparable markets, including the USA, Europe or even China – a highly unusual approach for Australia.

Question 6

Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices? Please provide details:

- describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.

Response

MTAA does not think Class I devices should be exempt from ARTG inclusion. Furthermore, the corollary effect of exempting these and other comparable medical devices from TGA oversight will not only be to undermine patient safety and efficacy, but to threaten Australia's leading competitive edge in the 3D printed medical device market.

In 2018, Deloitte estimated that the global market for 3D printing was worth $12 billion, an annual increase of 20 per cent compared to 2017. [1] According to the 2019 Global Opportunity Analysis and Industry Forecast, 2019–2026, the global 3D printing healthcare market alone was valued at $973 million in 2018. With a consolidated annual growth rate of 18.2 per cent, this is expected to increase to $3,692 million by 2026.[2]

As these products continue to play a growing role in mainstream health services, it is estimated that 3D printed personalised medical devices will constitute a market worth nearly $1.5 billion by 2027.[3] The Asia Pacific 3D printing medical device market alone, which was valued at around $177 million in 2017, is anticipated to grow by a staggering $600 million by 2027.[4]

In order to develop the industry in Australia and successfully access this growth market, it is essential that an effective regulatory regime exists that provides businesses, researchers, clinicians and patients with confidence and certainty. This will attract investment and promote the innovation necessary to maintain Australia's leading competitive edge, ensuring Australians have access to the best medical devices in the world.

[1] Deloitte, The future of Health Care: Potential, impacts and models of 3D printing in the Health Care sector, p.5.
[2] Kunsel, T. and Sumant, O., Global Opportunity Analysis and Industry Forecast, 2019–2026, 2019, available from: https://www.alliedmarketresearch.com/3d-printing-healthcare-market
[3] https://www.smartechanalysis.com/news/3dp-medical-technology/
[4] https://www.globenewswire.com/news-release/2020/04/28/2023150/0/en/Global-3D-Printing-Medical-Device-Market-2019-to-2026-Growth-in-the-Ageing-Population-Worldwide-Presents-Opportunities.html

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Inclusions in ARTG using alternative conformity assessment procedures

Question 7
Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

Response
No

The consultation highlights no less than six alternative potential conformity assessment pathways that could be implemented in parallel. These include against the National Safety and Quality Health Service Standards, the scope of registration provided by the National Disability Insurance Scheme Quality and Safeguards Commission, or the professional standards of the AHPRA, the Australian Qualifications Framework, the Oral Health Professional Association or the Australian Orthotic Prosthetic Association.

This assortment of organisations, frameworks and professional associations constitute a far more complex constellation of potential regulators and standards than at current. MTAA fails to see how delegating the assurance of conformity assessment of Class IIa to these organisations reduces the regulatory burden compared to having one, dedicated specialist regulator like the TGA with tightly defined conformity assessment pathways.

As stated in the consultation, crowns, bridges and veneers could follow an alternate procedure. We disagree with this due to complexity and accountability placed on these proposed manufacturers. The IMDRF guidance states current devices would become raw materials and the manufacturer would have accountability. They state oversight from a supplier of this main material is not sufficient to meet safety and performance. However, we believe there is oversight to these products as the materials are complex. The model they propose does not work for all types of manufactured patient-matched products. Especially these higher risk devices such as crowns. We believe they should not be raw materials but remain devices where the legal manufacturer can manage the safety profile of the product as the experts.

Specifically as an example:
The raw materials (e.g. Zirconia has specific elaborate instructions which state which cadcam or 3D should be used, specifications, etc.), and therefore the zirconia manufacturer, should still hold the responsibility or have responsibility over the lab technician or dentist to prepare the crown. Crowns are Class IIa which would involve significant post-market responsibility on the manufacturer. Some of these raw materials are special materials that require expert knowledge and investigation in adverse events. The supplier who owns the design portfolio of the main ingredient (the Zirconia in this case) is an expert in these technical aspects of intended use and design of the patient-matched device. In addition, suppliers would not wish to hand over their IP to a manufacturer or Alt CA provider. These relationships are set up with regulators within specific boundaries of confidentiality and security.

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

Question 8
Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.

Response
No

As outlined previously in this submission, MTAA does not believe that AHPRA or any of the organisations, frameworks, commercial peak bodies and professional associations outlined as potential substitutes for the TGA's capacity or technical expertise to fulfil the task of ensuring conformity assessment of personalised medical devices.

Even now, the rapidly changing technology and complexity of manufacturing 3D printed medical devices is beyond the regulatory capacity of these organisations. This capability gap will only increase commensurate with the pace and scale of technological and manufacturing advancements which are increasingly using machine learning, AI, complex algorithms, robotics and 3D printing.

Question 9
Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?

Response
No

By definition, a Class IIa device is a device where the risks associated with the manufacture and use of the device cannot be adequately self-managed. This is even more the case with the inherent complexity of personalised medical devices (when compared to "traditional" non-personalised ones which would retain the requirement for traditional arms-length conformity assessment pathways).

Question 10
Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?

Response
No
By definition, a Class IIa device is a device where the risks associated with the manufacture and use of the device cannot be adequately self-managed. This is even more the case with the inherent complexity of personalised medical devices (when compared to "traditional" non-personalised ones which would retain the requirement for traditional arms-length conformity assessment pathways).

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

General question

Question 11
Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

Response

The regulatory burden is not significantly higher for Class IIa patient-matched devices than was previously the case for custom-made devices. The only marked difference between the current regime as it was conceived and implemented is that it is actually enforceable.

MTAA acknowledges the concerns of low-volume artisanal device fabricators who make low-risk devices by hand, utilising traditional techniques and materials. Unfortunately, these proposed refinements are not well-targeted to assist this group of artisans and instead open the floodgates to a significant deregulation of medical devices in Australia. The proposed changes would put us out of step with the regulatory trajectory globally as well as creating regulatory arbitrages between medical device manufacturers making non-personalised devices and a small sub-section of those making personalised devices.

To the extent that refinements are required (and we are not certain that they are), they should be targeted at low-volume artisanal device fabricators who make low-risk devices by hand, utilising traditional techniques and materials.

Regardless, we think that this paper does not account for the clinical benefits created by the digitisation and mass personalisation of medical devices facilitated by the Patient-Matched Medical Device regime. We would respectfully suggest that creating regulatory cul-de-sacs specifically designed to slow the transition to Patient-Matched Medical Devices will not be beneficial for patients and the health system.

3. Additional Information – Regulation for Aligners

In addition to the above responses to the consultation. MTAA would like to draw attention to the precise reasons why enforcement of the new regulatory framework is necessary, not weakening it.

Orthodontic aligners, which in Australia are Class IIa customised devices (a custom-made medical device used in the oral cavity ~22 hours a day for up to 24 months), are increasingly being self-assessed and included on the ARTG as Class I.

Serious adverse clinical events can and do occur from the use of orthodontic clear aligners[5] and poor treatment-planning can even result in tooth loss.[6] For this reason, orthodontic clear aligners are consistently given a Risk Classification of Class II (or equivalent) in other IMDRF-aligned jurisdictions.

[5] https://www.ajodo.org/article/S0889-5406(17)30603-0/pdf
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5430001/

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

For example:

- Under 21CFR872.5470, the United States mandates orthodontic clear aligners as "Device Class II"[7] and FDA records show that Invisalign[8] Spark Aligners[9] and Clear Path[10] which have all registered as Class II devices in the United States, but have each self-assessed as Class I in Australia (please see page 13 with an excerpt from the U.S. Code of Federal Regulations); and
- Canada consistently classifies orthodontic clear aligners as "Device class 2" and Invisalign who have self-assessed as Class I in Australia operate in Canada pursuant to Licence No.: 10404 under Device Class 2[11]

In Australia, the classification level revolves around interpretation of the term "short-term use" for the purposes of Classification Rule 3.1(2)(b)(ii). In this regard we would note:

- The prescribed course of treatment is typically 12 months and often up to 18 or even 24 months, with the prescription nearly always to wear them whenever not eating and "for at least 22 hours a day." The delivered course of treatment is typically longer than the initially prescribed one for most aligner systems because of "corrections"

- The primary risk from bad treatment planning or device quality is permanent tooth loss and this does regularly happen, particularly with low quality aligner fabricators which do not use x-rays for their treatment planning.

Given the potential for tooth loss from poorly planned or manufactured aligners, it is unclear why Australia would proceed down a path of giving these devices a lower risk classification than other comparable jurisdictions.

[7] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NXC
[8] https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081960.pdf
[9] https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182826.pdf
[10] https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162609.pdf
[11] https://health-products.canada.ca/mdall-limh/information.do?companyId_idCompanie=114087&lang=eng

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
MTAA Office, Level 4, 97 Waterloo Road
Macquarie Park, NSW 2113 Australia
P: (02) 9900 0600 **W:** www.mtaa.org.au
E: reception@mtaa.org.au

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2020]
[CITE: 21CFR872.5470]
See Related Information on Orthodontic plastic bracket. in CDRH databases

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES
PART 872 -- DENTAL DEVICES

Subpart F - Therapeutic Devices

Sec. 872.5470 Orthodontic plastic bracket.
(a) Identification. An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

(b) Classification. Class II.