Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Level 12, 54 Miller St, North Sydney NSW 2060
PO Box 2016, North Sydney NSW 2059
P: (02) 9900 0600
E: mtaa@mtaa.org.au

MTAA Submission to TGA consultation:

Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

March 2019

Contents

1. Executive Summary

On 13th February 2019, the TGA opened the consultation: *Proposed regulatory scheme for personalised medical devices, including 3D-printed devices*. The proposed changes set out in this consultation, as stated by the TGA, "seek to better regulate personalised medical devices, including the introduction of new definitions". This consultation follows on from an earlier public consultation and public forums in 2017 and 2018, to which MTAA has also provided feedback.

TGA's proposed new definitions for personalised medical devices, including 3D printed devices aligns with the IMDRF guidance document *Definitions for Personalized Medical Devices* of October 2018[1]. Since TGA chairs the IMDRF Personalized Medical Devices Working Group[2], we are confident that the TGA positions expressed in this consultation document are aligned with the ongoing work that IMDRF undertakes in this area.

The other changes proposed in the TGA consultation document are:

- change the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites
- introduce a framework for regulating a medical device production system which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification
- update the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example 3D-printed models of patient anatomy
- regulate medical devices with a human origin component, for example a 3D-printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals, and
- clarify that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device.

MTAA has been a strong supporter of international regulatory convergence and harmonization wherever possible and appropriate, and this is our position too for personalized medical devices, including 3D-printed devices. Additional detailed comments to the TGA consultation paper are provided in the next pages.

[1] IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices, 18 October 2018, accessed 14 March 2019: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf

[2] IMDRF Work Items – Personalized Medical Devices, accessed 14 March 2019: http://www.imdrf.org/workitems/wi-pmd.asp

2. New definitions for personalised medical devices

MTAA agrees with the proposed new definitions for personalised medical devices and their grouping into these three categories:

- custom-made medical devices
- patient-matched medical devices, and
- adaptable medical devices.

We welcome the clarity that these new definitions bring in addressing the rapid advances in technology.

The introduction of the patient-matched category which, under the new regulatory framework, will not be eligible for the exempt status will ensure a level playing field between traditional manufacturers and entities currently performing manufacturing tasks without the regulatory controls applied to traditional manufacturers.

3. Requirements for supplying custom-made medical devices in Australia

The proposed changes to the regulatory requirements for custom-made devices align with the comparable requirements in the EU Medical Devices Regulations (MDR) therefore MTAA supports them (refer to Table 1).

Table 1: Proposed requirements for custom-made devices in Australia and corresponding EU MDR requirements

Proposed changes to regulatory requirements for custom-made devices in Australia	Existing regulatory requirements for custom-made devices in EU MDR
The manufacturer to provide a statement about a custom-made device to the patient receiving the device	MDR Annex XIII, section 1
TGA to enter and inspect custom-made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers	MDR Article 93, section 3
The manufacturer in Australia, or a sponsor of an overseas-manufactured custom-made device, to provide an annual report to the TGA of the custom-made devices it has supplied	MDR Article 86 section 1 Annex XIII, section 2
The documentation about an implantable custom-made device to be retained for a minimum period of fifteen (15) years	MDR Article 10 section 8

We agree with TGA's assessment that these changes would result in greater transparency for patients receiving custom-made medical devices and would assist with improving the informed consent process.

4. Production systems allowing healthcare providers to produce lower risk personalised devices

MTAA supports the proposal to regulate medical device production systems (MDPS) intended to be used by healthcare providers and/or facilities as medical devices, to limit their scope to low risk products only (Class IIa and below), and to require their inclusion in the ARTG.

It is reasonable in our opinion to classify and assess the MDPS according to the risk classification of the device they are intended to produce (Class IIa and below) but exempt the production equipment and consumable raw materials used in a MDPS from being considered medical devices on their own, unless they fit the definition of medical devices in their own right.

MTAA believes the proposal in relation to MDPS represents an acceptable middle ground. While the MDPS would require validation and inclusion in the ARTG, healthcare providers and/or facilities that use MDPSs to produce medical devices for treating their patients would not be considered as manufacturers under the regulatory framework in relation to those systems, hence they would not need conformity assessment certification for manufacturing with a MDPS.

5. Revising classification Rule 5.4 for medical devices that record diagnostic images

MTAA supports the proposal to update classification Rule 5.4 to include all medical devices that record diagnostic images, not just X-rays. This aligns with the principle that risk classification should primarily be driven by the intended purpose and the intended use of the medical device and be relatively technology neutral.

Software that records patient diagnostic images and 3D anatomical models intended to be used for diagnosis or investigation of the anatomy and planning a surgery would then be covered by this rule and be classified as Class IIa.

We feel that the right balance has been struck by exempting hospitals or healthcare practitioners from the requirement to undergo conformity assessment if they used an MDPS to produce the anatomical models for treating their patients, and the MDPS (classified as Class IIa) was included in the ARTG.

6. Medical devices with a human origin component

MTAA supports the proposal to align with comparable international regulators and regulate medical devices with a human origin component (both viable and non-viable) as Class III medical devices with a biological component rather than pure biologicals. This change will address recent developments in medical technology such as 3D bioprinting, or printing of patient specific implants that incorporate human origin material.

We understand that these devices would have to undergo a mandatory conformity assessment by the TGA in addition to being compliant with TGOs for controlling infectious disease transmission. It may be necessary for TGA to clarify the level of evidence required to qualify for an abridged assessment under the current conformity assessment procedures.

7. Clarification to rules pertaining to modified/ adapted medical devices

MTAA supports the addition of text in the regulations to clarify that a person will not be considered a manufacturer in circumstances where a medical device has been assembled or adapted for an individual patient and the assembly or adaptation is in accordance with validated instructions provided by the original manufacturer of the device.

We believe that the right balance has been struck by including a caveat for situations where devices placed on the market or put into service are adapted or modified in such as way that compliance with the essential principles may be affected. We agree that in these situations the person who adapts or modifies the device must assume the obligations incumbent on manufacturers and needs to be subject to the applicable regulatory requirements.

We would like to thank the TGA for consulting and engaging with industry on outlining the new regulatory framework for personalised devices, including 3D-printed devices, in Australia.