TGA Consultation – Proposed regulatory changes related to personalised and 3D printed medical devices

MTAA Submission - December 2017

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1 Executive Summary

On 9th November 2017, the TGA opened the consultation *Proposed regulatory changes related to personalised and 3D printed medical devices*. The consultation proposes changes to the current medical device regulatory framework in Australia to ensure adequate regulation of personalised medical devices such as those being enabled by 3D printing.

Currently, custom-made devices do not require regulatory oversight and are exempt from inclusion in the ARTG. Although they are required to comply with applicable essential principles of safety and performance, custom-made devices may be supplied with a justification for any non-compliance(s). Manufacturers of custom-made devices are not required to provide evidence of quality management system (QMS) certification.

In recent years, the relatively easily accessible 3D printing technology has enabled the making of personalised devices, including high-risk implantable devices, in much greater volumes than before. This development has shifted the risk from individual to population, while the regulations for custom-made devices remained the same.

The four proposals in the consultation cover the following:

1. New definitions of personalised devices
2. Changes to the conformity assessment procedure for custom-made devices
3. Changes to the definition of manufacturer
4. New risk classification for anatomical models and digital 3D print files

MTAA appreciates the opportunity to comment on the proposals of this consultation. MTAA supports alignment with European medical device regulatory framework and international best practices in this area.

In the next sections, we provide detailed feedback to each of the proposals in the consultation.

2 MTAA comments to consultation proposals

2.1 Proposal 1: New definitions of personalised devices

MTAA welcomes the narrowing down of the definition for custom-made devices, and the creation of a separate definition for patient-specific medical devices. The proposed revised definition for custom-made medical devices, with its narrowed-down scope, is in our opinion appropriate and it aligns with current EU and US overall approach to custom-made devices.

MTAA agrees with inclusion of wording in the revised definition of custom-made medical devices that unequivocally assigns responsibility for the design to healthcare professionals.

We notice that custom-made instruments, which are included in the old definition of custom-made devices, have been removed from the revised narrowed-down definition for custom-made devices. Custom-made instruments are included in the definition of custom-made devices in the Canadian and U.S. regulations, but not in the EU regulations. We would appreciate TGA's clarification on how it intends to regulate custom-made instruments going forward.

MTAA also supports the addition of new definitions for: customised medical device; personalised medical device; mass produced medical device; and medical device production system. The revised narrowed-down definition for custom-made devices and the proposed new definitions are reproduced below.

Custom made medical device *- means any device*

- *that is specifically made in accordance with a written request of any person authorised by Australian law by virtue of that person's professional qualifications as a healthcare provider which gives, under that person's responsibility, specific design characteristics; and*
- *that is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs; and*
- *for which there is no commercially available alternative medical device.*

Mass produced devices which need to be adapted to meet the specific requirements of any professional user and patient specific devices shall not be considered to be custom-made devices.

Customised medical device *- a medical device that is supplied by a manufacturer with a specified intended purpose and that must be adapted or assembled, in accordance with the manufacturer's validated instructions, to suit an individual patient prior to use.*

Patient-specific medical device *– a medical device based on a standard device template model that is matched to a patient's anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and which is produced through a process that is capable of being validated.*

Personalised medical device *– a device intended for a particular patient which could be a custom made, customised, or patient specific medical device.*

Mass produced medical devices *– medical devices that are produced in production runs or batches of the same product.*

Medical device production system *– a collection of products, including specified raw materials, that is intended to be used by a health care practitioner to produce a finished medical device and that may include the input of a digital patient image file.*

The system output must be validated with the specified components. The classification of the system is determined by the classification of the finished device.

MTAA's response to the questions asked in the TGA consultation on Proposal 1 (reproduced below) is provided hereafter.

Questions for consideration – Proposal 1

Is the proposed definition for custom-made device clear enough; or should additional measures be taken such as:

- *Should the number of custom-made device that a manufacturer or sponsor can supply in one year be limited? The FDA limits this number to 5 per year in the USA, a country whose population is more than 10 times that of Australia.*
- *Should the TGA implement an application and approval process for the use of a custom-made device? This is the approach taken by Health Canada.*

Do you have any other comments or suggestions about the proposed definitions?

Do you have any other comments or suggestions for alternative or additional strategies?

Limiting the number of custom-made devices that a manufacturer or sponsor may supply in one year is intended to ensure that the exemption from obtaining regulatory approval enjoyed by custom-made devices is not misused, inadvertently or otherwise. However, choosing an arbitrary number as the maximum number of custom-made devices that a manufacturer or sponsor may supply in one year may have unintended consequences and not necessarily be in the best interest of patients.

MTAA does not support implementing an application and approval process for custom-made devices (as per the revised narrowed-down definition). We believe that the current regulatory requirement to provide annual reports to the TGA, combined with a future regulatory requirement to allow the TGA to enter and inspect custom-made device manufacturing sites, will appropriately strengthen the controls and provide the transparency to the TGA about the manufacture and supply of custom-made devices (as per the revised narrowed-down definition).

3D printed patient-specific medical devices however, being excluded from the revised narrowed-down definition for custom-made medical devices, should be regulated under the existing regulatory framework for medical devices, except for low risk devices such as dental crowns that should be allowed to be 3D printed in dental offices under special arrangements.

2.2 Proposal 2: Changes to the custom-made conformity assessment procedure

MTAA supports changes that result in greater transparency for patients receiving custom-made medical devices and greater transparency to the TGA about the manufacture and supply of custom-made medical devices. The changes to the conformity assessment procedure for custom-made devices proposed in the TGA consultation are reproduced below.

It is proposed to change the conformity assessment procedure for custom-made devices 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.*

MTAA's response to the questions asked in the TGA consultation on Proposal 2 (reproduced below) is provided hereafter.

Questions for consideration – Proposal 2

Are there any issues or unintended consequences that may arise out of these proposed changes to the custom-made conformity assessment procedure?

If there are issues, can you provide suggestions for addressing them?

Do you have any other comments or suggestions for alternative or additional strategies?

MTAA supports making information about the custom-made device available to the patient and increasing the record retention period for implantable custom-made devices to 15 years. The obligation to provide the information about the custom-made medical device to the patient rests with the healthcare professional.

MTAA supports in principle changes that would allow TGA to monitor quality, safety and performance of custom-made medical devices. TGA oversight of custom-made medical devices must be equally applied to all entities engaging in making them, including healthcare facilities such as hospital laboratories and healthcare professionals' practices.

Healthcare facilities making custom-made medical devices on their own premises and their subcontracted workshops need to be regulated as manufacturers of custom-made medical devices, with responsibility for providing the written statements on compliance with the EPs, annual reports to the TGA and for retaining records for the required period of 15 years.

2.3 Proposal 3: Changes to the definition of manufacturer

MTAA supports the proposed revisions to the definition of manufacturer of medical devices and related exemptions (reproduced below).

However, a person is not the manufacturer of a medical device if:

- *(a) the person assembles or adapts the device for an individual patient; and*
- *(b) the device has already been supplied by another person; and*
- *(c) the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:*
  - *i. the labelling on the device;*
  - *ii. the instruction for using the device;*
  - *iii. any advertising material relating to the device;*
  - *iv. technical documentation describing the mechanism of action of the device.*

[Added text:]

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.

MTAA welcomes TGA's determination on 3D printing being a manufacturing process that impacts the finished devices' compliance with the essential principles, i.e., more than assembling or adapting a device.

3D printing is being used for a wide range of medical devices, from lower risk dental crowns to higher risk cranial, maxillofacial or other bone and joint replacements. The level of regulatory oversight applied to 3D printed devices and their manufacturing process needs to be proportionate with the level of risk, determined using the existing risk classification rules for medical devices.

The new definition of customised medical devices (Proposal 1) together with the added text clarifying exemptions from requirements applicable to manufacturers of medical devices (Proposal 3) will help minimise confusion around who is regulated as a medical device manufacturer and who is not.

We support TGA's proposal to regulate all entities engaging in 3D printing of higher risk patient-specific medical devices (mostly implants) as manufacturers, including healthcare practitioners and hospital laboratories.

We agree with TGA's proposal to introduce a new exemption from being regulated as a manufacturer for healthcare practitioners and hospital laboratories that use medical device production systems such as 3D printers to produce lower risk medical devices (Class II and lower) to treat their own patients; and to regulate as manufacturers healthcare providers that use medical device production systems to produce devices for supply beyond treating their own patients.

MTAA's response to the questions asked in the TGA consultation on Proposal 3 (reproduced below) is provided hereafter.

Questions for consideration – Proposal 3

*Are there any issues or unintended consequences that may arise out of these proposed changes to the definition of manufacturer regarding **customised devices**?*

*Are there are issues or unintended consequences that may arise out of these proposed changes regarding the use of **medical device production systems**?*

If there are any issues, can you provide suggestions for addressing them?

Do you have any other comments or suggestions for alternative or additional strategies?

In our opinion, clarification is needed around the use of 3D printing technology. Using the newly proposed definitions (Proposal 1) it appears that:

- 3D printing technology can be employed using patient imaging data to produce ***custom-made medical devices*** as well as ***patient-specific medical devices***.
- The difference of whether a 3D printed device is considered a custom-made or a patient-specific medical device depends on whether the 3D printing process has been validated, i.e., whether the 3D printed device was produced using a ***medical device production system***.

We would appreciate TGA's clarification on this matter.

2.4 Proposal 4: New classification for anatomical models and digital 3D print files

MTAA supports TGA's proposal to revise the classification rule 5.4 for medical devices intended to record diagnostic images to include anatomical models and digital 3D print files (reproduced below).

> ***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.*

MTAA agrees with the proposal to exempt hospitals and healthcare practitioners from being regulated as manufacturers, provided they use ARTG-included medical device production systems to produce anatomical models for treating their patients.

We recommend that companies producing software intended to record patient imaging that will be used for diagnosis or investigation of the anatomy be regulated as medical device manufacturers, applying all the rules relevant to Class IIa devices.

2.5 Proposal 5: New arrangements for devices with human material

MTAA supports TGA's proposal to regulate devices containing material of human origin, both viable and non-viable, as Class III medical devices, in alignment with the approach taken in Canada, Europe and the U.S.

We agree that it is more suitable to regulate devices made using 3D bioprinting, such as 3D printed implantable scaffolds with human materials, as Class III medical devices under the medical device regulatory framework rather than as biologicals under the biologicals regulatory framework.