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[redacted]
Business Improvement and Support Section
Medical Devices and Product Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

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

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide our views on the Therapeutic Goods Administration's ("TGA" or "Agency") "Consultation: Proposed regulatory changes related to personalised and 3D printed medical devices." AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies, including those that manufacture devices using 3D printing techniques.

AdvaMed applauds the Agency for creating this thoughtful Consultation Document. We strongly believe that the use of this technology in medical devices has already rapidly advanced, and will continue to increase in the future. Given the ever-growing prevalence of 3D techniques in manufacturing medical devices, we appreciate TGA's efforts both within and outside of Australia. Specifically, we note that TGA has spearheaded the approval of, and is now chairing, a new work item at IMDRF dedicated to advancing the harmonization of regulatory approaches to personalised and 3D-printed medical devices. We hope that our comments can help inform TGA's current thinking, both as it relates to its own regulatory regime, and as it leads the harmonization effort with its fellow regulators at IMDRF.

Below, we provide responses to several of the questions posed in the Consultation Document.

Responses to Questions Posed in the Consultation Document

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

- ***Should the number of custom-made devices 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.***

We do not believe that a limitation on the number of custom-made devices a manufacturer can supply in one year is necessary, as the definition provided includes clear criteria, and it is the responsibility of the manufacturer to document that all requirements are satisfied when declaring a device as custom-made. The custom-made pathway provides the value of reduced regulatory burden for medically needed products under very limited circumstances. We believe that any number chosen as a limit is necessarily arbitrary, and may result in patients not being able to access needed technology.

The proposed definition is the same as the one incorporated in the EU MDR, with the exception of the following sentence: "for which there is no commercially available alternative medical device." If TGA wishes to align with EU MDR, then it should remove this language from the definition. Nonetheless, if TGA wishes to retain "commercially available" in the definition, we believe it could be suitable to do so, as this approach offers the patient a potential benefit of medical access when no alternative is commercially available.

We also believe that it would be helpful to explicitly state that a 3D-printed device could meet the definition of custom-made device so long as the device fulfills the criteria in the definition. While we believe this is the intent of the document, an explicit statement to this effect would provide clarity.

We do not recommend an application and approval process for the use of a custom-made device and encourage TGA to look at both the United States (Custom Device Exemption) and European Union (MDR Annex XIII – Procedure for Custom-Made Devices) to develop a manufacturer declaration process, rather than an application and approval process. A device that meets the definition of custom-made, by its very nature, is unique and used in very limited circumstances. In light of this unique nature and very limited use, we believe that reduced regulatory burden for custom-made devices is in the best interest of patients.

See also our comments under questions 3(a) and 3(b) for "medical device production system."

1(b) Do you have any other comments or suggestions about the proposed definitions?

We would propose revising the definition of "patient specific" to add the following (additions indicated in underline) "***patient-specific medical device*** – a medical device based on <u>either</u> a standard device template model <u>or predetermined design range</u> 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." The document appears to incorrectly assume that a patient-specific medical device will always be based on a template. A patient-specific device may be based on a template, for instance, using a template and then either elongating or shortening the device. However, the construction of a patient-specific device may start with the patient's

anatomy, and then follow a predetermined design range, for instance, CT matching. Our proposed language would provide a technical correction to reflect this nuance.

Please clarify the definition of a "mass produced device," and provide examples, e.g., anything produced to a catalogue number (existing catalogues).

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

The proposal that "a manufacturer in Australia or sponsor of custom-made devices" should "provide an annual report to the TGA of the custom made devices it has supplied…" should be limited to high-risk medical devices. This would provide transparency into the highest risk devices.

2(b) If there are issues, can you provide suggestions for addressing them?

Please clarify the definition of "Adaptation," and provide examples.

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

The proposal to create a new category of medical device called "medical device production system" is intended to address what other global regulators have termed "point-of-care manufacturing." Under this TGA proposal, health care practitioners or hospital laboratories that use "medical device production systems" (as defined in proposal 1 above) that are included in the ARTG to produce medical devices of risk classification Class IIa and lower for use in treating their own patients would be exempt from medical device requirements.

We believe this proposal creates a global regulatory precedent, blurring (or potentially eliminating) the line between manufacturing and marketed product. While we believe this concept may have merit if appropriately constructed and implemented, further elaboration on the concept is warranted to ensure that there are no unintended consequences. Illustrative examples of device types that would be considered under this concept would be extremely helpful to explain and clarify how this concept could work in practice.

Some of our questions around how this concept might actually work in practice include:

- How would requirements/expectations for elements that are typically covered under manufacturing quality system controls be addressed? For example, there are fundamental quality systems and manufacturing control elements applied to a medical device manufacturing facility such as human resources, infrastructure, work environment and contamination control, validation processes, and particular requirements for validation of sterilization processes. How would these concepts apply only to the medical device production system when it involves a facility interface?

- How would significant "post-processing" operations like annealing and heat-treating operations, cleaning, sterilization and labeling of devices from a "medical device production system" be treated? We believe that 3D-printing systems have not yet developed to a point where these post-printing operations can be eliminated.

- Currently, manufacturers of 3D-printing systems rely on design owner to provide the device design and design control. How would ARTG listing work if the 3D-printing system were to reference multiple device manufacturer designs?

- As TGA leads harmonization efforts within IMDRF, we note that from a U.S. perspective, there are practical implications of the significantly different requirements for this "dual use" technology, specifically medical versus non-medical 3D printers in the marketplace, which would need to be addressed.

- The proposal would only apply to Class IIa and lower devices. We interpret this to mean that TGA would require health care practitioners or hospital laboratories that use "medical device production systems" (as defined in proposal 1 above) that are included in the ARTG to produce medical devices of risk classification higher than Class IIa in treating their own patients to meet medical device regulation requirements. Please confirm this understanding.

3(b) Are there any issues or unintended consequences that may arise out of these proposed changes regarding the use of medical device production systems?

From a legal perspective, we believe that this proposal potentially conflicts with the statutory definition of medical device in Australia. We believe this proposal may require legal changes as well as regulatory changes as we do not believe manufacturing is included within the TGA statutory definition of medical device. Therapeutic Goods Act of 1989.

4(a) Are there any issues or unintended consequences that may arise out of the proposed change to the classification of anatomical models and software?

Proposal 4 expands definition of devices intended to record diagnostic images to include "software and anatomical models intended for the diagnosis or investigation of the anatomy." We believe this definition is overly broad and would encompass all physical anatomical models into the definition of medical device, including those currently considered educational tools, like simulated bone models used by surgeons to explain the surgical procedure to a patient. We believe that limiting the definition to "software and anatomical models intended for diagnosis" achieves the objectives described by TGA in the consultation paper without encompassing anatomical models that are educational tools.

Moreover, we request that TGA clarify what is considered an anatomical model, and provide examples. We would propose that TGA include as an example of an "anatomical model" a 3D-printed dental model used to control the fitting of the Mandibular repositioning device in manufacturing.

5(a) Are there any issues or unintended consequences that may arise out of the proposed change to the pathway for medical devices that incorporate materials of human origin?

We agree with this proposal, and support this effort to harmonize with other global regulators.

AdvaMed appreciates the opportunity to provide our feedback on this important topic. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully Submitted,

/s/

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