AdvaMed
Advanced Medical Technology Association

March 29, 2019

Elizabeth McGrath
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 scheme for personalised medical devices, including 3D-printed devices

Dear Ms. McGrath,

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 scheme for personalised medical devices, including 3D-printed 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 appreciates the opportunity to provide comments in response to the Consultation Document. The use of this technology in medical devices has already rapidly advanced and we strongly believe it 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 chairs the personalised devices working group within the International Medical Device Regulators Forum (IMDRF) dedicated to advancing the harmonization of regulatory approaches to personalised devices, including 3D-printed medical devices. IMDRF finalized a definitions document at the end of 2018. The IMDRF working group is currently developing a guidance document for the regulatory pathways for personalised 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.

AdvaMed submitted comments responding to the prior public consultation and encourages TGA to reference those prior comments. Below, we provide additional feedback regarding some of the proposals put forward in this version of the Consultation Document.

TGA should provide sufficient transition periods for patient-matched medical devices currently on the market that correspond with risk.

The Public Consultation document proposes that any device that falls within the IMDRF definition of patient matched, which currently falls under the custom-made definition in Australia, would no longer be eligible for the custom-made exemption. Instead, these devices would require conformity assessment according to the device risk classification.

We support the adoption of the IMDRF definitions for custom-made and patient-matched medical devices by TGA and, as discussed above, appreciate its leadership in driving global convergence with respect to personalized medical devices. We are concerned, however, with the lack of detail in this consultation with respect to the implementation of this significant proposed change in regulatory approach to patient-matched medical devices. While it is clear that the exemption for patient-matched devices currently regulated under the custom-made definition would require conformity assessment according to the risk classification rules, we believe the consultation is lacking in details on transition provisions for patient-matched medical devices currently on the market under the custom-made exemption.

If TGA proceeds with its proposed approach, it should outline an appropriate mechanism to identify and notify sponsors/manufacturers of custom-made devices currently on the market that their exemption will be withdrawn. Patient-matched medical devices are a subset of custom-made medical devices (even under the proposed definitions). Therefore, it may not be clear to all sponsors of custom-made medical devices that their products would no longer qualify for this exemption. Thus, it is particularly important that TGA devise and implement an effective notification strategy.

Moreover, if TGA proceeds with the proposed revisions, it will need to include a sufficiently lengthy transition period to enable sponsors/manufacturers to prepare the necessary documentation and apply for a conformity assessment under the new rules. The length of the transition period should take into account the risk classification of the patient-matched medical devices, and the level of documentation required with respect to the risk classification of the device.

TGA should limit the annual report to moderate and high-risk custom devices

TGA is proposing additional requirements for devices that meet the definition of custom, including submission of annual reports of the custom-made devices the company has supplied. We believe this proposed requirement should be limited to moderate and high-risk medical devices, e.g., implants. This would provide the needed transparency into these devices.

In addition, the Public Consultation proposes that manufacturers of custom devices provide to the patient a written statement about the device, including whether it complies with the essential principles. We would appreciate additional clarification from TGA regarding its expectations for the contents of this written statement, including a suggested template and timeline for implementation.

TGA should address how conformity assessment of Medical Device Production Systems (MDPS) would take into account aspects where a facility shares responsibility.

The Public Consultation document includes a proposal to create a new category of medical device called "medical device production system." This proposal 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 the proposal) 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 support a risk-based regulatory framework for health care facilities manufacturing devices using 3D printing. Such a framework should include a risk-based approach to mitigation of sources of potential error of concern to all. Some of those particular risks are unique to the health care facility using the equipment and the mitigations would need to occur within that setting. Thus, we are concerned that a framework that focuses solely on the suppliers of the equipment/components, without controls imposed on the health care facility that uses the equipment/components to manufacture those devices, may not appropriately mitigate all risks. Our concern is heightened by what we believe to be an overly broad scope of the proposal: It would apply to any class I and IIa device. Class IIa devices include moderate risk devices such as surgical instruments utilized in direct patient care.

Specifically, TGA should address how the proposal would adequately mitigate all risks in the following areas where the facility and supplier share responsibilities:

- **Environmental and contamination controls.** In the manufacturing environment, these controls are addressed through Good Manufacturing Practices and the ISO 13485 standard for Quality Systems. TGA should describe how it envisions the conformity assessment procedure to work for ongoing environmental controls necessary to ensure the appropriate cleanliness and biological/biocompatibility requirements.

- **Post-processing operations.** TGA should detail how significant "post-processing" operations that would typically require manufacturing validation (e.g., annealing and heat-treating operations, cleaning, sterilization and labeling) many of which are dependent on the facility, not the MDPS itself, would be addressed through the conformity assessment procedure.

- **Cybersecurity.** We believe it would be important for TGA to describe how the conformity assessment procedure would address connectivity and cybersecurity controls to ensure that networks are maintained in accordance with the manufacturer's prescribed specifications and to reduce cybersecurity risk.

We would like to ensure the success of a framework to address point-of-care devices using 3D printing. We are concerned that creating a framework for a new category of medical device, an MDPS, without a clear path forward on these questions could result in a situation where certain risks may not be adequately addressed. We believe that such a scenario would be an unintended consequence and not consistent with enabling a successful system for point-of-care manufacturing using 3D printing. We respectfully suggest that TGA either add controls for health care facilities in the areas we mentioned and/or limit the scope of the proposal to class I devices.

TGA should specify that the systems that produce an anatomical model would be regulated as a class IIa medical device, not the anatomical model by itself.

Section four of the Consultation document proposes that "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."

We would recommend that TGA revise this proposal to include "software and systems that produce anatomical models intended for diagnosis or investigation of the anatomy." An anatomical model is not a device in and of itself. By contrast, an anatomical model is the output of a medical device, i.e., the output of the medical device that is producing the anatomical model. Our proposal is consistent with current regulation of x-ray systems: X-ray systems are regulated as medical devices, but the individual images generated by the systems are not separately regulated as devices.

In addition, we support the language in section four of the Consultation document that explicitly states that models intended for training or education purposes would not be subject to regulation. We would propose clarifying that such training/educational purposes would include use for informed consent, i.e., presentation to patients by a specialist to inform the patient about the procedure.

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,

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AdvaMed