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Therapeutic Goods Administration
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Public Submission – Consultation: Proposed regulatory scheme for personalised medical devices, including 3D printed devices

Response to the TGA consultation on proposed regulatory scheme for personalised medical devices

The Biomedical College within Engineers Australia is the organisation representing professional Biomedical Engineers in Australia. Our members work in many areas within the healthcare system, public and private, academia, research and development and manufacturing, applying engineering principles in conjunction with our clinical colleagues to deliver better health outcomes for Australians.

We welcome the opportunity to provide comment on the TGA proposals in this expanding area of healthcare delivery and recognise the need for regulatory systems to evolve, just as healthcare delivery, treatment modalities and the technologies to delivery positive outcomes evolves.

We are concerned however about what we perceive as overreach and proposed over-regulation along with imposed compliance burdens for no perceived benefit, either to the delivery of healthcare or a better outcome for the patient, particularly with low risk medical devices such as prostheses, customised wheelchairs and other aids for people with disabilities for example.

Current requirements for custom-made medical device manufacturers

The paper, as presented, is potentially misleading and does not clearly represent the obligations **already** imposed by the regulatory framework. Section 2 of the paper suggests the only requirements imposed on a manufacturer of a custom-made medical device are to –

- Notify the TGA of the custom-made medical devices they are manufacturing; and

- Prepare a written statement declaring the matters described in Schedule 3, Part 7.2 (2) and (3) of the Regulations (commonly known as a Declaration of Conformity)

The paper makes no mention of the requirements imposed under Schedule 3 Part 7.2 (4), (5) and (6) which include –

- keeping up to date documentation in relation to the device, including information in relation to the design, production and intended performance of the device;
- Ensuring that all measures are undertaken to ensure the manufacture process for the device is in compliance with those documented procedures; and
- Detailed postmarket reporting obligations.

Whilst brief in words, these requirements which are already in place outline what could be called good business practice, and form the core elements of a quality management system, a requirement similar to that imposed on all other medical devices except class I devices, and would be already in place and implemented by most, if not all, custom-made medical device manufacturers.

Supply of a Declaration of Conformity to the end user

The paper suggests introducing a requirement that the Declaration of Conformity be provided to the user of a custom-made medical device.

This is a practice undertaken by many 'mainstream' medical device manufacturers already and we agree, and support this concept.

Medical Device Production System

We believe the paper confuses the process of manufacturing a custom-made medical device with the output of the manufacturing process for the device in suggesting a Medical Device Production System (MDPS) *'…..like other systems would be considered to be medical devices and would be included on the ARTG*.' The ARTG is a Register of therapeutic goods, be they medicines, biologicals or medical devices. It is not a register of manufacturing processes, or the equipment used in those processes. These items, typically workshop or laboratory fabrication equipment, in and of themselves are not medical devices, and we do not believe the ARTG is an appropriate repository for them. Similarly, the manufacturing systems utilising these are not comparable to 'systems' as regulated by Schedule 3, Part 7.5 of the Regulations.

A more appropriate approach would be to establish and issue a Conformity Assessment Certificate for the manufacture of custom-made medical devices where appropriate (Class IIb and higher) and maintain a database of certificates issued, as is currently done with 'mainstream' manufacturers of medical devices which are assessed by the TGA. This certification process should take into account the utilisation of professional engineering

practices including design and process control (i.e. considered design, risk management, verification and validation processes).

The proposal in Section three of the paper where it is suggested that manufacturing equipment and consumables used in a MDPS would not be considered medical devices on their own, but none-the-less they would be *'…….classified and assessed according to the device they are intended to produce'*. This begs two questions, firstly how is it possible to classify a non-medical device and, secondly, which part of the medical devices regulatory framework gives the Agency the authority to regulate non-medical devices.

Further, the first paragraph in Section 3 suggests a MDPS '….used by a healthcare provider, or healthcare facility…..' would be regulated under the proposed framework. But, under the Heading **What would this mean?** It indicates *'Healthcare providers or healthcare facilities that use MDPS's to produce medical devices…….would not be considered manufacturers……'* and *'….. would not need conformity assessment certification.'*

It is unclear what the ultimate benefit of this proposed framework might be, compared with the effort/cost it would require to set-up, implement and maintain.

As we understand it, the paper introduces inequalities in the proposal to regulate MDPS's. Firstly, there is a proposal to regulate a MDPS and, by a means not described, enter that system on to the ARTG.

Yet under the heading '**What would this mean?**, the paper suggests "*Healthcare providers or healthcare providers that use MDPS's to produce medical devices would not be considered manufacturers under the regulatory framework in relation to those systems'.* This raises the question, is this establishing one system for the commercial sector and another system for healthcare providers or healthcare facilities. Our members would consider themselves '*healthcare providers'* regardless of being employed in the public or private sector,working within a *'healthcare facility'* and thereby their activities and the custom-made devices they produce not covered by this proposed framework.

In fact private practitioners, providing orthoses, custom-made wheel chairs and other aids for people with disabilities would also consider themselves to be 'healthcare providers' and thus not covered by the proposed framework.

It is the view of the EA Biomedical College that there should consistent expectations across all organisations undertaking the design and/or manufacture of medical devices, including those that are custom-made or personalised.

Record keeping

The paper suggests there are existing record keeping requirements of 5 years for custom-made medical devices.

Record keeping requirements fall under the conditions which can be imposed under Section 41FN of the Therapeutic Goods Act 1989 and are specified in Regulation 5.10.

We understand these requirements are imposed on a medical device as a condition of inclusion on the ARTG. Custom-made devices, by their nature and by regulation, are exempt from entry on the ARTG so this condition is not applicable.

None-the-less, the College supports a provision for record retention of custom-made devices and proposes –

- 15 years beyond the date of manufacture of the device for Class III and implantable Class IIb medical devices
- 5 years beyond the date of manufacturer, or until the existing device is replaced by a newer custom-made device for use by the user, for all classes of medical device.

Provision of an annual report

We question the practicalities and usefulness of this proposal, and ask what the TGA would do with the information provided.

There is already a notification process in place to advise the Agency of custom-made medical device manufacturing being undertaken, and we note that although this requirement was introduced in October 2002 with the implementation of the current regulations, it was not implemented until about ten years later, with very little notification to organisations affected to advise them of their new responsibilities. As a consequence the data currently held by the TGA is likely to reflect only a small part of this industry sector.

In implementing such a requirement there is –

- an imposition of additional resources for the custom-made device manufacturer to generate and provide the data; and
- a resource requirement on the TGA to collect, store, maintain and most importantly, having asked for the data, to undertaken a meaningful and useful analysis of the data.
  There is no benefit to anyone if the data is collected and simply stored '…..because it may be useful one day'

Broadly speaking, Section 41JA of the Act currently allows the Secretary to request information when a Conformity Assessment application is in process, or a certificate has been issued, or an application for inclusion on the ARTG is in process or the device is entered on the ARTG.

Rather than request annual reports from custom made medical device manufacturers, we believe it to be a better use of resources to amend Section 41JA of the Act to allow the Secretary to also be able to require information not only for inclusion applications or included devices, but also for exempt medical devices, as and when required, up to a period with similar timeframes as the record retention requirements and when an application for conformity assessment is required, a certificate issued for custom-made

medical devices or an issue arises which warrants active investigation of a low risk custom-made device or devices.

The end result would be the same without the additional resource overheads to either manufacturers or the TGA.

In this way, resources for both the manufacturer/sponsor and the TGA can be better utilised and focused on ensuring device performance and safety……for example focusing on investigating and assessing postmarket performance, and investigation reported adverse events.

Jurisdiction

We have already raised the question of the confusion raised by the paper's proposal and its potential impact, or not, on *'healthcare providers'* and *'healthcare facilities'*.

There is also the question of jurisdiction of the TGA over activities undertaken in healthcare facilities, hospitals and other institutions owned and operated by the State Governments. In part, Section 6 of the Act gives the TGA jurisdiction over corporations and over persons or corporations trading across State or national borders.

The applicability of the Act therefore to State operated institutions has never been clear, and it is generally been acknowledged in the past that the TGA has either been reluctant or unable to engage in regulation in these organisations, unless the organisation, or unit within the organisation, is incorporated. Some but not all States and Territories of Australia have adopted the Therapeutic Goods Act either by direct adoption, or by reference.

Custom-made medical devices for the healthcare professional

The current definition of a custom-made medical device includes the concept of a medical device custom-made to meet the special needs of a healthcare professional arising in the course of his or her practice. This circumstance is different to that where the custom-made device is to be used in relation to a particular individual or patient. No mention is made in the paper proposal of regulation of these healthcare professional related activities or the impact imposition of the proposed framework on the delivery of healthcare, delivery of clinical services, patient wellbeing or treatment outcomes, except as an example of a modified endoscope as a custom-made medical device in Attachment 1 which provides IMDRF definitions and examples.

Nor is any mention made of excluding such devices from the proposed framework, and this is of extreme concern to the College and its members. While not occurring on a daily basis, it is not uncommon for engineering and technical departments within healthcare institutions, research institutions and similar organisations to be requested to design and build or modify custom-made or customised medical devices, particularly when there is no commercial device available to suit the specific clinical need, time is of the essence or it is required as part of a research or teaching program, for example.

Further the requests vary widely in their specification and complexity from a simple patient ventilator circuit adaptor, production of a specific form of examination light or the example cited in the paper, to a complex anaesthetic gas delivery system or modification of a ventilator to suit specific clinical needs of a patient. Instances also occur occasionally of the urgent need for a particular device and delays in ordering and commercial supply would compromise clinical outcome for the patient.

The consultation paper is weighted heavily in discussing 3D printed custom-made medical devices, but does not seem to consider the fact that in producing a custom-made device, either for a named individual or a healthcare professional, many technologies are potentially used in its fabrication, and the proposal, as it stands, could impact heavily of workshop and laboratory activities currently undertaken in healthcare institutions.

Manufacture and provision of such custom-made devices is not undertaken lightly and is typically covered by standard operating procedures in the institution along with guidance in Australian Standards for managing such requests, design control, documentation, manufacturing, validation and labelling of the finished device along with on-going asset management requirements.

The advantages to the healthcare professional, the institution and ultimately the clinical outcome for the patient are many, the disadvantages few, with the risks already adequately and professionally managed.

The paper presents no evidence of potential issues or adverse events to exhibit a need to impose the proposals in the paper on these activities.

Further, the TGA cites its review program for medical devices is to align as closely as possible with the EU Medical Device Regulations recently introduced, The EU MDR is silent on defining such devices or on the regulation of such activities.

We believe, and recommend the manufacture of custom-made devices for use by the healthcare professional should continue to remain exempt from any proposed changes, and the requirements of Scheduler 3, Part 7.2 continue to apply in this area.

To do otherwise would impose significant resource implications and costs over an activity already well regulated and controlled by institution accreditation requirements, Australian Standards, internal procedures and in some instances, State based regulation. It would also restrict, in many instances, treatment options and impact on positive clinical outcomes for patients.

A risk based approach to regulation of custom-made medical devices

The College believes the most appropriate approach to be a risk based approach to the regulation of custom-made medical devices where those devices are produced in accordance with a request from a healthcare professional, specifying the design characteristics or construction of the device, and the device is intended to be used in relation only to a particular individual.

We propose –

- The current notification process for custom-made medical device manufacturers remains for custom-made medical devices manufactured to meet the needs of a specific individual;
- Notification of manufacture of custom-made medical devices to meet the specific needs of a healthcare professional be exempt from notification;
- Section 4JA of the Act be amended to allow the Secretary to request information in relation to medical devices exempted from entry on the ARTG by Schedule 4 of the regulations;
- For medical devices up to and including class IIa that the current regulatory framework in Schedule 3, Part 7.2 of the Regulations is applied;
- Manufacture of custom-made implantable class IIb and class III medical devices intended to meet the needs of a specific individual, either by a commercial organisation or a healthcare facility be regulated in the same way as 'mainstream medical devices; and
- Discussions commence with the States and Territories and other relevant stakeholders about a suitable regulatory framework for the manufacture of custom-made medical devices in State operated and funded healthcare institutions.

We would welcome the opportunity to discuss this submission with officers of the TGA at the earliest opportunity.

Yours Sincerely

The Board of the Biomedical College
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