Biomedical Engineering College

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ENGINEERS
AUSTRALIA

Personalised Medical Devices Consultation Team
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Thank you for the opportunity to provide comment on the proposed refinements to the regulation of personalised medical devices.

Engineers Australia is the peak member-based professional association for engineers. Established in 1919, Engineers Australia is constituted by Royal Charter to advance the science and practice of engineering for the benefit of the community. Our work is supported by around 100,000 individual members.

This submission has been developed with the support of members of Engineers Australia's Biomedical College.

You have requested responses to a series of questions proposed in the associated consultation paper. Our responses are provided below.

Exclusions

1. **Do you agree with the rationale for the proposed exclusion of products? If not, why not?**

No, the Biomedical College does not agree with the proposed exclusions.

The consultation paper proposes to not regulate medical devices '*…..where there is no risk to safety……*' We consider this statement to be fundamentally wrong. There is no such thing as zero risk, with all devices presenting some risk, the degree of risk is dependent on the frequency and severity of any potential hazard presented.

The Therapeutic Goods Act 1989 provides a definition of a medical device, and it is our view that if a device fits within that definition it is the responsibility of the TGA to provide regulatory oversight of the device. The concept of 'exclusion', as used in the Therapeutic Goods (Excluded Goods) Determination 2018 should only be used where there is a lack of clarity or ambiguity as to whether a device fits within that definition, or not.

We acknowledge that excluding a device from the jurisdiction of the TGA still requires compliance with requirements of the Competition and Consumer Act administered by the Australian Competition and Consumer Commission. However, whereas the regulatory framework for medical devices administered by the TGA is proactive in establishing mandatory safety and performance requirements prior to placing a medical device on the

market, the framework administered by the ACCC is only reactive in most instances and takes action once an adverse event or events has occurred.

Regulating safety and performance after the event is not an appropriate framework for regulating medical devices.

2. **Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.**

The proposal of excluding some medical devices from the jurisdiction of the Therapeutic Goods Act 1989 will leave the potential risks unaddressed prior to placing a product on the market.

The Essential Principles (of safety and performance) embodied in the medical devices regulatory framework provide a base level of compliance that must be demonstrated and documented prior to placing a product on the market.

Examples of unaddressed risk with seemingly benign and low risk devices include:

- The death of a number of infants when wooden tongue depressors were used in splinting limbs of neonates, where the timber was infected with a wood fungus that entered the patients' blood resulting in septicaemia;
- The triggering of an allergic reaction when spectacle frames were manufactured of a metal alloy containing high levels of Nickel; and
- The risk of fall injury, particularly in the elderly population, as a result of poorly constructed walking aids such as walking frames and rollators.

3. **Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?**

   Please provide an explanation for why:

   - **the product represents no, or insignificant levels, of risk; or**
   - **the product does not meet the definition of a medical device.**

As previously indicated, if a medical device falls within the definition contained within the Therapeutic Goods Act 1989, the TGA has a responsibility to provide regulatory oversight of that device. Excluding a device from the jurisdiction of the Act removes that oversight.

Following on from that, we note there appears to be conflict between determinations in two regulatory instruments for which we seek some clarification in relation to currently excluded or exempt devices. Item 9 of Schedule 1 of the Therapeutic Goods (Excluded Goods) Determination of 2018 specifically **excludes** *household and personal aids or furniture and utensils for people with disabilities* from the jurisdiction of the Therapeutic Goods Act 1989 whereas Items 2.12 and 2.13 of Part 2 of Schedule 4 of the Therapeutic

Goods (Medical Devices Regulations 2002 only **exempts** custom made devices from entry on to the ARTG.

Many assistive technology devices, for example, are custom made or patient matched for an individual client and fit within the intent of the words '*household and personal aids……for people with disabilities',* begging the question whether such devices exempt or excluded. Any adjustments to the regulatory framework for personalised medical devices must address and clarify this issue.

Exemptions

4. **Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**

No, the Biomedical College does not agree with the proposed exclusions.

The Australian Register of Therapeutic Goods serves many purposes but one of its most basic functions is to understand **who** is placing **what** on the market, thereby providing the TGA with a tool to identify the manufacturer and sponsor in the instance a hazard or risk is identified with a medical device. Exempting medical devices from entry on the ARTG removes that ability.

We believe that, even for health care professionals who manufacture patient matched medical devices, notification of that activity to the TGA should be required, as has always been the case.

However, the recently introduced annual reporting requirements for manufacturers of custom-made devices is overly burdensome and we question the rationale behind the requirements. We question why the TGA considers it necessary for this information to be provided for this category of devices and not other 'mainstream' medical devices. The framework requires custom-made device manufacturers to notify the TGA of their activities so, armed with that contact information, the TGA can ask an individual manufacturer or group of manufacturers to provide that information at any time as with 'mainstream' device manufacturers in the course of a post market review.

5. **Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.**

No, the potential risks cannot be adequately addressed if medical devices are exempted from entry on the ARTG.

By way of example, prior to 2002, non-sterile, reusable surgical instruments, which relied on manual dexterity for their use, were exempted from inclusion on the ARTG but were still considered a therapeutic device and regulated by the TGA. When it was found necessary to recall a range of orthopaedic hammers because of the presence of bodily residues even after cleaning and sterilisation, the TGA had to resort to the yellow pages phone book to try to identify suppliers of affected products.

6. **Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?**

   Please provide details:

   - **describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.**

We do not consider the acquiring of a particular qualification or accreditation, certification or any other form of credentialing provides sufficient oversight or reduces potential risk or addresses the regulatory provisions provided by the Therapeutic Goods Act 1989 and subordinate regulations.

While many health care professions have associations or institutions that provide certification or accreditation and credentialing for their members, including the Biomedical College within Engineers Australia, membership of such associations is voluntary and, as a consequence, not all practitioners in a profession will be members and subject to those requirements.

Furthermore, where credentialing is provided, it tends to focus more on competency of professional practice, not on competencies of risk minimisation and mitigation or on device design.

Inclusion in ARTG using alternative conformity assessment procedures

7. **Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?**

8. **Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.**

9. **Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?**

The Biomedical College agrees, in part, with the proposal for an alternative conformity assessment procedure for personalised medical devices.

We do not believe accreditation or credentialing by some professional associations alone is sufficient to mitigate potential risk with the manufacture of a personalised medical device.

As previously mentioned, membership of a professional association is, in most instances, voluntary meaning the association has some of control only over its members.

Furthermore, many associations exist only to provide continuing professional development opportunities or industrial advocacy and assistance for members.

While not singling out the dental healthcare professionals specifically, but only because they are cited in the paper as exemplar possibilities in accessing the alternative conformity assessment procedure, in relation to personalised dental medical devices, the paper suggests an inequality in access to the alternative conformity assessment procedures between

- A dental technician with a recognised AQF qualification; and
- A dental laboratory accredited by the Australian Oral Health Professional Association,

where the personalised medical device produced is to be used by a patient of the healthcare facility, a registered provider or AHPRA registered healthcare facility.

This suggests a sole practitioner dental technician need only have a recognised AQF qualification with no accreditation by any organisation, whereas a dental laboratory requires accreditation in some form as well as demonstrated competencies and qualifications. The same potential inequality will exist for other healthcare professionals depending on whether they practiced as a sole practitioner or partnership/incorporated body.

As with any healthcare profession, a recognised AQF qualification is only the beginning of a life-long learning process and typically a new graduate will spend time working with or under the supervision of a more competent practitioner. For this reason, many professional associations have tiered levels of membership such as graduate, member, senior member, fellow, etc, representing expected and demonstrated levels of competence.

As an example, as a Biomedical Engineering College, we would not consider a graduate member as having sufficient competencies and knowledge to act as a sole practitioner without supervision upon graduation. For the same reason, we would not consider any newly graduated healthcare professional competent or eligible to access the alternative conformity assessment procedure based on qualifications alone.

To be considered as a potential certifying organisation under the proposed framework, we believe an industry association, as a minimum, must have:

- formal qualification requirements for membership entry;
- ongoing continual professional development (CPD) requirements;
- formal oversight of members (for example, regular auditing of CPD compliance);
- a published Code of Conduct/Ethics and mandated compliance with that Code; and
- appropriate disciplinary procedures, up to and including de-registration or removal of credentials, for breaches of professional conduct or non-compliance with the Code of Conduct/Ethics.

Furthermore, having graduated levels of membership based on demonstrated competencies and commitment should be considered essential and access to the alternative conformity assessment procedure limited to full membership and above in a tier membership structure.

The consultation paper suggests medical devices manufactured

- within a healthcare facility accredited against the NSQHS Standards or
- by a provider registered with the NDISQSC or
- by a healthcare professional registered with AHPRA

could be eligible for an alternative conformity assessment procedure. In doing so, it precludes

- sole practitioners not operating within a healthcare facility and
- suppliers of personalised medical devices who are
    - supplying to clients who are outside the scope of the NDIS or
    - supplying to clients who may or may not be eligible for, but are not yet receiving NDIS funding or
    - healthcare professionals providing personalised medical devices but not required to be registered with AHPRA or the NDISQSC.

Examples of these exclusions include such professionals as orthotists, prosthetists, audiologists and biomedical engineers.

Whatever form the final ability to access the special conformity assessment procedure presents as, provision needs to be made for these categories of healthcare professionals to have access.

By way of example, Engineers Australia operates the National Engineering Register (NER). Entry onto the Register is based on an engineering professional's demonstrated levels of competence and commitment and is detailed in a number of specified areas of practice. Being entered on the NER is a mandatory state-based legislated requirement in some areas of practice such as building and structural engineering, but membership of Engineers Australia is not mandated in the relevant legislation.

As a consequence, a person entered on the NER must be able to demonstrate competence in a nominated area of practice, but membership of Engineers Australia is **not** a requirement.

In considering a professional association to act as a credentialing authority, it would be encouraging to see the organisation has procedures for assessing appropriately qualified health care professional who are not registered members of the association.

10. Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?

No. By their very classification, class IIa medical devices are only those towards the lower end of the risk spectrum, and that risk can be managed by an appropriate conformity assessment process.

In Conclusion

In order to be able to deliver on its regulatory responsibilities we believe it appropriate to have a tiered level of controls over personalised medical devices administered by the TGA -

- For manufacturers of custom made devices and utilising the conformity assessment procedure detailed in Part 7.2 of Schedule 3 of the Regulations, notification to the TGA of their activity and a broad scoping of the devices they manufacture;

- For manufacturers of Class I patient matched medical devices, notification to the TGA of their activity and scoping of the devices they manufacture utilising GMDN collective terms;

- For manufacturers of Class IIa patient matched medical devices and accessing the proposed alternative conformity assessment procedure, entry of the devices on the ARTG using GMDN preferred terms;

- For manufacturers of Class IIa patient matched medical devices and not accessing the proposed alternative conformity assessment procedure, implementation of an appropriate formally certified conformity assessment procedure as detailed in Regulation 3.8 of the Therapeutic Goods (Medical Devices) Regulations 2002.

We thank the TGA for the opportunity to provide comment on the proposed refinements to the regulation of personalised medical devices and would be happy to answer any questions you may have in relation to this submission.

Yours sincerely

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