AUSTRALIAN MEDICAL ASSOCIATION

[redacted]

AMA submission to the Therapeutic Goods Administration – Proposed refinements to the regulation of personalised medical devices

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The AMA supported the recent changes to the regulatory framework for personalised medical devices. The AMA believes the reform is important to ensure patient access to safe and quality products providing optimal outcomes.

The TGA and other regulatory bodies are faced with new challenges relating to a rapid increase in innovative technologies that mean new professions can be defined as manufacturers of medical devices (such as health practitioners registered under the Australian Health Practitioner Regulation Agency). The AMA understands that the recent regulatory reform has resulted in a duplication of regulation across multiple regulatory bodies for some medical devices.

The AMA does not want to see a situation where healthcare facilities face exorbitant costs while seeking Australian Register of Therapeutic Good (ARTG) registration, as healthcare facilities are already severely underfunded, and costs may pass on to the patient. However, patient safety is of the upmost importance and therefore the same quality and level of regulation must be maintained no matter who the most appropriate body is. The AMA believes that the TGA must remain the main body who determines and implements appropriate regulation for therapeutic goods. Having several other regulating bodies has the potential to cause confusion and non-compliance, and so this arrangement must not be the norm.

Therefore, the AMA supports the proposed improvements to Class I non-sterile, non-measuring patient-matched medical devices and Class IIa patient-matched medical devices, provided that the following principles are met:

- Patient-matched medical devices are regulated once, with the TGA being the default/primary regulator.
- Exemptions and alternative conformity assessment procedures are considered on a case-by-case basis in thorough consultation with the alternative regulating body.
- Alternative regulation is at least equivalent to TGA regulation.
- Alternative regulatory bodies must report to the TGA if there is a change in the way they regulate patient matched medical devices. From there, TGA regulation should automatically resume if regulation is eased.

- Health practitioners are not held accountable for errors that are produced as a result of a machine/material issue.
- The TGA reviews the impact of these changes 12 months after they have been implemented to ensure safety and quality systems are appropriate and there are no unintended consequences.

Patient-matched medical devices proposed to be excluded from TGA regulation

If a product meets the legal definition of a medical device, it is unlikely to be completely devoid of risk or the potential for patient harm. Therefore, the AMA believes that all products that meet the definition of a medical device should still be subject to TGA regulation. The powers under the TGA are fundamental to patient safety and practitioner confidence in the quality, safety, and efficacy of medical devices. Without TGA oversight, the AMA is concerned that the quality and safety of these products, even though they are considered 'low risk', will be compromised. For example, while prosthetic eyes may be considered 'cosmetic', a bad prosthetic fit can result in infection[1]. Deregulation may also result in potentially problematic materials being used that may cause damage and infection to the eye socket. Class I medical devices already have suitably lower regulatory requirements than higher Class medical devices[2].

The TGA must be properly funded and resourced to ensure the safety of the system is maintained.

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[1] Mourits DL, et al (2017) *Discharge and infection in retinoblastoma post-enucleation sockets*. Clin Ophthalmol. 2017;11:465-472

[2] *Therapeutic Goods (Medical Devices) Regulations 2002*.