AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T | 61 2 6270 5400
F | 61 2 6270 5499
E | info@ama.com.au
W | www.ama.com.au
42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

AMA submission to the Therapeutic Goods Administration – scope of regulated software-based products

devicereforms@health.gov.au

Introduction

Thank you for the opportunity to provide feedback on options to *exclude* or *exempt* certain software-based medical devices from the *Therapeutic Goods Act 1989* (TGA Act).

The AMA considers the definition of "medical device" in *s41BD Therapeutic Goods Act 1989*, and the regulatory oversight of them, fundamental to high quality healthcare. Clinicians and patients who use medical devices must be able to trust software-based device efficacy and accuracy.

Consistent with other international regulatory jurisdictions (Canada, and the EU), the AMA supports TGA education and guidance as the preferred redress for software-based device manufacturers/designers who are unsure if their proposed device falls into the definition of 'medical device' and subject to TGA regulation.

The AMA does not support a full regulatory '***exclusion'*** for software-based products that meet the legal definition of a medical device. The powers under the TGA Act are fundamental to patient safety and medical practitioner confidence in the efficacy and reliability of the medical devices used for patient diagnosis, treatment and monitoring. Poorly coded software or AI that generates an erroneous result, which is relied on by medical practitioners to make patient management decisions that threaten or diminish patient health, is as harmful as a malfunctioning, faulty or non-efficacious hardware device. In both cases, the risk to patient safety is substantially reduced if the software-based medical device is regulated by the TGA.

The range of regulatory classes and scale of TGA oversight already permit regulation alignment matched to the device manufacturer's assessed risk of potential patient harm. For example, low risk Class 1 devices are listed on the ARTG and have low barriers to market entry in Australia, but remain subject to TGA requirements to maintain evidence of device safety, quality and efficacy,

and remain subject to TGA post market monitoring, adverse event notification and, if necessary, TGA recall or hazard event notification if there is a problem. It is appropriate that *all* software devices, that perform the functions of a medical device definition in law, remain subject to these key post market TGA powers. This is paramount to the long-term safety and quality of care in Australia.

Software device *exemptions* where suitable frameworks for product or system oversight are already in place

The proposition to *exempt* (down-grade) TGA regulation if a software-based medical device is regulated by a different framework, is potentially problematic and best considered case by case. Before a decision to downgrade TGA regulation, a full investigation of the alternative oversight framework should be conducted to identify comparatively lower standards of regulation in the alternative framework. TGA regulation should be retained to fill these comparative gaps. Even if an alternative framework sets accreditation standards equal to or more stringent than TGA regulatory processes, contingencies should be built into any conditional *exemptions* to ensure that if, at a later date, the alternative accreditation or regulatory framework is weakened or removed, full TGA regulation *automatically* resumes.

Examples of existing alternative frameworks that are as robust as TGA requirements are rare. The National Pathology Accreditation Advisory Council (NPAAC) accreditation standards applied to pathology providers who claim against MBS and satisfy NPAAC accreditation standards may be one of these rare exceptions. We understand laboratory compliance with NPAAC standards is so rigorous, TGA usually accepts compliance with NPAAC requirements as the test for TGA approval. Even so, it remains the case that oversight and regulation of all aspects of pathology testing in Australia, will still require a mix of NPAAC accreditation standards and TGA regulation powers. Consequently, an *exemption* (partial de-regulation) under the TGA Act may be the way forward, to remove duplicated regulation of IVD software-based devices for NPAAC accredited pathology providers, while still ensuring TGA oversight for all non-approved pathology providers and commercial IVD software-based medical devices. TGA notification requirements for public health risks (such as COVID-19) should also be retained in relation to pathology services. In the unlikely event, NPAAC accreditation standards are downgraded in the future, the AMA would expect to see TGA regulation reapplied in full.

In contrast, the regulation of registered medical practitioners under the Medical Board is not a sound justification for automatic exemption of software-based medical devices used by medical practitioners. This proposition would pass responsibility for device safety and quality, efficacy and performance from the software developer/manufacturer, to the medical practitioner user. This is unreasonable because the user, is not involved in, or responsible for, the device development or algorithms, nor responsible for device efficacy or information accuracy. It is totally unacceptable to expect the medical practitioner, device user, to bear responsibility for patient harm under their own medical board regulation, when the patient harm is a direct result of erroneous information produced by a poorly designed software medical device.

TGA *exemptions* where there is no risk to safety

There is a wide variation in the type of medical-device software and software devices are rapidly evolving. If a software satisfies the legal definition of a medical device, it is unlikely, to impose nil risk of potential patient harm. Even an apparent low risk device that uses sensors or images to monitor an ongoing mild or self-limiting condition can increase the risk of patient harm in the following circumstances:

- The information from the software device is interpreted by the patient outside of a doctor:patient therapeutic relationship.
- The information from the software device generates unnecessary patient fear and anxiety about their condition, or alternatively, a dangerous false sense of security that causes a patient to delay a consultation with their treating doctor, when a face to face consultation is clinically appropriate.

The difference between best practice clinical guidelines, and clinical decision support software is substantial. Best practice clinical guidelines are a decision aide for medical practitioners to inform their own assessment of best practice treatments for an individual patient. As noted in the consultation paper, best practice clinical guidelines would not meet the definition of medical device. The AMA notes once the intent of a d*ecision support software* transitions to *specify* a patient treatment (individual patient radiotherapy dose plan), *provide* a diagnosis, *analyse* individual patient data to *screen* for a disease, or *provide* a therapy – it becomes clearly recognised as a medical device and subject to TGA regulation.

In contrast the clinical decision support software described on page 16 of the consultation paper, meets the definition of medical device, but the description of the intended use is framed as a medical practitioner *aide* to:

- analyse medical information about a patient;
- *support* or provide *recommendations* about the diagnosis or treatment of a disease.

The software intent makes clear the information produced by the clinical decision support software does not absolve the medical practitioner's responsibility to independently review the software recommendations.

The proposed exemption of clinical decision support software that fits the legal definition of a medical device, but only *recommends* a diagnosis, or treatment has the potential to become very confusing for medical practitioners. It is unclear how the TGA will monitor the continued appropriateness of a regulation exemption if, over time, the designer/developer changes the software algorithms and distributes these changes via software upgrades. A decision support software that formerly recommended a diagnosis or treatment could transition over time to become a decision support software that *provides* a diagnosis or *specifies* a treatment such as an individual patient radiotherapy dose plan. At this point the clinical decision support software

must become regulated because erroneous software generated individual patient diagnosis or treatments represent a serious threat to patient safety.

It is the AMA's preference, to maintain a clear logic so that if the function of a clinical decision support software meets the definition of a medical device, it remains subject to TGA requirements to meet all relevant Essential Principles and demonstrate device efficacy and information accuracy pre-market. Before some form of conditional *exemption* is granted for a clinical decision support software described on page 16 of the consultation paper, the AMA would welcome TGA clarification about how software decision support software that is exempt today, will be monitored over time to ensure the level of TGA regulation always remains aligned with the evolving software function.

Conclusion

In principle, the AMA does not support the use of *exclusion* powers in the TGA Act for software based medical devices that fit the legislated definition of medical device. TGA powers to require manufacturers to demonstrate compliance with Essential Principles including software efficacy and accuracy pre-market are central to patient safety. As are the TGA requirements for post market monitoring, adverse event reporting, public alerts and if necessary, software device recall.

In AMA's view there are very few existing software-based devices suitable for *exemption*. Exemptions due to regulatory overlap with alternative accreditation/regulation frameworks must be assessed case by case. The AMA would expect alternative framework/accreditation systems would only justify a TGA exemption if the alternative framework is equal to, or more robust than TGA pre and post market requirements. If an exemption is granted, and the alternative accreditation framework is weakened or removed in the future, full TGA regulation should resume.

Exemptions because the software device presents no risk to patient harm, is fraught. The AMA does not know of any software that meets the definition of a medical device but poses *no* risk to patient harm if information produced from the software is erroneous.

Even a clinical decision support software that is described by the software designer, as an *intended aide for clinical decision making*, advises medical practitioners to independently review the software recommendations and not intended to be relied upon fully, could set a dangerous precedent. Especially if the algorithms in the software are changed over time via software upgrades, to bring the functionality of a software previously advisory, to something that is equal to the type of clinical decision support software that *provides* a patient diagnosis, or *specifies* an individual patient treatment.

The AMA would prefer to maintain a clear logic so that if clinical decision support software meets the definition of medical device it remains subject to TGA regulation. This cautious approach

acknowledges the rapidly evolving medical device software industry and helps future-proof against a software device exemption that maybe defensible today but becomes problematic in the future.

The issues raised in the scope of regulated software-based products are very technical and complex. Before any action is taken on which type of medical device software is carved out of TGA regulation by *exclusion* or *exemption*, it may be beneficial to hold further discussions with impartial stakeholders who have deep expertise on these issues. AMA would like to remain engaged to ensure the impact on medical practitioners from carve out decisions, are taken into account.

May 2020

Contact

Leonie Hull
Senior Policy Adviser
lhull@ama.com.au