28 April 2020

Ms Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Department of Health

Submitted via online consultation submission form

Therapeutic Goods Administration Consultation Paper on Software-Based Medical Devices

The Australian Healthcare and Hospitals Association (AHHA) welcomes the opportunity to provide comments on the Therapeutic Goods Administration (TGA) consultation paper on the *Scope of Regulated Software-Based Products*.

AHHA is Australia's national peak body for public hospitals and healthcare providers. Our membership includes state health departments, Local Hospital Networks (LHNs) and public hospitals, community health services, Primary Health Networks (PHNs) and primary healthcare providers, aged care providers, universities, individual health professionals and academics. As such, we are uniquely placed to be an independent, national voice for universal high-quality healthcare to benefit the whole community.

In general, AHHA supports the proposed approach of internationally aligning the Australian regulatory framework for medical devices where appropriate, not regulating products where there is no risk to patient safety or public health and noting that products are still subject to relevant consumer laws, and not regulating a product where an appropriate patient safety framework for a product or system oversight is already in place.

AHHA supports the tiered approach to the regulation of software-based medical devices based on the risk to a patient or public health from use of the device. AHHA also supports recognition of certification of products from internationally reputable regulators where an equal or higher certification level has been applied. AHHA agrees that manufacturers

PO Box 78 Deakin West ACT 2600 Unit 8, 2 Phipps Close Deakin ACT 2600
T. +61 02 6162 0780 F. +61 02 6162 0779 E. admin@ahha.asn.au W. www.ahha.asn.au
ABN 49 008 528 470

should not be subject to unnecessary regulatory oversight on the proviso that patient safety and public health in Australia are not compromised.

The carve-out mechanism described in the consultation paper provides for excluded and exempted software-based medical devices not being regulated under qualifying circumstances. AHHA agrees in principle that some medical devices could safely be used without TGA oversight or with reduced oversight. However, this should only be in circumstances where there is no risk to patient safety or public health through the proper use or non-compliant use of the software-based medical device.

The consultation paper suggests a threshold of medical devices that "are considered to pose no significant threat of harm" (page 15). AHHA consider this too high a level of risk for a medical device to be allowed to be unregulated or have a reduced regulatory oversight. Without seeking to place unnecessary burden on producers of software-based medical devices, the higher public policy priority is patient and public health safety, and the relevant threshold should reflect this.

AHHA also recommends that there be a requirement to review the appropriateness of a software-based medical device continuing to be granted excluded or exempted status. As noted in the consultation paper, the digital health environment is rapidly evolving with many health-based products crossing or blending traditional boundaries of therapeutic product definitions. AHHA therefore recommends that software-based medical devices that are excluded or exempted from TGA regulatory requirements have this status reviewed every two years, or other period considered appropriate in the circumstances, to assess if the absence of regulatory oversight remains appropriate.

The classification rules outlined in Appendix 2 of the consultation paper appear to appropriately grade the potential risk to patient safety and public health.

I would be happy to further discuss any of these points with you.

Sincerely,

Dr Linc Thurecht
Senior Research Director
Australian Healthcare and Hospitals Association