AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM: D19-8592

Adjunct Professor John Skerritt
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Therapeutic Goods Administration
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Via email: devicereforms@tga.gov.au

John

Dear Professor Skerritt

Submission to the Consultation: Regulation of software, including Software as a Medical Device (SaMD)

The Australian Commission on Safety and Quality in Health Care (the Commission) welcomes the opportunity to provide a submission to the Therapeutic Goods Administration's (TGA) public consultation concerning regulation of software, including Software as a Medical Device (SaMD).

The Commission supports the TGA's efforts to minimise public health and safety risks and maintain consumer confidence through the proposed amendments to the regulation of software, including SaMD. The Commission notes that many SaMD products fall outside of the TGA's current classification system for medical devices, and are not generally subject to other forms of government regulation or standards. The TGA's proposed regulation for SaMD will improve the monitoring of SaMD products to reduce potential and actual risks of patient harm.

The consultation paper considered the regulatory impact of the proposed changes, including administrative and compliance costs by SaMD manufacturers and sponsors. It is recognised that SaMD products, particularly mobile applications, operate in a rapid and agile market. Consideration should be given to more frequent inspections, beyond the suggested annual inspection indicated in the consultation paper, to maintain conformance with TGA regulations. SaMD manufacturers and sponsors should be encouraged to demonstrate conformance in parallel to any software update to their product or service. In this instance, a validation process may be suitable compared to a full conformity assessment procedure, which may ease regulatory impacts and encourage regular software updates.

The Commission is undertaking a project that bears relevance to the TGA's proposed regulation of SaMD. The Australian Government Department of Health (the Department) has contracted the Commission to develop national standards and a certification framework for digital mental health services (DMHS). A number of DMHS within the project's scope may be classified as SaMD under the proposed changes to the classification rules, including mobile applications (apps) and online mental health treatment services.

It is intended the national standards and certification framework will have broad applicability for any DMHS seeking a quality assurance measure for their product or service. Consultation with stakeholders to date has shown support for the harmonisation of national standards for DMHS with the National Safety and Quality Health Service Standards and the National Standards for Mental Health Services. Harmonisation of the national standards and certification framework for DMHS with the TGA's SaMD regulation can promote user choice and confidence when engaging with a DMHS.

The current consultation phase of the Commission's project runs to 30 June 2019. The Commission will provide recommendations to the Department for the development and implementation of the certification framework and national standards for DMHS. If approved by the Department, the next phase of the project will see the development of the certification framework and national standards commence from the second half of 2019.

The Commission would welcome future opportunities to collaborate with the TGA regarding the regulation of SaMD products. This will allow the Commission to consider the implications for the DMHS project and determine appropriate alignment with the TGA's SaMD regulation.

For further information regarding this response, please contact:

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Yours sincerely

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