AUSTRALIAN COMMISSION
ON **SAFETY** AND **QUALITY** IN **HEALTH CARE**

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Consultation: Scope of regulated software-based products

Response from the Australian Commission on Safety and Quality in Health Care

Summary

The Australian Commission on Safety and Quality in Health Care (the Commission) is pleased to provide a response to the TGA's consultation on the scope of regulated software-based products. This response is informed by the Commission's work in developing the National Safety and Quality Digital Mental Health (NSQDMH) Standards.

Introduction

The Commission supports the proposed principles set out in the consultation paper aiming to reduce or remove unnecessary regulatory burden where there is no risk to safety, or where suitable frameworks for product or system oversight are already in place.

These principles require clear definitions of:

- Software requiring regulation due to the level of risk associated with its use
- Software that does not meet the definition of a medical device
- Software that does meet the definition of a medical device but does not require regulation because there is no risk to safety, or it is regulated elsewhere.

The Commission broadly supports the approach outlined in the consultation paper to clarify the types of software products that would be considered as a medical device and those that would not, based on the legislative definition of a medical device.

Under the revised classification system, digital mental health services that provide diagnosis or screening, monitoring, treatment or therapy through information will be classified as Software as a Medical Device (SaMD) and thus subject to the TGA regulatory framework. It is also acknowledged that risk as defined in the legislation refers to *the exposure to the chance of injury or loss, a hazard or dangerous chance,* rather than the more commonly used definition of risk that is determined by the severity of harm combined with the likelihood of occurrence.

The Commission has provided responses below to the questions in the consultation paper and outlined areas that the TGA may wish to further consider.

What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

The Commission has identified specific areas or risks associated with digital mental health services recommended for further consideration by the TGA. These include how some digital mental health services may be classified, and whether they are exempted or excluded.

Depression

It is unclear how software used for treatment of depression would be classified using the updated risk matrix (page 8). Depression may be a symptom, a mild disorder or a major disorder with life threatening potential. The diagnostic category alone does not easily differentiate the level of risk for individuals using software (e.g. an app or web-based cognitive behavioural therapy) to treat depression.

Suicide prevention

Under the proposed TGA classification rules (page 8), software developed to assist with suicide prevention could be classified as a higher risk due to the significant exposure to the chance of injury or dangerous chance for the individual.

However, some suicide prevention programs have a primary preventative focus, rather than targeting people who are actively suicidal. Classifying all suicide prevention software at a high level may not be appropriate and would potentially present an undue regulatory burden to service providers or software developers.

Privacy and data security as a risk

The revised essential principles for SaMD serve to clarify expectations in relation to cybersecurity, management of data and information and the requirements for the development, production and maintenance of regulated products.

However, it is unclear how these essential principles inform the determination of privacy and data security risks associated with software. The revised classification system for software (page 8) appears to be based only on the risk of the disease or condition to be diagnosed, screened or monitored, and/or the risk of the treatment and whether it is provided directly to a user or is provided via a health professional.

The Commission's consultation and research for the NSQDMH Standards has highlighted privacy and data security as a major concern and a potential risk of harm to users of digital mental health services. The Commission has included actions related to privacy, data security and transparency in the draft NSQDMH Standards.

It is not apparent from the consultation paper how the potential risk to the privacy and data security of the user is taken into account in determining the risk associated with software. It is also unclear how a determination of the risk of a privacy or data security breach would be made unless some form of assessment of the software was undertaken.

Mental health prevention

There is no explicit reference as to how software that provides a preventive approach for a mental illness is to be classified, despite prevention being specifically referenced in the legislative definition of a medical device.

The consultation paper indicates that software for "maintaining or encouraging a healthy lifestyle" (page 14) is not classified as a medical device and would be excluded from TGA regulation. However, there may be some risk in automatically subsuming software offering preventive interventions into the category of "healthy lifestyle".

For mental health disorders, prevention can encompass a broad range of actions that may appear superficially to cross-over with actions that are designed to maintain or encourage a "healthy lifestyle". A clear and explicit statement is required in relation to the classification of software providing preventive actions for mental illnesses.

The inclusion of "rehabilitation" (page 14) under the heading of maintaining or encouraging a healthy lifestyle as a suggested exclusion to the definition of a medical device is potentially misleading. Many rehabilitation services provide much more than just maintaining or encouraging a healthy lifestyle.

Monitoring

Further guidance is required in relation to the classification of software that monitors symptoms, rather than a disease or condition. For example, following the risk criteria, a mood or sleep monitoring app may be classified as a medical device if it is to be used by

someone with major depression or bipolar disorder as opposed to someone without a diagnosed mental health condition.

Providing therapy through provision of information

The consultation paper refers to software for "providing therapy through provision of information" (page 7). This implies a passive approach to the provision of information which could be inappropriately and broadly interpreted. It does not differentiate software that pursues active engagement and the provision of therapy via a structured treatment approach (e.g. digital cognitive behavioural therapy). It would be useful to clarify the intent of this category.

SMS and webchat digital counselling

There is a reference to a secure messaging service being excluded from TGA regulation when it relates to the transfer of information or results (page 14). In the mental health sector, messaging services (e.g. text and webchat) are used to provide digital counselling and suicide prevention interventions. It should be explicitly stated whether or not secure messaging software that is providing information as an active intervention is excluded.

Of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products

The Commission has been contracted by the Australian Government Department of Health (the Department) to develop the NSQDMH Standards. The draft NSQDMH Standards are available for public consultation until 29 May 2020.

The Commission is scheduled to provide the final version of the NSQDMH Standards to the Department in June 2020.

The Commission defines a digital mental health service as a mental health, suicide prevention or alcohol and other drug service that uses technology to facilitate engagement and the delivery of care. Some software that fits within this definition also meets the definition of a medical device and could be subject to TGA regulation.

The NSQDMH Standards could provide an additional oversight mechanism to TGA regulation. It is important to note that the NSQDMH Standards are designed to be applied at the level of the digital mental health service provider, rather than at the level of the individual software product.

At this stage, implementation of the NSQDMH Standards by service providers will be voluntary. The Department is considering the development of an independent assessment scheme for digital mental health services.

Describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

The Commission has no further comments to add in relation to this question.

Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?

The Commission is aware that many countries have been grappling with determining an appropriate regulatory framework for SaMD. There are challenges in finding the balance between the necessary processes to demonstrate compliance with regulations and the desire for agility and innovation in the digital health sector.

Regulation should not unduly constrain the development of digital health initiatives which offer promise to enhance care options in a scalable and cost-effective way. However, some

level of oversight is required to provide quality assurance and to protect the public from harm.

In developing the NSQDMH Standards the Commission has reviewed the approach taken by the Food and Drug Administration in the United States. The Commission has also reviewed the work of the United Kingdom's National Health Service (NHS) in developing an app library, and the NHS Digital Health Technology Standard.