Professor John Skerritt
Therapeutic Goods Administration
Deputy Secretary
Health Products Regulation Group
Commonwealth Department of Health

By email to devicereforms@tga.gov.au

Dear Professor Skerritt,

Regulation of software as a medical device

Thank you for the opportunity to participate in consultation on the regulation of health software, including software as a medical device (SaMD). Telstra Health appreciates being able to provide a formal response to the proposals put forward.

Telstra Health acknowledges that currently medicines and medical devices have well-established regulatory frameworks, but that the TGA is concerned that health software has limited regulatory oversight and monitoring for ongoing safety, quality and performance. Telstra Health agrees that safety, quality and performance are critical for any service in healthcare, and to engender community trust in digital health specifically.

Telstra Health has carefully considered the TGA's consultation paper and notes that the proposed approach is based on the framework for the Australian Register of Therapeutic Goods. Telstra Health has reviewed this approach carefully, and considers that a regulatory approach originally designed for devices and medicines is not fit for purpose for software, is unlikely to achieve the intended benefits, and could have the unintended consequence of increasing risks to patients and users through inhibiting improvements and upgrades in software. The opportunity to meaningfully regulate safety of software differs from medicines and devices in two important ways.

Firstly, software is not a static entity, but is upgraded frequently – often multiple times a year. These upgrades include enhancements to improve safety, quality, usability, security, and to manage risks in response to a constantly changing IT threat environment. There are also frequent upgrades required to incorporate regular changes to the Pharmaceutical Benefits Scheme and Medicare Benefits Schedule, and related policies and processes. In order to better manage these issues, contemporary software is increasingly moving toward Software as a Service (SaaS) models, where updates are made on a continual release cycle.

A regulatory compliance process that, on the TGA's own estimate, would take up to 12 months, is unworkable in an environment where software needs to be able to be upgraded frequently and quickly. As an unintended consequence, this risks having a counterproductive impact in inhibiting software vendors from quickly releasing product upgrades in response to security threats, such as viruses – ultimately, this could increase rather than reduce privacy, security, and safety and quality risks to patients and health services.

Secondly, contemporary clinical software is not a self-contained, standalone, static product. Much clinical software is highly configurable to meet specific user and health service needs. For example, software products can be configured by clinical users on what level of decision support is offered, what clinical pathways are codified, and the levels and kinds of alerts. Software is also differently configured in different installations to effectively integrate and interact with connecting systems.

In this context, accrediting software as a static, standalone product would for many products not be meaningful, as it cannot take into account the particular configurations and integrations that have been implemented in specific installations of the software. At the same time, it would not be workable for the TGA to accredit every different configuration or installation of software.

Regarding compliance process and costs, Telstra Health notes with concern the TGA's own estimate that each software product would take up to 12 months and cost $100,000 for accreditation. Telstra Health considers this estimate to be a prohibitive increase in the compliance burden for health software vendors, particularly in a context, as noted above, where software is undergoing continuous evolution through upgrades. Telstra Health is concerned that the proposed approach does not satisfy the TGA's stated intent to minimise the unnecessary regulatory burden, and considers it is likely to inhibit innovation and improvement in digital health solutions. Ultimately, this could put at risk improvements in safety and quality for patients, through inhibiting the timely development and implementation of digital health solutions that deliver well-documented health benefits such as reducing medication errors.

Telstra Health notes that the consultation paper acknowledges that "in many cases [good software development and security] are already being done by developers and manufacturers". Telstra Health agrees with this acknowledgement, and notes that mature software vendors are motivated to provide safe, fit for purpose, and flexible solutions, supported by robust clinical governance and security processes. Good software development practices are critical to this.

In this context, Telstra Health considers that the TGA should take into account a number of factors in considering what is the appropriate role the TGA should play in relation to health software:

1. The maturity and coverage of digital health standards have been developing over many years and continue to develop in Australia and internationally.
2. There is increasing voluntary adoption of standards and guidelines that define best practice software development and clinical safety in digital health.
3. Healthcare providers themselves play an important role in deciding how health software solutions are configured including for alerts and decision support.
4. The overarching purpose of clinical software is to help improve the safety, quality and efficiency of healthcare, such as through reducing errors and duplication. Actions that inhibit the development, adoption and continuous improvement of clinical software risks undermining this purpose.
5. In designing mechanisms to improve safety, quality and performance in digital health, careful consideration should be made to take into account the benefits and risks in the context of practicality and workability; enabling healthcare providers to access contemporary, affordable digital health solutions that help improve the quality and safety of care; and the viability of digital health service delivery.

Thank you again for the opportunity to comment on the TGA's consultation paper. I encourage you to continue to engage with consumers, the clinical community, health services, and the digital health sector, as you consider what is the appropriate role of the TGA in facilitating a digital health ecosystem that is trusted, and enables real benefit for consumers, providers, and health system funders.

Kind regards

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