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Therapeutic Goods Administration
Deputy Secretary
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Commonwealth Department of Health

By email to devicereforms@tga.gov.au
And submitted electronically at www.tga.gov.au

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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, supplementary to our participation in several face to face, written and virtual consultations over the past 18 months.

Safety, quality and performance are critical for any service in healthcare, and to engender community trust in digital health. Telstra Health acknowledges that currently, medicines and medical devices have well-established regulatory frameworks, but that the TGA is concerned that health software is subject to insufficient regulatory oversight, given that the digital health environment is rapidly evolving and many products in this domain present uncertainly for regulators as to the classification of these new products as therapeutic goods.

Telstra Health is committed to an effective, workable regulatory framework and is keen to continue our engagement with the TGA to get the right outcome. We are the largest Australian-based provider of digital health services, with 33 different core software solutions for our customers across the hospital, aged, community and Indigenous care, disability, pharmacy, and virtual care sectors. The number of tailored, integrated solutions greatly outnumbers those 33. This footprint and experience with supporting healthcare delivery gives us unique insight into the opportunity and impact of any sector-wide reform in Australia.

Telstra Health has carefully considered the TGA's consultation paper, and we respectfully recommend that more work needs to be done before the framework can be considered in its final stages of refinement.

In the following submission, we offer some examples and insights informed from our experience working with health and aged care providers, governments, as an operator of national health infrastructure, and a collaborative participant in the Australian digital health ecosystem.

Our key areas of concern are:

1. While the intent of the draft framework is to define an appropriate subset of health software as the subject of regulation, the proposed classifications are problematic and run the risk of being broader than anticipated. The proposed compliance obligations on all health software (even those that are excluded), and the focus on singular entities or 'products', may not meet stated policy objectives, nor be implementable in the Australian context, and may attract unintended consequences. Further, the proposed approach does not reflect the way is which digital health systems are deployed and continually iterated within clinical settings, and that software may perform different functions in different healthcare delivery contexts;

2. A requirement for all health software (even if exempt) to report all adverse events to the TGA does not account for existing clinical governance processes within healthcare settings processes to address adverse events, would be unworkable, and burden industry, healthcare providers, and the regulator alike;
3. The practical implications of implementing the proposed compliance approach would likely include reduced time to market with software improvements, and prohibitive financial cost that would ultimately be borne by health and aged care providers;
4. The proposed approach may 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 benefits, and is also likely to inhibit our ability to be responsive to arising clinical imperatives; and
5. Lastly, we strongly recommend that a framework to regulate SaMD should operate in concert with the existing regulatory models in healthcare, in order to avoid conflicting requirements, overlap of scope, and to meet the stated objective of not over-regulating.

In light of these concerns, Telstra Health encourages the TGA to consider our request to extend consultation by at least 12 months to allow for a review of the guidelines to regulate SaMD, in consultation with clinicians, health service providers and funders, and industry stakeholders.

1. Fitness for purpose

It is clear that the intent of the draft framework is to define an appropriate subset of health software that is akin to a medical device in performing a therapeutic function. However, the proposed classification system does not reflect the nature of risk in health software, or the way in which digital health systems are deployed and continually iterated in practice, and that software may perform different functions in different healthcare delivery contexts.

Nature of risk

We have approached our analysis of the framework by initially focusing on the nature of risk in the use of health software, and our first observation is that it is not apparent how the current proposals address a defined source of risk of harm to the community posed by health software. We also note the examples of harm the TGA have provided all relate to scenarios that include a traditional hardware medical device, rather than health software per se.

Without the source of risk clearly defined, it follows that the definitions and classifications are problematic. Further, it is important to be aware that digital health has an increasing role in quality and safety at organisation and system levels, as well as in direct patient care.

Scope issues

The criteria for software to be deemed a medical device (SaMD) or not, is in some cases inconsistent with the level of risk and governance needed to assure safe use of products that perform those functions. This inconsistency goes ultimately to the problematic nature of the classification system itself, rather than whether or not particular software should be included or excluded.

For example, software intended to provide information on drug to drug interactions, and software intended to help patients improve medication adherence is excluded because the intended purpose is not therapeutic[1] and systems designed to alert clinicians to medication prescribing risks are not deemed medical devices, whereas systems that provide similar alerts regarding recommended chronic disease pathways, are deemed medical devices. The framework also proposes that clinical decision support

[1] TGA, *Consultation: Scope of regulated software- based products;* March 2020; Page 13

software may be excluded from regulation, perhaps overlooking that most clinical software has some form of clinical decision support. The framework also applies compliance requirements on software that is deemed excluded from regulation, with products not deemed medical devices to be "addressed through guidance"[2], and finally, the rules set out that even excluded software must commit to a range of undertakings, including demonstrating that all 'products' meet certain principles.

Again, these examples illustrate the problematic nature of the classification system itself, rather than highlight the need to include or exclude particular software.

'Product' focus

We consider that the way in which the draft framework seeks to identify and regulate individual software products as stand-alone discrete entities is inherently challenging, and may not serve the stated policy objective, nor be implementable in the Australian context, and may result in unintended consequences.

Software in healthcare has always been interdependent on other technical, people and paper-based systems- and integration, interoperability and interdependence is rapidly increasing. In fact, increased integration and interoperability is a priority of all governments, clinical stakeholders, and a core function of all modern clinical software systems. The proposed model does not provide sufficient clarity to be able to navigate interconnected or interdependent systems, which is the norm in health software architecture and operation, particularly as health services and systems become more connected. For example, if systems such as the My Health Record are exempt, the status of connecting systems which feed into, display or interpret and analyse data from the My Health Record is unclear. This example is important because it goes to the interoperation of many systems in order that a clinician can view information or an alert on screen at the point of care to assist them in a clinical decision.

An unintended consequence of the framework may be that functionality in software is unnecessarily compartmentalised, so that compliance processes can be undertaken for those particular functions. This would itself likely introduce new risks to the safe functioning and usability of software, and undermine the intent of the framework.

The safety and fitness for purpose of any health software depends on *how it is deployed and iterated* under the clinical leadership of the healthcare organisation, and in the context of clinical governance frameworks both in that organisation, and of the vendor. Further, the intent or function of identical software may differ in different care environments (through user configuration), depending on how the healthcare provider wants that software to contribute to care and quality, and if and how it operates within the broader organisation and systems.

This is a crucial consideration, as the draft SaMD framework classifications are focused on the *intent* of software. We therefore recommend that any framework should reflect the governance and process relating to health software development and deployment in context, rather than the narrow focus on the intent of individual products.

Our view is that the most influential factor on whether use of clinical software in a care setting poses risk of patient harm, is the robustness of the combined clinical governance approach of both the software vendor and the healthcare provider. This includes elements throughout the lifecycle:

- Full and shared understanding of the clinical and technical opportunity or problem to be overcome;
- Use of best practice software development methods, including embedded risk assessment, quality assurance and testing processes;
- Application of Standards, including those that enable safe integration and interoperability between products and systems. Examples include unique patient identifiers and use of standardised clinical terminologies, adherence to patient identification standards, standardised

[2] TGA, *Consultation: Scope of regulated software- based products;* March 2020; Page 11

messaging formats, and standardised formats to record medicines and medical terms;

- Deployment methodology to verify the software or system is introduced to operate in the intended fashion. This is a key focus of clinical leadership within organisations implementing new digital health systems, and includes User Acceptance Testing;
- Education and change management for users;
- Measurement and benefits realisation, including where health software systems are used to assist with healthcare organisations' accreditation and compliance;
- Best practice risk and incident management processes; and
- Post market monitoring and improvement, including oversight and feedback loops with clinical users. This is where most software companies spend most of their effort.

Notwithstanding that digital systems are designed to improve outcomes, safety, experience and efficiency, unexpected issues with function and performance are par for the course in any system. The measure of quality and safety is how those issues are identified and addressed.

We are happy to work with the TGA on how this framing might be reflected in the regulatory framework.

2. Reporting of adverse events

The proposed requirement that all health software (even if exempt) must report all adverse events to the TGA does not account for existing clinical governance processes that operate in health services to address adverse events, and the relationship with the broader health regulatory context. Such a requirement would be unworkable, and burden industry, healthcare providers, and the regulator alike.

Adverse events reporting is already an embedded part of healthcare delivery, including events that pertain to digital health systems.

The approach we take in our own business to supporting this process with healthcare providers is to apply a risk framework through which all incidents or issues are assessed, according to a context-relevant risk matrix. Under this framework, some low level incidents may be found to be the result of user error, a configuration bug, or an issue caused by a third party service. Such incidents are assessed and addressed appropriately, including technical fixes, communication and support to users, and process reviews. In our example, the Telstra Health Clinical Governance Framework draws on recommendations from the ACSQHC, ISO, and international clinical safety standards, and importantly, complements the clinical governance and adverse event reporting processes in healthcare organisations.

3. Practical implementation of compliance under this framework

Telstra Health has concerns relating the practical implications of implementing this compliance approach. We consider the likely cost of this regime to be a prohibitive increase in the compliance burden for health software vendors already operating in a highly regulated health service delivery sector, and that those costs would ultimately be borne by health and aged care providers, and add a very high opportunity cost for innovative technology solutions to support healthcare. The timing for implementation in August 2020 is also problematic.

Telstra Health has 33 core products in our portfolio, which we iterate frequently to meet the needs of the clinicians who use them, maintain system security and meet evolving regulatory requirements (such as MBS and PBS changes, and quality measures for aged care providers). The number of tailored, integrated solutions greatly outnumbers those 33.

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. This estimate does not include vendors' own time and financial costs for compliance, and participation in compliance processes, which are likely to far exceed this amount for *each* product, and various instances that form part of integrated solutions. We note that even Class 1 devices must be certified by the manufacturer and an application must be made for inclusion on the ATRG.

Further, the consultation paper sets out that even products not deemed medical devices would be "addressed through guidance"[3], and finally, the rules set out that even excluded software must commit to a range of undertakings, including demonstrating that all 'products' meet certain principles, and reporting of all adverse events.

Further to our assertion that the framework and compliance approach is not yet fit for purpose, the digital health industry is focused in 2020 assisting providers in health and aged care, and governments, to respond to the COVID-19 crisis. This has meant changes to clinical workflows, increased use of digital health data to support patient care and workforce planning, and in direct support for contact tracing by population health departments. In recent weeks, rapid, responsive development has been key to assist our customers to respond to COVID-19 in their hospitals, aged care homes and through virtual health care delivery solutions.

There has been an unexpected and unprecedented demand on the digital health industry, and so the intended implementation timeframe of August 2020 is difficult timing for the commencement of a new sector-wide compliance regime.

4. Unintended consequences for safety and quality

Flowing from concerns about timeliness and costs of compliance, the proposed approach may 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 benefits, and is also likely to inhibit our ability to be responsive to arising clinical imperatives.

The lengthy and costly process may significantly disincentivise development and implementation of functionality that is useful to assist clinicians in the quality and efficiency of their work, including frequent iterations to keep in step with emergent security threats, rapid clinically driven workflow changes, and usability improvements.

Given that improving safety and quality is the core purpose of health software, we consider this risk to be a high priority for resolution.

5. The healthcare regulatory context

Lastly, we strongly recommend that risks pertaining to software in health be considered in the context of their governance and use, and recognise the role of existing standards and clinical governance frameworks. A framework to regulate SaMD should complement the existing regulatory models in healthcare, in order to avoid conflicting requirements and overlap of scope.

We propose that regulatory and governance models in other parts of healthcare may be leveraged and built upon, including the frameworks governed by the ACSQHC, who have been active in digital health for some years.

Such an approach would also address our concern that the proposed approach does not satisfy the TGA's stated intent to minimise unnecessary or duplicative regulatory burden, and considers it would be less

[3] TGA, *Consultation: Scope of regulated software- based products;* March 2020; Page 11

likely to inhibit innovation and improvement in digital health solutions.

Working with the TGA going forward

Telstra Health understands the general intent of the TGA to mitigate harm and assure quality of manufactured goods used in healthcare, but encourages the TGA to consider our request to extend consultation by at least 12 months to allow for a review of the guidelines to regulate SaMD, in consultation with clinicians, health service providers and funders, and industry stakeholders.

This extension will create the possibility of a framework that best meets the needs of the community, clinicians, and funders and regulators of healthcare, and supports the positive role digital health technology has to play in the measurement and improvement of the safety and quality of care, and to meet emerging population health priorities.

As Australia's largest provider of digital health solutions, the team and I are happy to constructively collaborate with the TGA on any of the issues raised in this submission.

Kind regards

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Professor Mary Foley AM

Managing Director

Telstra Health