Submission to the Therapeutic Goods Administration's

Consultation: Scope of regulated software–based products

13 May 2020

I congratulate the TGA on its consultative approach to the range of issues associated with the cyber security of connected medical devices and software. While stakeholders and commentators may differ over policy, this consultation enables stakeholder engagement, and through the opportunity for broad comment, hopefully will promote understanding, balance, and compliance. As part of this process, I offer the following comments and four recommendations for consideration, applicable to the matters of ARTG inclusion exemption, TGA regulatory exclusion, and international jurisdiction.

First, I recommend that the TGA continue its ongoing engagement with stakeholders. Policy, privacy and security issues around software and data will continue to evolve. Consultation and feedback should be regular, allowing policy to also evolve. This recognition of the pace of change, and the need to move with it, is explicit in Health Canada's commitment that: "due to the fast-changing technological environment, Health Canada will continue to adapt its policy approach to Software as a Medical Device (SaMD) as this field evolves". The TGA should make the same commitment, appropriately resourced, to assist with ongoing regulatory relevance.

Second, p.10., paragraph 3 notes there is considerable alignment between other countries and organisations and their approaches to similar regulation. It states that these approaches have been considered by the TGA and provides links to guidance published by Health Canada and the EU. In regard to considering data as an integral part of the functioning of medical software and as a factor in determining exclusions or exemptions, I see a general absence of relevant material in the TGA's proposal. I believe that the EU's *Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR* is a more complete and nuanced approach. Examples include:

- the definitions of Input Data, Output Data and Software driving or influencing the use of a device (all p.5);
- Sections 9.c., 9.f.2., and 9.f.3.; and
- Figure 2.

My reasoning for this is a belief that the functioning of medical software inherently depends on the collection, transmission, analysis and presentation of data. My general concern is that the regulation of software may be pointless without similar attention to ensuring the availability and veracity of the data that is collected, processed, fused and used for a purpose – be it for an individual or to influence public health policy. I therefore recommend that the TGA review international norms for data related to medical software and include them as a factor when considering ARTG inclusion exemption and TGA regulatory exclusion.

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Third, and related to the previous recommendation, I believe the Proposed carve–out principles (pp.10-11) are reasonable for the carve out of software from regulation, accepting that unnecessary bureaucracy impacts the efficiency and effectiveness of service delivery. However, to explicitly strengthen the integral part that data plays in the functioning of medical software, I recommend that the first proposed carve–out principle be amended as follows (bold text): "it can be demonstrated that there are already adequate (or similar) alternative mechanisms in place for oversight for software-based products **and their medical data**;"

Finally, p.7., paragraph 2 notes that "the former regulatory framework considered harm that can directly be caused by a physical interaction with a medical device; however, it did not adequately address the risk of patient harm where information is the source of harm". I support the recognition of "information" (data) as a valuable 'good', albeit one with the risk of harm if it is compromised in some way. I believe there is another dimension to this, which occurs as data is aggregated. Data has value (aggregated, bulk data even more so) and, consequently, is the target of malicious actors. Therefore, I recommend that the TGA conduct a review of the need for regulation of medical software data. Such a review may lead to the conclusion that there are sufficient other controls in place, or it might lead to a similar, consultative approach on the need for the regulation of this data. Regardless of the outcome, I believe that medical data is sufficiently important to patients, medical practitioners, and to society that it warrants consideration.