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Re: **Consultation Submission**

Consultation: Scope of regulated software-based products

As Surgical Director of RACS ASERNIP-S, I welcome the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) public consultation: Scope of regulated software-based products.

ASERNIP-S acknowledges the challenge posed in regulating Software as a Medical Device (SaMD). The proposed reform attempts to address the limitation of the form regulatory framework that previously considered only the physical interactions of medical devices and the potential to cause harm. As per TGA's preamble, "...information is the source of harm. Software that processes data to provide information to be used in treating a person, for example, a diagnosis of a disease, or the specification of a therapy to be delivered, can cause harm when the information is incorrect" (page 7, Consultation: Scope of regulated software-based products, March 2020 [Consultation]).

ASERNIP-S agrees that all software-based devices that have the potential to cause harm should be subjected to rigorous review before their inclusion on the Australian Registry of Therapeutic Goods (ATRG). The summary of classification rules (Table 1, page 8, Consultation) and need for the minimum conformity assessment procedures are a sensible and reasonable start.

The challenge in regulating medical devices is their rapid development and revision. Many revisions constitute minor adjustments that improve the device functionality as originally assessed and do not alter how the device fundamental behaves. In contrast, other revisions represent significant changes in design that have significant impact on the device's safety profile. For SaMDs, significant changes in code that controls functionality and generation of information used to diagnose or manage health should be considered novel designs and subject to review.

A further challenge when considering the regulatory framework for SaMDs is the nature of industry, which spans small start-up companies to multination technology giants. This diversity means individual companies have varying ability to fund the regulatory processes for inclusion of a SaMD on the ARTG and may stifle development of SaMDs by the start-up entrepreneurs.

The concept of "Carve-out" based on exclusion and exemption as applied to SaMDs is welcomed. However, the application of these concepts is problematic, and the Consultation document attempts to address this through defining SaMDs that could be potentially excluded and exempted from regulation.

ASERNIPS submits that the following pieces of software, irrespective of whether the software provides class based or patient specific information, are removed from the exclusion or exemption list unless adequate alternative oversights are available:

i) Predictive analysis and

ii) Clinical Decision Support Software

A major concern of ASERNIP-S is the increasing deployment of software that incorporates Artificial Intelligence (AI)/Machine Learning (ML) for these two applications. While laboratory-based applications could fall under the NATA/RCPS regulation, those that provide the logic that operates AI-assisted clinical decision-making tools would not.

Due to the dynamic nature of multifactorial events affecting patient care, there exists undetected underlying changes referred to as "data drift" which renders the model obsolete. Machine Learning algorithms are self-learning and constantly evolve based available data and input from patients or clinicians (i.e., information). Prospective collection of data ensures currency of the dataset and Machine Learning models thus mitigating the risk of "data drift" and are considered non-static devices.

Data collection is based on sampling the population that will shift over time. The ML model must be re-trained regularly. Such retaining could be considered major upgrades and potentially subject to ongoing review to assess the risk for harm. The constant need for review may be prohibitive and that an alternative process of regulatory oversight is needed following the initial conformity assessment based on the proposed classifications in Table 1 on page 8 of the Consultation document, for example:

i) A formal regular reporting by the manufacturer demonstrating how data drift risk is being addressed. As an example, a specialist assessment body provides oversight i.e., the manufacturer must submit an annual report to demonstrate compliance.

ii) Updates to code and changes to predictive models are fully disclosed to the TGA for independent review.

iii) SaMDs are subject to regular maintenance and reporting programs as mandatory requirements of ARTG listing. In doing so, Software providers collect post-market data to proactively identify potential adverse events.

Again, thank you for the opportunity to comment on the TGA public consultation: Scope of regulated software-based products.

Yours sincerely

[redacted]

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