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Device Reforms
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via e-mail: devicereforms@tga.gov.au

Dear Sir / Madam

Re: Regulation of software, including Software as a Medical Device (SaMD)

Becton Dickinson (BD) has read with great interest the above consultation document, as published by the Therapeutic Goods Administration (TGA) in February 2019.

Responses to the questions posed in the document are provided below.

Questions

1. **Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?**

   BD appreciates the TGA's efforts in addressing the important and rapidly advancing area of software as a medical device (SaMD), and the work of the TGA in furtherance of a program to consider the perspectives and requirements for proposed SaMD regulation. The proposal's intent is consistent with that of international medical technology industry working models and emerging guidance, as cited within the proposal.

   By integrating SaMD into the current regulatory framework, and in consideration of the recently released draft guidance for Medical Device Cyber Security issued by the TGA, the

proposal may help to effectuate a total lifecycle approach to security that would enhance the safety of SaMD products to the Australian market.

Specific comments on each of the three proposed changes are provided below.

Changes to the Classification Rules

There is no mention of *in vitro* diagnostic (IVD) medical devices within the consultation document. As such, the assumption is made the proposed changes to the Classification Rules will only have potential impact on Schedule 2 (Classification rules for medical devices other than IVD medical devices) of the Therapeutic Goods (Medical Devices) Regulations 2002. This important distinction should though be confirmed by the TGA.

The summary of Classification Rule 11 from the EU MDR 2017/745 on Page 8 of the consultation document does not accurately reflect this Rule, that in full reads:

> Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:
>
> — death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
>
> — a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.
>
> Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.
>
> All other software is classified as class I.

On page 8, the consultation document states:

> "The European rule is in accordance with the IMDRF recommendations; however, it does not provide enough detail to capture the different risk categories of SaMD identified by IMDRF."

While the proposed Australian Classification Rule does not have to mirror it's equivalent in the EU MDR (although, to remove ambiguity, that would be preferred), it should be drafted in a way that will remove the possibility (or at least minimise the possibility) of the same product being classified differently in the two jurisdictions.

As written, there is a very real possibility that SaMD impacting a serious deterioration in a person's state of health would be Class IIb in the EU and Class III in Australia. In situations where the Australian Sponsor relies upon Conformity Assessment conducted in the EU to support an application for inclusion on the Australian Register of Therapeutic Goods (ARTG), this difference in classifications would lead to additional regulatory hurdles in Australia.

Such a situation should be avoided unless considered absolutely necessary to protect the health and safety of the Australian public.

The proposed Australian Classification Rule is also incomplete in that it doesn't include the catch all "All other software is classified as class I" as in the EU MDR.

The International Medical Device Regulators Forum (IMDRF), in their document "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF/SaMD WG/N12FINAL:2014), provides the following suggested categories for the classification of SaMD products (bold text is the Australian equivalent medical device classification):

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV (**III**)	III (**IIb**)	II (**IIa**)
Serious	III (**IIb**)	II (**IIa**)	I (**I**)
Non-serious	II (**IIa**)	I (**I**)	I (**I**)

Without reproducing them in this document, the IMDRF then also provides criteria for determining which category a SaMD product should fall into. When comparing the above table, together with the IMDRF criteria, it is clear the proposed changes to the Australian Classification Rules, in relation to the IMDRF guidance:

- Overly complicate the healthcare situation / condition; and
- Generally over-classify SaMD products.

Given the significant impact over-classification of medical devices can have on including medical devices on the ARTG, BD strongly recommends additional consultation (preferably in a face-to-face workshop format) on this proposal.

Requiring SaMD to be included in the ARTG

In the absence of identifying and implementing a mechanism to prevent the Australian general public from downloading "unregistered" SaMD products, that are not supported by an Australian Sponsor, the immediate impact of implementing this proposal would be to criminalise the act of importing (downloading) these products (per Chapter 4, Part 4-11, Division 3 of the Therapeutic Goods Act 1989). As alluded to in the consultation document, there may be a very large number of Australians who have or will engage in such behaviour and inadvertently import such products. With current resources the TGA does not have the ability to enforce this proposal should it be implemented. Should the TGA seek adequate resources to enforce the proposal within the existing cost recovery model, the question as to who will pay for these resources needs to be addressed. Certainly BD, and presumably the wider Australian MedTech Industry, would be unwilling to contribute to such costs.

While the intent of the proposal is admirable and noble, operationalising it is almost impossible in the absence of a coordinated internationally agreed path forward. The US FDA regulates what they term "Mobile Medical Applications" (MMAs) and also maintains a list of MMAs that have been cleared by way of pre-market submissions (see www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm). The most famous of these is likely the "ECG App" available on the Apple Watch that received a De Novo clearance as a Class II medical device from the US FDA in September 2018.

Until such time as regulators (such as the membership of the IMDRF) agree on a coordinated plan to educate manufacturers of SaMD products and take enforcement action for deliberate breaches of existing regulatory controls, the non-regulated supply of these products will continue. If managed in a coordinated and strategic way, the "trickle" effect globally coordinated education / enforcement campaign would be significant and could see the end of such products escaping regulatory controls in major markets.

The TGA has the ability to regulate such products using existing legislation. There is also an existing ability for the TGA to take enforcement actions for non-compliance with existing legislation. Rather than criminalise established behaviours of the Australian general public, it would be more effective long-term to eliminate any criminal behaviours that exist within Australia under the existing legislative controls and to encourage other international regulators to act in a similar way within their own jurisdictions.

Changes to the Essential Principles

Becton Dickinson is generally supportive of an overhaul of the Australian Essential Principles to more appropriately address the development requirements associated with SaMD products (and software in general when included within or operating in association with medical devices). Importantly though revisions to the Essential Principles should look to adopt the software requirements detailed within the EU MDR General Safety and Performance Requirements.

Any revision to the Essential Principles should not introduce additional development / validation or labelling requirements for SaMD than those already imposed by the EU MDR General Safety and Performance Requirements. Critically, revisions to the Essential Principles should not remotely require the creation of software or software enhancements specifically for the Australian market.

Consideration should be given by the TGA to ensuring new or revised Essential Principles do not apply to IVD medical devices unless there is a demonstrable specific need. As is the case with the existing Essential Principle 15 (Principles applying to IVD medical devices only), this could be achieved by ensuring any new or revised Essential Principles are specifically limited to non-IVD medical devices.

2. **What do you consider to be the benefits and disadvantages of the particular proposals for change?**

The benefits for the proposal include the establishment of guidelines and objectives in alignment with international standards and best practices for software development that may provide a harmonised approach to SaMD products. By incorporating best practices and a common understanding of expectations, the regulation of SaMD products may be applied uniformly across both traditional medical device and non-medical technology companies alike. The emergence of SaMD products presents unique issues for consideration, including the regulatory requirements, quality management integration and regulator expectations for minimising public health and safety risks, as well as maintaining consumer confidence for software that provide advice or analysis in furtherance of diagnosis, or aid in the treatment of specific health conditions. To this end, the proposal may work to eliminate inconsistent practices across industries where non-medical technology organisations have not traditionally been engaged.

There are challenges presented by the definitions for patient harm and high risk for SaMD products; these may require additional clarification than what is posed by the SaMD consultation. Specifically, providing explanation on how patient harm may be reviewed within the context of a SaMD product for confidentiality, integrity and availability for risk management and assessment.

Additionally, direct-to-consumer applications contemplated under the SaMD consultation may require more clarification for how patch management and associated communication processes may be reviewed. The dependencies of the proposal and the TGA's draft medical device cyber security guidance will require coordination for organisations to understand and adhere to the proposal's intent for communicating risk and providing software updates and patches as required to reduce potential harm.

Further, additional information for the implementation of coordinated vulnerability disclosure in alignment with international best practices under the proposal is required for coordination with the TGA's draft medical device cyber security guidance.

3. **Do you believe there will be any unintended consequences arising from the proposed changes?**

The potential misapplication of the SaMD regulatory framework for software that does not fall under the classification for increased regulatory review (exclusive of Class I) may create an unintended outcome of uncertainty around device classifications, or inconsistent application of classifications for SaMD product. This is particularly of concern given the divergence of TGA proposal from both the EU MDR and the IMDRF guidance.

Additionally, the introduction of non-medical technology organisations and smaller organisations without established Quality Management Systems and a lifecycle approach to product security may benefit from the inclusion of security guidance, such as the Medical Device and Health IT Joint Security Plan (www.healthsectorcouncil.org/the-joint-security-plan). The Joint Security Plan ("JSP") is a full lifecycle approach to product cyber security that was developed in partnership between Medical Device Manufacturers, the U.S. government regulators and Healthcare Delivery Organisations. The JSP was designed to apply to organisations of all sizes. Including best practices in alignment with the JSP may help to prevent inequalities in the ability of organisations to meet the standards contemplated by the proposal and to ensure compliance.

4. **What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?**

   BD has developed a Product Security approach to securing medical devices in alignment with the SaMD proposals. However, we would request additional information on the pre-market requirements and review of SaMD products versus traditional medical device products.

   As is the case with our Industry peers, BD is making significant investments over the next several years to transition our products to the EU MDR. Should the implementation of the TGA proposals create divergence from the requirements of the EU MDR this would have the potential to significantly impact our ability to ensure SaMD and software enabled medical devices complied with divergent elements within what will become the Australian requirements.

5. **What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.**

   As commented above, BD current employs a full lifecycle approach to Product Security that all software and software-enabled medical devices follow. Clarification around the pre-market review process for SaMD versus traditional medical device products would help to provide analysis of this question.

   The financial impact of complying with Australian requirements that do not closely align with those of the EU MDR would need to be assessed once they were fully understood. Ideally there would be no unique Australian requirements; absolutely there should not be such divergence as to require specific software to be written for the Australian market. There should also be no labelling, development and/or validation requirements in Australia that are not already required in the EU MDR.

6. **What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.**

   Any revisions to the Australian Classification Rules and Essential Principles should absolutely not be introduced until the deadline for all medical devices to complete the transition to the EU MDR; i.e. 27 May 2024. To introduce these revisions earlier than this, in the absence of

flexible transition arrangements, will lead to a misalignment of requirements between Australia and the EU. In turn this has the potential to lead to unnecessary, unplanned extra costs and/or the unavailability of SaMD medical devices for an extended period of time.

Becton Dickinson looks forward to continued active consultations as the TGA develops their thinking around regulating SaMD products.

Yours sincerely,

Becton Dickinson Pty Ltd – Australia/New Zealand