Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Level 12, 54 Miller St, North Sydney NSW 2060
PO Box 2016, North Sydney NSW 2059
P: (02) 9900 0600
E: mtaa@mtaa.org.au

MTAA Submission to TGA consultation:

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

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1. Executive Summary

On 13th February 2019, the TGA opened the consultation: *Regulation of software, including Software as a Medical Device (SaMD)*. This consultation, as stated by the TGA, "focuses on proposed regulatory reforms for medical device software, including software that functions as a medical device in its own right (SaMD), and the impact of these reforms. The proposed changes set out in this consultation seek to better regulate software, including SaMD, and will wherever possible be harmonised with international best practice."

The proposed changes are:

- ensuring the classification rules for medical devices will appropriately classify SaMD products according to the potential harm they could cause to patients
- excluding SaMD products from the personal importation provisions in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) so that SaMD products will be required to be included in the ARTG and have an Australian sponsor
- ensuring the essential principles for medical devices include clear and transparent requirements for demonstrating the safety and performance of SaMD and other regulated software

It is proposed that the transition period will coincide with the transition in Europe to the Medical Device Regulation (MDR) 2017/745.

MTAA supports the proposal to update the way medical device software is regulated provided the resulting regulatory requirements align with international best practice and guidelines. MTAA does not support an Australian-only regulatory framework for medical device software.

The level of regulatory oversight for medical devices including software depends on the risk classification. Therefore, international harmonization of regulatory requirements for medical device software needs to start with aligning the risk classification rules.

MTAA submits that the proposed risk classification for SaMD in Australia should follow the IMDRF guidance document *Software as a medical device: Possible Framework for Risk Categorization and Corresponding Considerations*[1].

MTAA's detailed comments to the TGA consultation paper are provided in the next pages.

[1] IMDRF Final Document "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Consideration, accessed 15 March 2019: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf

2. Changes to the classification rules

The proposed changes to classification rules appear to be uniquely Australian, with no direct equivalence with the risk classification rules for SaMD in the IMDRF guidance document or the risk classification rules for software in the EU MDR (both are reproduced hereafter).

IMDRF risk classification for SaMD:

Table 1: IMDRF risk classification for SaMD

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	II
Serious	III	II	I
Non-serious	II	I	I

Criteria for Category IV (highest risk class)

- *SaMD that provides information to treat or diagnose a disease or conditions in a critical situation or condition is a Category IV and is of very high impact.*

Criteria for Category III

- *SaMD that provides information to treat or diagnose a disease or conditions in a serious situation or condition is a Category III and is of high impact.*
- *SaMD that provides information to drive clinical management of a disease or conditions in a critical situation or condition is a Category III and is of high impact.*

Criteria for Category II

- *SaMD that provides information to treat or diagnose a disease or conditions in a non-serious situation or condition is a Category II and is of medium impact.*
- *SaMD that provides information to drive clinical management of a disease or conditions in a serious situation or condition is a Category II and is of medium impact.*
- *SaMD that provides information to inform clinical management for a disease or conditions in a critical situation or condition is a Category II and is of medium impact.*

Criteria for Category I (lowest risk class)

- *SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or condition is a Category I and is of low impact.*
- *SaMD that provides information to inform clinical management for a disease or conditions in a serious situation or condition is a Category I and is of low impact.*
- *SaMD that provides information to inform clinical management for a disease or conditions in a non-serious situation or condition is a Category I and is of low impact.*

EU MDR risk classification for software, including SaMD:

Software is classified according to **Rule 11**, Annex VIII, section 6 Active Devices.

> *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.*

The TGA consultation document states that the EU risk classification rule is in accordance with the IMDRF recommendation, but it has gaps in relation to the categories of SaMD identified by the IMDRF. The IMDRF Table 1 would potentially look as follows if populated with the risk classes according to the EU risk classification rule:

Table 2: EU MDR risk classification for software, including SaMD

State of healthcare situation or condition	Provide information used to treat or diagnose	Monitor physiological processes (vital/ non-vital)
Critical	III	IIb (vital) / IIa (non-vital)
Serious	IIb	IIb (vital) / IIa (non-vital)
Non-serious	IIa	IIa

The column “Provide information used to treat or diagnose” in Table 2 (EU MDR risk classification criteria) is equivalent with the column “Treat or diagnose” in Table 1 (IMDRF risk classification criteria).

The EU MDR criterion “Monitor physiological processes” could be considered equivalent to IMDRF’s criterion “Drive clinical management”. The EU MRD’s criterion “resulting in immediate danger to the patient” could be considered equivalent to IMDRF’s criterion “critical” or “serious” for the patient.

The comparison in Table 3 shows the similarities and differences in risk classification between the IMDRF criteria “Drive clinical management” and “Inform clinical management” (left side), and the EU MDR criterion “Monitor physiological processes” for both vital and non-vital physiological processes (right side).

Table 3: Comparison between IMDRF risk classification of SaMD used for driving/ informing clinical management (translated into EU risk classes) and EU MDR risk classification of software used to monitor physiological processes

IMDRF risk classification (using EU risk classes)			EU MDR risk classification
Sate of healthcare situation or condition	Drive clinical management	Inform clinical management	Monitor physiological processes (vital/ non-vital)
Critical	IIb	IIa	IIb (vital) / IIa (non-vital)
Serious	IIa	I	IIb (vital) / IIa (non-vital)
Non-serious	I	I	IIa

The EU MDR definitions will lead to over-regulation of software in the EU and will be out of synch with IMDRF-aligned jurisdictions in the rest of the world, including the U.S. (U.S. FDA chairs the IMDRF working group on SaMD).

Proposed Australian classification rules:

The proposed Australian classification rules for SaMD (pages 8-9 of the consultation document) are reproduced below and summarized in Table 4.

Table 4: Proposed Australian classification rules for SaMD

State of healthcare situation or condition	Processes data to provide information for:					Directs patient activity based on:	
	Diagnosis			Treatment		Input from patient	Non-interactive intervention
	For direct diagnosis	For patient screening	As clinician's diagnosis aid	For direct treatment	As clinician's treatment aid		
Critical	III	III	IIa	III	IIa	IIb	I
Serious	III	IIb	IIa	IIb	IIa	IIb	I
Non-serious	IIa	IIa	IIa	IIa	IIa	IIa	I

Software that processes data (e.g. - images, sensor data, big data) to provide information for diagnosing a disease or condition and that is intended to:

- *Make a direct diagnosis (e.g. – self testing, emergency situation, rural or remote medicine) for:*
  - *a critical situation where the disease or condition is fatal or debilitating in a short timeframe, or poses a risk to public health, or a serious situation where the disease or condition is not life threatening but may cause a serious deterioration in a person's state of health if not identified. The device is Class III.*
  - *any other situation. The device is Class IIa.*
- *Screen patients to determine the need for further assessment for:*
  - *a disease or condition that is fatal or debilitating in a short timeframe, or that poses a risk to public health. The device is Class III.*

  - *a disease or condition that is not life threatening but may cause a serious deterioration in a person's state of health if not identified. The device is Class IIb.*
  - *any other situation. The device is Class IIa.*
- *Aid a clinician in making a diagnosis. The device is Class IIa.*

Software that processes data to provide information for treatment or intervention in a disease or condition and that is intended to:

- *Specify a treatment or intervention that will be administered without further consideration (e.g. – the patient will inject the amount of insulin calculated) where:*
  - *the treatment or intervention, or its absence, could result in death or debilitation. The device is Class III.*
  - *the treatment or intervention, or its absence, could be harmful. The device is Class IIb.*
  - *the treatment or intervention, or its absence, is unlikely to cause harm. The device is Class IIa.*
- *Recommend a treatment or intervention for a clinician to decide and administer. The device is Class IIa.*

Software that provides therapy through direct interaction with a patient where:

- *The software directs patient activity based on input from the patient and could result is patient harm (e.g. – directing a recovering heart patient to undertake activity that is too vigorous). The device is Class IIb.*
- *The software directs patient activity based on input from the patient and the activity is unlikely to cause harm. The device is Class IIa.*
- *The software directs patient activity based on a non-interactive intervention. The device is Class I.*

A comparison between Table 4 and Table 1, and between Table 4 and Table 2 shows that the proposed Australian classification rules for SaMD align with neither the IMDRF SaMD guidance nor the EU MDR Rule 11. In general, the EU risk classifications appear to be higher than the IMDRF risk classification for equivalent intended purposes (Table 3).

Since it is not possible to align with both the IMDRF SaMD guidance and the EU MDR Rule 11 across all classification criteria, Australia should choose alignment with the IMDRF SaMD guidance because this is the international guidance also followed by the U.S. FDA.

For the same SaMD device that has a higher risk class in the EU and a lower risk class as per IMDRF, the inclusion in the ARTG will not be impeded if the applicant relies on a CE Marking approval, because the CE marking approval will be more than enough to satisfy the requirements for ARTG inclusion.

We recommend having the proposed Australian SaMD risk classification guidelines on pages 8-9 of the TGA consultation document "fitted" within the IMDRF classification criteria and the risk categories of Table 1.

3. Requiring SaMD to be included in the ARTG

MTAA supports amending the medical device regulations so that all SaMD products are required to be included in the ARTG by excluding them from the provisions for personal importation. This will ensure protection of patient safety through appropriate TGA oversight of SaMD products.

Inclusion in the ARTG of SaMD products will level the playing field between software companies that are new entrants in the medical technology field and traditional medical device companies that develop medical device software.

We understand that excluding SaMD from personal importation exemption is intended to close a loophole in the current regulations, as personal importation was only intended for the importation of a small number of products, for a short period of time (usually three months), whereas today software can be downloaded, often from overseas suppliers, by millions of Australians and use it for months or years.

We do however question the ability of the TGA to enforce this requirement, i.e., to have all SaMD included in the ARTG and preventing a user to download SaMD from a website outside Australia. Also, an unintended consequence of excluding SaMD from personal importation exemption will be that Australian users will not have access to innovative SaMD if overseas developers do not support supply to Australia.

4. Changes to the essential principles

MTAA supports making changes to the essential principles to include references to and specific requirements for software, including SaMD products. This will improve clarity for software designers and developers and will ensure that the regulatory framework remains flexible to capture new and emerging software technologies.

We would like to thank the TGA for engaging with industry in shaping the future regulation for SaMD in Australia.