
ARCS
AUSTRALIA

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Submitted by emailing Device Reforms devicereforms@tga.gov.au

CONSULTATION ON REGULATION: SOFTWARE, INCLUDING SOFTWARE AS A MEDICAL DEVICE (SAMD)

ARCS Australia Ltd (ARCS) welcomes the opportunity to provide a submission to the TGA in response to call for feedback on how software, including Software as a Medical Device (SaMD) is regulated in Australia.

ARCS background

ARCS is a national, membership-based organisation focused on the development and growth of the healthcare sector by development of innovative drugs, diagnostics and therapies. ARCS has provided education, career pathways, professional development, networking opportunities and advocacy for the sector for over 35 years.

ARCS is an education affiliate of MTP Connect, the federally funded growth centre for the MedTech, Biotech and Pharmaceutical sector. This affiliation acknowledges our unique role in providing education to the sector.

Our membership is made up of individuals working in clinical research, regulatory affairs, health economics, medical information and other disciplines related to the development and quality use of therapeutic goods. ARCS members are based in industry, academia, medical research institutes, government, hospitals and patient groups.

Through its members ARCS has a broad and effective reach throughout the healthcare sector, and provides a neutral forum to develop, agree and implement aligned policies and initiatives.

ARCS and its members are dedicated to improving the quality of life of healthcare consumers through professional development.

Consultation

We are in alignment with the proposal to implement regulatory changes to ensure SaMD of products are subjected to adequate scrutiny prior to being made available for use in Australia and allow oversight of safety, intended performance and quality conformance with in the frame work established for therapeutics goods in the post market arena.

We support the proposal to:

- ensure classification rules for medical devices are commensurate to the level of risk posed by their use with a suggestion for consideration in the implementation of the changes
- exclude SaMD from the personal importation provision
- include additional clarification to the essential principles to assist with understanding their applicability to SaMD; we recommend this be done as an extension to essential principle 12.1.

Detailed responses to the questions are included in the following section, *Consultation questions and ARCS' Responses.*

The response is prepared on the basis of the review of the material included in the consultation paper by ARCS internal expertise.

ARCS would like to thank the TGA for the opportunity to contribute to the consultation. We would be pleased to provide any additional clarification if required; ARCS welcomes the outcomes of the review.

Yours sincerely,

Consultation questions and Responses:

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?

We support the proposal to ensure classification rules for medical devices are commensurate to the level of risk posed by their use.

We note that the existing classification rules have been applied effectively to induce higher classifications to SaMD where the risks have been analysed in conjunction with considerations for the platform given the software can not exist in isolation of the platform. We acknowledge however such interpretations are left to the internal standards of the manufacturers and may not produce consistent outcomes. Hence updating the rules is a superior solution. What it means is that some of the SaMDs may already be compliant when the changes are introduced, requiring minimal changes to regulatory documents and probably no changes to the product.

We propose TGA considers adopting the European classifications in Australia as formal regulatory changes and provides additional clarity of the purposes of the SaMDs for interpretational consistency through other means, e.g., new notices, guidance documents, expansion of definitions or inclusion of new definitions in the Dictionary section of the regulations to preserve consistency with respect to the rest of the classification rules.

A proposed definition of software as a medical device could be as follows:

> Software as a medical Device (SaMD)
> Software as a medical device: (a) means a medical device that is intended by the manufacturer: (i) to depend for its exclusion on a device which may or may not be a medical device on its own to act as a platform; and (ii) to act by presenting the intended functionality to the user by means of the interface elements supported by the platform; and (iii) provides information to directly or indirectly influence a therapeutic decision either to a human user or other devices; but (b) does not include software that is incorporated/embedded in to the medical device and validated through its manifestation of the interfaces provided by the medical device

A couple of examples of European definitions and classifications are:

- short term is defined as 60mths to 30 days for the purposes of other rules
- the determination of classification is not directly reliant on the environment of use or the user expertise
- fatal, ie., impending death is a new regulatory concept to the best of my knowledge
  the concept of software providing therapy through direct interaction with patient, is ambiguous. Even in the scenario provided, it could be thought of as providing prescriptive information as opposed to communicating energy to influence the patient response

We support the proposal to exclude SaMD from the personal importation provision:

- It brings it in line with the intension of the provision
- given the nature of software running on undedicated-hardware, SaMD introduces a new risk viz., ease of intentional or inadvertent transfer of the device to other members of the

Australian public; such a risk cannot be clearly ascribed to an entity or person, let alone be mitigated

We support the proposal to include additional clarification to the essential principles under Principle 12.1 as shown below, to assist with understanding their applicability to SaMD.

- Principle *12.1 Medical devices incorporating electronic programmable systems* which includes the below description, has been applied to SaMDs as applicable, where programable systems were taken to mean the software and the associated platform:

  A medical device that incorporates an electronic programmable system must be designed and produced in a way that ensures that: (a) the performance, reliability, and repeatability of the system are appropriate for the intended purpose of the device; and (b) any consequent risks associated with a single fault condition in the system are minimised.

- Expansion of Principle12.1 will be immensely beneficial if it is augmented with an expansion/addition of definitions to the Dictionary section of the regulation to address the principles supporting the development of SaMD.

- Clarification of the misconception that a mitigation for every single fault condition in software running on a given microprocessor can be mitigated by the same or another piece of software running on the same processor would be beneficial.

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

Benefits: All three proposals are beneficial in promoting consistent understanding of the requirements for SaMD and enable oversight under the same framework applicable to other medical devices.

Disadvantages: Deviating from the proposal for classification rules from the EUMDR 2017/745 in the regulation while all the additional clarifications could be made available to the manufacturer (developer) via other means is a potential disadvantage given the size of the Australian market both in the premarket and post market paradigm.

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

Some of the unintended consequences from the proposed changes to the regulations include:

(a) an unnecessary hurdle to *innovation (in all its myriad of meanings)*
(b) denial of access to solutions with therapeutic purpose available to other markets
(c) delay in access to solutions with therapeutic purpose available in other markets
(d) denial of access to solutions with therapeutic purpose even if unavailable in other markets
(e) delay in access to solutions with therapeutic purpose even if as yet unavailable in other markets
(f) unnecessary cost to the development
(g) unnecessary ongoing burden
(h) pushing Australia away from the position from leaders in field of medical research and solution development to conservative thinkers
(i) not in keeping with the expectations of the current generation

A possible mitigation to the above unintended consequences could be extensive education through public discourse augmented by appropriate communication by the device industry/industry bodies with appreciation of the intent of the changes in improving the safety and performance of SaMD. For example, the device industry has been paying a premium for medical grade PVC many times more than general purpose PVC and may have specific insight into the basis for the benefit of regulatory burden.

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

ARCS has commenced the development of a curriculum and associated course modules to provide education in relation to the requirements and processes associated with sponsoring the medical devices in Australia.

The proposed changes, the insights and detailed considerations documented in the consultation paper enables us to better align with the intent of the TGA and other international regulators.

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.*

ARCS is an independent professional development body with no industry affiliation, so this does not apply.

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

As the industry association, this does not apply to us, but in general, a transition period of 5 years appears to be achievable for most manufacturers