Consumers Health Forum of Australia

SUBMISSION

CONSULTATION: REGULATION OF SOFTWARE, INCLUDING SOFTWARE AS A MEDICAL DEVICE (SaMD)

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Consumers Health Forum of Australia 2019
Consultation: Regulation of software, including Software as a Medical Device (SaMD)

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Introduction

Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF appreciates the oppourtunity to provide input into your consultation on the regulation of software as a medical device.

The CHF is generally supportive of improving the regulation of software as a medical device (SaMD). Doing so makes healthcare options safer, more effective and increasingly available to consumers; empowering them to make decisions that improve their heath.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

Consultation Response

With respect to the specific changes proposed in the consultation paper for the regulatory scheme for SaMD:

1. **Changes to the classification rules**

We support the change to explicitly include regulations that classify SaMD as a medical devices, in Class IIa or above depending on their purpose, in alignment with the IMDRF regulatory principles. This will increase the quality of SaMD available in Australia through increased safety and efficacy requirements as per each level of classification.

2. **Requiring SaMD to be included in the ARTG**

We in principle support the change to require SaMD to be included in the ARTG, as doing so will ensure that SaMDs undergo the necessary assessment for safety, efficacy and quality that consumers expect all medical devices to undergo.

However we express concerns about the practicalities of doing so and wish to see an articulation from the TGA of how they intend to interface the fast paced nature and large volume of content of the tech industry with the ARTG listing process.

For example, some "App stores" have in excess of two million apps that are routinely being updated as software problems are identified or operating systems advance. While most of these apps are not intended to be used for health or medical purposes, many apps are. Can the TGA demonstrate how it intends to regulate such a large number of apps, which is constantly growing, to be on the ARTG? How will updates of any software on the ARTG affect its inclusion on the ARTG- will it need to reapply after every update? As new apps are created daily and existing apps update multiple times a month, how will the TGA accelerate the ARTG approval process to ensure that apps are made available to consumers in a timely fashion that is economical for industry?

We would suggest it likely an impossible task to do and that the TGA should instead pursue a whitelisting approach instead of a blacklisting approach. Research done by the CHF through Australia's Health Panel has found that consumers believe that the Government should have a role in reviewing and rating SaMDs such as health apps. We believe this is a function that should be served by the TGA. By proactively identifying and promoting SaMDs that can demonstrate compliance, efficacy and safety as exemplars of appropriate use of software for medical purposes; the TGA will be able to direct consumers to software that is known to be safe and effective. Particularly for low risk SaMDs. This will allow consumers to reliably be able to access and use SaMDs they know to be effective and use market forces to encourage industry to incorporate ARTG listing into their development process. This could function similar to the "Assessed Listed" approval pathway for complementary medicines.

Additionally, given the nature of SaMDs an approval process similar to the new "Provisional Approval" pathway for medicines may be an option worth investigating. It would accelerate the approval process time while lowering the regulatory burden on SaMD developers and potentially for software to be iterated and improved while being used by consumers.

3. Changes to the essential principles

We support the change to explicitly include software in the "Essential Principles" to clarify to both industry and consumers how the principles apply to software used for medical purposes.

In particular we believe it should be clearly articulated in the Essential Principles that SaMDs must have consumer security and privacy designed in from the ground floor.

Additionally we believe that the TGA must produce additional documentation about how exactly they will be regulating SaMDs. For example will they be regulating the algorithms and computer code that are used to construct SaMD sot just the final SaMD products themselves. We would argue that it is critical for the algorithms, computer code and process used to create SaMDs to be regulated, scrutinised and assessed to ensure consumers have access to safe and effective SaMDs.

Additional Considerations

In addition to the above, the CHF poses the following questions to the TGA for consideration as the process of regulating SaMDs progress:

1) If SaMDs are recognised as therapeutic good and listed on the ARTG, does the TGA have proposed pathways via which SaMDs will be able to be attract rebates or subsidies such as through prescription?

Without such a pathway articulated mandating inclusion on the ARTG may be an unworkable proposition. Increased compliance costs could be passed on from developers to consumers, reducing the accessibility of SaMDs. This is of particular concerns as many SaMDs such as apps are used by consumers who may not otherwise be able to afford or

access face-to-face care. By enabling SaMDs on the ARTG to be attract rebates or compliance costs could be offset for SaMD developers.

We would strongly urge the TGA to involve SaMD developers, health professionals and consumers in the process to determine potential rebates and subsidies. In addition we suggest that the TGA designs a phased implementation, initially starting with SaMDs that are high class devices that are used for high risk health situations e.g. clinical decision support apps. Not only would this address the high risk cases while ironing any issues encountered in the roll out of new regulations, it would also allow for the benefits of ARTG listing to be fully realised and potentially make the process more efficient and appealing to developers.

2) Will the TGA be producing guidance about how SaMDs, as therapeutic goods, will interact with the advertising restrictions and requirements?

In particular, what processes will be implemented to monitor the health claims being made and advertised by SaMDs and what measures will be available to penalise those who make unjustified claims? This question become particularly pertinent if the requirement for all SaMDs to be listed on the ARTG is revisited and a whitelisting approach si adopted by the TGA.

3) Will adverse events reporting related to SaMDs be incorporated directly into the SaMDs themselves?

We would strongly urge that the ability for consumers to report adverse events, for all medical devices not just SaMDs, be explicitly required to occur in a consumer friendly manner via clarifications to the Essential Principles. For not only Manufacturers and Sponsors but the TGA as well.

4) How does the TGA intend to regulate to storing of consumer health data in SaMDs if they are developed by overseas companies? Will they require all data to be stored on servers in Australia?

We would strongly urge for considerations around patient data safety be explicitly accounted for in the clarifications to the Essential Principles.

5) How does the TGA intend to account for parallel importation in the regulation of SaMDs?

Specifically, given the ease with which a consumer is able to circumvent geographic restrictions placed on software and technology, how will the TGA propose to effectively and meaningfully regulate SaMDs? For example, phone apps that are blocked from an App Store in a specific country or region can still be accessed within that region by changing the country the account accessing the App Store is registered to.

6) Will the TGA require eIFUs or equivalent to be provided by SaMD developers to Health Professionals? And equivalents to medicine “CMIs” or implantable devices “Patient Implant Cards” to be provided to consumers?

We would urge the TGA to mandate that all medical devices, including but not limited to SaMDs, are required to provide consumers and health professionals with comprehensive and comprehensible information about the medical device to allow for them to make informed decisions about whether the device is appropriate for use by the consumer. These

could be based off CMI leaflets and Patient Implant Cards, noting that these examples do have issues that should not be duplicated here.

Consultation Questions

Finally, in answer to the direct questions posed in the consultation paper:

> **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?**

Yes. The CHF supports the proposal with above listed amendments and additional considerations

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

As above described above. In brief, we consider the advantages to be: Better SaMDs that more effective, safer and of higher quality. The primary potential disadvantage would be that slow approval times and excessive compliance burdens impacting the accessibility and financial viability of SaMDs

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

The most significant unintentional consequence is potentially reducing the number of SaMDs available on the Australian market, denying healthcare options to consumers who may be unable to access or afford face-to-face healthcare.

Additionally, consumers simply bypassing geoblocking restrictions placed on the usage of SaMDs to access ones not available in Australia is a potential consequence. Whether they are SaMDs waiting for approval or SaMDs that have had approval denied.

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

The additional considerations listed above, in particular adopting a whitelisting approach as opposed to a blacklisting one.

> **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.**

N/A

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

Depending on the direction and detail of the final regulatory framework, the CHF will likely need a short period of time to develop consumer targeted resources that explain the changes to how SaMDs are regulated.