Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Email: devicereforms@tga.gov.au
Attached – TGA Coversheet

Re: TGA Consultation: Regulation of software, including Software as a Medical Device

The Health Care Consumers' Association (HCCA) is a health promotion charity and the peak consumer advocacy organisation in the Canberra region. Last year we celebrated forty years of incorporation. HCCA provides a voice for consumers on health issues and provides opportunities for health care consumers to participate in all levels of health service planning, policy development and decision making.

HCCA involves consumers through:

- consumer representation, and consumer and community consultations,
- training in health rights and navigating the health system,
- community forums and information sessions about health services, and
- research into consumer experience of human services.

HCCA is a member-based organisation and for this submission we consulted with HCCA's E-Health Consumer Reference Group and our Health Policy Advisory Committee.

Thank you for the opportunity to put forward consumer views on these issues.

Yours sincerely

K Dwan

Dr Kathryn Dwan
Manager, Research and Policy

12 April 2019

HCCA Response:

TGA Consultation on the Regulation of software, including Software as a Medical Device (SaMD)

Submitted 12 April 2019

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Executive Summary

HCCA supports regulation of software, including Software as a Medical Device (SaMD), that helps ensure safety, quality and access for consumers.

HCCA welcomes the opportunity to provide input to the TGA's consultation on the regulation of software, including Software as a Medical Device (SaMD).

Overall, HCCA supports TGA's proposed changes to the regulation of medical device software in Australia. Our consumers feel that the existing medical device framework does not adequately address more recent (and future) advances in technology. TGA's consultation paper recognises a variety of issues and proposes a range of regulatory changes to help address the gaps in the regulation of software and software as a medical device. We provide more detailed comments in our submission below.

Consideration must be given to stand-alone software that informs, drives or replaces clinical decisions, or software that directly provides therapy to a patient. Advances have been made across a range of products that have the potential to provide incredible improvements in health care, and can be relatively easily accessed by consumers.

Consumers see the need for improved regulation of SaMD products that present higher risks to patients. The developers of these products must provide supporting evidence for their safety and performance in accordance with criteria that are in line with the TGA's essential principles for medical devices. They must also be monitored for their ongoing safety, quality and performance, in such a way as to allow for post-market actions (such as recalls or suspensions) where necessary. The impact on consumers of post-market actions, and how these are effectively managed, must also be considered.

Our submission addresses the first three of the consultation feedback questions posed by the TGA, as these are the most relevant to our organisation. We make some additional comments at the end, addressing

- ongoing consumer input,
- balancing risk and access, and
- communication.

Recommendations:

Software that informs, drives or replaces clinical decisions, or software that directly provides therapy to a patient, presents higher risks to consumers. On this basis we make the following recommendations:

1. We support the TGA in developing and implementing regulations for software (including Software as a Medical Device) that are standardised and consistent with international controls.
2. Regulation for software, including Software as a Medical Device, must ensure a robust process for post-market monitoring that includes the capacity for consumer feedback.
3. Regulation for software, including Software as a Medical Device (SaMD) must balance risk and consumer access. Where risk is higher, sufficient information must be provided for consumers to make informed choices. This could be in a similar way to Consumer Medicines Information which is to be made available for prescription pharmaceuticals.
4. Changes to the regulation of medical device software must be appropriately communicated to all relevant stakeholder groups, including consumers. This should include advice on, and encouragement to, report adverse events with medical device software.
5. Regulation covering data management in Australia for software, including Software as a Medical Device, should provide consumer protection and transparency for the collection and use of personal data. Standardised or regulated consent models need to be in place, along with consumer visibility about data storage (what is being stored and where it is being stored).
6. Regulation of software, including Software as a Medical Device (SaMD) must minimise the cyber security risks.

Detailed Consumer Feedback on Consultation 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?

Consumers feel strongly that medical device software needs to be effectively regulated. The area of medical device software is a rapidly developing space, and these products are not currently subject to the national therapeutic goods regulatory framework. Medical device software has the potential to cause harm, so this is an issue of ensuring safety and quality for consumers.

HCCA welcomes the TGA's proposals to standardise Australia's regulations for medical device software with those internationally. We know that a standardised approach is safer for consumers.[1] It can also streamline processes for industry. This can have a flow-on effect, helping to ensure consumer access and choice to available software, without the impediments that can be caused by developers having to meet non-standard regulations.

In our consultation with consumers, there was some concern that for the effectiveness of regulation, SaMD products would be excluded from the personal importation provisions, but that doing this may limit consumer choice.

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

> *We expect that the regulatory measures proposed should improve transparency for consumers in the choice, use, and post-purchase evaluative reporting of these products.* (Consumer)

Better regulation for medical device software has many benefits:

- Greater consumer confidence in the safety and effectiveness of these products in Australia. Consumers want transparency about the balance of risk and benefit, so that they can determine what is best for their situation, especially where software is a part of an implantable medical device.
- Ongoing monitoring and evaluation, including consumer feedback.
- Standardisation of definitions and regulation internationally.
- Classification of software using the existing devices classification approach in Australia.
- Recognition of the need to minimise the cyber security risks presented by medical device software.

The consumer experience is paramount in relation to medical device software, as there may not be any intermediary or advisory role of a health professional prior to

purchase. The input of consumers' shared experience (in terms of adverse events) will be critical in TGA's monitoring of these products, following regulatory reform.

However, we are concerned that there is little discussion in the consultation paper about how this feedback from consumers will be sought, stored, reviewed and reported for everyone's benefit. There is also interest in how compliance with the regulations would be enforced by the TGA.

Consumers also hold concerns about data management. In our consultation, consumers told us that the digital context and regulation in Australia varies significantly from that of Europe. In Europe support is provided by the General Data Protection Regulation in the European Union (EU). This regulation provides consumer protection and transparency for the collection and use of personal data across the EU. The regulatory context in Australia is not as strong.

Rapid developments in medical device software, along with consumer uptake, mean that software vendors can now potentially collect and monitor vast amounts of data from individuals. Standardised or regulated consent models are important. There should be greater visibility for consumer awareness about data being stored, and where this data is being stored (i.e. which country). A consumer told us

> *Consumers will often consent to more intrusive data collection if they believe that it may help their condition or help a loved one. [There is] significant potential for software to be used for the collection of data that would not be of any use in treatment of a condition and the potential for misuse of the data is huge.*
>
> *Consumers would welcome any improvement in regulation regarding the collection and use of personal and health data from [medical device] software and regulate the consent models used by such software. Consent models offered by vendors are often complex… We would welcome discussions as to how consent could be simplified or standardised.* (Consumer)

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

We believe that overseas vendors of medical device software may avoid Australia, if the regulatory process is too hard and time consuming. If so, it is possible that Australian consumers may miss out on opportunities to use innovative medical device software that could otherwise provide benefit. For example, a consumer mentioned that

> *some of Apple Watch's software/hardware features relating to heart health are not available in Australia. One of the mitigating factors could be to ensure sufficient information is available to help consumers to become well informed about how to use their medical device software to manage the potential risks.*

Consumers want to feel empowered to access and use medical device software as part of shared decision making. Consumers expressed concern to us about several possibilities:

- Health professionals becoming the intermediaries to the selection and/or use of medical device software
- Limited access to the data collected by the medical device software about the individual that could be useful for decision making, such as where data was only accessible through a medical practitioner
- Privacy of the data collected by a medical device. For instance, consumers were unsure who might have access, how the information might be used beyond the individual, and whether they would be informed
- Additional costs of little value to consumers, such as the requirement to purchase an additional monitoring plan from a particular provider to enable software to operate, or constant in-app purchase suggestions
- Difficulties in transferring data and/or history from one product to another

Other issues

Ongoing consumer input

HCCA believes is it vital for the TGA to work closely with consumers in the further development, implementation and monitoring of these new regulatory arrangements for medical device software.

Communication

It is important that these changes to the regulation of medical device software are appropriately communicated to all relevant stakeholder groups, including consumers. HCCA would be keen to inform consumers about these regulatory changes and what this may mean in practice. This would include advice on, and encouragement to, report adverse events with medical devices, including medical device software.

On an ongoing basis, we believe transparent communication about risks and adverse events are important to consumers for informed decision making. This should be both at the individual product level (similarly to Consumer Medicines Information for prescription pharmaceuticals) as well as at category or other levels for medical devices/software.

Balancing risk and access for consumers

Consumers are at higher risk when software informs, drives or replaces clinical decisions, or where software directly provides therapy to patients. We believe it is important that these risks are appropriately regulated, and that consumers are provided with enough information for them to make informed choices. However, we emphasise that regulation must balance risk and consumer access – so as not to limit consumer access to software, including Software as a Medical Device (SaMD).

Concluding comments

Thank you for the opportunity to provide feedback to the TGA's consultation on the regulation of software, including Software as a Medical Device (SaMD).

HCCA looks forward to seeing how this consumer feedback in incorporated and we would be glad to discuss any aspect of our feedback in more detail.

References

[1] Standardising to measure quality (ARHQ) - https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/chtoolbx/understand/index.html