Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

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

Re: TGA Consultation on the proposed regulatory scheme for personalised medical devices, including 3D-printed devices

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 Submission:

TGA Consultation on the

Proposed Regulatory Scheme for Personalised Medical Devices, including 3D-printed devices

Submitted 12 April 2019

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Executive Summary and Recommendations

HCCA supports regulation for personalised medical devices that helps ensure safety, quality and access for consumers

Personalised medical devices and 3D-printed devices are transforming health care. These kinds of devices are allowing technology and materials to be personalised for consumers and changing health care in ways that could not previously have been envisaged. HCCA's consultation with consumers on the proposed regulatory scheme for personalised medical devices, including 3D-printed devices, identified strong support for clearer regulation in this growing area of technology.

As these changes occur and health care continues to be transformed, HCCA welcomes the opportunity to provide input to the proposed regulatory scheme for personalised medical devices, including 3D printed devices, in Australia. We support the overarching plan to introduce regulatory controls that better suit the emerging technologies in personalised medical devices. We believe it is appropriate to set definitions and risk classification that meet consumer needs for safety and performance of personalised medical devices.

During consultation, consumers told us that they appreciate the positive impact of standardised definitions internationally, but ultimately they want safety and monitoring processes in place that really work.

The current regulatory scheme relies primarily on doctor's reporting, and this in itself is a regulatory failure. If a mistake or problem arises from a doctors own actions, the likelihood of reporting is considerably lower.[1] It is difficult to make a report as a consumer or carer, so a key improvement would be to enhance systems to allow consumer reports. This would help ensure that all reports can be monitored and scrutinised by the TGA to identify problematic trends at an early stage, thereby ensuring safety.

Recommendations:

1. HCCA supports the TGA developing and implementing regulations for personalised medical devices that are standardised and consistent with controls internationally.
2. Appropriate patient information about personalised medical devices should be made available for consumers and their carers. This could be similar to Consumer Medicine Information (CMI) that is required from sponsors for prescription medicines.
3. The TGA must regulate for appropriate conformity assessments to ensure the safety, quality and compliance of personalised medical devices.

4. Regulation of personalised medical devices must include ongoing monitoring and enhanced reporting systems to allow for a streamlined process of consumer reporting.
5. The TGA must have a strong framework in place for addressing non-compliance by sponsors with Australian regulation for personalised medical devices.

Detailed Consumer Feedback on Regulatory Changes

1. New Definitions for personalised medical devices

Consumers believe that standardisation is a fundamental starting point to many improvements in health care, including the proposed changes to the regulation for medical devices. We know that clear and standardised definitions are safer.[2] The absence of alignment and standardisation can lead to a less than satisfying experience for, or harm to, patients and families.[3] HCCA supports the TGA's plan to set in place regulation that is consistent with international definitions. This can potentially provide for safe, quality devices that are more easily accessed by Australian consumers. We believe that accessibility for consumers tends to improve with standardised regulation, as it can enable manufacturers to more easily extend the reach of its products.

We note that the examples for each of the 3 defined categories (provided at Appendix 1) are useful for understanding the differences between each category, particularly between Custom-Made and Patient-Matched Medical Devices.

2. Changing the requirements for supplying custom-made medical devices in Australia so that additional information must be provided to the TGA and patients, and to allow the TGA to inspect manufacturing sites

The proposed process will provide greater transparency about the manufacturing of custom-made medical devices. It will also improve the capacity for the TGA to monitor the quality, safety and performance of these devices. The improvements sparked by this change will potentially improve the informed consent process and allow for shared decision making. Having additional patient information available about these devices will help consumers with the ongoing monitoring of their device. This information could be along the lines of the requirements for prescription medicines (such as Consumer Medicines Information).

3. **Introduce a framework for regulating medical device production systems to allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification**

   We support the proposed framework, because it should help make sensible distinctions about risk. Medical device production systems need to be appropriately regulated. The proposed framework will ensure they meet the quality standards outlined in the TGA's essential principles for medical devices. HCCA believes that healthcare providers need flexibility to be able to produce devices for their patients, without each individual provider having to go through the process of manufacturing certification.

   Introducing this framework will allow greater access to lower risk devices for consumers and health professionals. It may also reduce the potential regulatory burden for manufacturing certification from the TGA by ensuring a clearer regulatory framework is in place now and into the future.

4. **Update the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example 3D printed models of patient anatomy.**

   Requiring conformity assessment for Class IIa medical devices is consistent with the proposed framework for regulating medical device production. It is important to consumers that appropriate conformity assessment is applied to models or software that is intended to be used for diagnosis or investigation of the anatomy. This will help ensure quality and safety in the accuracy and true representation of the patient's anatomy for diagnostic or surgical planning purposes, as technology in this area continues to develop.

5. **Regulate medical devices with a human origin component, for example, a 3D-printed implant incorporating cells form the patient, as medical devices with a biological component rather than as pure biologicals**

   The proposed changes to regulations for medical devices with a biological component will more closely align Australia's regulatory framework with that of other international jurisdictions. This will make it easier for consumers to have access to these sorts of devices. It will also help to ensure the quality and safety of these devices for consumers. Easing the regulatory burden for manufacturers through the standardisation of international regulation may have the flow-on effect of increasing consumer access.

6. **Make it clear that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device.**

   HCCA supports these clarifications to the regulations. In implementing these changes, it is also important that there is awareness amongst stakeholders – particularly relevant health professionals and manufacturers – of the risks and penalties for noncompliance. We suggest that this is included in a communication plan as part of the implementation and monitoring of this regulatory work on medical devices.

   Healthcare providers need to be confident that as long as the assembly or adaption of a device is in accordance with the validated instructions from the original manufacturer that they are not considered to be a medical device manufacturer. Consumers can then be more confident that devices are either being used as intended, or that the appropriate conformity assessment procedures are undertaken. HCCA believes that this should help manage risk to consumers.

Concluding Remarks

Thank you for the opportunity to provide feedback on the proposed regulatory scheme for personalised medical devices, including 3D-printed devices. This is important work as both technology and materials for medical devices are continuing to advance exponentially.

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

References

[1] Patient harm and medical error as threats to the Doctor Identity - a new lens for improving patient safety?, Fiona Tito-Wheatland (2017) https://openresearch-repository.anu.edu.au/handle/1885/117703

[2] Standardising to measure quality, ARHQ (2018). - https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/chtoolbx/understand/index.html

[3] 'Standardize Before You Improve', Robert Lloyd (3 July 2018) http://www.ihi.org/communities/blogs/standardize-before-you-improve