Consumers Health Forum of Australia

SUBMISSION

CONSULTATION: PROPOSED REGULATORY SCHEME FOR PERSONALISED MEDICAL DEVICES, INCLUDING 3D-PRINTED DEVICES

March 2019

Consumers Health Forum of Australia 2019
Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

Canberra, Australia

P: 02 6273 5444
E: info@chf.org.au

twitter.com/CHFofAustralia
facebook.com/CHFofAustralia

Office Address
7B/17 Napier Close,
Deakin ACT 2600

Postal Address
PO Box 73
Deakin West ACT 2600

Consumers Health Forum of Australia is funded by the Australian Government as the peak healthcare consumer organisation under the Health Peak and Advisory Bodies Programme

CONTENTS

Contents

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 the proposed regulatory scheme for personalised medical devices, including 3D-printed devices

The CHF is generally supportive of the proposed changes to the way personalised medical devices are regulated. We believe they will reduce the risks consumers are exposed to, increased the standard of efficacy and potentially make such devices more accessible and affordable. However there are some areas that will require additional work.

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

In regards to the suggested aspects of the regularly scheme:

1. introduce new definitions for personalised medical devices;

We believe that the proposed definitions are appropriate. They clearly articulate the different categories personalised devices fall into and align with international definitions.

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

We broadly support this suggested change to the regulations.

However the TGA will need to produce clear guidance and requirements for the "Manufacturer Statement about a customer made device" that is provided to the patients to ensure that they are given a useful, practical and understandable document. We would strongly recommend that they be clearly articulated and prescribed requirements as opposed to recommended guidelines to avoid the issues associated with medicine CMI leaflets.

Additionally we believe the TGA will need to issue guidance that explains about how this statement will interact with Patient Implant Cards that are already provided to patients.

We believe that documents about custom made implantable medical devices (and any implantable device) should be kept for at least the minimum expected lifetime of the device. We are unsure how this compares to the suggested 15 year requirement. As an alternative we suggest the requirement to be "15 years or the 'minimum expected lifetime'; whichever is the longer period". This would ensure that should a custom made implanted device encounter serious issues within its lifetime of use, the relevant documentation will be available.

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

While we broadly support this proposed aspect, we argue that the framework needs to extend beyond simply regulating healthcare providers to produce low risk devices and consider individuals/non-health care providers. With the increasing availability of 3D printers, the TGA needs to specifically consider how the electronic files will be regulated at a manufacturer level to ensure people who self-manufacture medical devices are not at risk of producing a faulty device.

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;

We support this proposed update. We agree that any medical devices used to assist in diagnosis should consistently have rigorous standards applied to ensure they are effective and accurate.

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

We support this proposed aspect. It ensures that Australia's regulatory pathway is aligned with international standards, lowering barrier of entry for new devices and improving accessibility to consumers. Additionally, it enforces high levels of assessment for safety, efficacy and quality to ensure consumers will have access to top quality medical devices.

6. clarify 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.

We support this proposed clarification. It will ensure that the final products are high in safety, efficacy and quality based on validated/assessed manufacturer instructions that permit the variability of a device (within specifications) to be adapted for a consumer, allowing the consumer to have access to a personalised device optimised for their specific requirements.

We emphasise the importance of the TGA Regulations covering the processes and algorithms that create the medical devices as well as the devices themselves. Will likely need additional resourcing and subject matter experts to do effective and appropriate review of the algorithms and code to ensure they are safe and will not lead to device failure.

In regards to other questions raised in the consultation paper:

We note that a potential disadvantage to consumers is reduced accessibility and affordability of personalised medical devices, potentially having a negative impact consumer health outcomes. This would be caused by devices becoming unavailable in Australia due to non-conformity with the new regulations. However given these proposed regulations are aligning to standards already in place in the US and Canada; we expect many if not all manufacturers are likely to already comply with those larger jurisdictions requirements.

Conversely, by making the Australian regulations more clearly aligned with those of larger jurisdictions, we see that personalised medical devices may instead become more affordable and accessible as more manufacturers realise the low cost for them to extend their products into the Australian market.

Similarly, we expect that that transitional arrangements need only be brief as many if not all manufacturers are likely to already comply with those larger jurisdictions requirements.

As noted previously, given the specialised skills in IT required to properly asses the algorithms, computer code and other processes used to make personalised and custom medical devices the TGA will likely need to increase their resourcing and expertise in this area to ensure devices applications are reviewed in both a timely and correct manner.

Finally we expect that the TGA would need to engage in a fairly extensive consumer education and engagement campaign to ensure that the ways that personalised medical devices are regulated and can make informed decision on where and how they should access them. This is particularly important given the increasing availability of personal 3D printers which could be used by individuals to make their own medical devices.