



Consumers Health
Forum OF Australia

SUBMISSION

Proposed regulatory changes
related to personalised and 3D
printed medical devices

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regulatory changes related to personalised and
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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

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Introduction

The 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 consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

We welcome the opportunity to make this submission in response to the consultation paper on proposed regulatory changes related to personalised and 3D printed medical devices released by the Therapeutic Goods Administration (TGA) in November 2017.

New manufacturing technologies present many challenges and possibilities. They tend to fit in a more decentralised and distributed system than traditional technologies, and are part of a rapidly evolving and immature market. They also reinforce non-traditional innovation paradigms that are similarly decentralised and distributed. Regulating their use in health effectively is vital both to patient safety and improving health outcomes. Striking a balance between managing risk and enabling growth presents opportunities for the TGA to keep patients safe and promote innovation.

Consumers expect medical devices to be regulated, and would be surprised to learn how many custom-made medical devices currently avoid scrutiny. Confidence in an effective safety and quality regime is essential to maintain a functioning health system, and changes to how custom-made medical devices are regulated is required to maintain this confidence.

CHF supports the TGA's efforts in this area. We believe that including all custom-made products on some form of register is necessary, and recognise that treating custom-made devices in the same regulatory manner as mass-manufactured devices will see fewer such devices see use with consumers. A balance is required, and our recommendations look at ways to maintain the balance between safety and innovation, as well as take advantage of the unique advantages that custom made medical devices present to consumers, health professionals and manufacturers.

The core principles we have followed in developing our submission are based on the issues of access, choice and accountability.

Access

Consumers deserve access to the best healthcare possible. For custom-made medical devices to be accessible, several factors must be addressed. Costs to the patient and the health system must be kept in mind when making regulatory changes. Further, access requires that effective innovation is not stifled, and ideally is promoted and supported.

Choice

A patient-centred approach requires clear communication between consumers, health professionals and manufacturers so the consumer can make an informed choice about their health care. With custom devices of any kind, a clear communication of the benefits and risks is vital, as is communication of the limits to which a device or manufacturing process has been validated scientifically.

Accountability

Consumers can only be protected from harm effectively when there is clarity around who is accountable at each stage of the process. Who is responsible for communication, consent, documentation, adverse event reporting and recalls are only possible when the party responsible is accountable, and the relevant information recorded and maintained.

Core Recommendation – Registering custom devices

CHF supports the use of a register of all custom medical devices regardless of definition, but does not have a strong preference as to whether it would be as a subset of the Australian Register of Therapeutic Goods (ARTG), a standalone register or another alternative.

Requirements for what information is supplied to the register can be different for each type of defined custom device, and should vary based on the class of the device in the medical device classification system and the intended use.

Without some form of registration, access to custom medical devices in terms of cost is harmed, as is patient safety in terms of accountability. Through an effective registration framework, pathways to reimbursement through Medicare or the NDIS become possible, as too does private health insurance coverage for custom medical devices that can be included on the Prostheses List.

Without a register of how a custom medical device was manufactured and who is using the device, adverse event reporting and any subsequent recalls become near impossible. The broad advertising methods currently used for recalls do not work effectively for the smaller number of consumers of custom medical devices. It is also not a reasonable expectation of consumers to know the ins and outs of how a custom medical device has been prepared for them – for example, a recall of all devices made with a certain 3D printing process is unlikely to garner a response from consumers using such devices.

The proposed register must not however stifle access and innovation through high application costs or overly onerous documentation requirements. It must also include methods to handle ‘edge cases’ or potential innovations. Alternative methods for consumers to report adverse events or other issues and complaints may also need to be investigated.

Effective regulations and a well-designed register with appropriate associated internal TGA processes could in fact aid innovation. This topic and further recommendations in response to specific proposals in the consultation paper are made in this submission about how this might be achieved.

Response to Proposals and Recommendations

Proposal 1: New definitions for personalised devices

CHF broadly supports the definitions proposed. We agree that the vocabulary in the current regulatory framework to describe devices intended for a particular patient is inadequate, and that the suggested definitions are an improvement.

Recommendation 1: Investigate caveats for new definitions in current regulatory arrangements

We recommend that a method for manufacturers whose devices fall under the new definitions in Proposal 1 and thus would have their devices listed on the ARTG to apply for exemptions from requirements be created. If many similar exemptions are requested of the TGA, this should inform a process of altering requirements for listing on the ARTG for devices under that definition, or manufactured with a technology or process.

Recommendation 2: Pathway for newly defined custom-made devices to move towards being validated by research and commercially available

Rather than arbitrarily limiting how many newly defined custom-made devices can be made, the limit should instead be used as a trigger to move the development and manufacture of that device onto clear and supported pathways towards research, higher regulatory compliance and/or commercial viability as appropriate.

For example, if a device for a rare condition is being manufactured more than the limit, then more could be produced provided that publishable academic research is undertaken on their use and effectiveness. Alternatively, a commercial manufacturer could be engaged to develop the device and move it from custom-made to one of the new definitions, such as mass produced medical device or customised medical device.

With the device's inclusion on a register, this also allows the TGA to see when custom made devices are being made for the same purpose by different health professionals, manufacturers or sponsors, presenting the opportunity for connecting them and fostering innovation.

Leveraging other government agencies and projects, such as the Department of Industry, Innovation and Science and their 'BizLab', the TGA recommended pathways could improve the government support of effective innovation.

Proposal 2: Changes to the custom-made conformity assessment procedure

CHF supports the changes recommended to the custom-made conformity procedure, however some become redundant if the core recommendation of inclusion in the ARTG or an alternative register is followed.

The patient must be given the manufacturer's statement about a custom-made device, and that statement must include information on the risks associated with it. Consent and clear communication of risks must be a required part of the conformity assessment procedure. The manufacturer's statement should also include guidance on how to report adverse events.

Supplying an annual report on custom made devices becomes redundant if those devices are included on a register, as does the requirement for a manufacturer to retain documentation for 15 years as the register should hold that information permanently. We do however support the documentation being retained by the manufacturer for 15 years too, as redundancy in this case is beneficial and aligning with EU standards in general is positive.

We also support the proposal that the TGA be allowed to enter and inspect custom made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers. There needs to be a process for caveats to be created for specific manufacturing processes or custom device types. The ability to inspect is vital, but what is being checked for should be open to discussion and change as required by new devices and new manufacturing technologies. It is not possible to forecast perfectly the needs of an evolving and immature market, so measures to allow changes are required to ensure access and effectively futureproof regulations.

Recommendation 3 – My Health Record

Further to providing the patient with the manufacturer's statement when gaining informed consent, the patient should have this documentation stored on their My Health Record should the patient have one. Other documentation related to the device should also be stored here. This would require the TGA to work with the Australian Digital Health Agency (ADHA) to add this information to what can be uploaded to My Health Record by conformant clinical software. That process will take time, and in the interim we recommend that consumers be supported to upload this information to their record themselves.

Proposal 3: Changes to the definition of manufacturer

CHF broadly supports the proposed change to the provision that states when a person is not the manufacturer of a custom device, and to the change that allows healthcare practitioners to use approved medical device production systems for devices of Class IIa and lower without being regulated as manufacturers.

We also agree that it is not sufficient to only regulate the raw material for a 3D printer or other manufacturing technology where the manufacturing process affects the engineering qualities of the custom-made device, and that the new definition of a medical device production system provides a clear way to manage this.

Recommendation 4 – Supply of Essential Principles assessment

The proposed provision states that modifications to devices or processes outside those in accordance with validated instructions provided by the manufacturer that affect compliance with the essential principles mean the modifier assume the obligations incumbent on manufacturers. To be able to make a judgment on whether compliance with the essential principles is affected, the manufacturer should be required to supply the same conformity assessment they have undertaken to the modifier.

Recommendation 5 – Investigate shared responsibility

Moving all the obligations incumbent on manufacturers when assembly or adaptation falls outside the validated instructions provided by the manufacturer may stifle innovation. A method of retaining shared responsibility should be investigated. This could take the form of submitting modifications or adaptations back to the original manufacturer to be assessed for their likelihood of affecting the essential principles.

Recommendation 6 – Further exemptions for medical device production systems for health facilities

We support the exclusion of laboratories or practitioners that use ARTG registered medical device production systems from the obligations of manufacturers when the patients are their own.

We do not fully support that the exclusion be removed should devices be supplied for patients that are not their own.

While regulation is required to ensure one health facility's medical device production system does not become a for-profit manufacturer by stealth, a patient's access to a device should not be hindered because they have been admitted to the wrong hospital. It is a high cost to have medical device production systems sitting unused in hospitals, as it is also a high cost for each facility to have their own system.

We recommend that further exemptions are created to ensure consumer access for hospitals and healthcare practitioners that use approved medical device production systems to produce medical devices of Class IIa and lower for patients that are not their own outside their own hospital. A sensible boundary may be for patients that are not their own but are within the same Primary Health Network (PHN) or state. Where a health facility without access to a relevant medical device production system can demonstrate clinical need and the ability to not affect compliance with essential principles by ensuring sterile transit etc, they should be able to receive the device.

Limiting the amount that the facility with the medical device production system can charge to reflect cost price may be enough regulation to ensure they do not become manufacturers by stealth. Registration of the devices manufactured should also allow the TGA to see where this exemption is being abused. It could also allow the TGA to provide recommendations to health facilities on the commercial viability of procuring their own relevant medical device production system.

Proposal 4: New classification for anatomical models and digital 3D print files

We support the proposed change to the existing rule for recording diagnostic images, however believe the provisions for software are insufficient.

Much of the best software that can be used to turn images into 3D files is not specific to the medical field and hence is unlikely to apply for inclusion in the ARTG. This software is also not recording diagnostic images, but is using them as an input to create a 3D model. A better method may be to remain software agnostic, but introduce the requirement for technical considerations such as accuracy to be proven by the practitioner using the software in question.

The classification of the recording device and software should also be dependent on the end use and the risk associated with inaccuracy, as well as the likelihood that the inaccuracy would cause an issue. This determination should be made by the healthcare professionals involved, based on an assessment process defined by the TGA. For example, there is often no need for a functional testing platform to be very accurate, except in cases where a specific custom medical device for a specific patient or patient group is being created.

It should also be noted that in many cases a health professional will be making an assessment on the accuracy required regardless. 3D printed objects have a resolution that approximates the curves of the digital model with a series of flat faces. More of these faces means higher resolution that better approximates the digital model, but also more computing time and more manufacturing time. Recording technical considerations such as this on the register from our Core Recommendation will help the TGA track best practices and identify when the practitioner's judgment was incorrect, and thus produce more effective future regulation.

Proposal 5: New arrangements for devices with human material

We support the classification of medical devices that contain as a component, but are not wholly comprised of, human origin material as Class III medical devices. We recommend that this change be monitored closely, as the field is still not yet commercially viable and stifling the innovation before it arrives is a negative for consumers. The reduced fee structure should increase access, and we trust that the TGA's assessment of being well placed to evaluate devices containing components of human origin is correct.