‘Value’ of Innovative Technologies

Custom-made Medical Devices: 3D Printing Technology

What are Custom-made Medical Devices?

Custom-made devices are one-off medical devices prescribed for the exclusive use of a particular patient, such as prostheses, orthoses, hearing-aid inserts, and dental appliances.

Devices intended by their manufacturers to be assembled, installed, adjusted or fine tuned before being put into use are not considered custom-made devices. Furthermore, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are also not considered to be custom-made devices.

Applications and Benefits

- ‘Personalised medicine’ model – likely to offer better anatomical fit for better patient outcomes than “off the shelf” devices manufactured to standard specifications
- More accessible - due to increased application of 3D printing technology to the manufacture of medical devices (including some implants)

Reimbursement and Access Challenges

Reimbursement of custom-made devices is not possible due to the current Prostheses List (PL) criteria which state that the “product must be included on the Australian Register of Therapeutic Goods” (ARTG).

Therapeutic Goods Administration (TGA) Regulatory Requirements

Custom-made medical devices are exempt from entry in the ARTG, however they are still regulated in that the manufacturer must apply a conformity assessment procedure to their manufacture, and adverse events must be reported to the TGA, who may take appropriate regulatory action such as recalling the product due to safety and performance reasons.

Definitions

“Custom-made medical devices are medical devices made specifically in accordance with a request by a health professional specifying its design characteristics or construction and intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice” **– TGA Guidance**

“Custom-made device means any device specifically made in accordance with a duly qualified medical practitioner’s written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient” **– European Council Directive**

“..describes two types of custom devices: one specific to the special needs of the physician’s practice, and the other specific to the patient’s unique physiological/ pathology needs” **– FDA Guidance**

MTAA Reccommendations

Custom-made medical devices should be included on the PL and be reimbursed by private health insurers.

Legislative changes to enable Prostheses List Advisory Committee (PLAC) to accept applications for custom-made devices for entry in the PL, even though they do not have an ARTG number i.e. custom-made medical devices can be lawfully supplied without the need for an ARTG entry, such as devices supplied under certain conditions as part of the Special Access Scheme or Authorised Prescriber Scheme.

Custom-made medical devices should be able to be included in the ARTG, if the sponsor wishes to voluntarily do so, in a manner which is not prohibitive by time and cost.

Regulatory Requirements in Australia and Other Jurisdictions

Australia
TGA Guidelines

Custom-made medical devices are not required to undergo premarket assessment by the TGA and are exempted from inclusion in the ARTG. However, a system or procedure pack that contains one or more custom-made medical devices is not considered a custom-made medical device.

Conformity Assessment Procedures for devices used for a Special Purpose applies.

According to the TGA requirements – the manufacturer/sponsor must:

- prepare a written statement in relation to the device
- prepare and maintain documentation in relation to the device
- notify the TGA about any adverse events or problems with the device or its use
- establish and maintain a postmarket monitoring system.

Europe
European Council Directive

Custom-made medical devices are exempted from the CE marking of conformity when they are placed on the market.

Manufacturer or his authorised representative must draw up the statement containing the information:

- prepare a written statement in relation to the device
- the name and address of the manufacturer
- data allowing identification of the device in question
- a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient
- the name of the medical practitioner or other authorised person who made out the prescription and, where applicable, the name of the clinic concerned
- the specific characteristics of the product as indicated by the prescription.

Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.

United States
FDA Guidance

Custom-made medical devices are exempt from Premarket Approval (PMA) requirements and conformance to mandatory performance standards. To qualify for exemption, the device needs to address the following:

- devices created or modified in order to comply with the order of an individual physician or dentist
- the potential for multiple units of a device type (not to exceed 5 units per year)
- qualifying for the custom device exemption
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed.

The definition takes into account multiple considerations such as anatomical location, disease state, material, technology, and indications.

Custom Devices are not exempt from any other requirements, including, but not limited to:

- Quality System Regulation including Design Controls
- Medical Device Reporting
- Labelling
- Corrections and Removals
- Registration and Listing.

Device should include the following information:

- a statement that the device is a custom device
- the name of the ordering physician
- identifying information for the patient (if applicable) whom the device is intended to treat,
- indications for use
- sterilisation status
- relevant composition information (materials, components, etc.)
- storage conditions.

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