Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical devices reforms: Personalised medical devices

Guidance on progress of regulatory refinements to personalised medical devices.

Last updated: 16 October 2024

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Project overview

A new framework has been introduced to ensure an appropriate level of regulation is applied to Personalised Medical Devices to manage the risk these devices may pose.

Prior to 25 February 2021, most personalised medical devices (PMD) met the definition of 'custom-made' and were exempt from the requirement to be approved by us and included in the Australian Register of Therapeutic Goods (ARTG) before they could be imported, exported or supplied (though they were subject to other regulatory obligations).

Over the past two decades, rapid advances in computing technology and materials science have resulted in significant changes to medical imaging technology, manufacturing technology and, as a result, medical device technology.

Newer methods of manufacture such as 3D printing allowed more complex and, in some cases, higher-risk medical devices to be personalised for an individual patient and supplied under the custom-made medical device exemption.

Following extensive consultation and liaison with other global regulators, we developed a new regulatory framework for PMD.

This new framework has been introduced by the Government to ensure an appropriate level of regulation is applied to PMD to manage the risks they may pose.

The new framework came into effect on **25 February 2021**, and includes:

- new definitions for personalised medical devices, including patient-matched and adaptable medical devices, that reduce the scope of the custom-made medical device exemption
- changes to the conditions of exemption for custom-made medical devices
- new requirements for the inclusion of Medical Device Production System (MDPS) in the ARTG.

Medical Device Production Systems (MDPS)

MDPS are a new concept in medical device regulation where an end-to-end system for the manufacture of medical devices can be included in the ARTG, thereby allowing medical devices to be manufactured within healthcare facilities without the need for the facility to include those devices in the ARTG.

While the definition of an MDPS is included in the *Therapeutic Goods (Medical Devices) Regulations 2002*, this definition **will not take effect** until a subsequent legislative instrument declaring an MDPS to be a medical device is in place.

This subsequent legislative instrument is likely to be drafted following work currently underway with the International Medical Device Regulators Forum (IMDRF) and once we have established regulatory structures to appropriately assess and evaluate these systems. This work is progressing.

Patient-matched medical devices (PMMD)

Most of the devices that were previously supplied under the custom-made medical device exemption will now meet the definition of a PMMD.

To enable the continued manufacture and supply of PMMDs a transition period was established. If you intend to supply your PMMD on or after 1 July 2029, you must notify us of your intention to transition before 1 November 2024.

The transition notification period for patient-matched medical devices (PMMDs) will end on 1 November 2024. Under the *Therapeutic Goods (Medical Devices) Regulations 2002*, **all PMMDs will continue to be exempt from ARTG inclusion until 1 July 2029** and can be manufactured and/or supplied until this date.

After 1 July 2029, all PMMDs (including notified PMMDs) must be included in the ARTG before they are imported into, supplied within, or exported from Australia (unless they are exempt, excluded or otherwise approved by us).

There will continue to be a 'low-volume' exemption allowing the first five of a kind of PMMD to be supplied in a financial year by one entity without requiring an ARTG inclusion.

Exempt devices are exempt from inclusion in the ARTG, **but they are not exempt from regulation**. Manufacturers and sponsors of exempt medical devices still need to comply with TGA regulatory obligations for medical devices, including meeting the Essential Principles and advertising requirements.

Useful guidance

- A Step-by-step guide – How to submit a custom-made medical device / patient-matched medical device notification
- Personalised medical devices (including 3D-printed devices)
- Regulatory framework for personalised medical devices: Frequently asked questions
- Refinements to the Personalised Medical Devices Framework
- General requirements for advertising personalised medical devices to consumers

Consultations

Consultation	Status
Proposed regulatory changes related to personalised and 3D printed medical devices	Consultation closed 22 December 2017
Proposed regulatory scheme for personalised medical devices, including 3D-printed devices	Consultation closed 31 March 2019
Proposed refinements to the regulation of personalised medical devices	Consultation closed 14 July 2021

For more information see Consultations and reviews.

Dental Sector Working Group

The DSWG is no longer operational.

On 29 November 2023, the Point-of-care (POC) Manufacturing of Medical Devices - Dental Sector Working Group was established. This Working Group is an extension of the time-limited Personalised medical devices: Australian Dental Sector Working Group (DSWG).

For membership and meeting statements visit the the POC Manufacturing of Medical Devices Steering Committee and Working Groups page.

Contact us

If you have any questions or comments, email devices@tga.gov.au.

You can also send an email to devices@tga.gov.au with 'SUBSCRIBE PMD' in the subject line to receive:

- notification when guidance documents and other information resources are published
- updates about the new framework
- details about webinars and workshops.

More information

- Personalised medical devices
- Custom-made medical devices
- Point-of-care manufacturing of medical devices