Personalised Medical Devices Framework

Regulatory changes to custom-made medical devices

Rebecca Bateson
Assistant Director, Devices Emerging Technology and Diagnostics, Therapeutic Goods Administration

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Welcome

• This webinar is being recorded
• Slides will be made available on the TGA website
• To ask a question to the speaker – Please use the Q&A tool
  – Messages will only be visible to the moderator and speaker
  – Questions will be answered at the end of the presentation
• If you need to contact the moderator – please use the ‘Chat’ function
• Relevant links will be sent to you via the chat function box
• Live polls will be conducted throughout this event.

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Overview

• Custom-made medical devices exempt under the *Therapeutic Goods (Medical Devices) Regulations 2002*

• Traditionally these devices were low risk

• Rapid advances in technology mean they can now be high risk

• Public consultation and collaboration through the International Medical Device Regulator’s Forum

• A new regulatory framework for personalised medical devices commencing on **25 February 2021**
Overview of the changes

25 February 2021 –
regulatory amendments commence

- Custom-made medical devices
  Exempt from inclusion in the ARTG
- Patient-matched medical devices
  Must be included in the ARTG
- Devices produced using a Medical Device Production System (MDPS)
  MDPS must be included in the ARTG
- Adaptable medical devices
  Must be included in the ARTG
Custom-made medical devices

- Continue to be exempt from inclusion in the ARTG
- Excludes
  - Patient-matched devices (new definition)
  - Adaptable medical devices (new definition for an existing concept)
- New obligations
  - Information to be supplied with the device
  - Record keeping requirements
    - a minimum of 5 years after the date of manufacture if the device is non-implantable; or
    - a minimum of 15 years after the date of manufacture if the device is implantable.
  - Annual reporting
  - Inspection and review
25 February 2021 – new regulatory requirements commence

Custom-made medical devices
- Exempt from inclusion in the ARTG
- Must meet the essential principles
- Must notify the TGA of supply

Statement from the manufacturer to be provided with the device

01 October 2021 – first annual report due

Record keeping and annual reporting requirements commence

Allow entry and inspection
Provide documentation when requested
Patient-matched medical devices

- Manufactured within a “design envelope”
- Production processes can be validated, verified or reproduced
- No longer exempt – must be included in the ARTG
- Notify the TGA by **25 August 2021** to access transition arrangements
- Submit an application for inclusion **before 1 November 2024**
25 February 2021 – new definition commences
25 August 2021 – notification period for transitional devices ends

Custom-made medical devices that will meet the definition of a patient-matched medical device

Notify the TGA that you will be transitioning your custom made medical device to a patient-matched device included in the ARTG

01 November 2024 – transition period ends

Patient-matched medical devices
Transition period for eligible manufacturers and suppliers

New devices must be included in the ARTG

Acquire appropriate conformity assessment evidence/certification

Submit an application for inclusion in the ARTG

Patient-matched medical devices
Must be included in the ARTG
Medical Device Production System

- A validated, multi-component design and production system that a manufacturer can supply to health professionals and healthcare facilities, to produce a specific type of personalised medical device in-house.
MDPS continued

• COMING SOON – definition commences 25 February but there’s more work to be done before MDPSs can be included in the ARTG.

• Health professionals (or a suitably qualified person within a healthcare facility) who use an MDPS to produce a medical device will not need to meet the regulatory obligations of a manufacturer.

• The MDPS must:
  – be included in the ARTG;
  – classified at the same level as the device it produces; and
  – be supplied with comprehensive instructions to allow the healthcare professional (or qualified person) to safely produce a device commensurate with the intended purpose of the MDPS.
Adaptable medical device

• A new definition for an existing concept

• Mass-produced and designed to be modified at the point of care to suit a particular patient.

• Definition introduced to provide clarity

• Adaptable medical devices continue to require inclusion in the ARTG before they can be supplied.

• Essential principle 13.4(3) will specifically require adaptable medical devices are supplied with instructions to allow safe modification/assembly at the point of care.
Diagnostic images and anatomical models

From 25 February 2021, the following will be classed as Class IIa:

- devices used to record patient images for diagnosis or monitoring of a disease, injury or disability or the investigation of a physiological process, where the images are acquired through a method that relies on energy outside the visible spectrum (ultrasounds and magnetic resonance imaging (MRI), for example);

- anatomical models (physical or virtual) for the diagnosis and/or monitoring of a disease, injury or disability or the investigation of a physiological process; and

- software-based devices that are used to generate a virtual anatomical model for the diagnosis and/or monitoring of a disease, injury or disability or the investigation of a physiological process.
Important dates – what to do

• Read the guidance
• Take the stakeholder survey
• Register for transition by **25 August 2021**
  o Custom-made to patient-matched
  o Reclassification
• For custom-made devices – submit your first annual report by **1 October 2021**
• Submit your application for inclusion/reclassification by **1 November 2024**
Finding help - SME Assist

- **Targets** the needs of small to medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation
- **Assists** users with navigating the ‘regulatory maze’
- The service offers:
  - guidance articles
  - interactive decision tools
  - educational face-to-face workshops across Australia
  - recorded presentations on regulatory obligations
  - email and phone support
  - a subscription service to keep up-to-date with news and events

The TGA website (and SME Assist hub) contains useful information about the regulation of therapeutic goods and contact details for different areas of TGA.
More information

- **TGA website**: [www.tga.gov.au](http://www.tga.gov.au)
- **TGA Facebook**: [https://www.facebook.com/TGAgovau/](https://www.facebook.com/TGAgovau/)
- **TGA Twitter**: [https://twitter.com/TGAgovau](https://twitter.com/TGAgovau)
- **TGA YouTube**: [https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw](https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw)
- **TGA Linkedin**: [https://www.linkedin.com/company/therapeutic-goods-administration/](https://www.linkedin.com/company/therapeutic-goods-administration/)
- **TGA Instagram**: [https://www.instagram.com/tgagovau/?hl=en](https://www.instagram.com/tgagovau/?hl=en)

**SME Assist**
- Email: sme.assist@tga.gov.au
- Phone: 1800 020 653
Rebecca Bateson and Brian Chamberlain are currently reading over your submitted questions.

We’ll be back shortly for Q&A

We appreciate your participation to complete our live poll.
Q&A

Rebecca Bateson
Assistant Director in the Devices Emerging Technology and Diagnostics Section

Brian Chamberlain
Manager of the Medical Devices Information Unit (MDIU)