Australian Government
Department of Health
Therapeutic Goods Administration

Personalised Medical Devices Framework

Regulatory changes to custom-made medical devices

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TGA Health Safety Regulation

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.

Difficulties hearing from computer?

Check your settings located under "**Audio & Video"** tab located top of your screen:

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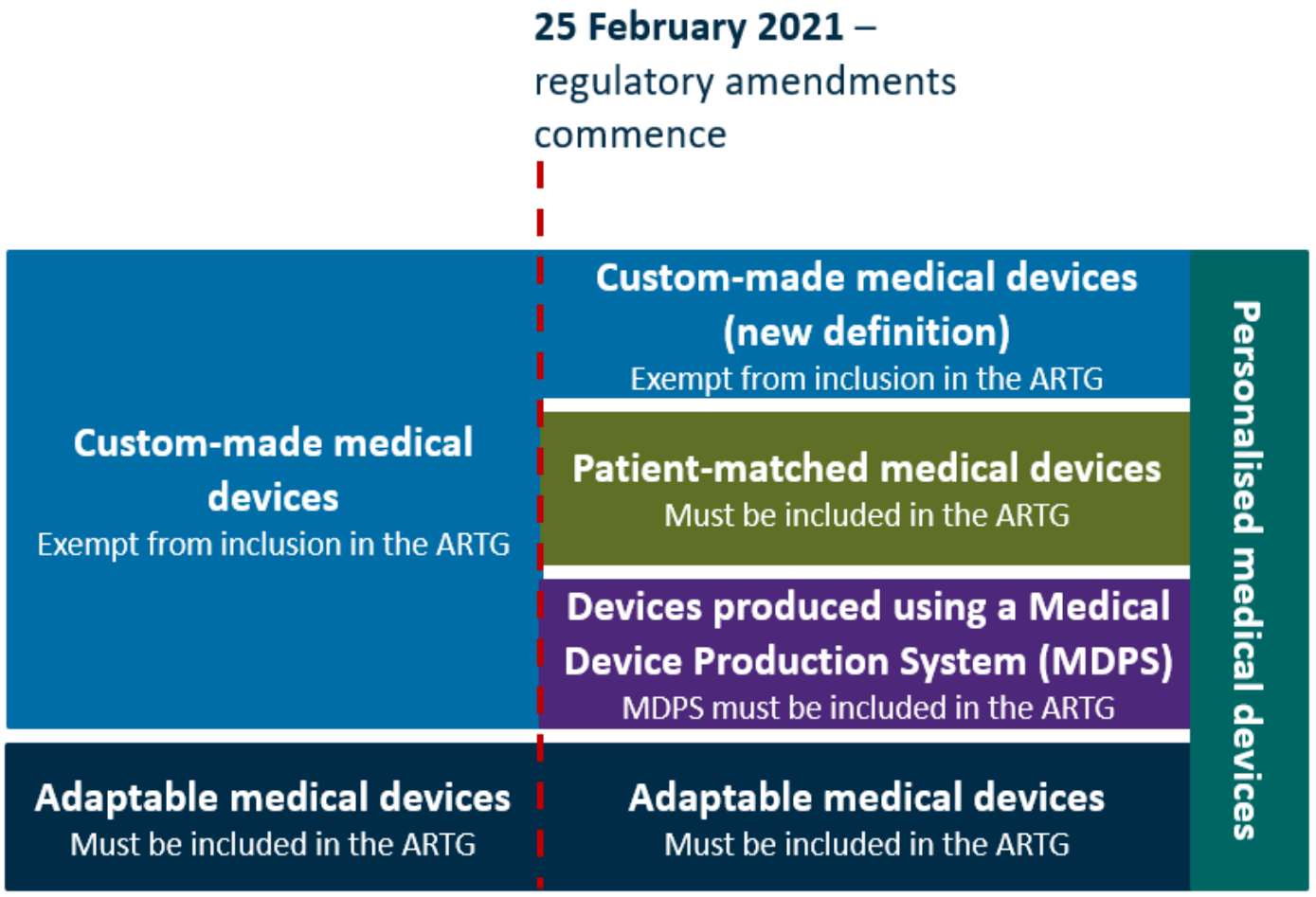
Overview

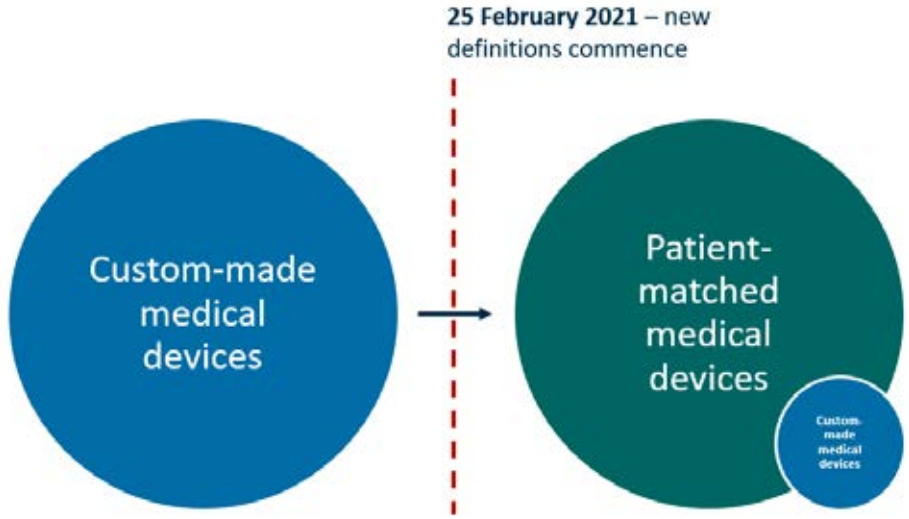
- Custom-made medical devices exempt under the *Therapeutic Goods (Medical Devices) Regulations 2002*
- Traditionally these devices were low risk
- Rapid advances in technology mean they can now be high risk
- Public consultation and collaboration through the International Medical Device Regulator's Forum
- A new regulatory framework for personalised medical devices commencing on **25 February 2021**

Overview of the changes



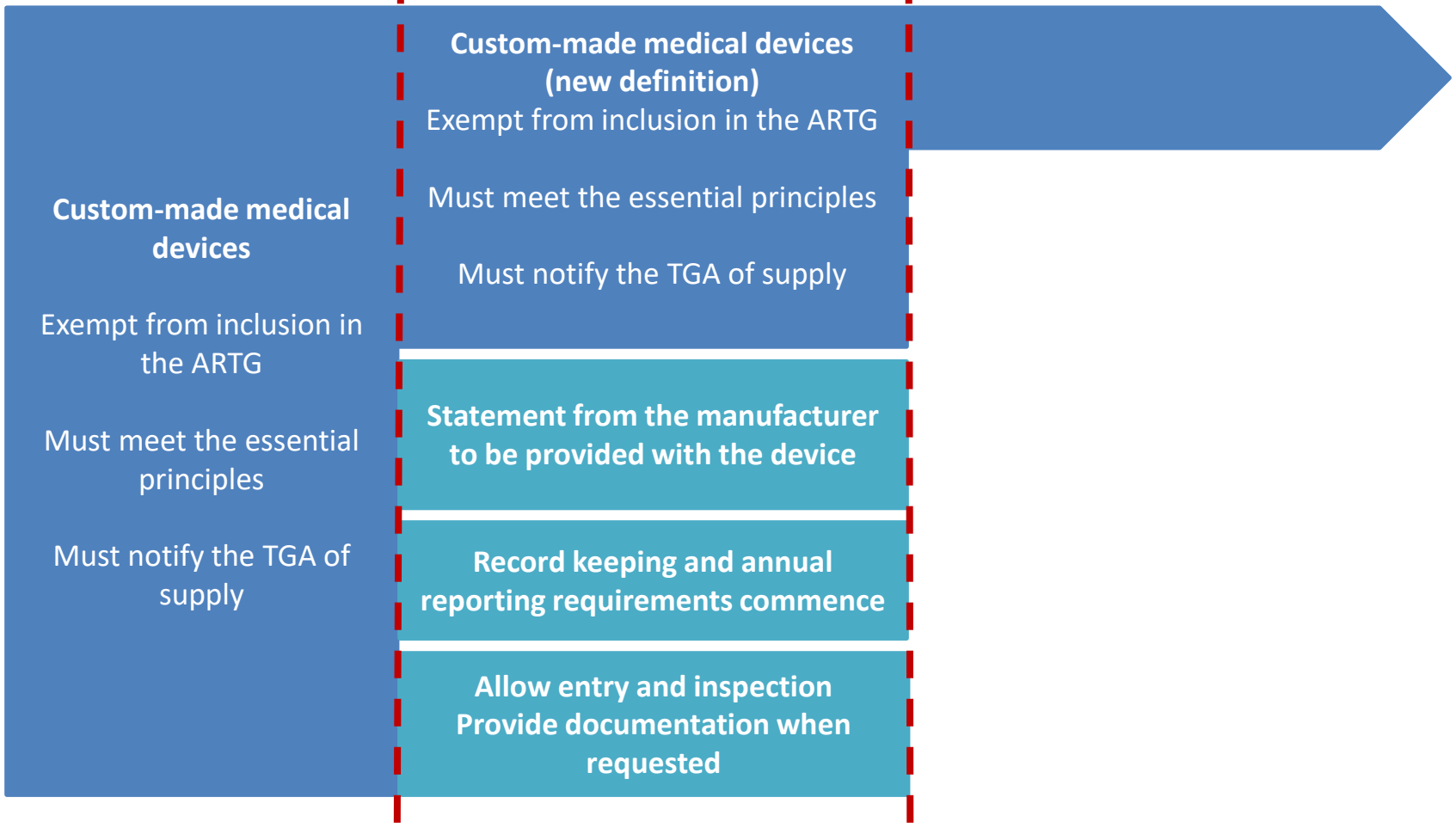
Custom-made medical devices

- 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

01 October 2021 – first annual report due



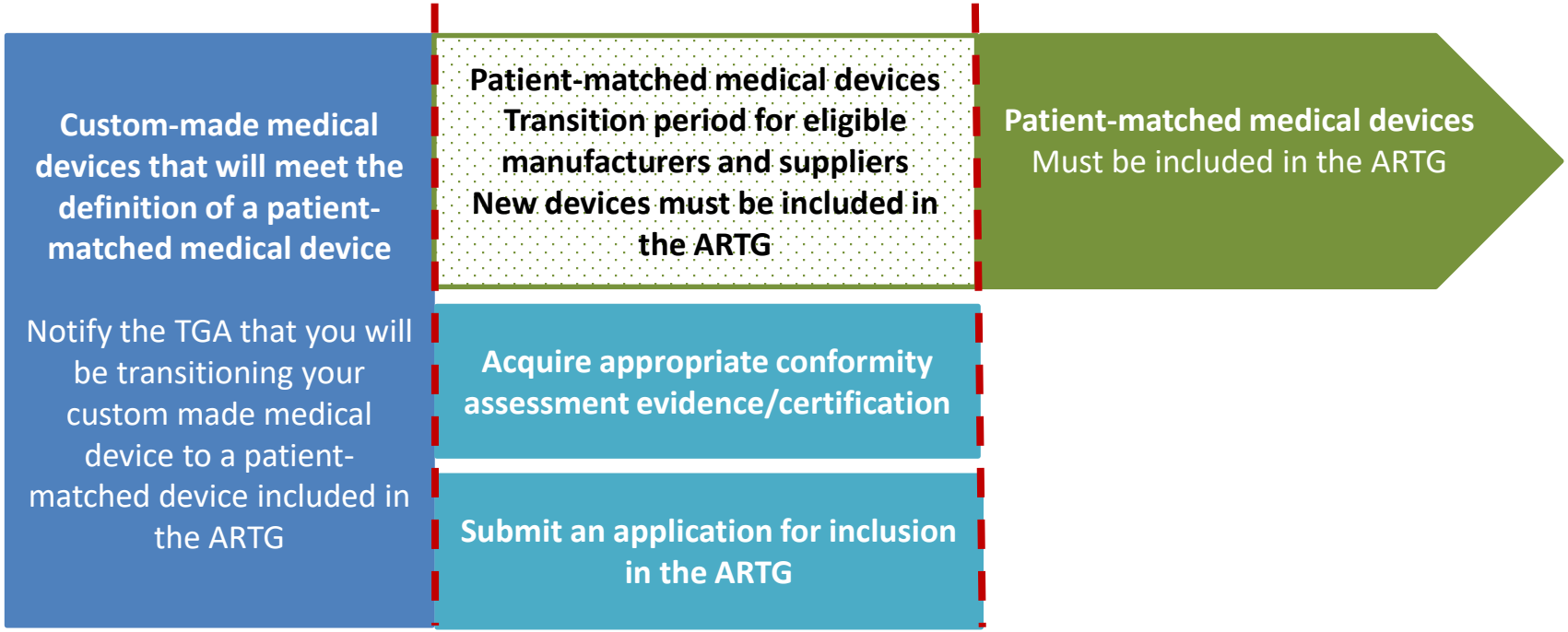
Patient-matched medical devices

- 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

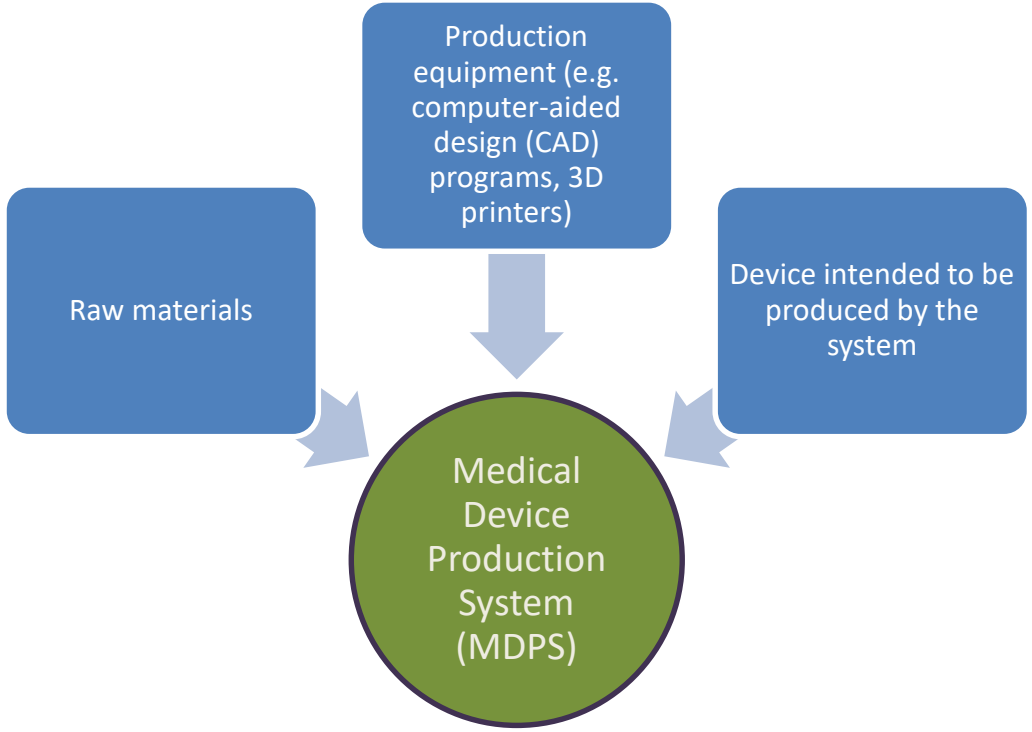
25 August 2021 – notification period for transitional devices ends

01 November 2024 – transition period ends



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**
    - Custom-made to patient-matched
    - 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

tga.gov.au/sme-assist
sme.assist@tga.gov.au
1800 020 653

More information

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TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
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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.

LIVE POLL

Q&A

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Brian Chamberlain
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Australian Government

Department of Health

Therapeutic Goods Administration