# TGA Newsletter article

A new framework for medical devices that are designed, manufactured or otherwise adapted for particular individuals- referred to as personalised medical devices- will commence on **25 February 2021**. This new framework changes how many custom made medical devices are regulated including many assistive technology devices.

The new regulatory framework will affect anyone who manufactures, imports or supplies personalised medical devices. You should read the guidance published on the TGA website to understand how the new framework will impact your business.

## Overview of the personalised medical devices framework

The new framework:

- reduces the scope of the existing definition of a custom-made medical device;
- introduces new definitions for 'patient-matched' and 'adaptable' medical devices;
- changes the existing exemption for custom-made medical devices to:
    - require annual reporting of custom-made devices supplied in the previous financial year;
    - require documentation about the device to be retained for 5 years (for non-implantable devices) or 15 years (for implantable devices);
    - require manufacturers to provide information about each custom-made medical device to the intended recipient; and
    - allow the TGA to inspect production facilities;
- introduces the new concept of a Medical Device Production System (MDPS) and a framework for regulating these systems to allow healthcare providers to produce personalised devices for treating their patients, without the need for manufacturing certification; and
- updates the classification rule for medical devices that record diagnostic images to include a broader range of technology now used for the purposes of recording patient images for diagnosis and investigation, including anatomical models.

## What does this mean for the assistive technology industry?

The primary change for the assistive technology industry is that the majority of existing custom-made medical devices, which are currently exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG), will no longer be exempt. As a general guide, if you are manufacturing, importing or supplying more than five of the same kind of a device in a 12-month period, your device is unlikely to meet the new definition of a custom-made medical device, and you will need to take steps to ensure it has TGA approval and is included in the ARTG. This is because even at these relatively low production volumes, it is generally possible for process validation or product verification to occur.

There are transition provisions that allow time for you to apply to have your device included in the ARTG. You have until 1 November 2024 to submit an application to the TGA for inclusion of your device in the ARTG. To qualify for the transition arrangements you must:

1. notify the TGA that you are a manufacturer or supplier of custom-made medical devices; and then
2. apply for the transition period **before 25 August 2021**.

Once you have submitted a transition notification form, you must submit an application for inclusion in the ARTG by **1 November 2024**.

Further communication and educational material will be made available in early 2021 including the opportunity to engage directly with the TGA through webinars. To receive more information about the changes and their impact on you, we encourage you to take a short survey. Responding to the survey will ensure you receive information about the areas of the framework that are of interest to you including opportunities to attend webinars and reminders about important deadlines.

Full guidance for the new personalised medical devices framework is available on the TGA website.