Personalised Medical Devices

April 2021

The way that custom-made medical devices are regulated in Australia is changing. These changes will impact anyone who is manufacturing, importing or supplying custom-made medical devices.

From **25 February 2021** a new framework commenced for regulating medical devices that are designed, manufactured or otherwise adapted to suit a particular individual. These kinds of products will collectively be known as ***personalised medical devices***, and they include ***custom-made medical devices***.

If you currently supply custom-made medical devices and are not aware of your regulatory obligations, you should review the information available on the TGA website.

The main impact of these changes is that most of the devices currently being supplied as custom-made medical devices will need to be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG).

As a general guide, if you are manufacturing, importing or supplying more than five (5) of a kind of medical device in a year it is unlikely that the device will meet the new definition of custom-made under the new framework. If you are the manufacturer, importer or sponsor of device impacted by this change, you will need to:

- Ensure you have submitted a custom-made medical device notification before 25 August 2021.
- Submit a transition notification form to the TGA before 25 August 2021.
- Ensure you have appropriate evidence of conformity assessment and submit an application for inclusion in the ARTG by 21 November 2024.

To receive more information about the changes and their impact on you, see the personalised medical devices landing page on the TGA website. You can also subscribe to receive regular updates directly by sending an email to devices@health.gov.au with “SUBSCRIBE PMD” in the subject line.

Please note: If your device is required to be included in the ARTG and you do not submit a transition notification form before 25 August 2021 you will not be able to continue supplying the device until you have a valid inclusion in the ARTG.

The ASO has formed a working group with major stakeholders including the ADA, other dental specialist bodies and independent labs and is working with the TGA to clarify and streamline the compliance process for the dental industry. We will continue to update the ASO information hub on the TGA regulatory changes as this progresses: https://www.aso.org.au/tga-regulatory-changes-custom-made-medical-devices