Information for NSW Health staff

TGA Medical Device Reforms: **Personalised medical devices (including 3D-printed devices)**

Personalised medical devices (PMDs) are specifically designed, manufactured, assembled, modified or adapted to cater to the unique needs of individual patients. This involves a collaborative effort from healthcare professionals, engineers and scientists to develop medical devices that align with an individual's unique anatomical and/or physiological needs.

The Therapeutic Goods Administration (TGA) uses the following three specific terms to describe personalised medical devices:

1. custom-made medical devices
2. adaptable medical devices
3. patient-matched medical devices.

This factsheet provides an overview and definition for each term.

Further information can be found on the TGA's website at https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-personalised-medical-devices

Custom-made medical devices

- Are manufactured as a one-off for the sole use of a particular patient or health practitioner to meet an individual's specific needs that cannot be met at the appropriate level of performance by an alternative device available on the market. For example, a prosthetic leg or hip prosthesis manufactured as a one-off for a specific individual because no other device on the market is deemed suitable for their needs.
- Are exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG) but are still regulated by the TGA (with less regulations compared to other PMDs).
- The TGA devices must be notified within two months of manufacture of these devices or initial supply (if manufactured overseas). Further information can be found at https://www.tga.gov.au/sites/default/files/2023-12/How-submit-custom-made-medical-device-patient-matched-medical-device-notification-guide.pdf
- The health professional prescribing the custom-made device is responsible for specifying its design characteristics and/or construction.

Adaptable medical devices

- Adaptable medical devices are mass-manufactured and are designed to be modified, adapted or assembled at the point of care to suit a specific individual after purchase. For example, plaster-infused or thermoplastic bandages, and tooth-filling materials like composite resins and bone cements.
- These devices come with clear manufacturer instructions on how to safely modify, prepare or assemble them without changing the intended purpose of the device.
- When used as per manufacturer instructions, the person making adaptations would not be considered a manufacturer, and the adaptable device does not need separate ARTG registration. For example, addition of padding to prefabricated/premade splints, adjustment of moon boots and adjustment of compression garments for lymphoedema.
- When manufactured from scratch using one or more materials/components that are not registered in the ARTG, then the final product must be included in the ARTG. For example, hand splints made from base materials.

Patient-matched medical devices

- Are manufactured within a specified design envelope using production processes to match the anatomical, and/or physiological features of a particular individual, or a pathological condition of a particular individual. For example, ankle/foot orthoses, knee/elbow prosthesis, socket for prosthetic leg, silicone bolus and 3D-printed bolus commonly used in radiation therapy, retainers, aligners and orthodontic temporary anchorage devices.
- These devices must be included in the ARTG before they are imported into, supplied within, or exported from Australia.
- Patient-matched medical devices that met the definition of a custom-made medical device before 25 February 2021 must be notified to the TGA by 1 November 2024. More information at https://www.tga.gov.au/sites/default/files/2023-12/How-submit-custom-made-medical-device-patient-matched-medical-device-notification-guide.pdf
- Complete one online notification form for each “kind of medical device” at https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-device-inclusion-process/what-kind-medical-device-it

Notification to the Therapeutic Goods Administration

- Every local health district (LHD) and speciality network (SN), as an individual legal entity, should have a TGA business services (TBS) account.
- Before notification of custom-made or patient-matched medical devices, your LHD or SN will need a client identification number (Client ID) and a secure online TBS account.

Please refer to “definitions” on the CEC’s dedicated web page (see boxed insert below). A recording of a 2024 webinar hosted by CEC staff can also be accessed here: Medical device reforms: Management of manufacturing medical devices at point of care including PMDs

The **Clinical Excellence Commission** is supporting NSW Health staff through the reforms. Visit its dedicated page at www.cec.health.nsw.gov.au/keep-patients-safe/medical-device-governance-program. Email enquiries to cec-medicaldevicegovernance@health.nsw.gov.au