Information for NSW Health staff

TGA Medical Device Reforms

Strategy 1: Improve how new devices get on the market

The Therapeutic Goods Administration (TGA) has introduced Medical Device Reforms to strengthen Australia's regulatory system for medical devices, ensure greater transparency of its systems and procedures, and be more patient-focused. The TGA has three strategies in place to administer these reforms. This factsheet provides an overview of strategy 1, which aims to strengthen the governance of:

- personalised medical devices (that is, devices produced, adapted and/or assembled to suit an individual's unique needs, including 3D-printed devices)
- reclassification of certain medical devices from class II to class III (in effect since Nov 2021)
- software as a medical device; that is, software that functions as a medical device and has a medical purpose (for example, a smartphone application that monitors atrial fibrillation and sleep apnoea, and artificial intelligence text-based products)
- software-based medical devices (for example, cardiac MRI analysers and ECG machines).

What is the classification of my medical device?

All NSW Health staff that manufacture or modify medical devices (including 3D-printed devices) should access this link to assist in classifying a medical device: www.tga.gov.au/resources/what-classification-my-medical-device

What are the changes to the personalised medical devices framework?

- Most "custom-made" medical devices have been reclassified as "patient-matched" medical devices.
- Patient-matched devices must be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) before being manufactured, imported, or supplied within, or exported from, Australia (in volumes of more than five per financial year).
- If you manufacture and/or supply five or less patient-matched medical devices in a financial year, you are exempt from requiring an ARTG entry but must meet all other regulatory requirements for medical devices, including reports to the TGA detailing the devices you have manufactured and supplied.

How are software-based medical devices regulated?

Since February 2021, it is a requirement that software-based medical devices be included in the ARTG (there are some exclusions, such as digital mental health and electronic patient records. Determine if your software is regulated: www.tga.gov.au/sites/default/files/my-software-regulated.pdf.

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