Information for NSW Health staff

TGA Medical Device Reforms

Strategy 3: Provide more information to patients about the devices they use

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 3, which aims to:

- provide consumers with essential information about medical devices
- improve consumer awareness of the safety and performance of medical devices
- raise consumer awareness of how to report adverse events.

Mandatory information at two stages

Since December 2021, it is mandatory for health professionals to give patients information on their implantable medical devices at the following two stages.

BEFORE the device is implanted: **Patient Information Leaflets** (PILs) should be provided to patients and include information identifying the device, the purpose of the device, how to use the device safely, and information on how to report any medical device adverse event or concern.

AFTER the device is implanted: **Patient Implant Cards** (PICs) should be provided to patients and include the name and model of the device, batch/lot number and serial number of the device, and the manufacturer's name, address and website.

PILs and PICs are produced by the medical device sponsor. Clinicians should document in the patient's medical record that this information has been provided.

The TGA's guide, "Five questions to ask your health professional before you get a medical implant", can be accessed at www.tga.gov.au/products/medical-devices/specific-types-medical-devices/five-questions-ask-your-health-professional-you-get-medical-implant. This resource can also be printed in 10 languages: Arabic, Croatian, Farsi, Greek, Italian, Korean, Mandarin, Spanish, Turkish and Vietnamese.

Consumer reporting of medical device adverse events

It is mandatory for health professionals to report an adverse event related to any medical device. Patients are encouraged to report any issues to their treating medical officer, and to the TGA at www.tga.gov.au/safety/reporting-problems/report-adverse-event-or-problem-consumers

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