Information for NSW Health staff

TGA Medical Device Reforms

Strategy 2: Strengthen monitoring and follow-up of devices already in 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 to administer these reforms.

This factsheet provides an overview of strategy 2. It aims to improve patient safety through improved data analysis, data-sharing and post-market surveillance of medical devices. This will allow for rapid identification and follow-up in the event of an issue with a medical device. The following will be introduced under this strategy:

- a Unique Device Identification (UDI) system
- the Australian Unique Device Identification Database (AusUDID)
- mandatory adverse event reporting by healthcare facilities.

What is a UDI?

The UDI system that will be introduced under these reforms is based on a globally accepted coding standard and will be applied to specific medical device models, including implants, from around the world. The purpose of the system is to improve the way medical devices are identified, tracked and traced, so that action can be taken swiftly in the event of a safety concern.

What is AusUDID?

AusUDID will support the establishment of the UDI system in Australia. The database will enable timely access to complete, accurate and consistent information about medical devices in use in Australia.

What are the changes to reporting medical device adverse events?

From March 2025, it will be mandatory for health professionals to report medical device adverse events to the TGA. The purpose of the new mandate is to better facilitate the reporting of adverse events that impact Australians in order to make medical devices safer for everyone. This information will then enable the TGA to rapidly identify and respond to significant medical device issues.

Work is in development to streamline this reporting mandate at local, state and commonwealth levels. The CEC will continue to provide updates as this work progresses. In the interim, NSW Health staff should continue to report all medical device adverse events using current processes.

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