Information for NSW Health staff
TGA Medical Device Reforms
Overview

Medical Device Governance Program by the CEC

Tracking and tracing medical devices, particularly those implanted in patients, is increasingly important in monitoring safety, administering recalls and facilitating communication with patients who may have been implanted with a potentially problematic device. As such, the Australian Government's Therapeutic Goods Administration (TGA) is undertaking a significant program of reforms to strengthen the regulation of medical devices in Australia.

The Clinical Excellence Commission (CEC) – the lead agency supporting safety and quality improvement across the NSW Health system – is coordinating implementation of the reforms in partnership with the Ministry of Health, Agency for Clinical Innovation, HealthShare NSW, eHealth NSW, Health Infrastructure, Local Health Districts and Speciality Health Networks.

Together, the role of these partners is to raise awareness among healthcare professionals to ensure they understand their new responsibilities, comply with the reforms, and help navigate better outcomes for patients.

The reforms were developed by the TGA in response to several reviews and inquiries that prompted the need for enhanced patient safety measures. These included the independent Expert Review of Medicines and Medical Devices Regulation 2015 and the Senate Community Affairs References Committee inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters (2017).

Unlike the regulation of medicines, the variety and diversity of products that fall under classes of medical devices means that, for many devices, randomised control trials are impractical. As such, the regulation of medical devices in countries across the globe involves managing risk through a combination of pre-market assessment and post-market monitoring.

Further, medical technology is constantly evolving and becoming increasingly complex. The TGA, like other global regulators, faces the ongoing challenge of balancing public access to innovative medical devices with consumer protection.

The TGA has three strategies in place to administer the reforms (a factsheet is available for each):

- Strategy 1: Improve how new devices get on the market
- Strategy 2: Strengthen the monitoring and follow-up of devices already in use
- Strategy 3: Provide more information to patients about the devices they use.

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