Improving Access to Medicines – Unique Device Identification system for the safety of medical devices

The Australian Government will strengthen patient safety through the establishment of a Unique Device Identification (UDI) System for medical devices.

The system is an Australian first and will allow tracking and tracing of medical devices that have been implanted in patients. It will enhance the ability for doctors to notify patients quickly if there is a safety issue with a medical device and strengthen Australia’s post market medical device adverse event system.

The UDI system is a key pillar of the Government’s response to the Senate Inquiry into The number of women in Australia who have had transvaginal mesh implants and related matters. It underpins the response to four recommendations made by the Senate Committee, relating to post-market surveillance and monitoring throughout the healthcare system.

Why is this important?

In 2017–18 there were more than 2.8 million devices implanted and funded by private health insurance alone – with many more implanted in the public system.

Implementing a UDI system protects patient safety and allows for a quick response to any safety issues that may arise with implanted devices.

Who will benefit?

Patients who have medical devices implanted will benefit from the additional safety and monitoring protections the UDI system will provide.

How much will this cost?

The Government will invest $7.7 million from 2020–21 to 2023–24 through the Therapeutic Goods Administration to support this initiative.