# Media Release

**19 August 2024**

Private Healthcare Australia
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## More action needed to protect patients from harmful medical devices following TGA crack down on spinal cord stimulators

Doctors should be legally obliged to report adverse events involving medical devices to the Therapeutic Goods Administration to help protect patients from harmful products and procedures.

The Australian Government should also introduce tougher measures to ensure dangerous and ineffective medical devices are swiftly taken off the Medicare Benefits Schedule (MBS) and Prescribed List of Medical Devices. This would take them off the market for doctors and private hospitals, so they can't be used.

Today the ABC reported 12 spinal cord stimulator devices have been cancelled from the Australian Register of Therapeutic Goods (ARTG). Another 70 spinal cord stimulator devices have had conditions of supply imposed. These measures took effect on 1 August 2024.

The TGA's action comes after an ABC Four Corners 'Pain Factory' series exposed thousands of adverse events connected to the devices, including many classified as 'severe' and 'life threatening'.

CEO of Private Healthcare Australia Dr Rachel David said the TGA's action was too late for many people who sustained terrible, life-changing injuries.

'Patients have been raising the alarm about poor outcomes from spinal cord stimulators for years, and private health funds alerted the Department of Health and Aged Care to high rates of revision procedures in January 2023.'

'Australian patients, clinicians and health funds should not have to rely on media reports to trigger the removal of ineffective and harmful medical devices and technologies from the private health system. Until last month, health funds have been forced to pay for these devices despite knowing they don't work and can cause harm.'

When there is significant concern about the safety of a device or technology, Dr David said the TGA should suspend use until independent evidence for safety and efficacy is provided.

'After well publicised medical disasters such as the pelvic mesh scandal, Australian patients deserve better,' she said.

Spinal cord stimulators are devices implanted into the back during surgery to send low levels of electricity directly into the spine to attempt pain relief. People with chronic back pain pay on average $58,000 for the surgery, which has no sustained benefits that outweigh the costs and risks, according to two respected Cochrane Reviews.

PHA data from 5,852 patients over a 10-year period to 2021 found 41% required surgical reintervention within three years. The revision surgery rate for hip and knee replacements is 2.7% and 2.4% within three years.

In March 2023, legislation passed making it mandatory for public and private hospitals to report medical device related adverse events to the TGA. Regulations to support implementation are due by 22 March 2025. Despite a Senate committee recommending mandatory reporting of adverse events by doctors, this has not occurred.

*Private Healthcare Australia is the peak representative body for Australia's private health insurance industry. PHA represents 22 Australian health funds. 14.8 million Australians (55% of the population) have private health insurance.*

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In 2023, the Greens pushed for this to be included in the legislation mandating hospital reporting, but the AMA successfully lobbied against it claiming it was an "unnecessary compliance burden".

'Doctors have the skills and knowledge to identify a medical device related adverse event, so should be obliged to report them,' said Dr David.

The definition of an adverse event should also be made clearer, and not left up to device manufacturers to determine. For example, one manufacturer was of the view that unplanned surgeries to fix faulty leads did not qualify as an adverse event.

PHA also wants to see an enforceable Code of Conduct for the medical technology industry that aligns with the code of conduct for pharmaceutical companies. Under the code for pharmaceutical company representatives, Medicines Australia must disclose support, incentives and other benefits provided to prescribing doctors by pharmaceutical companies.

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