

Therapeutic Goods Administration
PO Box 100
WODENACT 2606

21 March 2019

Dear Sir/Madam

CONSULTATION: PROPOSED RECLASSIFICATION OF SPINAL IMPLANTABLE MEDICAL DEVICES

Painaustralia welcomes the opportunity to provide input to the Therapeutic Goods Administration's (TGA) consultation around the proposed reclassification of spinal implantable medical devices.

Painaustralia is the national peak body working to improve the quality of life of people living with pain, their families and carers, and to minimise the social and economic burden of pain. Members include pain and other specialists, health practitioners, health groups, consumers and researchers. Painaustralia works with our network to inform practical and strategic solutions to address this complex and widespread issue. As such, the issue of implanted medical devices and their quality and safety regulation is important to our members and stakeholders.

The consultation draft rightly notes that spinal implants can provide significant benefits to patients with diseases or injuries of the spine and can contribute to improvements in quality of life. For example, reduction in back pain increases productivity, reduces dependence on medications, and in general facilitates more activity, leading to improvements in quality of life.

As noted in our submission to TGA's consultation on the Unique Device Identification Database¹, recent device failures and subsequent findings have revealed a poorly regulated industry that has put consumers at considerable risk of harm, including those with persistent and chronic pain. In particular this has highlighted the need for more patient education and information around medical devices and the potential risks that they may pose.

Overall, Painaustralia is supportive of the proposed reclassification of all spinal implantable medical devices (excluding some ancillary components) from Class IIb (medium-high risk) to Class III (high risk).

Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps

As noted in the consultation paper, there are two major categories of spinal implantable medical devices: fusion and non-fusion implants. Painaustralia has received input from our member organisation, the Neuromodulation Society of Australia and New Zealand (NSANZ) in response to the proposed reclassification.

NSANZ is supportive of the the proposed reclassification of spinal implantable medical devices which in their view are practical, sensible and reasonable. It is NSANZ's view that spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps do not form part of the spinal implantable devices under review i.e. spinal disc replacement implants or any implantable devices that come into contact with the spinal column as they are not used in any way to treat spinal pathologies or physical/structural abnormalities of the spine or spinal column. NSANZ's input is attached for your consideration (Attachment A).

Informed decisionmaking support for consumers

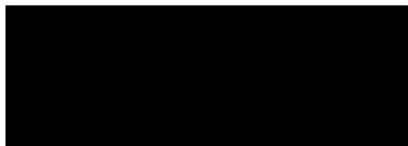
Medical devices have been a life-changing invention for many, but people with such devices which include spinal implants or those considering them, have a right to be informed.

Additional steps also need to be taken to ensure that consumers are aware of these regulatory changes and the mechanisms in place they can access in an adverse event.

Targeted education and awareness campaigns are needed to aid in informed decision-making by consumers, especially around device failure adverse events as well as replacement rates. We need to ensure better awareness and provide more effective support to people living with pain as a result of an implanted device.

We trust that the matters raised in our submission will be useful in helping the TGA finalise the proposed reclassification of spinal devices and welcome the opportunity to discuss our submission with you further.

Yours sincerely



Carol Bennett
Chief Executive Officer

ⁱ Painaustralia 2019. Submission to TGA consultation on medical devices. Access online [here](#).