

Therapeutic Goods Administration  
PO Box 100  
WODENACT 2606

21 February 2019

Dear Sir/Madam

## CONSULTATION: MEDICAL DEVICES

Painaustralia welcomes the opportunity to provide input to the Therapeutic Goods Administration's (TGA) consultation around medical devices in particular the proposed creation of a the Unique Device Identification System (the UDI System).

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.

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, the inability of regulators to trace devices has been a systematic failure of our health and safety regulatory regime.

Painaustralia is therefore supportive of the proposed introduction of the UDI System in Australia, including the development of the UDI database (AusUDID). We also support the proposal that the TGA be responsible for developing and maintaining the UDI database, and the AusUDID.

Consumers have also welcomed the proposal noting that current regulations need overhauling.

*Much needs to be done, including clinical trials and evaluations. There isn't the data, let alone the "device database" or appropriate independent clinical follow up. Some surgeons keep their own data, but won't record "issues" because it can skew their own results. Not independent, and the TGA doesn't seem to be impartial either. There needs to be mandatory reporting of complications by ALL health professionals, not just a couple who do the right thing. TGA's data is being provided mostly by consumers. Those of us that have connected the dots or been supported to do so, in order to be counted in the "mesh" tally of injury.  
-Consumer with an implanted medical device*

Additional steps also need to be taken to ensure that consumers are aware of these regulatory mechanisms. 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 devices.

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We note that the The Basic UDI-DI will be linked to other device information via a link between the UDI database and Eudamed. Eudamed contains other information about medical devices including: registration details, certificates, adverse incidents, clinical investigation and market surveillance. Provisions must be made to ensure that data collected through the database protects and preserves patient privacy and confidentiality and to ensure that this data cannot be used for commercial purposes.

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

Yours sincerely

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