



Australian Government



Australian
**Small Business and
Family Enterprise**
Ombudsman

16 November 2020

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100 WODEN ACT 2606

via email: devicereforms@tga.gov.au

Dear Medical Devices Reform Unit

Options for the introduction of an Australian Unique Device Identification (AusUDI) System

The introduction of a Unique Device Identification (UDI) system within Australia (known as the AusUDI) has the potential to strengthen the medical supply chain and benefit Australia's therapeutic goods industry. To achieve this, we offer the following comments:

- 1) The AusUDI should mirror other international UDI systems. The EU and the US have commenced implementation of their own UDI systems and Australian businesses that sell products within these international jurisdictions are already complying with UDI requirements. A parallel system would reduce the complexity of complying with multiple UDI system requirements and ease the burden on small business.
- 2) The administration of the AusUDI should be included within the current TGA medical device approval process. When devices are approved by the TGA, businesses go through an expensive and lengthy approval process. The process ensures the quality and safety of therapeutic goods within Australia, however it is a significant imposition on small business. Merging the AusUDI application into the current TGA approval process should reduce administrative and cost burdens.
- 3) We recommend the TGA ensure that AusUDI is sufficiently tested and small business is well-prepared for its implementation. This would be achieved by:
 - a. conducting trial phases of the AusUDI on a small number of devices;
 - b. producing easy to understand education guides; and
 - c. ensuring that there are sufficient support services available.

Thank you for the opportunity to comment. If you would like to discuss this matter further, please contact Paul Buckingham on 02 6243 7821 or at Paul.buckingham@asbfeo.gov.au.

Yours sincerely

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Australian Small Business and Family Enterprise Ombudsman

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