



Australian Government



Australian
**Small Business and
Family Enterprise**
Ombudsman

1 December 2020

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

via email: devicereforms@tga.gov.au

Dear Sir/Madam

Proposed enhancements to adverse event reporting for medical devices

The current process has made it hard for a small business to actively engage with the Therapeutic Goods Administration (TGA) to address issues with their medical devices, placing the burden onto the small business sponsor. Further, when a small business sponsor wants to access information about adverse events, the current notification system does not allow for effective analysis.

We recommend the following changes to the proposed enhancements:

- 1) The TGA should align its terminology to the European Union's definitions, or other comparable jurisdiction. This would reduce the administrative burden on small business who operate in multiple jurisdictions.
- 2) The current proposal for a 90 day time frame will not allow small business to finalise an investigation. Instead, when a business cannot conduct an investigation in a 90 day period, the TGA should require an interim report to highlight any new information discovered.
- 3) The TGA should introduce the proposed audit system, however should refrain from replicating the pharmacovigilance program. The audit system should utilise publicly accessible information and the TGA's own data to reduce reporting and create an effective audit.
- 4) The TGA should improve communication between all stakeholders. This can be achieved through regular educational programs, stakeholder feedback sessions and improving the TGA's online platforms (ie. DAEN, SARA and TGA website). The TGA should focus on making information more accessible, easy to understand and readily available to everyone.

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

Yours sincerely

Kate Carnell AO
Australian Small Business and Family Enterprise Ombudsman

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