Reporting Adverse Events to the Therapeutic Goods Administration (TGA)

Report adverse events

The Therapeutic Goods Administration (TGA) regulates health products in Australia. As part of this role, they ask consumers, health professionals and others to report adverse events to them. Adverse events include:

- reactions and side effects caused by medicines or vaccines
- problems and faults related to implants and other medical devices

Whether minor or serious, all adverse events are important to report.

Your report counts

Even the most extensive research may not detect every possible adverse event before a health product goes on the market. Some adverse events are so rare that they may only be detected after thousands of people have used a product for a long time.

Your report can help to spot a problem that may not have been known about before.

The TGA investigate and take action

The TGA carefully investigate reports, and if they find there is a problem, they will take action. Some actions may include:

- notifying the community through safety alerts
- updating product information, labels or instructions
- recalling a product
- cancelling the approval of a product so that it can no longer be used in Australia

Seek support then report

You should always seek healthcare or advice from a health professional, such as a doctor or pharmacist, as your first priority. You don't need permission to report an adverse event, but taking care of your health should be your first step.

If in doubt, report it

Whether it is a vaccine, a medicine prescribed by your doctor or a bandage you bought from the supermarket, if you think a health product caused your adverse event, we want you to report it. Even if you are not sure what caused your adverse event, or if it seems obvious, unimportant or embarrassing, you should still tell the TGA.

Submit your report on the TGA website

You can report your adverse event by visiting www.tga.gov.au/reporting-problems

When you submit your report you will be asked to provide:

- your contact details
- a description of your adverse event (what happened, when it happened, how long it lasted)
- details of the product that may have caused your adverse event (including any other medicines you are taking)

The TGA encourage you to provide as much detail as you can. In some cases, they may contact you for further information.

Your personal information is confidential

After reviewing your report, the TGA will remove your name and other identifying information before publishing your report in the public Database of Adverse Event Notifications.

Visit the TGA website to find out more information about how they handle personal information.

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This document has been reviewed and endorsed by the Consumer Advisory Group for consumers and the community