What to include in a report

Each report must include:

- ✓ your contact details
- ✓ a description of the adverse event
- ✓ details of the therapeutic good suspected of causing the adverse event.

Please include as many other details about the adverse event as possible. Personal information is kept confidential.

TGA staff may contact you for further information if it could assist in assessing the case, or if the report is of an event of special interest to the TGA.

You don't need to be certain, just suspicious!

You don't need to be absolutely certain that the therapeutic good caused the event – a suspicion is enough. All reports can contribute to the TGA's investigation of a potential problem.

How you can report

You can report:

- online
- by post
- via email
- via fax

Visit www.tga.gov.au and follow the link to 'Report a problem'. Information about how the TGA handles personal information under the *Privacy Act 1988* can be found via this link.

We thank you for reporting adverse events. These reports are an essential part of ensuring the safety of medicines, vaccines and devices in Australia.

Therapeutic Goods Administration

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Australian Government
Department of Health
Therapeutic Goods Administration

Reporting side effects and other problems with medicines, vaccines and medical devices

Information for consumers

Your role in reporting a side effect or problem

All medicines and vaccines can cause side effects. All medical devices can potentially develop faults or cause problems.

Side effects and other problems are also called adverse events, which are defined as unwanted and sometimes harmful occurrences from using medicines, vaccines or medical devices (collectively known as therapeutic goods). Importantly, adverse events related to the use of a therapeutic good are not always caused by the therapeutic good itself.

Consumers can provide very useful first-hand information about their experiences with medicines, vaccines and medical devices and how these have affected them.

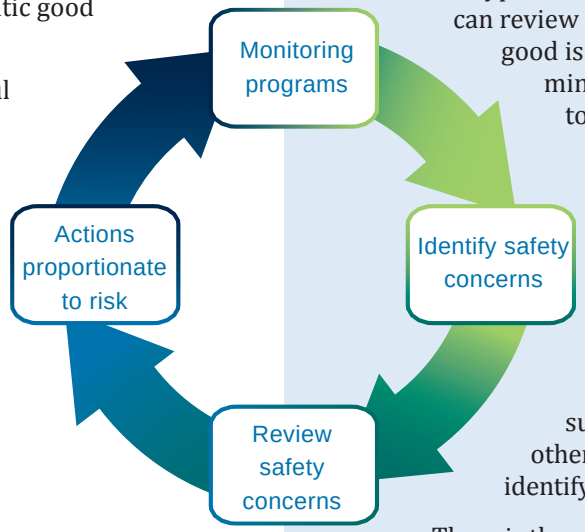
When you submit a report of an adverse event to the Therapeutic Goods Administration (TGA) you contribute to the ongoing collection of information that enables us to ensure the safety, effectiveness and quality of therapeutic goods.

If you have any concerns about an adverse event it is important to also speak to a health professional.

Why we need your reports

Even the most extensive research and testing before a therapeutic good is first marketed cannot identify every possible adverse event. For example, some may be so rare that it takes thousands of people using the therapeutic good for a long period before they can be identified. Many adverse events are minor, but some can be serious and even life-threatening.

It is important for people to report adverse events as these are used to identify problems which might not have been known about before. If a previously unknown type of adverse event is found, the TGA can review the way that the therapeutic good is used and can take action to minimise risk and maximise benefit to the patient.



Analysis of adverse event reports is one way that the TGA monitors the safety of therapeutic goods used in Australia. The TGA also monitors the latest scientific studies, undertakes testing and liaises with therapeutic goods suppliers and regulators from other countries around the world to identify emerging issues.

There is the potential for an adverse event to occur with the use of any therapeutic good, including:

- medicines supplied on prescription
- implanted medical devices
- medical devices or over-the-counter or complementary medicines purchased from a retail outlet, or any other source, for example health facilities or the internet.

What action does the TGA take?

Each adverse event report is analysed by TGA staff to identify potential emerging problems for detailed investigation.

De-identified adverse event reports become available on the publicly accessible Database of Adverse Event Notifications.

If the TGA identifies a safety concern we can take regulatory action. This can include:

- disseminating information for consumers and health professionals regarding the problem
- updating information, labelling or instructions with new adverse effects, precautions or warnings
- requiring postmarketing studies
- imposing limits on how products can be used
- investigating manufacturing sites
- recalling products from the market
- suspending or cancelling products.

What you should report

You can report suspected adverse events to any therapeutic good available in Australia.

The TGA particularly requests reports of:

- suspected adverse events involving new medicines or medical devices
- suspected drug interactions
- unexplained adverse events (i.e. that are not described in the Consumer Medicine Information or device Instructions for Use)
- serious adverse events, such as those requiring medical attention.

Even if you are unsure whether to report, you should report serious adverse events.