What to include in a report

Each report must include:

- ✓ contact details for the reporter
- ✓ identifying features of the device – e.g. device name, manufacturer, supplier, catalogue/batch/ serial numbers
- ✓ a description of the event
- ✓ the outcome, or in the case of a 'near miss', the possible outcome.

Please include as many other details as possible.

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

You can report any suspected adverse event involving a medical device, even if you think it might already be known. You don't need to be absolutely certain that the device caused the incident – 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
- via email
- by post
- 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 suspected adverse events. These reports are an essential part of ensuring the safety of medical devices in Australia.

Therapeutic Goods Administration

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Australian Government
Department of Health
Therapeutic Goods Administration

Reporting medical device adverse events

Information for health professionals

TGA Health Safety Regulation

Your role in reporting an adverse event

As a health professional, you can play an important role in ensuring the ongoing safety of medical devices in Australia by reporting adverse events to the TGA.

Medical devices range from simple items such as tongue depressors to complex products such as MRI machines and implantable pacemakers.

When you submit a report you contribute to the ongoing collection of information to ensure the safety, quality and performance of medical devices.

Why we need your reports

Analysis of adverse event reports is one way that the TGA monitors the safety of therapeutic goods used in Australia.

The TGA's medical device Incident Reporting and Investigation Scheme is focused on collating and analysing medical device adverse events and acting to protect the public if issues are identified.

As health professionals, you are likely to observe adverse events or 'near misses' associated with the use of medical devices. When you submit a report you contribute to the ongoing collection of information about medical devices and allow the TGA to act to protect the public.

What actions does the TGA take?

Each adverse event report the TGA receives is entered into a database, which is regularly analysed by TGA staff to identify potential emerging problems for detailed investigation.

The TGA takes a risk-based approach to investigations.

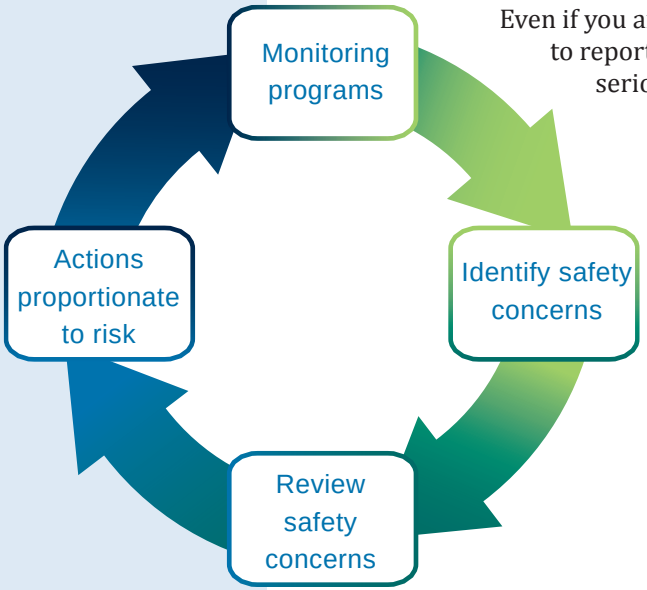
During an investigation:

- scientific, engineering and clinical experts assess the information
- expert advisory committees may be consulted to provide advice on specific technical matters.

If the TGA identifies a safety concern relating to a medical device, we can take regulatory action. This can include:

- disseminating information for consumers, health professionals and industry regarding the problem
- updating the Instructions for Use with new adverse effects, complications, contraindications, precautions or warnings
- increasing postmarket surveillance
- imposing limitations on their use
- requiring product correction
- investigating manufacturing sites
- recalling products from the market
- suspending or cancelling products.

Reports become available on the publicly accessible Database of Adverse Event Notifications.



What you should report

You can report any suspected adverse event or near miss relating to a medical device.

If the adverse event happens in a health facility you can report it to the quality/risk manager who will coordinate reporting to the TGA and the supplier of the device.

Please keep the device, if possible, for analysis.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors.

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