Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reporting adverse events

Everyone can play an important role in monitoring the safety of therapeutic goods in Australia

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If you think you may be experiencing a side effect after using a medicine or vaccine or a problem involving the use of a medical device, seek advice from a health professional as soon as possible.

Overview of adverse events

Adverse events are unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine or medical device (collectively known as therapeutic goods). Adverse events include side effects to medicines and vaccines, and problems or incidents involving medical devices.

Examples of adverse events are any unfavourable and unintended sign, symptom or disease associated with the use of a therapeutic good. An abnormal laboratory finding could be one example of an unfavourable and intended sign.

In the case of medical devices, an adverse event can also be a problem or incident that has caused, or could cause, harm to patients, caregivers, health professionals or others. These can include 'near misses' – events that might have led to a death or serious injury. It may be that timely intervention from a health professional prevented an adverse event.

Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good.

Everyone can play an important role in monitoring the safety of therapeutic goods in Australia by reporting suspected adverse events to the TGA.

Frequently asked questions

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Why report adverse events to the TGA?

When a therapeutic good is first registered and made available in Australia, information about its safety and effectiveness is usually only available from clinical trials.

Clinical trials provide information about many of the possible adverse events associated with a therapeutic good, but do not detect all possible adverse events because they:

- usually do not continue for long enough to detect adverse events that take a long time to develop
- do not include enough patients to detect adverse events that occur rarely
- do not include all of the different types of people who might eventually use the product and who might be more susceptible to some adverse events, such as older people, children, pregnant women or people with other medical conditions.

The TGA, like other regulatory agencies around the world, monitors the safety of therapeutic goods to contribute to a better understanding of their possible adverse events when they are used outside the controlled conditions of clinical trials.

Reports by consumers and health professionals provide important information for the TGA's safety monitoring program.

Who can report an adverse event?

Anyone can.

Information about the number of adverse event reports received each year by the TGA can be found at Adverse events: Australian statistics on medicines and Adverse events: Australian statistics on medical devices.

Most adverse event reports are made by sponsors (e.g. pharmaceutical companies and medical device suppliers), but many are also made by state and territory health departments, hospitals, health professionals and consumers.

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

Reporting medicine or vaccine adverse events

Consumers: report a side effect of a medicine or vaccine using the online form.

Health professionals:

- report an adverse event of a medicine or vaccine
- report via email, fax or mail using the National Adverse Events Following Immunisation (AEFI) reporting form

All medicines and vaccines can cause side effects or other adverse events.

Medicines include:

- prescription medicines
- over-the-counter medicines that are purchased without a prescription
- complementary medicines, such as:
    - herbal medicines
    - naturopathic or homeopathic preparations
    - nutritional supplements, like vitamins and minerals.

For further information on the features and functionality of the online adverse event reporting forms, users should refer to the Adverse Event Management System (AEMS) Guidance for

- Health Professionals, and
- Sponsors.

Reporting medical device adverse events

Medical device consumers: report problems or incidents through the consumer online Medical Device Incident Report form.

Health professionals: report problems or incidents online through the health professional online Medical Device Incident Report form.

Sponsors and manufacturers: report using the TGA's online reporting system.

The TGA's medical device Incident Reporting and Investigation Scheme (IRIS) is responsible for the management of all reports of adverse events or problems associated with medical devices.

Medical devices range from a bandage that you would put on a scratch to high risk products such as pacemakers that are implanted in your body. Other examples of medical devices include:

- artificial hips
- blood pressure monitors
- breast implants
- catheters
- condoms
- lubricating eyedrops
- MRI scanners
- orthodontics, such as braces and fillings
- syringes
- tongue depressors.

Typical problems with medical devices include:

- deficiencies in labelling, instructions or packaging
- defective components
- performance failures
- poor construction or design.

Which events should I report?

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

Every report counts. While an individual report may not be enough to determine whether a particular therapeutic good caused an adverse event. All reports help to build a picture of the safety profile of a product and assist with the TGA's safety monitoring program.

The work of the TGA is based on applying scientific and clinical expertise to decision making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and other therapeutic goods.

The TGA particularly needs to know:

- all suspected adverse events to new therapeutic goods
- all suspected medicine and/or vaccine interactions
- unexpected adverse events (that is, adverse events that do not appear in the Product Information, Consumer Medicine Information and/or product labelling)
- serious adverse events, such as those suspected of causing:
    - death
    - danger to life
    - admission to hospital
    - prolongation of hospitalisation
    - absence from productive activity
    - increased investigational or treatment costs

- birth defects.

What information do I need to report?

Reporters are encouraged to provide as much detail as possible, but at bare minimum are asked to provide:

- contact details for the reporter (name, address, phone number)
- patient identifier (such as initials, date of birth or age, but not their full name)
- details of the product involved
- details of the suspected adverse event.

By providing all information relevant to a specific adverse event, you can help TGA staff to assess the possible role of the product in causing the adverse event.

The TGA asks for contact details from people making reports so that it can seek further information about suspected adverse events - we cannot accept anonymous reports.

Providing as much information as possible will reduce the need for the TGA to follow up. However, it is important not to delay reporting an adverse event if some information is not available. If we need more information, we will contact you.

Any information identifying the reporter or patient is kept confidential. See the 'Privacy information' section below for further information.

What happens to reports

Medicine and vaccine adverse event reports that the TGA receives are entered into the TGA Adverse Event Management System (AEMS). Medical device incident reports are recorded in the Incident Reporting and Investigation Scheme (IRIS) database.

Information recorded in the database includes the adverse event, the therapeutic good involved, and other relevant information, such as relevant medical history, laboratory results and how the adverse event was treated.

Serious reports are usually entered into the AEMS within two working days and a letter of acknowledgement is sent to the reporter. Each report is given a unique ID number. If you need to add more information about the case you can use the ID number to have it added to your existing report.

All adverse events are risk assessed and entered into the appropriate database for future reference. The information is used by TGA staff to help identify safety signals. A safety signal is a 'flag' for a possible safety concern. When the TGA identifies a signal, it undertakes a detailed evaluation to establish the possible role of the therapeutic good in causing the adverse event.

After a report has been entered into the AEMS (14 days) or IRIS database (3 months), information is transferred to the publicly accessible and searchable Database of Adverse Event Notifications. This time lag enables TGA staff to check and analyse the information in the report.

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

What can the TGA do in response to a safety concern

If the TGA identifies a safety concern relating to a therapeutic good, it can take regulatory action to ensure that the product continues to have acceptable safety, efficacy/performance and quality for its intended use. The TGA also seeks to ensure that health professionals and the public are aware of the safety concern and any changes to the availability and recommended use of the product.

Actions the TGA can take in response to a safety concern include:

- informing health professionals and consumers through alerts and articles in publications such as Medicines Safety Update and Medical Devices Safety Update (see the 'Publications' page for

further information)

- requiring changes to product labelling, or adding warnings, precautions and adverse event information to the Product Information and Consumer Medicine Information
- cancelling the registration of the product, or limiting the population in which it can be used
- requiring the sponsor to undertake post-marketing studies to investigate the safety concern if more information is needed before a judgment can be made about the need for further action.

Safety publications

For safety-related publications, see the 'Safety of medicines and medical devices' section of the TGA's publications page.

Reporting adverse events using General Practitioner software

Medical practices using the Best Practice or Medical Director software can download and install templates to their software to create Adverse Drug Reaction (ADR) reports. Completed reports can be emailed, faxed or posted to the TGA.

Note: the RTF documents below should not be opened using Word or they may become corrupted. Please read the 'How to install the ADR template' guidance before opening and downloading the template documents.

Best Practice

How to save a document to your own computer

- Best Practice: How to install the ADR template
- Best Practice: How to use the ADR template
- Best Practice: Adverse Drug Reaction report template (rtf,116kb)

Medical Director

- Medical Director: How to install the ADR template
- Medical Director: How to use the ADR template
- Medical Director: Adverse Drug Reaction Report template (rtf,542kb)

Privacy statement

The TGA collects a variety of personal information in the course of performing its functions.

Information about how the TGA handles personal information under the *Privacy Act 1988* can be found on the Privacy web page.

Supporting documents

Medical Director Adverse Drug Reaction Report template [application/rtf, 541.88 KB]

Best Practice Adverse Drug Reaction report template [application/rtf, 116.02 KB]

Topics: Over the counter (OTC) medicines Safety