



Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices: how to stay included

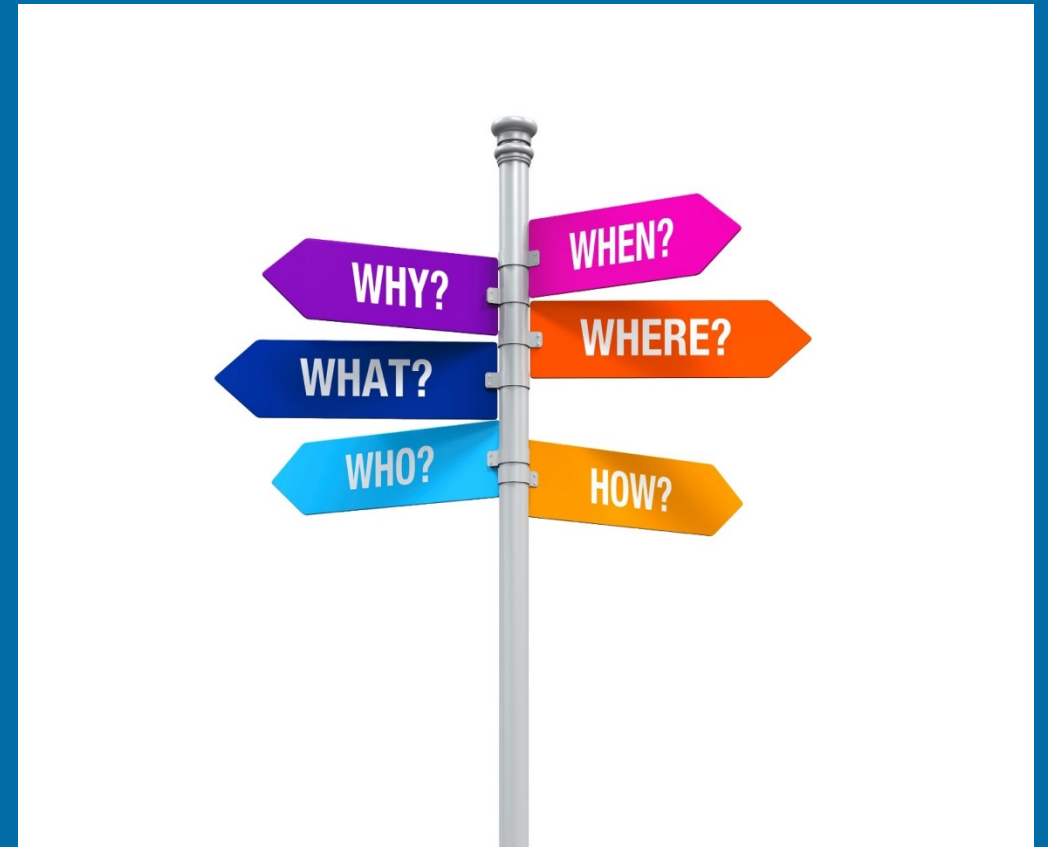
Adverse event reporting and all it entails

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TGA Health Safety
Regulation

Overview

- Why
- When
- What
- How
- Common misconceptions or errors made
- Reporting of adverse events relating to SAS/Clinical trials/Authorised Prescriber



IRIS – (Medical Device) Incident Report Investigation Scheme

“A scheme intended to help maintain the standard of devices used in health care through voluntary cooperation between users, government and industry through the investigation of adverse events and incidents”



Sponsor – mandatory obligations

Why Report

- Sponsors must report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death
 - These are conditions of inclusion set out in the Therapeutic Goods (Medical Devices) Regulations (2002)

When to report

- Within **two days** of becoming aware of an issue of serious public health threat or concern that will require prompt action to reduce the hazard
- Within **ten days** of becoming aware of a death or serious injury
- Within **thirty days** of becoming aware of an event that might have led to serious injury or death

Exemption rules

The Australian Regulatory Guidelines for Medical Devices (ARGMD) documents outlines 8 exemption rules – none of which apply if;

- A device, event or issue specifically identified by the TGA as an issue that requires close monitoring
- An adverse event normally subject to a reporting exemption, where a change in trend (usually an increase in frequency) or pattern is identified
- Adverse events associated with user error, as the TGA may use this data to identify trends with this and similar products that may lead to recommendations for:
 - corrective action for the device
 - revising the labelling or Instructions for Use
 - identifying a need for increased user education.

What is an adverse event/incident?

An event that resulted in, or could have resulted in (had effective intervention not taken place) serious injury, illness or death to patient, healthcare worker or other person.

A medical device adverse event is an event associated (caused or partially attributable) with the use (or misuse) of a medical device.

Faults that may affect the quality, timeliness and cost-effectiveness such as, problems with getting the device to operate, repeated repairs, device design and difficulty of use.

The TGA encourages users to report issues of concern with the devices that they use.



What is a serious injury?

Serious injury (also known as serious deterioration in state of health) is:

- A life threatening illness or injury
- A permanent impairment of a body function (The term “permanent” means irreversible impairment or damage to a body structure or function. The term excludes minor impairment or damage).
- Permanent damage to a body structure
- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

(In this context, medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess whether an event should be reported)



It is often difficult to determine whether an adverse event was caused by a medical device.



When in doubt it is better to report than not to report.

Medical Device Adverse Events

The preferred method of reporting is online

Log into eBS

Select “Medical device adverse event reporting”

A list of all reports submitted by the sponsor can be found here

Start a new report and save it as a draft or submit an initial report

Enter information - you can update the report to follow-up or final

Device Incident Report (DIR) number will be available immediately

Save or print your report

The screenshot shows the 'Sponsors / Manufacturers Medical Device Incident Report' web form. At the top left is the Australian Government logo and 'Department of Health and Ageing Therapeutic Goods Administration'. At the top right is the title 'Sponsors / Manufacturers Medical Device Incident Report' and 'Web Version: 1.3'. Below the title is a note: 'All fields marked with a * are mandatory fields'. The form is divided into several sections: 'Report Details' with fields for Report Type, Date of Report, TGA Report Number, TGA Form ID, Date of Adverse Event, Date Manufacturer Aware, Report Category, and Reporter's Reference Number; 'Reporter Details' with fields for Title, First Name, Surname of Contact, Company / Institution, Position / Occupation, Address Line 1, Address Line 2, Phone, Fax, Email, Country (set to Australia), Town / Suburb, State / Province, and Postcode; 'Healthcare Facility Details' with similar fields to Reporter Details; and 'Device Identification' with fields for Device ARTG Number, GMDN Code, and GMDN Text. A small green icon is visible in the bottom right corner of the form area.

What happens to the report?

Initial risk assessment...

- Reports are entered into the IRIS database
- Urgent reports are addressed immediately by the IRIS coordinator
- Focus is on unusual problems, potentially serious problems, or problems that have high levels of incidences
- After risk assessment the level of investigation is determined
- Many reports are not investigated, however they are utilised for trending and monitoring purposes



What happens to the report?

- The TGA investigator contacts the sponsor (company) and the reporter, and works with them to resolve any issues
- Reports are treated as confidential and the reporter and sponsor are informed of the outcome of the investigation
- Most reports are placed onto the Database of Adverse Event Notifications (DAEN)



Common Issues noted with reports submitted

- Proof Reading – check accuracy, be careful of cut and paste
- Lack of Information or Relevancy – provide all requested information and ensure information is accurate and relevant to the event
- Duplicates – ensure all parties in your company are aware of what has already been sent to the TGA
- If you are unsure about anything to do with a report, please email iris@tga.gov.au before resubmitting or creating a new report



Common Issues noted with reports submitted

- DIR number not provided on follow-up and final reports when submitted by email
- More than one ARTG number being put into the applicable field
- ARTG numbers not being provided for other devices involved
- **Similar event rates**
 - Similar events are based on the clinical event description and not the cause of an event
 - The rate should preferably be provided in the form of an incidence rate, for example: 0.4%, the number should include the number sold for example 12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none, write “0” or “nil”



Common Issues noted with reports submitted

- Brand name of the device absent
- Attachments need to be referenced, however all the relevant information must be put into the report
- Device analysis results not being provided or only selected sections of the results
- Information not in the correct data entry field
- Medicines being reported to the devices section
- Overseas reports being entered into the database

Further information on how to fill in the report can be found in the FAQs on the TGA website



Why do I have to answer a questionnaire if the final report has most of the information in it?

A questionnaire is usually required due to:

- conflicting or inadequate information supplied in the final report
- clarification required regarding the information supplied
- concern the response does not address the issue

The majority of questionnaires sent to the sponsor are as a result of the receipt of a report from a health care professional or consumer which the TGA has decided to investigate. Reports from these sources do not usually contain enough information to satisfy the TGA that the device is safe

SAS/Clinical trials/Authorised prescriber

It is important to distinguish between clinical trials and use of a product in an individual patient as part of clinical practice. Use of unapproved products in individual patients as part of clinical patient care should be done using the provisions of the Special Access or Authorised Prescriber Scheme and not as a clinical trial.



Useful Links:

- <https://www.tga.gov.au/clinical-trials>
- <https://www.tga.gov.au/form/special-access-scheme>
- <https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorized-prescribers>
- <https://www.tga.gov.au/sites/default/files/devices-argmd-01.pdf>

Clinical Trials

A notification under the CTN Scheme (or application under the CTX Scheme) is required for all clinical investigational use of a product in Australia, where that use involves:

- a product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- use of a registered or listed product outside the conditions of its marketing approval



Clinical Trials

A clinical trial should always have a specific aim that addresses a scientific question

Adverse event information can be found in the clinical trial handbook:

<https://www.tga.gov.au/publication/australian-clinical-trial-handbook>

Essentially it states:

Sponsors of clinical trials are required to report to TGA **single cases of serious unanticipated device related adverse events**



SAS (Special Access Scheme)

The SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Patients are grouped into two categories under the scheme:

- Category A patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'
- Category B patients are all other patients that do not fit the Category A definition

SAS (Special Access Scheme)

Adverse event information can be found in the SAS handbook:

- <https://www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme>

this states:

The onus for reporting adverse drug reactions and adverse device events from SAS usage lies **primarily** with the treating doctor. ...**however**...Sponsors should report to the TGA all those serious and unexpected adverse drug reactions or serious unanticipated device related adverse events of which they have been informed

Authorised prescriber

- There are circumstances where patients may require access to medicines or medical devices that have not been approved for supply by the TGA.
- In these circumstances a medical practitioner may be granted authority to become an authorised prescriber of a specified unapproved therapeutic good (or class of unapproved therapeutic goods) to specific patients (or classes of recipients) with a particular medical condition.

Adverse events information can be found at the link below:

- <https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorized-prescribers>

The onus for reporting to TGA of adverse drug reactions and adverse device events occurring in the context of the Authorised Prescriber mechanism lies **primarily** with the treating doctor.....**however**...Sponsors should report to the TGA all those serious and unexpected adverse drug reactions or serious unanticipated device related adverse events of which they have been informed.

References

- Database of Adverse Event Notifications (DAEN) <https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx>
- Australian Regulatory Guidelines for Medical Devices (ARGMD) <https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>
- FAQs <https://www.tga.gov.au/frequently-asked-questions-about-filling-device-incident-report>
- Report a medical device adverse event (sponsor/manufacture) information <https://www.tga.gov.au/form/report-medical-device-adverse-event-sponsormanufacturer>
- Medical device incident reporting (MDIR) user guide 2013 <https://www.tga.gov.au/publication/medical-device-incident-reporting-mdir-user-guide-2013>
- *Therapeutic Goods (Medical Devices) Regulations (2002)*
- <https://www.tga.gov.au/clinical-trials>
- <https://www.tga.gov.au/form/special-access-scheme>
- <https://www.tga.gov.au/access-unapproved-therapeutic-goods-authorized-prescribers>
- <https://www.tga.gov.au/access-unapproved-therapeutic-goods-special-access-scheme>
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