Adverse event reporting

Last updated:
12 November 2021

The primary function of post market event monitoring is to improve the health and safety of patients, health care professional, users, and others by reducing the likelihood of adverse events being repeated. Adverse event reporting allows the TGA to monitor medical device use, monitor their performance in the real world and identify trends that may indicate emerging safety and performance issues. These activities allow the TGA to take appropriate regulatory action to address these issues, thereby reducing the impact on the public.

Reportable adverse events

It is an automatic condition of inclusion under 5.7 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237) that sponsors of a medical device report adverse events or near adverse events to the TGA Incident Reporting and Investigation Scheme (IRIS) (https://www.tga.gov.au/node/289286).

It is important to note that the act of reporting a problem is not an admission of manufacturer, sponsor, user, or patient liability for the event or its consequences.

Only adverse events that occur in Australia are required to be reported to the TGA. Adverse events that occur overseas for devices supplied in Australia do not need to be reported to the TGA but records of these events should be available if requested.

Note

Any remedial action that arises overseas for devices supplied in Australia must be reported to the TGA Recalls team. Contact details for the team and more information about how to report this information, please see the Uniform Recall Procedure for Therapeutic Goods (URPTG) (https://www.tga.gov.au/node/289356).

Adverse event

An adverse event is an occurrence involving a medical device that meets the following criteria:

- death of a patient, health care provider, user or other person; or
- a serious injury or serious deterioration to a patient, health care provider, user or other person, including;
    - a life-threatening illness or injury;
    - permanent impairment of a body function;
    - permanent damage to a body structure; or
    - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Near adverse event

A 'near adverse event' is an occurrence involving a medical device that might have led to a death or serious injury if, for example, the timely intervention of a healthcare practitioner is the only reason a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

- an event associated with the device occurred; and
- if the event occurred again, it might lead to death or serious injury as outlined above.

Exemptions for reporting

There are eight exemption rules (#exemption-rules) that can apply to the requirement to report an adverse event.

However, the exemption rules **do not** apply when:

- a device, event or issue specifically identified by the TGA as an issue that requires close monitoring - sponsors of devices that are affected will be notified by the TGA when this occurs
- 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 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.

If a sponsor/manufacturer believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented.

The exemption rules were included in a public consultation on proposed enhancements to adverse event reporting (https://www.tga.gov.au/node/283552), and may be revised in the future.

Exemption rules from reporting adverse events to the TGA

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Rule No.	Exemption rule	Examples of adverse events exempt f reporting
1	**Deficiency of a new device found by the user prior to its use** Regardless of the existence of provisions in the Instruction for Use provided by the manufacturer, deficiencies of devices that will be always detected by the user and where no serious injury has occurred, do not need to be reported. *Please note: If the device is used the exemption does not apply - the event must be reported.*	• A user performs an inflation test (standard procedure) prior to inse the balloon catheter in the patient required in the instructions for use accompanying the device. Malfunc on inflation is identified. Another balloon is used. Patient is not injur • Sterile single-use device packagin labelled with the caution 'do not u package is opened or damaged'. Opened package seals are discove prior to use, device is not used. • An intravenous administration set protector has fallen off the set dur distribution resulting in a non-ster fluid pathway. The intravenous administration set was not used.
2	**Adverse event caused solely by patient conditions** When the manufacturer has information that the root cause of the adverse event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use.	• An orthopaedic surgeon implants joint and warns against sports-rela use. Patient chooses to go water s and subsequently requires premat revision. • The early revision of an orthopaed implant due to loosening caused b the patient developing osteoporo

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	To justify not reporting, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to a death or serious injury. A person qualified to make a medical judgement would accept the same conclusion.	• A patient died after dialysis treatm The patient had end-stage-renal disease and died of renal failure.
3	**Service life of the medical device** The service life is defined as 'the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified'. The service life must be specified by the device manufacturer and included in the master record (technical file). When the only cause for the adverse event was that the device exceeded its service life and the failure mode is not unusual, the adverse event does not need to be reported. Assessment of whether an event is exempt from reporting under this rule must be based on the information in the master record, on the label or in *Instructions for Use* for the device.	• Loss of sensing after a pacemaker reached its end of life. The elective replacement indicator has shown u due time according to the device specification. Surgical explanation pacemaker is required. • A drill bit was used beyond the en its specified life. It fractured during invasive operation. Operation time prolonged due to the difficulty to retrieve the broken parts.
4	**Protection against a fault functioned correctly** Adverse events that did not lead to serious injury or death, because a design feature protected against a fault becoming a hazardous situation (in accordance with relevant standards or documented design inputs) do not need to be reported. • An infusion pump stops, due to a malfunction, but gives an appropriate alarm (for	• Microprocessor-controlled radiant warmers malfunction and provide audible appropriate alarm, in compliance with relevant standard and there was no injury to the pat • During radiation treatment, the automatic exposure control is eng and the treatment stops. Although patient receives less than an optim dose, the patient is not exposed to excess radiation.

Rule No.	Exemption rule	Examples of adverse events exempt f reporting
	example, in compliance with relevant standards) and there was no injury to the patient.	
5	**Remote likelihood of occurrence of death or serious injury** Adverse events that could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported. If an adverse event resulting in death or serious injury occurs, the adverse event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains remote, previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Please note: A change in the trend (usually an increase in frequency) of these non-serious outcomes must be reported.	The manufacturer of a pacemaker suppl to the market identified a software bug determined that the likelihood of occurr of a serious injury with a particular settir remote. No patients experienced any adverse health effects. The manufacturer of blood donor sets obtains repeated complaints of minor le of blood from these sets. No patient inju from blood loss or infections of staff hav been reported. The chance of infection c blood loss has been re-evaluated by manufacturer and deemed remote.
6	**Expected and foreseeable side effects that are documented in manufacturer's Instructions for Use or labelling** Side effects that are clearly identified in the manufacturer's labelling or are clinically well known as being foreseeable and having a certain functional or numerical predictability when the device was used as intended need not be reported.	A patient receives a second-degree burr during the use of an external defibrillato an emergency. The risk assessment documents that such a burn has been accepted in view of the potential patien benefit and a warning is provided in the *Instructions for Use*. The frequency of bu is occurring within range specified in the device master record. A patient has an undesirable tissue reac that is previously known and documente the device master record.

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	Some of these events are well known in the medical, scientific, or technology fields. Others may have been clearly identified during clinical investigation and labelled by the manufacturer. Documentation, including the risk assessment, for the particular side effect should be available in the device master record prior to the occurrence of adverse events. The manufacturer cannot conclude in the face of events that they are foreseeable unless there is prior supporting information.	A patient who has a mechanical heart va developed endocarditis ten years after implantation and then died. Placement of central line catheter result an anxiety reaction and shortness of bre Both reactions are known and labelled s effects.
7	**Adverse events described in an advisory notice** Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the TGA.	A manufacturer issued an advisory notic and undertook a recall of a coronary ste that migrated due to inadequate inflatic an attached balloon mechanism. Subsec examples of stent migration were summarised in quarterly reports require the recall action and individual adverse events did not have to be reported.
8	**Reporting exemptions granted by the TGA** Upon request by the sponsor, common and well-documented events may be exempted by the TGA from reporting or changed to periodic reporting on a case by case basis.	

What do I need to report?

Ultimately the following information must be provided to the TGA's IRIS system in relation to an adverse event or near adverse event (the event):

- The source of the report including contact details for the reporter.
- Identification of the device (please provide as much information as possible including, but not limited to, model name, trade name, UPI, UDI, batch numbers, serial numbers, software revision number, etc.)
- The ARTG number the device was supplied under (can be active or cancelled).
- The date of the event.
- A detailed description of the event.
- If implantable, date of implant and if applicable, date of explant
- Details of any investigations and corrective actions undertaken by the sponsor and/or manufacturer following notification of the event.
- Information on similar events information and supply data.

The adverse event will be 'coded' by the TGA staff with the relevant adverse event reporting terminologies defined by the International Medical Device Regulators Forum (IMDRF) (http://www.imdrf.org/documents/documents.asp) using the information provided in the adverse event report. Whilst some international regulators require the manufacturer to undertake the coding, in Australia, the TGA currently performs this task when assessing the adverse event report. These codes assist in internationally harmonised trend analysis of adverse event reports.

It is possible that initially the sponsor will not have all of this information available. There are three stages of report submission associated with adverse events and near adverse events:

- Initial report (#initial)
- Follow-up report (#follow-up)
- Final report (#final)

> **Note**
>
> There are legislative time frames associated with the provision of an initial report. These time frames relate to the severity of the event and are outlined below.

Initial report

Sponsors must make an initial report in line with the legislative time frame and provide additional information as it becomes available. The time frames governing the initial reporting of the Event are set out in the Regulations (https://www.legislation.gov.au/Details/F2018C00899/Download).

Type of event	Time frame for initial report
Events that represent a serious threat to public health	Forty-eight (48) hours after you become aware of the event or occurrence
If the event leads to death or a serious deterioration in the state of health, of a patient, a user of the device, or another person	Ten (10) days after you become aware of the event or occurrence
An event, occurrence or recurrence which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person	Thirty (30) days after you become aware of the event or occurrence

Follow-up report

The TGA acknowledges that the manufacturer's investigation of some events will take time. You are expected to provide the TGA with information regarding the status of any internal manufacturing investigation at regular intervals and no less than every thirty (30) calendar days.

Final report

Sponsors must make a final report within one hundred and twenty (120) calendar days of the submission of an initial report. The TGA expects that the manufacturer has had sufficient time to undertake a detailed investigation of the reported adverse event. Your final report should ensure that all requisite information as outlined under “What do I need to report?” has been provided to the TGA. We will push back reports that do not contain the information required to meet these obligations. Sponsors should pay particular attention to the provision of any similar event information, corrective and preventative actions (CAPA), and manufacturer's device analysis.

Note

Similar events: Sponsors must provide information about similar events, for the previous three (3) years, to the adverse event within the "Other Similar Events Manufacturer/Sponsor Aware of" field of their final report. Similar event information allows the TGA to develop a clearer picture of the incidence of the reported event both in Australia and worldwide. The help text within the MDIR reporting form provides clear guidance in relation to the required content and structure for this information. Reports that deviate from this content and structure will be pushed back for correction.

How do I report an adverse event?

Sponsors of medical devices included in the ARTG are strongly encouraged to submit reportable adverse events electronically through the Medical Device Incident Reporting MDIR application (https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx?sid=1376644749) contained within the TGA TBS portal (https://www.tga.gov.au/node/287189). Guidance for use of the MDIR application can be found at Medical device incident reporting (MDIR) guide (https://www.tga.gov.au/node/285126).

Note

Breaching conditions of inclusion including failure to report adverse events or near adverse events within the relevant time frames may lead to suspension or cancellation of the device from the ARTG (section 41G of the Act (https://www.legislation.gov.au/Details/C2019C00066)). In some instances failure to meet these requirements may result constitute a criminal and civil offence (section 41MN of the Act (https://www.legislation.gov.au/Details/C2019C00066)).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	October 2019
V2.0	Added Exemptions for reporting section	Medical Devices Branch	November 2019
V2.1	Amended date of final adverse event report and additional information in line with amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*	Medical Devices Surveillance Branch	October 2021

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)

Alert/Advisory (https://www.tga.gov.au/topics/alertadvisory)