Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consumer questions and answers: DAEN - medical devices

Database of Adverse Event Notifications

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- Click on the plus or minus icon next to the question to toggle the answer on or off or [Open all (#) | Close all (#)].
- If you want to print all questions & answers, you need to Open all before you print.

What is the Database of Adverse Event Notifications (DAEN) - medical devices?

It is an online database that you can use to find information about adverse events (#what-is-an-adverse-event) (also known as incidents) or near adverse events (#what-is-an-adverse-event) (potential adverse events) related to the use of medical devices that have been reported to the TGA since 1 July 2012.

Will the Database help me work out whether a medical device is safe to use?

No, the Database of Adverse Event Notifications (DAEN) - medical devices **cannot** be used to evaluate whether a medical device is safe or not. **It is not a substitute for professional medical advice**.

The TGA cannot give medical advice and strongly encourages seeking the advice of a health professional if you or someone in your care suspect/s they are experiencing an adverse event with a medical device.

If I find the medical device I'm looking for in the Database, does this mean that the medical device is dangerous and I should stop using it?

No. Do not make changes to your use of a medical device based on information in the Database. Always seek the advice of a health professional before making any change to your use of a medical device.

If a medical device is authorised for use by the TGA, it means that the benefits are considered to outweigh its risks, if used as authorised. The benefit-risk balance is determined after a careful assessment of the benefits and risks of the medical device. It is then up to a health professional, patient or consumer to then decide if they wish to use the medical device.

For things to consider when interpreting search results, see About the DAEN - medical devices: limitations of the data and search results (https://www.tga.gov.au/node/289290).

Where does the information in the Database come from?

Information in the Database comes from reports made to the TGA by patients, consumers, health professionals and sponsors (https://www.tga.gov.au/node/287245) of medical devices. The reports in this Database start from 1 July 2012 up to 3 months prior to the date of access. The TGA uses this time to analyse each adverse event report (https://www.tga.gov.au/node/287462).

Why is the amount of historical information in DAEN - medical devices different from DAEN - medicines?

Medical device adverse event reports held by the TGA prior to 1 July 2012 are not structured in a format that meets the minimum requirements for publication in DAEN - medical devices.

What does the TGA do with the information in the Database?

The TGA uses the information in the Database to help evaluate the benefits and risks of medical devices and to monitor their safety once they are made available in the marketplace.

Can someone who has reported an adverse event to the TGA be identified in the Database?

No, the reporter of the adverse event and the people who experience an adverse event reported to the TGA cannot be identified in the Database. All personal information reported to the TGA, and included in the Database, is de-identified in line with the Privacy Act and National Privacy Principles.

Why is the TGA publishing the Database?

The Database was created to support better health outcomes by providing access to information we gather while monitoring medical device safety in Australia. It is part of the work we do to monitor the safety of medical devices for consumers.

As demand for information about medical devices grows, along with our ageing population, publishing information on medical device safety online by a reputable Government agency improves public access to this important information. The TGA is

committed to improving transparency to build trust and confidence in its work.

Medical device adverse event information reported to international regulatory agencies is also available online from the US FDA (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).

How do I use the Database?

Detailed information about how to use the Database can be found at Instructions for searching the DAEN - medical devices (https://www.tga.gov.au/node/289292). Put simply, you can search the Database using a medical device trade name, manufacturer, sponsor (https://www.tga.gov.au/node/287245), GMDN term (https://www.tga.gov.au/node/282893) (device descriptor e.g. 'hip', 'pump') or an ARTG (https://www.tga.gov.au/node/287250) number. Once you have typed in 3 characters a list will appear. Then just click on the medical devices you are interested in, select a date range and press 'Search'.

Where do the technical terms used in the Database come from?

Some of the more technical terms are from the Global Medical Device Nomenclature (GMDN) (https://www.tga.gov.au/node/282893) and the International Organization for Standardization (ISO). GMDN is an internationally used system to identify and classify medical devices. The TGA uses the GMDN system as one of the criteria to distinguish one kind of medical device from another. The TGA uses an ISO standard (ISO/TS 19218 - 2011) (/node/289292#advanced-search) to group different adverse event types.

The TGA uses these terms because they are the international standard in medical device terminology. These terms are used internationally by other medical device regulators. Their use allows the Database to be used to share information on medical devices worldwide, improving medical device safety globally.

For descriptions of other terms used in the Database, see DAEN - medical devices: about the search results (https://www.tga.gov.au/node/289291).

What type of information is available in the search results?

Your search generates two types of report:

1. The medical device summary - this report provides general details of the reported medical device/s involved in each report.
2. The list of reports - this report provides further details of the reported medical device/s and a description of the adverse event for each report (de-identified).

See DAEN - medical devices: about the search results (https://www.tga.gov.au/node/289291) for more information.

When I ran the same search on different days I got a different result. Why is that?

The Database is a 'living' database that is constantly updated and maintained to ensure it reflects the latest adverse event information. The number of adverse event reports can decrease from one month to the next for one or both of the following reasons:

- The TGA receives a follow-up report of an existing individual adverse event report. Sometimes these follow-up reports provide new information on the reported medical device or reported event description; and
- The TGA identifies that more than one report has been submitted about a particular adverse event. When duplicate reports are identified, they are combined into a single report.

The database is then updated with this new or changed information.

How do I print the search results?

The search results can be printed as a pdf report by clicking on the 'Print version of this report' link located at the top right of the search results. You can then print the report or specific pages using the print range option in Adobe Reader.

The search results should not be printed using the browser print option as the information will not display correctly.

About adverse events

What is an adverse event? What is a near adverse event?

An adverse event is defined as an event that led to a death or a serious injury or serious deterioration to a patient, user or other person.

A near adverse event is an event that might have led to a death or injury. It be may be that due to the timely intervention of a healthcare practitioner a death or injury did not occur.

Where can I find further information?

More information about a medical device is generally available in the instructions for use and/or labelling and packaging of a product.

Information on a range of health and wellbeing topics including medical devices is available from Healthdirect Australia (http://www.healthdirect.gov.au/).

The Early Warning System (https://www.tga.gov.au/node/287452) includes current and historical information on safety concerns for medicines and medical devices.

The System for Australian Recall Actions (https://www.tga.gov.au/node/287445) (SARA) provides information about recall actions occurring in Australia for medicines and medical devices.

Why are adverse events monitored?

The TGA, like other regulatory agencies around the world, monitors the safety of medical devices to contribute to a better understanding of their possible adverse effects when they are used in the market place and outside of any pre-market assessment.

Adverse events reported by the public and health professionals provide important information for the TGA's medical device safety monitoring program.

What should I do if I or someone I know experiences an adverse event?

If you suspect that you are experiencing an adverse event you should consult a healthcare professional. You or the health professional can then report the event to the TGA (/node/287456#adr). Detailed information on what to report (https://www.tga.gov.au/node/289286) is available on the TGA website.

What adverse events should I report?

You should report any adverse event or near adverse event that involved or could have involved harm to patient or a user of a medical device, even if you think it might already be known about. You don't need to be absolutely certain that the medical device is the cause of the adverse event- a suspicion is enough. All reports contribute to the TGA's investigation of medical device safety.

The TGA may contact you for further information regarding the medical device adverse event report.

Topics:

Safety (https://www.tga.gov.au/safety/safety)