Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

About the DAEN - medical devices

Database of Adverse Event Notifications

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Limitations of the data and search results

The Database of Adverse Event Notifications - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since July 2012.

The Database of Adverse Event Notifications - medical devices does not contain all known information concerning a medical device, and an assessment of the safety of a medical device cannot be made based on this information. The TGA uses the adverse event reports to identify when a safety issue may be present.

Information on the original data and interpreting the search results

Causality

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter.
- Adverse events are suspected of being associated with the use of a medical device, but this relationship is usually not certain - the adverse event may be related to an underlying illness, a person's anatomical structure or to other factors.
- There might be no relationship between the adverse event and the medical device - it may be a coincidence that the adverse event occurred when the medical device was used.

Adverse event information

- The search results provide limited information about the severity of the adverse events.
- The search results cannot be used to determine the incidence of an adverse event (that is, how often the adverse event has occurred in users of a particular medical device), or the likelihood of a user experiencing that adverse event, as they do not include information on:
    - the total number of users of a medical device
    - the total number of adverse events occurring
    - the number of medical devices supplied in Australia or overseas
    - adverse events received prior to 1 July 2012.

- The search results cannot be used to make accurate numerical comparisons between adverse events associated with different medical devices.

Medical devices information

- The report provided to the TGA may not contain information on all the medical devices used in the reported event.
- The Database will only include other reported medical devices involved in the search results where at a minimum a manufacturer and trade name are known. For other reported medical devices involved to be searchable they must contain at a minimum a manufacturer, trade name and GMDN term.
- The search results provide limited information about the duration of use of the medical device or the maintenance of the medical device.

About the data

- The Database does not include information about the benefits of the medical device, so the search results cannot be used to determine if the benefits of using the medical device outweigh the risks.
- The Database does not include information about medical devices or therapeutic devices that have not or were not included on the ARTG (at the time the product was supplied); except where the adverse event report also includes a suspected device that was or is entered on the ARTG.
- The Database may include ARTG numbers that have been cancelled as the ARTG number/s included in a report are based on when the product was supplied. Note: Only current ARTG

numbers are available in the public version of the ARTG.

- The information in the Database does not include all known adverse events. Additional information about known adverse events is usually included in the manufacturer's instructions for use or on the product labelling.
- 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
- The search results do not include information from the last three months. This is to allow the TGA time to review the new reports submitted and assess the information.
- The information in the Database is based on the information provided by the reporter.
- The data does not include any personal information within the meaning of the *Privacy Act 1988*.
- The Database may include listed and registered therapeutic devices. These devices will not have a device classification and the displayed GMDN text may be from the previous Universal Medical Device Nomenclature System (UMDNS).
- Where follow-up reports are received for existing adverse event reports, the report details may be updated. This means that the search results can change over time.
- Despite regular checking, it is possible that the database contains some duplicate reports, as a single adverse event can be reported by multiple sources, and this may not be easily identified.

Reporting levels

- The number of reports received is influenced by various factors including:
    - the market share of the medical device
    - the length of time the medical device has been on the market

    - publicity about a possible link between an adverse event and a medical device
    - regulatory actions
    - the user reporting events to sponsors and/or the TGA.
- Adverse event reports from consumers and health professionals to the TGA are voluntary; therefore not all adverse events may be reported by these groups. This is the same around the world.
- It is mandatory under the *Therapeutic Goods Act 1989* for sponsors and manufacturers to report serious or potentially serious adverse events associated with their medical device to the TGA. As a result, the search results in the DAEN - medical devices may reflect a higher ratio of serious to non-serious adverse event reports.

Topics: Safety