Australian Government
Department of Health
Therapeutic Goods Administration

About the DAEN - medicines

Database of Adverse Event Notifications

30 January 2019

Limitations of the data and search results

The Database of Adverse Event Notifications - medicines contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia.

The Database of Adverse Event Notifications - medicines does not contain all known information concerning a medicine, and an assessment of the safety of a medicine cannot be made based on this information. The TGA uses the adverse event reports to identify when a safety issue may be present (signal detection (//www.tga.gov.au/tga-safety-monitoring-medicines)).

The TGA strongly advises people taking prescription medicines **not** to change their medication regime without prior consultation with a health professional.

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 related to a medicine, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.

Adverse event information

- The search results do not provide 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 patients taking a particular medicine), or the likelihood of a patient experiencing that reaction, as they do **not** include information on:
    - the total number of patients taking the medication
    - the number of medicines supplied in Australia or overseas
    - the total number of adverse events occurring.
- A case report often describes more than one sign or symptom observed in a patient, and so the case description often includes multiple MedDRA (//www.tga.gov.au/medical-dictionary-regulatory-activities-meddra) reaction terms describing the adverse events. This means that in the medicine summary (//www.tga.gov.au/about-search-results-daen-medicines) the total number of reported adverse events is usually greater than the number of case reports.
- The search results cannot be used to make accurate numerical comparisons between adverse events associated with different medicines.

Medicines information

- The report provided to the TGA may not contain information on all medicines taken by a patient or sufficient information to identify the specific medicine/s taken by a patient.
- The reporter may provide the TGA with either the trade name or the active ingredient. If only the active ingredient name is provided, the database will not include the trade name of the product.
- The report provided to the TGA may also contain information on non-medicinal products taken by a patient.

- If a medicine has multiple active ingredients, it may not be possible to determine which, if any, of the ingredients were associated with a particular adverse event.
- The search results do not provide information about dosage strength or duration of use of the medicine.
- In some instances the adverse event reported may have been caused by the other ingredients (excipient ingredients) in the medicine.
- For prescription medicines assessed by the TGA since the end of 2009, information about the benefit-risk profiles is often available in the Australian Public Assessment Reports (AusPARs) (//www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars).

About the data

- The Database does not include information about the benefits of the medicine, so the search results cannot be used to determine if the benefits of taking the medicine outweigh the risks.
- The Database does not include information about medicines accessed via the Special Access Scheme, Authorised Prescriber scheme, clinical trial notification scheme or clinical trial exemption scheme; except where the adverse event report also includes a suspected general marketed medicine.
- The Database does contain reports involving medicines or products advertised as a medicine that are not on the Australian Register of Therapeutic Goods (ARTG).
- The information in the Database (//www.tga.gov.au/overview-how-tga-manages-medicine-adverse-event-reports) does not include all known side effects. Additional information about side effects is in the Consumer Medicines Information (//www.tga.gov.au/consumer-medicines-information-cmi) and the Product Information (//www.tga.gov.au/product-information-0) available on the TGA website.
- The search results do not include information from the last ninety days. This is to allow TGA time to review the new reports submitted and code (//www.tga.gov.au/overview-how-tga-manages-medicine-adverse-event-reports) the information.
- As part of the data entry (//www.tga.gov.au/node/4600%5D) process, the possible link between the medicine and the adverse event is classed as being 'suspected', 'not suspected' or 'interaction'. If there is no suspected link between any medicine and the adverse event, that report remains in TGA's internal database but will not be included in the DAEN.
- The information in the database is based on the information provided by the reporter.

- The report entry date does not necessarily reflect the date of the adverse event.
- The data does not include any personal information within the meaning of the *Privacy Act 1988*.
- Each adverse event report is coded (//www.tga.gov.au/overview-how-tga-manages-medicine-adverse-event-reports) before being entered into the database, and this process is subject to the limitations of the coding terminology being used.
- When follow-up reports of a single case are received, the case 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 case can be reported by multiple sources, and this is not always easy to identify.

Reporting levels

- The number of reports received is influenced by various factors including:
    - the market share of the medicine
    - the length of time the medicine has been on the market
    - publicity about a possible link between an adverse event and a medicine
    - regulatory actions.
- Adverse event reports (//www.tga.gov.au/reporting-problems) from consumers and health professionals to the TGA are voluntary, so there is under-reporting by these groups of adverse events related to therapeutic goods in Australia. This is the same around the world.
- It is mandatory under the *Therapeutic Goods Act 1989* for sponsors (//www.tga.gov.au/role-sponsor) to report to the TGA all serious adverse events suspected of being related to their medicines. As a result, the search results in the DAEN may reflect a higher ratio of serious to non-serious adverse event reports.

Category: Medicines safety
Tags: reporting problems
URL: https://www.tga.gov.au/node/4588 (https://www.tga.gov.au/node/4588)