



Therapeutic Goods (Information Specification— Database of Adverse Event Notifications) Instrument 2023

I, Anthony Lawler, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 25 September 2023

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	30 September 2023.	30 September 2023

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 61(5D) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) biological;
- (b) manufacturer;
- (c) medical device;
- (d) medicine;
- (e) Register;
- (f) Secretary;
- (g) sponsor;
- (h) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

adverse event means the following:

- (a) in relation to a medicine or biological—an adverse event that occurs in relation to a person in Australia following the administration of a medicine or a biological;

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- (b) in relation to a medical device or other therapeutic good—an adverse event that occurs in relation to a person in Australia following use of a medical device or other therapeutic good that led, or might have led, to the death of, a serious injury to, or serious deterioration in the health of, that person.

Note: An adverse event may not necessarily have a causal relationship with the administration or use of the therapeutic good.

DAEN – Medical Devices means the Database of Adverse Event Notifications for medical devices and other therapeutic goods, maintained by the Therapeutic Goods Administration.

DAEN – Medicines means the Database of Adverse Event Notifications for medicines and biologicals, maintained by the Therapeutic Goods Administration.

defect, in relation to a medical device or other therapeutic good, means any of the following that might lead, or might have led, to the death of, a serious injury to, or serious deterioration in the health of, a person:

- (a) any malfunction or deterioration in the characteristics or performance of the medical device or other therapeutic good;
- (b) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the medical device or other therapeutic good.

event outcome, in relation to a medical device or other therapeutic good, means one of the following outcomes reported to the TGA in relation to an adverse event:

- (a) death;
- (b) injury;
- (c) no injury;
- (d) unknown.

event type, in relation to a medical device or other therapeutic good, means the event type described in the IMDRF Terminology Document that is applicable to the adverse event.

IMDRF Terminology Document means the *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*, published by the International Medical Device Regulators Forum, as in force or existing from time to time.

MedDRA means the *Medical Dictionary for Regulatory Activities* published by the MedDRA Maintenance and Support Services Organization, as in force or existing from time to time.

other therapeutic good means a therapeutic good that is not a medicine, biological or medical device.

report source category, in relation to a medical device or other therapeutic good, means one of the following categories describing the person who reported the adverse event:

- (a) consumer;
- (b) health professional;

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- (c) industry;
 - (d) government;
 - (e) other.

Therapeutic Goods Administration, or ***TGA***, means the part of the Department known as the Therapeutic Goods Administration.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

The kinds of therapeutic goods information set out in the tables in Parts 1 and 2 of Schedule 1 are specified for the purpose of subsection 61(5C) of the Act.

Note: Kinds of therapeutic goods information specified under subsection 61(5D) of the Act may be released by the Secretary to the public under subsection 61(5C).

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Therapeutic goods information

Note: See section 5.

Part 1—DAEN – Medical Devices

Column 1	Column 2
Item	Kinds of therapeutic goods information
1	information about an adverse event or defect in relation to a medical device or other therapeutic good, that has been reported to the TGA and is recorded in the DAEN – Medical Devices (<i>medical device adverse event report</i>), as follows: <ul style="list-style-type: none">(a) details of the medical device or other therapeutic good;(b) details of the manufacturer of the medical device or other therapeutic good;(c) details of the sponsor of the medical device or other therapeutic good;(d) details of any other therapeutic good reported to have been involved in the adverse event;(e) the description of the adverse event;(f) the event outcome;(g) the event type;(h) the report source category;(i) the date that the medical device adverse event report was received by the TGA;(j) the unique number allocated to the medical device adverse event report by the TGA

Part 2—DAEN – Medicines

Column 1	Column 2
Item	Kinds of therapeutic goods information
1	information about an adverse event in relation to a medicine or biological that has been reported to the TGA and is recorded in the DAEN – Medicines (<i>medicine adverse event report</i>), as follows: <ul style="list-style-type: none">(a) details of the medicine or biological;(b) details of any other therapeutic good administered to the person who is reported to have suffered the adverse event (the <i>relevant person</i>);(c) the age of the relevant person;(d) the gender of the relevant person;(e) the adverse event description term, as described in the MedDRA, that relates to the adverse event;(f) the date that the adverse event was recorded by the TGA;(g) the unique number allocated to the adverse event report by the TGA
2	information collated by the TGA from reports of adverse events received by the TGA in relation to a medicine or biological and recorded in the DAEN – Medicines (<i>relevant cases</i>), as follows:

Column 1	Column 2
Item	Kinds of therapeutic goods information
	(a) the number of relevant cases;
	(b) the number of relevant cases where death was a reported outcome;
	(c) the number of relevant cases in which the medicine or biological was reported to be the only therapeutic good suspected of being related to the adverse event;
	(d) the system organ class terminology, as described in the MedDRA, for the part of the body that was reported as being affected by each adverse event;
	(e) the adverse event description term, as described in the MedDRA, that relates to each adverse event

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022

1 The whole of the instrument

Repeal the instrument.

Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013

2 The whole of the instrument

Repeal the instrument.

Therapeutic Goods Information (Joint Recalls Portal) Specification 2013

3 The whole of the instrument

Repeal the instrument.