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

I, Nick Henderson, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 23 September 2022

Nick Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Database of Adverse Event Notifications) (Information) Specification 2022*.

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 2022.	30 September 2022

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 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) medicine;
(c) Register;
(d) Secretary;
(e) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

adverse event means an adverse event that occurs in relation to a person in Australia following the administration of a medicine or a biological.

Note: An adverse event may not necessarily have a causal relationship with the administration of the medicine or biological.

DAEN means the Database of Adverse Event Notifications maintained by the Therapeutic Goods Administration.

MedDRA means the *Medical Dictionary for Regulatory Activities* published by the MedDRA Maintenance and Support Services Organization.

Therapeutic Goods Administration, or ***TGA***, means that 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 table in 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.

Column 1	Column 2
Item	**Kinds of therapeutic goods information**
1	information relating to an adverse event that has been reported to the TGA (***adverse event report***), as follows: (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 ***relevant person***); (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 relating to a medicine or biological that is collated by the TGA from adverse events that have been reported to the TGA in relation to the medicine or biological and recorded in the DAEN (***relevant cases***), as follows: (a) the number of relevant cases; (b) the number of relevant cases that have resulted in death; (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 Information (Database of Adverse Event Notifications) Specification 2012

1 The whole of the instrument

Repeal the instrument.