Therapeutic Goods (Database of Adverse Event Notifications) (Arrangement for Computer Programs) Instrument 2023

I, Anthony Lawler, as delegate of the Secretary of the Department of 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

Contents

1 Name

This instrument is the *Therapeutic Goods (Database of Adverse Event Notifications) (Arrangement for Computer Programs) 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 7C(1) 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) medical device;
(c) medicine;
(d) Secretary;
(e) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

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.

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

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 Arrangement for computer programs

The use of the computer program mentioned in column 2, of each item in the table in Schedule 1, is arranged for the purposes mentioned in column 3.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Arrangement for computer programs

Note: See section 5.

Arrangement for use of computer programs to make decisions		
Column 1	**Column 2**	**Column 3**
Item	**Computer program**	**Purposes**
1	DAEN – Medical Devices	any purposes in relation to the making of decisions, under subsection 61(5C) of the Act, to release to the public therapeutic goods information of the kind specified in an instrument made under subsection 61(5D) relating to the DAEN – Medical Devices
2	DAEN – Medicines	any purposes in relation to the making of decisions, under subsection 61(5C) of the Act, to release to the public therapeutic goods information of the kind specified in an instrument made under subsection 61(5D) relating to the DAEN – Medicines

Note 1: At commencement, the instrument made under subsection 61(5D) relating to the DAEN – Medical Devices and DAEN – Medicines is the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023*, which is a legislative instrument made under subsection 61(5D) of the Act and may be accessed at www.legislation.gov.au.

Note 2: Under subsection 61(5C) of the Act, the Secretary may release to the public therapeutic goods information of a kind specified under subsection 61(5D).

Schedule 2—Repeals

Note: See section 6.

Repeal of instruments			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Name of instrument**	**Delegate**	**Date of making**
1	Arrangement made under subsection 7C(1) of the Act in relation to decisions under section 61(5C) relating to the DAEN – Medicines	Dr John Skerritt	25 June 2012
2	Arrangement made under subsection 7C(1) of the Act in relation to decisions under section 61(5C) relating to the Joint Recalls Portal	Dr Larry Kelly	11 April 2013
3	Arrangement made under subsection 7C(1) of the Act in relation to decisions under section 61(5C) relating to the DAEN – Medical Devices	Dr Larry Kelly	13 June 2013
4	Arrangement made under subsection 7C(1) of the Act in relation to decisions under section 61(5C) relating to the Joint Adverse Event Notifications System – Medical Devices	Dr Larry Kelly	13 June 2013