

Therapeutic Goods (Database of Recalls, Product Alerts and Product Corrections) (Arrangement for Computer Programs) Instrument 2025

I, Tracey Duffy, as delegate of the Secretary of the Department of Health and Aged Care, make the following instrument.

Dated 28 February 2025

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health and Aged Care

1 Name

This instrument is the *Therapeutic Goods (Database of Recalls, Product Alerts and Product Corrections) (Arrangement for Computer Programs) Instrument 2025.*

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. Sections 1 to 6 and anything in this instrument not elsewhere covered by this table	The day after this instrument is made.		
2. Schedule 1	The day after this instrument is made.		
3. Schedule 2	5 April 2025.	5 April 2025	

Note: This table relates only to the provisions of this instrument as originally made.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) Secretary;
- (b) therapeutic goods.

In this instrument:

Act means the Therapeutic Goods Act 1989.

DRAC means the database known as the Database of Recalls, Product Alerts and Product Corrections, maintained by the TGA.

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

For each item of the table in Schedule 1, the use of the computer program mentioned in column 2 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Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.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	Comput progran	•	
1	DRAC	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 DRAC	
	Note 1:	At commencement, the instrument made under subsection 61(5D) of the Act relating to the DRAC is the <i>Therapeutic Goods (Information Specification—Database of Recalls, Product Alerts and Product Corrections) Instrument 2025</i> , which is a legislative instrument 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.

Therapeutic Goods (System for Australian Recall Actions)
(Arrangement for Computer Programs) Instrument 2023

1 The whole of the instrument

Repeal the instrument.