

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

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

Dated 22 March 2023

Adjunct Professor John Skerritt Deputy Secretary Health Products Regulation Group Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods* (System for Australian Recall Actions) (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	31 March 2023.	31 March 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Note: This table relates only to the provisions of this instrument as originally made.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:

- e: 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.

SARA means the database known as the System for Australian Recall Actions, maintained by the Therapeutic Goods Administration.

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Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.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		2 Column 3			
Item	Comput progran	-			
1	SARA	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 SARA			
	Note 1:	t commencement, the instrument made under subsection 61(5D) relating to the ystem for Australian Recall Actions is the <i>Therapeutic Goods (System for Australian ecall Actions) (Information) Specification 2023</i> , which is a legislative instrument ade under subsection 61(5D) of the Act and may be accessed at ww.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	<i>Therapeutic Goods Act 1989:</i> Subsection 7C(1)	Dr Larry Kelly	14 March 2013			