



# **Therapeutic Goods (System for Australian Recall Actions) (Information) Specification 2023**

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

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) (Information) Specification 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Note: This table relates only to the provisions of this instrument as originally made.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 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) device number;
- (b) health practitioner;
- (c) listing number;
- (d) Register;
- (e) registration number;
- (f) Secretary;
- (g) therapeutic goods.

In this instrument:

**Act** means the *Therapeutic Goods Act 1989*.

**active ingredient** has the same meaning as in the Regulations.

**class of recall action** means the classification of the recall determined by the TGA, based on the seriousness of the problem with the therapeutic goods being recalled and the degree of the safety risk.

Note: The TGA classifies recall actions as one of the following:

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- (a) Class I – Most serious safety-related;
  - (b) Class II – Urgent safety-related;
  - (c) Class III – Lowest risk.

**level of recall action** means the level of recall determined by the TGA, which reflects the extent of supply of the therapeutic goods that are the subject of recall action and the persons or bodies notified, or required to be notified, of the recall action.

Note: The TGA determines the level of recall action as one of the following:

- (a) Wholesale level;
- (b) Hospital level;
- (c) Retail level;
- (d) Consumer level.

**recall action** means one or more of the following four actions taken by the responsible entity to resolve a problem with therapeutic goods supplied in Australia that have, or potentially have, deficiencies relating to safety, quality, efficacy or performance, or the presentation of the goods:

- (a) Recall— permanently removing the goods from the market;
- (b) Product Defect Correction—taking corrective action in relation to the goods, such as repairing, modifying, adjusting or relabelling the goods, which may take place at the user's premises, the responsible entity's premises or any other agreed location;
- (c) Product Defect Alert—raising awareness about the problem with the goods and describing the actions that health practitioners or patients may take to mitigate risks due to that problem;
- (d) Hazard Alert—where the goods have been implanted into patients, providing precautionary information to health practitioners and their patients about the identified deficiencies and how to manage affected patients.

**recall commencement date** means the date the recall action to be undertaken by the responsible entity was agreed to by the TGA.

**recall instructions** means instructions or advice given by the responsible entity to all persons impacted, or likely to be impacted, by the recall action.

**Regulations** means the *Therapeutic Goods Regulations 1990*.

**responsible entity** means:

- (a) where therapeutic goods are included in the Register—the person in relation to whom the goods are included in the Register; or
- (b) where therapeutic goods are not included in the Register—the supplier of the goods in Australia.

**TGA recall reference** means the unique identification number that the TGA assigns to a recall action.

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

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

*trade name* has the same meaning as in the Regulations.

## **5 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.

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# Schedule 1—Specified kinds of therapeutic goods information

Note: See section 5.

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Column 1	Column 2
Item	Kinds of therapeutic goods information
1	<p>information about recall actions in relation to therapeutic goods, that is held by the TGA in its System for Australian Recall Actions database, as follows:</p> <ul style="list-style-type: none"><li>(a) the recall commencement date;</li><li>(b) a product description of the goods, including all trade names, the active ingredients (where relevant) and other information to identify the goods;</li><li>(c) the type of goods, such as medicine, biological or medical device;</li><li>(d) the recall action taken or being taken, such as a Recall, Product Defect Correction, Product Defect Alert or Hazard Alert;</li><li>(e) the class of recall action;</li><li>(f) the level of recall action;</li><li>(g) the registration number, listing number or device number of the goods;</li><li>(h) the TGA recall reference;</li><li>(i) the responsible entity;</li><li>(j) recall instructions;</li><li>(k) contact information of the responsible entity</li></ul>

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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods Information (System for Australian Recall Actions) Specification 2013***

#### **1 The whole of the instrument**

Repeal the instrument.