



# Therapeutic Goods Information (Stakeholder Consultation on the System for Australian Recall Actions) Specification 2013

*Therapeutic Goods Act 1989*

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I, JOHN SKERRITT, a delegate of the Minister for Health, make this Specification under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

Dated 24 January 2013

(signed by)

**JOHN SKERRITT**  
Delegate of the Minister for Health

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## 1 Name of Specification

This Specification is the *Therapeutic Goods Information (Stakeholder Consultation on the System for Australian Recall Actions) Specification 2013*

## 2 Commencement

This Specification commences on the day after it is registered.

## 3 Definitions

In this Specification:

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

*Recall action* means action taken by the Responsible Entity in order to resolve a problem with therapeutic goods supplied in Australia that have, or may potentially have, deficiencies relating to safety, quality, efficacy or presentation. Recall actions may include: the permanent removal of therapeutic goods from supply in the market; the taking of corrective action in relation to therapeutic goods, such as repair, modification, adjustment or relabelling which may take place at the user's or the Responsible Entity's premises or any other agreed location; and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage such patients.

*Register* means the Australian Register of Therapeutic Goods.

*Responsible Entity* means, in the case of therapeutic goods on the Register, the person in relation to whom the goods are included in the Register or, in the case of therapeutic goods not on the Register, the supplier of those therapeutic goods or any another person who undertakes the recall action.

*TGA* means the Therapeutic Goods Administration, being a division of the Department of Health and Ageing.

## 4 Therapeutic goods information, persons and purposes

The kinds of therapeutic goods information, persons, bodies and purposes, mentioned in Schedule 1 are specified under subsection 61(5AB) of the Act for the purposes of subsection 61(5AA) of the Act.

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## **Schedule 1      Specified kinds of therapeutic goods information, persons, bodies and purposes**

(section 4)

The following kinds of therapeutic goods information, persons, bodies and purposes:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary under subsection 61(5AA) of the Act to the following specified persons and bodies for the following specified purposes.

- (a) the following kinds of therapeutic goods information in relation to recall actions, being information kept by the TGA in its prototype System for Australian Recall Actions (SARA) database:
- (i) the recall commencement date, being the date on which the recall action commences;
  - (ii) a product description of the therapeutic goods being recalled including the brand name(s) of the goods, any active ingredients in the goods (where relevant) and any other information that is necessary to identify the goods;
  - (iii) the product type, e.g., whether it is a medicine or a medical device;
  - (iv) the recall action taken, i.e., whether the therapeutic goods have been or are being permanently removed from the market, whether other corrective action has been, or is being, taken or if a hazard alert has been issued;
  - (v) the class of recall, being Class I, Class II or Class III, with Class I representing the greatest risk and Class III the lowest risk, to safety;
  - (vi) the level of recall action being taken, i.e., whether it is a recall of therapeutic goods from hospitals, wholesalers, retailers and/or consumers;
  - (vii) the ARTG number of the recalled goods (where applicable), being the identifier number for the therapeutic goods that are registered, listed or included in the Register;
  - (viii) the TGA recall reference, being the unique identifier number the TGA gives to the recall action;
  - (ix) the Responsible Entity;
  - (x) recall instructions, being instructions given by the TGA or the sponsor to health practitioners and consumers of the therapeutic goods being recalled; and
  - (xi) contact information, being information about the person that the customer or consumer should contact for additional information about the therapeutic goods the subject of the recall action.

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- (b) the following persons and bodies:
- (i) ACCORD Australasia Ltd;
  - (ii) AusBiotech Ltd;
  - (iii) Australian Dental Association Inc;
  - (iv) Australian Dental Industry Association;
  - (v) the Australian Medical Association;
  - (vi) the Australian Self-Medication Industry Incorporated;
  - (vii) the Complementary Healthcare Council of Australia;
  - (viii) Consumers Health Forum
  - (ix) Generic Medicines Industry Association of Australia;
  - (x) IVD Australia;
  - (xi) Medicines Australia;
  - (xii) Medical Technology Association of Australia;
  - (xiii) National Prescribing Service;
  - (xiv) Pharmacy Guild of Australia;
  - (xv) Royal Australian College of General Practitioners;
  - (xvi) Royal Australasian College of Physicians;
  - (xvii) Royal Australasian College of Surgeons; and
  - (xviii) Members, agents or employees of the bodies mentioned in (i) – (xviii) above;
- (c) for the purposes of obtaining feedback from the persons and bodies mentioned in paragraph (b) about the functionality, suitability (in terms of informing the public about recall actions) and presentation of the TGA's prototype SARA database or as part of the development and improvement of that database.
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## Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>