Therapeutic Goods Information (Early Warning System) Specification 2013

Therapeutic Goods Act 1989

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

Dated 30th May 2013

(Signed by)

JOHN SKERRITT
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Early Warning System) 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*.

ARTG means the Australian Register of Therapeutic Goods.

Potential safety concern, in relation to therapeutic goods or a type of therapeutic goods, means any potential safety problem linked to the therapeutic goods or the type of therapeutic goods. Safety concerns include known safety problems, changes to known problems, new problems and coincidental events. At the time the potential safety concern is initially detected, the TGA may not know if the concern is caused by the therapeutic goods.

Safety information, in relation to therapeutic goods or a type of therapeutic goods, means information about, or relevant to, the safe use of the therapeutic goods or the type of therapeutic goods.

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

4 Therapeutic goods information

The kinds of therapeutic goods information mentioned in Schedule 1 are specified under subsection 61(5D) of the Act for the purposes of subsection 61(5C) of the Act.

Schedule 1 Specified kinds of therapeutic goods information

(section 4)

The following kinds of therapeutic goods information:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

Kinds of therapeutic goods information relating to a potential safety concern about therapeutic goods or a type of therapeutic goods, being kinds of information released by the TGA in the form of a communication described as a monitoring communication or an alert communication:

Item	Information	Description
(a)	Title of communication	Either: a) the name of the therapeutic goods involved (trade name and/or active ingredient) and a reference to the potential safety concern in relation to the therapeutic goods or type of therapeutic goods; or. b) a description of the type of therapeutic goods involved and a reference to the potential safety concern in relation to therapeutic goods of that type.
(b)	Concern	Information briefly describing the potential safety concern about the therapeutic goods or type of therapeutic goods.
(c)	Product details	Information identifying therapeutic goods involved, including the ARTG number (if relevant) and the sponsor and manufacturer of the therapeutic goods.
(d)	Indications or intended purpose	Either: a) where the potential safety concern is about therapeutic goods, the indications for the therapeutic goods in the relevant ARTG entry or entries (for a medicine) or the intended purpose of the therapeutic goods in the relevant ARTG entry or entries (for a medical device or a therapeutic device); or b) where the potential safety concern is about a type of therapeutic goods, a description of the kinds of indications for which therapeutic goods of the relevant type have been approved as included in relevant ARTG entries (for a type of medicine) or kinds of intended purpose for which therapeutic goods of the relevant type have been approved as included in relevant ARTG entries (for a type of

		medical device or a type of therapeutic device);
(e)	Monitoring and investigation information	Information in relation to therapeutic goods or a type of therapeutic goods: a) about whether the TGA is continuing to monitor reports and events relating to the potential safety concern, or the incidence, rate and patterns of events relating to the potential safety concern; b) about whether the TGA (or the TGA in conjunction with the sponsor or sponsors of the therapeutic goods) is investigating, or will investigate, the potential safety concern; c) summarising the progress of the TGA's monitoring and investigation of the potential safety concern (or in the case of a concern being investigated with the sponsor or sponsors, of that joint investigation); d) summarising the TGA's investigation of the potential safety concern (or in the case of a concern being investigated with the sponsor or sponsors, of that joint investigation) including an outline of any conclusions of, or in relation to, such investigations; e) outlining any outcomes arising from, or in relation to, such investigations, including for example that no further action is considered to be required at the time, that the TGA will continue to monitor reports and events relating to the potential safety concern, that therapeutic goods, or some batches of therapeutic goods have been recalled, or that action has been taken to suspend or cancel therapeutic goods from the ARTG.
(f)	Expert advisory committee comments	Information consisting of a summary of any advice or recommendations provided by an expert advisory committee established under Divisions 1-1EB of Part 6 of the Therapeutic Goods Regulations 1990 about the potential safety concern in relation to the therapeutic goods or type of therapeutic goods.
(g)	Safety information for consumers and health professionals	Safety information for consumers and health professionals: a) about the therapeutic goods or type of therapeutic goods involved in the potential safety concern and any related information about the therapeutic goods or type of therapeutic goods that provides background or context to that information, including information that has been provided to the TGA about the therapeutic goods or therapeutic goods of that relevant type; or b) arising out of the detection and/or investigation of the potential safety concern including (if relevant)

		any specific recommended actions that should be taken in relation to the safe use of the therapeutic goods or type of therapeutic goods.

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