



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) 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 14 June 2013

(Signed by)

JOHN SKERRITT
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) 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*.

Adverse event means (in relation to a medical device) an event that led to the death of, or to a serious injury or serious deterioration to, a patient, user or other person, including:

- (i) a life-threatening illness or injury;
- (ii) permanent impairment of a body function;
- (iii) permanent damage to a body structure; or
- (iv) a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

ARTG means the Australian Register of Therapeutic Goods.

Medical device means:

- (i) in relation to reports of adverse events or near adverse events reported as having occurred in Australia, a medical device as defined in the Act; or
- (ii) in relation to reports of adverse events or near adverse events reported as having occurred in New Zealand, a medical device as defined in the *Medicines Act 1981* of New Zealand.

Medsafe means the New Zealand Medicines and Medical Devices Safety Authority, within the New Zealand Ministry of Health.

Near adverse event means (in relation to a medical device) an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event it is sufficient that:

- (i) an event associated with the device happened and, if the event were to occur again, it might lead to a death or serious injury; or
- (ii) testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

TGA means the Therapeutic Goods Administration, being 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 1: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

Adverse events, or near adverse events, in Australia

1. Kinds of therapeutic goods information relating to reports in Australia of adverse events, or near adverse events, reported to have involved a medical device (being a medical device as defined in the Act) kept by the TGA:

Item 1	Information	Description for adverse events, or near adverse events, in Australia
(a)	Report number	A unique reference number assigned by the TGA to each report.
(b)	Report date	The date that the TGA received the finalised report (in some instances the TGA receives an initial and final report).
(c)	Trade name	The trade name (i.e. the brand name) of the medical device.
(d)	Sponsor	The person in relation to whom that medical device or that kind of medical device is included in the ARTG.
(e)	Manufacturer	The manufacturer of the medical device.
(f)	ARTG number	The ARTG number of the medical device or kind of medical device.
(g)	GMDN term	The Global Medical Device Nomenclature term relating to the medical device.
(h)	Device classification	The classification of the medical device.
(i)	Sterile	Whether the information contained in the ARTG in relation to the medical device or kind of medical device indicates that the device or devices of that kind are supplied in a sterile state (this will be a yes or no).
(j)	Single use	Whether the information contained in the ARTG in relation to the medical device or that kind of medical device indicates that the manufacturer of the medical device has stated that the medical device is intended by the manufacturer to be a single-use medical device (this will be a yes or no).
(k)	Model number	The model number of the medical device, as reported.
(l)	Software version	The version of the controlling software used in or by the medical device, as reported.
(m)	Event description	A brief description of the reported adverse event or near adverse event (this will usually be a summary of the information provided by the person making the report about

Item 1	Information	Description for adverse events, or near adverse events, in Australia
		the circumstances of the reported event).
(n)	Reported event outcome	Which of the following categories the TGA considers that the event, as reported, falls within: (i) death; (ii) injury; (iii) no injury; or (iv) unknown.
(o)	Report source category	Whether the reporter – as described by them – appears to fall within one of the following categories: (i) consumer; (ii) health professional; (iii) industry; (iv) government; or (v) other.
(p)	Event type	Which of the following categories the TGA considers that the event, as reported, falls within: (i) activation, positioning or separation; (ii) computer hardware; (iii) computer software; (iv) connection or fitting; (v) electrical/electronic; (vi) external conditions; (vii) implantable device failure; (viii) incompatibility; (ix) infusion/flow; (x) marking, labelling or instructions for use; (xi) material; (xii) mechanical; (xiii) non-mechanical; (xiv) output issue; (xv) packaging/shipping; (xvi) protective; (xvii) temperature; (xviii) unintended function; (xix) use error; or (xx) other.
(q)	Details of other medical devices reported as being involved	The trade name, manufacturer, sponsor, GMDN term and ARTG number (where known) of any other medical device reported to have been involved in the adverse event or near adverse event.

Note 2: The GMDN term referred to in item 1(g) is contained in the GMDN database which is a collection of terms that use a unique 5-digit code to identify particular medical devices. The database is maintained by a not-for-profit company based in the United Kingdom (the GMDN Agency). International regulatory authorities, including the TGA, liaise with the GMDN Agency to request amendments to existing codes and the creation of new codes. Other GMDN users may also make applications to the GMDN Agency.

Note 3: Medical device classifications referred to in item 1(h) are set out in Division 3.1 of Part 3 of the Therapeutic Goods (Medical Devices) Regulations 2002, for the purposes of section 41DB of the Act.

Note 4: The Model number referred to in item 1(k) above may actually be a catalogue or part number if the person reporting the adverse event, or near adverse event, provides that number in error rather than providing the model number. In such cases it may not be possible for the TGA to identify the corresponding model number.

Adverse events, or near adverse events, in New Zealand

2. Kinds of therapeutic goods information relating to reports in New Zealand of adverse events, or near adverse events, reported to have involved a medical device (being a medical device as defined in the *Medicines Act 1981* (NZ)), being information provided by Medsafe to, and kept by, the TGA:

Item 2	Information	Description for adverse events, or near adverse events, in New Zealand
(a)	Report number	A unique reference number assigned by Medsafe to each report.
(b)	Report date	The date that Medsafe received the finalised report.
(c)	Trade name	The trade name (i.e. the brand name) of the medical device.
(d)	Sponsor	The person or entity responsible for importing into New Zealand, exporting from New Zealand and/or manufacturing in New Zealand the medical device.
(e)	Manufacturer	The manufacturer of the medical device.
(f)	GMDN term	The Global Medical Device Nomenclature term relating to the medical device.
(g)	Device classification	The classification of the medical device.
(h)	Sterile	Whether the information in relation to the medical device or kind of medical device indicates that the device or devices of that kind are supplied in a sterile state (this will be a yes or no).
(i)	Single use	Whether the information in relation to the medical device or that kind of medical device indicates that the manufacturer of the medical device has stated that the medical device is intended by the manufacturer to be a single-use medical device (this will be a yes or no).
(j)	Model number	The model number of the medical device, as reported.
(k)	Software version	The version of the controlling software used in or by the medical device, as reported.
(l)	Event description	A brief description of the reported adverse event or near adverse event (this will usually be a summary of the information provided by the person making the report about

Item 2	Information	Description for adverse events, or near adverse events, in New Zealand
		the circumstances of the reported event).
(m)	Reported Event outcome	Which of the following categories Medsafe considers that the event, as reported, falls within: (i) death; (ii) injury; (iii) no injury; or (iv) unknown.
(n)	Report source category	Whether the reporter – as described by them – appears to fall within one of the following categories: (i) consumer; (ii) health professional; (iii) industry; (iv) government; or (v) other.
(o)	Event type	Which of the following categories Medsafe considers that the event, as reported, falls within: (i) activation, positioning or separation; (ii) computer hardware; (iii) computer software; (iv) connection or fitting; (v) electrical/electronic; (vi) external conditions; (vii) implantable device failure; (viii) incompatibility; (ix) infusion/flow; (x) marking, labelling or instructions for use; (xi) material; (xii) mechanical; (xiii) non-mechanical; (xiv) output issue; (xv) packaging/shipping; (xvi) protective; (xvii) temperature; (xviii) unintended function; (xix) use error; or (xx) other.
(p)	Details of other medical devices reported as being involved	The trade name, manufacturer, sponsor, GMDN term (where known) of any other medical device reported to have been involved in the adverse event or near adverse event.

Note 5: The GMDN term referred to in item 2(f) is contained in the GMDN database which is a collection of terms that use a unique 5-digit code to identify particular medical devices. The database is maintained by a not-for-profit company based in the United Kingdom (the GMDN Agency). International regulatory authorities, including Medsafe, liaise with the GMDN Agency to request amendments to existing codes and the creation of new codes. Other GMDN users may also make applications to the GMDN Agency.

Note 6: Medical device classifications referred to in item 2(g) are set out in Schedule 2 of the Medicines (Database of Medical Devices) Regulations 2003 (NZ).

Note 7: The Model number referred to in item 2(j) above may actually be a catalogue or part number if the person reporting the adverse event, or near adverse event, provides that number in error rather than providing the model number. In such cases it may not be possible for Medsafe to identify the corresponding model number.

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>