Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Information (Stakeholder Consultation on Database of 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(5AB) of the *Therapeutic Goods Act 1989*.

Dated 19 April 2013

(signed by)

JOHN SKERRITT
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Stakeholder Consultation on Database of 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.

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 occurred 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.

Register means the Australian Register of Therapeutic Goods.

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 and persons, and the 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.

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

(section 4)

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

Note 1: 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 bodies and kinds of persons for the following specified purposes.

1. Kinds of therapeutic goods information relating to reports of adverse events, or near adverse events, reported to involve a medical device that are kept by the TGA:

Item	Information	Description
(a)	Report number	A unique reference number assigned by the TGA to each report.
(b)	Report date	The date that the TGA received the report.
(c)	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; (xiii) unintended function; (xix) use error; or (xx) other.
(d)	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	Information	Description
		the circumstances of the reported event).
(e)	Event outcome	Which of the following categories the TGA considers that the event, as reported, falls within: (i) death; (ii) serious injury; (iii) temporary injury; (iv) no injury; or (v) unknown.
(f)	Report source	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 (iv) other.
(g)	Trade name	The trade name (i.e. the brand name) of the medical device.
(h)	Sponsor	The person in relation to whom that medical device or that kind of medical device is included in the Register.
(i)	Device classification	The classification of the medical device.
(j)	Manufacturer	The manufacturer of the medical device.
(k)	ARTG number	The Australian Register of Therapeutic Goods number of the medical device or kind of medical device.
(l)	Model number	The model number of the medical device, as reported.
(m)	Software version	The version of the controlling software used in or by the medical device, as reported.
(n)	Sterile	Whether the information contained in the Register in relation to the medical device or kind of medical device indicates if that device or devices of that kind are supplied in a sterile state (this will be a yes or no).
(o)	Single use	Whether the information contained in the Register in relation to the medical device or that kind of medical device indicates if the manufacturer of the medical device has indicated that the medical device is intended by the manufacturer to be a single-use medical device (this will be a yes or no).
(p)	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, as reported.
(q)	GMDN term	The Global Medical Device Nomenclature term relating to the medical device.

Note 2: Medical device classifications referred to in item (i) are set out in Division 3.1 of Part 3 of the Therapeutic Goods (Medical Devices) Regulations 2002, for the purposes of section 41BD of the Act.

Note 3: The Model number referred to in item (l) 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.

Note 4: The GMDN term referred to in item (q) 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.

2. Bodies and kinds of persons

(a) the Consumers Health Forum of Australia;
(b) the National Prescribing Service;
(c) AusBiotech;
(d) IVD Australia;
(e) the Medical Technology Association of Australia;
(f) the New Zealand Medicines and Medical Devices Safety Authority;
(g) the Pharmaceutical Management Agency, New Zealand;
(h) the Health Quality & Safety Commission New Zealand;
(i) the Office of the Health and Disability Commissioner of New Zealand;
(j) the Medical Technology Association of New Zealand;
(k) Product Evaluation Health New Zealand;
(l) the New Zealand Association of Pathology Practices Inc;
(m) the New Zealand Orthopaedic Association;
(n) the New Zealand Association of Plastic Surgeons;
(o) the New Zealand Hospital Pharmacists' Association;
(p) Catherine Ryan, of D C Consultants, PO Box 28874, Remuera, Auckland, New Zealand 1541; and
(q) employees, members or agents of the bodies mentioned in (a) – (p) above;

3. Purposes:

For the purposes of the bodies and kinds of persons mentioned under Part 2 of Schedule 1 providing feedback to the TGA about:
(a) the proposal to establish the publicly accessible database of reports containing the kinds of information listed under Part 1 above of adverse events, or near adverse events, involving medical devices; and
(b) the functionality, suitability (in terms of informing the public about adverse events and near adverse events involving medical devices) and presentation of a prototype of that database.

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