Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012

Therapeutic Goods Act 1989

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

Dated 21st November 2012

(Signed by)

JOHN SKERRITT
Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012*.

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 any untoward medical occurrence in a patient administered medicine and which does not necessarily have to have a causal relationship with this medicine. An adverse event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicine, whether or not considered related to this medicine.

Medsafe means the New Zealand Medicines and Medical Devices Safety Authority.

Register means the Australian Register of Therapeutic Goods.

TGA means the Therapeutic Goods Administration.

4 Therapeutic goods information, persons and purposes

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

1 List of Reports in relation to a medicine – Australian adverse events

(a) the information given to the TGA by users, medical practitioners or other persons, when reporting an adverse event in relation to a medicine in relation to a person, and recorded by the TGA under or in relation to the headings set out in the below table, being information kept by the TGA in a database of adverse event information known as the Joint Adverse Event Notifications System (the JAENS) and able to be extracted from that database as part of a document titled a List of Reports, for any particular period of time:

Medicine	**Other medicine taken at time of the adverse event (if any)**	**Age**[1]	**Gender**[2]

(aa) the information listed below that is derived by the TGA from, or allocated by the TGA in relation to, the information provided by the person reporting an adverse event in relation to the medicine, being also part of the information that is kept by the TGA in the JAENS and able to be extracted from that database as part of a document titled List of Reports:

(i) the report entry date, being the date that the reported adverse event is recorded by the TGA[3];
(ii) the adverse event description term that relates to the reported adverse event as described in the Medical Dictionary for Regulatory Activities (MedDRA)[4]; and
(iii) the unique case number allocated by the TGA to the adverse event report.

1 Meaning the age of the person reported to have suffered the adverse event.
2 Meaning the gender of the person reported to have suffered the adverse event.
3 This date will in most cases be the same date or very close in time to the date that the adverse event was reported.
4 MedDRA is an internationally recognised set of terms relating to medical conditions, medicines and medical devices, maintained and distributed by the MedDRA Maintenance and Support Services Organisation (MSSO). The MedDRA is available for viewing by subscribers to the MSSO's services from www.Meddramsso.com.

1A List of Reports in relation to a medicine – New Zealand adverse events

(a) the information given to the TGA by Medsafe in relation to an adverse event in relation to a medicine and recorded by the TGA under or in relation to the headings set out in the below table, being information kept by the TGA in the JAENS and able to be extracted from that database as part of a document titled a List of Reports, for any particular period of time:

Medicine	**Other medicine taken at time of the adverse event (if any)**	**Age**[5]	**Gender**[6]	**Report entry date**[7]	**MedDRA term**[8]	**Case number**[9]

1B List of Reports in relation to a medicine – Australian and New Zealand adverse events

(a) for a medicine in relation to which the TGA keeps information in the JAENS of the kind mentioned under both headings 1 and 1A above (whether under the same product name or not), a combination of that information.

2 Medicine Summary in relation to a medicine – Australian summaries

(a) the information listed below, collated by the TGA in relation to a medicine based on information provided to the TGA by users, medical practitioners or others, when reporting an adverse event in relation to the medicine in relation to a person, being part of the information kept by the TGA in the JAENS and able to be extracted from that database in the form of a document titled a Medicine Summary, for any particular period of time:

(i) the number of cases of reported adverse events in Australia for the medicine;
(ii) the number of such cases reported to have resulted in death;
(iii) the number of such cases in which the medicine was reported to be the sole suspected medicine (that is, the only medicine suspected of being related to the reported adverse event);
(iv) the system organ class terminology, as described in the MedDRA, for the part of the body which each adverse event was reported as affecting (e.g. the cardiovascular system); and

5 Meaning the age of the person reported to have suffered the adverse event.
6 Meaning the gender of the person reported to have suffered the adverse event.
7 Meaning the date advised by Medsafe that the reported adverse event was recorded by or on behalf of Medsafe.
8 Meaning the adverse event description term that relates to the reported adverse event as described in MedDRA.
9 Meaning the unique case number allocated by or on behalf of Medsafe to the adverse event report.

(v) the MedDRA adverse event description term that relates to each reported adverse event (e.g. an injection site reaction).

2A Medicine Summary in relation to a medicine – New Zealand summaries

(a) the information listed below, collated by or on behalf of Medsafe in relation to a medicine and provided by Medsafe to the TGA, being information kept by the TGA in the JAENS and able to be extracted from that database in the form of a document titled a Medicine Summary, for any particular period of time:

(i) the number of cases of reported adverse events in New Zealand for the medicine;
(ii) the number of such cases reported to have resulted in death;
(iii) the number of such cases in which the medicine was reported to be the sole suspected medicine (that is, the only medicine suspected of being related to the reported adverse event);
(iv) the system organ class terminology, as described in the MedDRA, for the part of the body which each adverse event was reported as affecting (e.g. the cardiovascular system); and
(v) the MedDRA adverse event description term that relates to each reported adverse event (e.g. an injection site reaction).

2B Medicine Summary in relation to a medicine – Australian and New Zealand adverse events

(a) for a medicine in relation to which the TGA keeps information in the JAENS of the kind mentioned under both headings 2 and 2A above (whether under the same product name or not), a combination of that information.

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