# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

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

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health and Ageing, is responsible for administering the Act.

Section 61 of the Act lists a number of persons or organisations, such as the World Health Organisation and State or Territory authorities that have functions relating to therapeutic goods, to which the Secretary may release specified kinds of therapeutic goods information.

The Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012 (the Specification) is made by the Minister under subsection 61(5D) of the Act and specifies the kinds of therapeutic goods information that the Secretary may then release to the public under subsection 61(5C) of the Act.

The Specification has the effect of permitting the Secretary to release to the public therapeutic goods information of a kind mentioned in the Specification.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as, relevantly, information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions (this includes the adverse event information held by the TGA relating to New Zealand set out in the Specification).

The Specification commenced on the day after it was registered on the Federal Register of Legislative Instruments.

## BACKGROUND

In June 2011 the Australian and New Zealand Governments agreed to proceed towards a joint scheme for regulation of therapeutic goods. The creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries. The scheme will be administered by a single regulatory agency, the Australia New Zealand Therapeutic Products Agency.

As part of the staged approach to achieving that goal, the Australian and New Zealand Governments agreed that the TGA and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) would begin a program of joint projects to maintain the momentum for the establishment of the Agency. One of the projects is the establishment of a joint publicly accessible database of adverse event notifications relating to medicines used in Australia and New Zealand.

Both the TGA and Medsafe have a publicly accessible database on their respective websites that contains information about adverse events in each country, respectively. In the case of

the TGA, the information is currently available to the public in the Database of Adverse Event Notifications (the DAEN). In the case of Medsafe, adverse event information is currently available to the public in the database known as the Suspected Medicine Adverse Reaction Search (SMARS).

The establishment of a joint database that contains information about adverse events in both countries – to be known as the Joint Adverse Event Notifications System, or the JAENS - will provide a number of benefits to both the TGA and Medsafe as well as for health-related industries and consumers. Those benefits include providing consumers with more information about the number and types of adverse events reported in both countries relating to particular medicines (and therefore assisting consumers to be better informed about their safety), and supporting therapeutic research and analysis relating to the incidence of adverse events.

The purpose of the Specification is to support the release to the public of adverse event information relating to both Australia and New Zealand contained in the JAENS by identifying, under subsection 61(5D) of the Act, the kinds of information that the Secretary may publish under subsection 61(5C) of the Act (in the form of the new database).

The adverse event information relating to New Zealand that will form part of the JAENS will be provided to the TGA by Medsafe on a regular basis for inclusion in the JAENS.

It is intended that the JAENS be accessed by the public via the website established to provide information in relation to the Australia New Zealand Therapeutic Products Agency (currently, www.anztpa.org).

It should be noted that the JAENS is to be distinguished from the DAEN which was launched on 1 August 2012 (the DAEN may be viewed and accessed on the TGA's website, www.tga.gov.au).

The DAEN contains the same information relating to adverse events reported in Australia (that is, adverse event reports received by the TGA) as will be contained in the JAENS, but does not contain information relating to New Zealand adverse events.

The DAEN also differs from the JAENS in that it contains Australian adverse event information dating from 1971, whereas the JAENS only contains such information dating from the year 2000.

Subsection 61(5D) of the Act empowers the Minister to, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

Under subsection 61(5C) of the Act, the Secretary may release to the public therapeutic goods information of a kind specified by the Minister under subsection 61(5D) of the Act.

The information that will be released by the Secretary through access to the JAENS will be in either of two forms, for adverse events relating to each of Australia and New Zealand:

- a list of reports of adverse events in relation to a medicine, that contains a short description of each adverse event reported as having occurred in relation to the medicine within a specified period (a 'list of reports'); and
- a summary of all adverse events reported as having occurred in relation to a medicine within a specified period (a 'medicine summary').

For a medicine in relation to which the JAENS contains information relating to both Australia and New Zealand (whether the medicine has the same product name in both countries or not), the JAENS will also be able to display a list of reports or a medicine summary that combines both the Australian and New Zealand adverse event information specified in the instrument in relation to that medicine.

The information proposed to be released in response to a request for the first type of report (the list of reports) includes the name of the medicine reported as being involved in an adverse event, the reported nature of the adverse event (in the form of the descriptive term relating to the relevant event set out in the Medical Dictionary for Regulatory Activities (MedDRA)[1]) and the patient's reported age and gender.

The information proposed to be released in response to a request for the second type of report (the medicine summary) includes the number of adverse events reported as being related to a medicine during the specified period, the system organ class terminology, as described in the MedDRA, for the part of the body which each adverse event was reported as affecting and the MedDRA adverse event description term that relates to each reported adverse event.

The medicine summary would also include, in relation to a medicine for a specified period, the number of reported adverse events in which the medicine was reported to have been the sole suspected medicine involved (that is, the only medicine noted by the person reporting the adverse event as having been related to the event), and the number of reported adverse events noted by those providing the information as having resulted in death.

An adverse event is defined in the Specification as any untoward medical occurrence in a patient administered medicine and which does not necessarily have to have a causal relationship with that medicine. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicine, whether or not considered related to the medicine.

The kinds of therapeutic goods information that the Secretary can decide to release is set out at Schedule 1 to the Specification.

## CONSULTATION

Key stakeholders were consulted in May 2012 in relation to the publication of adverse event information on the DAEN, and access to a prototype of the DAEN was arranged for those stakeholders for the purposes of obtaining feedback on its functionality, suitability (in terms of informing the public about adverse events involving medicines) and presentation.

These stakeholders included a number of bodies representative of specific industries relating to therapeutic goods (including Medicines Australia, the Generic Medicines Industry Association of Australia, the Australian Self-Medication Industry Incorporated and the Complementary Healthcare Council of Australia), relevant consumer bodies (the Australian Consumers Association (Choice) and the Consumers' Health Forum of Australia) the Australian Medical Association, as well as Medsafe, the New Zealand Ministry of Health, the

[1] 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.

New Zealand Pharmacovigilance Centre, University of Otago, New Zealand and the New Zealand Self Medication Industry Association Incorporated.

The stakeholders' comments were considered by the TGA, and a number of changes were incorporated into the version of the DAEN that was released to the public on 1 August 2012 in response to that feedback.

When stakeholders were invited to test and comment on the prototype of the DAEN, they were informed that the DAEN would initially only include Australian adverse event information, and that adverse event information relating to New Zealand would be added at a later date.

The Specification is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

In relation to compatibility with human rights, it is considered that the Specification is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is attached.

**ATTACHMENTS**

1. Statement of compatibility for a legislative instrument that does not raise any human rights issues (Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012).