EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

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 a division 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 of the Department of Health and Ageing can release specified kinds of therapeutic goods information. Section 61 also allows the Minister for Health to make a legislative instrument setting out other circumstances in which the Secretary can release therapeutic goods information to the public under that section.

The Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013 (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 release to the public under subsection 61(5C) of the Act.

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

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.

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 with a joint scheme for the regulation of therapeutic goods. The creation of a joint regulatory scheme applying in 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 (ANZTPA).

To that end, the Australian and New Zealand Governments agreed that the TGA and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) would undertake a program of joint projects leading up to the establishment of ANZTPA. One of the projects is the establishment of a single, publicly accessible database of adverse event notifications relating to medicines and medical devices in Australia and New Zealand.

As part of that project, Medsafe launched a publicly available database of adverse event information relating to adverse events involving medicines reported in New Zealand, known as the Suspected Medicine Adverse Reaction Search (SMARS), on 27 June 2012. The SMARs can be accessed on Medsafe's website at www.medsafe.govt.nz.

The TGA launched its own publicly available database of adverse event information relating to adverse events involving medicines reported in Australia, known as the Database of Adverse Event Notifications (DAEN), on 1 August 2012. The DAEN can be accessed on TGA's website at www.tga.gov.au.

This launch was followed, on 1 November 2012, by the launch of the publicly available database the Joint Adverse Event Notifications System (the JAENS), which contains information about adverse events involving medicines in relation to both Australia and New Zealand. The JAENS can be accessed on the ANZTPA website at www.anztpa.gov.au. The JAENS combines information relating to adverse events involving medicines in the SMARS and DAEN databases in the one place in preparation for the establishment of ANZTPA.

The establishment of these databases is considered to have provided a number of benefits to both the TGA and Medsafe as well as to health-related industries and consumers, including permitting consumers to trace the number of events reported relating to particular medicines and - in relation to the JAENS - providing consumers with more information about the number and types of adverse events reported in each country in relation to particular medicines. Wider benefits also include assisting consumers to be better informed about the safety of medicines, and supporting therapeutic research and analysis relating to the incidence of adverse events.

The next stage of the project is to provide a publicly accessible database of adverse event notifications relating to adverse events, and near adverse events, involving medical devices in Australia in a similar database to the DAEN. The Australian database is to be known, at least initially, as the Database of Adverse Event Notifications – Medical Devices (DAEN-MD) and will be searchable on the TGA website at www.tga.gov.au. The DAEN-MD will contain information relating to reports of adverse events and near adverse events involving medical devices dating from 1 July 2012.

The final stage of the project is to provide a publicly accessible database of adverse event notifications relating to adverse events, and near adverse events, involving medical devices in Australia and New Zealand. The joint Australian and New Zealand database is to be known as, at least initially, as the Joint Adverse Event Notifications System – Medical Devices (JAENS-MD). It is intended that the JAENS-MD will be searchable on the ANZTPA website at www.anztpa.gov.au.

The JAENS-MD will combine information relating to adverse events, and near adverse events, involving medical devices in the DAEN-MD (i.e. Australian information) and information relating to adverse events and near adverse events involving medical devices in New Zealand from 1 January 2013 in the one place. At this stage, New Zealand is not proposing to establish its own separate database.

It is expected that the establishment of the DAEN-MD and the JAENS-MD will extend to the area of medical devices the benefits described above in relation to medicines, and in so doing will provide a broader picture of the incidence and nature of adverse events, and near adverse events involving medical devices in Australia and New Zealand.

The DAEN-MD aspect of the project will also address recommendation 20 of the review to improve the transparency of the Therapeutic Goods Administration (June 2011), which provided that "*the TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods*". A copy of this report is available on the TGA's website at: www.tga.gov.au.

The purpose of the Specification is to provide a legal basis under the Act to support release to the public of therapeutic goods information in both the DAEN-MD and JAENS-MD.

Subsection 61(5D) of the Act empowers the Minister to, by legislative instrument, specify kinds of therapeutic goods information that may be released to the public 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 kinds of information that the Secretary will be able to release in this manner in the DAEN-MD (Australian reports only) and JAENS-MD (Australian and New Zealand reports) are listed in Schedule 1 to the Specification, and will be in either of two forms:

- a 'medical device summary', which provides a small number of kinds of information about a report of an adverse event or a near adverse event relating to a medical device, such as report date (the date the TGA received the report), trade name (the brand name of the medical device) and the manufacturer of the medical device; and
- a 'list of reports' of adverse events or near adverse events in relation to a medical device, which provides the same information as a 'medical device summary' as well as an expanded range of kinds of information including, for example, a brief description of the adverse event or near adverse event, the model number of the medical device (as reported) and whether the person reporting the event appears to fall within the categories of consumer, health professional, industry, government or other.

An adverse event in relation to a medical device is defined in the Specification as an even that has led to the death of, or to a serious injury or a 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.

A near adverse event is defined in the Specification as 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 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 a serious injury.

The TGA already collects from industry (sponsors and manufacturers of medical devices), healthcare professionals, patients and consumers information about reported adverse events and near adverse events involving medical devices in Australia as part of the TGA's post market compliance and monitoring functions. Sponsors of medical devices are obliged to report adverse events to the TGA and healthcare professionals and patients are encouraged to do so. The TGA has 'incident report' forms available on its website for this purpose.

In the case of the JAENS-MD, Medsafe will provide the TGA with information about reported adverse events, and near adverse events, involving medical devices in New Zealand on a regular basis for inclusion in the JAENS-MD.

CONSULTATION

In March 2013, the TGA contacted a number of Australian stakeholders and Medsafe wrote to a number of New Zealand stakeholders:

- seeking feedback about the proposal to establish a publicly accessible database of adverse events for medical devices; and
- inviting them to test and provide input in relation to the functionality, suitability (in terms of informing the public about adverse events involving medical devices) and presentation of a prototype of that database.

The prototype database that was tested by Australian and New Zealand stakeholders was in the form of the DAEN-MD.

The Australian stakeholders who were contacted included the Consumers Health Forum of Australia, the Medical Technology Association of Australia and the National Prescribing Service.

A full list of these stakeholders is set out at Schedule 1 of the *Therapeutic Goods Information (Stakeholder Consultation on the Database of Adverse Event Notifications – Medical Devices) Specification 2013*.

This earlier specification authorised release under the Act of therapeutic goods information to these stakeholders for the purposes of facilitating this testing and the obtaining of feedback about a number of matters. These matters included the proposal to establish the database of adverse events for medical devices, the functionality, suitability (in terms of informing the public about adverse events involving medical devices) and presentation of a prototype of the database and any impacts on industry that might result from its launch.

Feedback from stakeholders was taken into account in developing the final version of the DAEN-MD for public release and the development of the JAENS-MD. Many of the suggestions made by stakeholders have been applied to improve the databases. Other suggestions made by stakeholders may also be applied over time.

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 set out below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

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

This legislative instrument 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*.

Overview of the Bill/Legislative Instrument

The Therapeutic Goods Information (Adverse Event Notifications – Medical Devices) Specification 2013 is made by the Minister for Health under subsection 61(5D) of the *Therapeutic Goods Act 1989*. It permits the Secretary of the Department of Health and Ageing to release to the public specified kinds of information relating to adverse events or near adverse events reported to have involved medical devices in Australia and New Zealand that is held by the Therapeutic Goods Administration. The information authorised to be released by the Secretary includes descriptions of such events and the medical device reportedly involved, but does not include personal information within the meaning of the *Privacy Act 1988*.

Human rights implications

As this instrument does not set out any measures other than providing the legal authority for the release of certain kinds of information relating to medical devices as outlined above, the instrument is not considered to engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

John Skerritt, delegate of the Minister for Health