

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### **Therapeutic Goods Information (Stakeholder Consultation on Database of 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 such information.

The Therapeutic Goods Information (Stakeholder Consultation on Database of Adverse Event Notifications – Medical Devices) Specification 2013 (the Specification) is made by the Minister under subsection 61(5AB) of the Act and specifies the kinds of therapeutic goods information that can be released, the kinds of persons to whom that information can be released, and the purposes for which it can be released, by the Secretary under subsection 61(5AA) of the Act.

The making of the Specification has the effect of permitting the Secretary to release therapeutic goods information of a kind mentioned in the Specification to the bodies and the kinds of persons mentioned in the Specification, for the purposes set out 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.

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 products. 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. One of these projects was the establishment of a single, publicly accessible database of adverse event notifications relating to medicines and medical devices in Australia and New Zealand. The TGA launched its publicly available database of adverse event information relating to adverse events involving medicines reported in Australia, known as the Database of Adverse Event Notifications (the DAEN), on 1 August 2012.

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 contained information about adverse events in relation to medicines in Australia and New Zealand.

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 relating 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.

It is now proposed to make public information relating to adverse events involving medical devices in a similar database to the DAEN, to be known as the Database of Adverse Event Notifications – Medical Devices (the DAEN-MD).

The DAEN-MD will contain information about adverse event reports, and near adverse event reports, relating to medical devices that is held by the TGA. This will be an initial step towards the subsequent establishment of a publicly available database that contains information about adverse events in relation to medical devices in Australia and New Zealand.

It is expected that the establishment of the DAEN-MD (and, later, a combined Australia-New Zealand database of medical devices adverse event information) will extend to 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 in the case of medical devices, relating to therapeutic goods in Australia (and, later, in New Zealand).

Currently, the proposed DAEN-MD is not yet in its final form and there is a need for a prototype to be evaluated and tested by informed users in order to provide feedback to the TGA on the proposal to establish the DAEN-MD, and its functionality, suitability (for release to the public) and presentation.

The TGA already collects from industry (sponsors and manufacturers of medical devices), healthcare professionals, patients and consumers information about adverse events involving medical devices 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 on its website 'incident report' forms for this purpose.

It is therefore proposed that access to a prototype of the DAEN-MD be given for a short period to a number of bodies that represent specific industries relating to medical devices (such as the Medical Technology Association of Australia, and AusBiotech) as well as to

an important consumer body (the Consumers Health Forum of Australia) and other bodies such as Medsafe and the New Zealand Association of Pathology Practices, so that they can provide feedback. They are set out in Part 2 of Schedule 1 to the Specification.

The making of the Specification has the effect of permitting the Secretary to release to these bodies, and to their employees, members or agents, the kinds of therapeutic goods information relating to adverse events, and near adverse events, involving medical devices reported in Australia that is proposed to be released by the TGA in the form of the new database, for the purposes of obtaining feedback from those bodies and persons about the proposal to establish the DAEN-MD and about the DAEN-MD's functionality, suitability (in terms of informing the public about adverse events involving medicines) and presentation.

An adverse event in relation to a medical device is defined in the Specification as an event 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 occurred 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 information proposed to be released by the Secretary through access to the prototype of the database is described in Part 1 of Schedule 1 of 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, and 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.

The kinds of therapeutic goods information that the Secretary can decide to release, the bodies and kinds of persons to whom the Secretary can decide to release that information and the purposes for which the Secretary can decide to release that information, are set out at Schedule 1 to the Specification.

## CONSULTATION

The TGA wrote to a number of Australian stakeholders, and Medsafe wrote to a number of New Zealand stakeholders, seeking feedback both about the proposal to establish the DAEN-MD and to invite 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 Australian stakeholders who were contacted included the Consumers Health Forum of Australia and the Medical Technology Association of Australia.

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 (Stakeholder Consultation on Database of Adverse Event Notifications – Medical Devices) Specification 2013).