EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Early Warning System) 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 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 Secretary can also, in particular circumstances, release therapeutic goods information to the public under that section.

The Therapeutic Goods Information (Early Warning System) Specification 2013 (the Specification) is made by the Minister under subsection 61(5D) of the Act and specifies particular 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 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.

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 the projects is the establishment of a trans-Tasman early warning system (EWS) to provide advice about potential safety concerns associated with particular kinds of therapeutic goods - medicines and medical devices.

This will involve initially the publication by the TGA of early warning information in relation to therapeutic goods that are available for supply in Australia and the separate

publication by Medsafe of early warning information about therapeutic goods that are available for supply in New Zealand. The TGA and Medsafe are also working towards the establishment of a joint early warning scheme.

The establishment of the EWS is expected to provide a number of benefits to both the TGA and Medsafe as well as for consumers, health professionals and health-related industries, including through providing consumers and health professionals with more information about potential safety concerns associated with medicines and medical devices (therefore assisting consumers and health professionals to be better informed), and is expected to lead to increased reporting of adverse events (which will assist in the investigation of potential safety concerns).

The establishment of the EWS also addresses part of one of the recommendations of the Report of the Review to improve the transparency of the TGA (released on 21 July 2011). Recommendation 16 of that Report stated that the TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls to health practitioners and to consumers. A copy of this Report is available from the TGA website (http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm). The Government agreed to the recommendation in December 2011.

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.

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.

The purpose of the Specification is to support the release to the public of information relating to potential safety concerns about therapeutic goods that are supplied in Australia, 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.

The EWS encompasses two different kinds of communications about a product that can be issued by the Secretary to the public.

These communications to the public will be one of the following:

- a ‘monitoring communication’, providing either initial advice about a potential safety concern identified by the TGA or in relation to which it has received information about a medicine, therapeutic device or medical device supplied in Australia, or follow-up advice in the form of a progress report about the investigation of such a concern that such an investigation has been concluded and the outcome of that investigation; and
- an ‘alert communication’ providing information about, and recommendations arising from, the TGA’s investigation of a potential safety concern with a medicine, therapeutic device or medical device supplied in Australia.

A ‘potential safety concern’ means any potential safety problem linked to therapeutic goods or a type of therapeutic goods. Safety concerns include known safety problems, changes to known problems, new problems and coincidental events. At the time the potential safety concern is detected, the TGA may not know if the concern is caused by the therapeutic goods.

The intention of the monitoring communication is to highlight potential safety concerns that are identified by the TGA or about which it has received information for the purpose of raising public awareness in relation to that concern and to provide information about the importance, and to stimulate, the reporting of adverse events. Not all of these concerns will result in the TGA taking action. This may be because after an investigation, the TGA has not found evidence to support a link between the events and the therapeutic goods in question. The TGA may reinvestigate these safety concerns if more information is identified at a later date.

An alert communication is issued once a potential safety concern has been investigated, and may contain more information about the concern. It may provide information about actions that may need to be taken by health professionals and consumers.

Therapeutic goods information that can be released by the Secretary by reason of the making of the Specification (as described in the Specification) includes monitoring and investigation information consisting of information in relation to therapeutic goods or a type of therapeutic goods:

a) about the nature of a potential safety concern relating to the goods or the type of goods;
b) about whether the TGA is continuing to monitor reports and events relating to the potential safety concern, or the incidence, rate and patterns of events relating to the potential safety concern;
c) about whether the TGA (or the TGA in conjunction with the sponsor or sponsors of the therapeutic goods) is investigating, or will investigate, the potential safety concern;
d) summarising the progress of the TGA's monitoring and investigation of the potential safety concern (or in the case of a concern being investigated with the sponsor or sponsors, of that joint investigation);
e) summarising the TGA's investigation of the potential safety concern (or in the case of a concern being investigated with the sponsor or sponsors, of that joint investigation) including an outline of any conclusions of, or in relation to, such investigations;
f) outlining any outcomes arising from, or in relation to, such investigations, including for example that no further action is considered to be required at the time, that the TGA will continue to monitor reports and events relating to the potential safety concern, that therapeutic goods, or some batches of therapeutic goods have been recalled, or that action has been taken to suspend or cancel therapeutic goods from the ARTG.

It can also include 'safety information' (defined as information about the safe use of the therapeutic goods or the type of therapeutic goods) for consumers and health professionals:

a) about the therapeutic goods or type of therapeutic goods involved in the potential safety concern and any related information about the therapeutic goods or type of therapeutic goods that provides background or context to that information, including information that has been provided to the TGA about the therapeutic goods or therapeutic goods of that relevant type; or
b) arising out of the detection and/or investigation of the potential safety concern including (if relevant) any specific recommended actions that should be taken in relation to the safe use of the therapeutic goods or type of therapeutic goods.

Information about the EWS can be found at the TGA website at www.tga.gov.au.

The kinds of therapeutic goods information that the Secretary can decide to release are listed in Schedule 1 to the Specification.

CONSULTATION

In April 2012, the TGA and Medsafe jointly hosted a number of workshops in Australia and New Zealand with key stakeholders to obtain information about the proposal to establish an EWS, the proposed design of it and, generally, how safety information about therapeutic goods should be communicated.

The stakeholders who attended included over 50 bodies representative of:

- specific industries relating to therapeutic goods (including Medicines Australia, Medicines New Zealand, the Generic Medicines Industry Association of Australia, the Australian Self-Medication Industry Incorporated, the New Zealand Self Medicating Industry, the Complementary Healthcare Council of Australia, AusBiotech, Medical Technology Association of Australia and the Medical Technology Association of New Zealand);

- consumer bodies (including the Australian Consumers Association (Choice) and the Consumers' Health Forum of Australia);

- health professional bodies (including the Australian Medical Association, the National Prescribing Service, Pharmaceutical Society of New Zealand and the Royal Australasian College of Physicians); and

- government (including the Australian Competition and Consumer Commission, Departments of Health from Victoria, Western Australia, South Australia and New South Wales, PHARMAC, the Health Quality Safety Commission of New Zealand and the Canterbury District Capital and Coast District Health Boards (also from New Zealand)).

The stakeholders' comments were considered by the TGA and Medsafe during the development of the EWS. The workshop documents, including a summary of the feedback received, and a complete list of the organisations that were represented at the workshops, are available on the TGA website (www.tga.gov.au).

In March 2013, the TGA and Medsafe released a consultation paper describing the proposed EWS process including the decision criteria for the issuing of monitoring and alert communications, the proposed web pages and hypothetical example communications, for the purposes of obtaining further stakeholder feedback on the proposal.

The TGA and Medsafe received 35 submissions from bodies representative of industry, consumers, health professionals and government. The stakeholders' comments were considered by the TGA and Medsafe, and a number of changes were incorporated into the final version of the EWS. The Australian version of the consultation document and a list of the 28 bodies that made submissions to the TGA are available on the TGA website (www.tga.gov.au).

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 WITH HUMAN RIGHTS

Statement of Compatibility with Human Rights

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

Therapeutic Goods Information (Early Warning System) 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 (Early Warning System) 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 potential safety concerns about therapeutic goods, including the name of the therapeutic goods to which the potential safety concern relates, a brief description of the potential safety concern, information about monitoring and investigations undertaken by the Therapeutic Goods Administration (including in conjunction with the sponsor of the goods) and the outcome of such monitoring and investigation, and relevant safety information associated with the concern. The information to be released does not include personal information within the meaning of the *Privacy Act 1988*.

Human rights implications

This legislative instrument does not 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