**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

**Therapeutic Goods Information (Stakeholder Consultation on the System for Australian Recall Actions) 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 and 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 (Stakeholder Consultation on the System for Australian Recall Actions) 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 the Secretary may then release under subsection 61(5AA) of the Act, the bodies to which the Secretary of the Department of Health and Ageing (the Secretary) may release such information under subsection 61(5AA) and the purposes for which the Secretary may release that information.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department (of which the TGA is a division) 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.

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 begin a program of joint projects. One of the projects is to allow public access to elements of existing databases of recall actions relating to therapeutic goods in both Australia and New Zealand. Initially, this will involve public access to a sub-set of information held in TGA’s database of Australian recall actions and, separately, a database of New Zealand recall actions operated by Medsafe.

Access by the public to a database of Australian recall actions is expected to provide a number of benefits for health-related industries and consumers, including permitting consumers to access information about recall actions relating to therapeutic goods that are supplied in Australia including prescription, over-the-counter and complementary medicines, medical devices (including in-vitro diagnostic medical devices) and biologicals.

Public access to a database of Australian recall actions will also address recommendation 16 of the Report of the Review to improve the transparency of the TGA (released on 21 July 2011) - 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. The Government agreed to the recommendation in December 2011.

In the Specification, recall action is defined as action taken by the Responsible Entity (which includes the person in relation to whom therapeutic goods are included in the Australian Register of Therapeutic Goods) to resolve a problem with therapeutic goods supplied in the market that have, or may potentially have, deficiencies relating to safety, quality, efficacy or presentation. The definition also sets out a non-exhaustive list of types of recall actions.

The release of information about Australian recall actions as part of the publicly available version of the TGA’s recall database will, once it is in its final form, be supported by a legislative instrument under subsection 61(5D) of the Act. Subsection 61(5D) enables the Minister to specify in an instrument kinds of therapeutic goods information which the Secretary may then release to the public under subsection 61(5C) of the Act.

The New Zealand Government, through Medsafe, has already made available a database of New Zealand recall actions on its website, [www.medsafe.govt.nz](http://www.medsafe.govt.nz). The TGA proposes to release information about Australian recall actions on [www.tga.gov.au](http://www.tga.gov.au).

The proposed database in which this information is to be released (the System for Australian Recall Actions or SARA) will allow public access to a sub-set of information that is already held in the TGA’s database of Australian recall actions that the TGA keeps for the purpose of performing its monitoring and compliance functions under the Act. Currently, only Australian recall actions that involve consumers are published on the TGA’s website. Information about other Australian recall actions (such as recalls involving wholesalers or hospitals) is provided by the TGA to a limited group of external stakeholders such as State and Territory recall coordinators (with the sponsor of the goods providing information to others affected by the recall). The final version of the SARA database (following testing and feedback from stakeholders) will allow access by the public to information about Australian recall actions more generally for the first time.

The SARA database is not yet in its final form and there is a need for it to be evaluated and tested by informed users. It is anticipated that the feedback provided by these users will assist the TGA to finalise the database and the content proposed to be available to the public via the database.

It is therefore proposed that access to a prototype of the SARA database be given for a short period to a number of bodies that represent specific stakeholders (including industry) relating to therapeutic goods as set out in Schedule 1 of the Specification.

The making of the Specification under subsection 61(5AB) of the Act will provide a legal basis under section 61 of the Act for the release by the Secretary of therapeutic goods information in the prototype of the SARA database to the bodies and persons described in the Schedule.

The information proposed to be released by the Secretary (as set out in Schedule 1 of the Specification) will be in either of two forms:

* a list of recalls – this search return will show a list of recall actions that match the search criteria used from which a specific recall can then be selected by the user to view the details about that recall; or
* recall details – this search return will show summary information about a specific recall action that has been selected from the list and provides greater detail than that which is viewable in the list of recall actions.

**CONSULTATION**

In December 2012 and January 2013, the TGA wrote to a number of bodies that the TGA took the view would be in a position to provide useful feedback about the SARA database. They were advised about the proposal and invited to participate in testing of a prototype.

The stakeholder bodies contacted were the bodies listed in Schedule 1 of the Specification, and included industry, consumer and practitioner bodies, for example, Medicines Australia, the Generic Medicines Industry Association of Australia, the Australian Self Medication Industry Incorporated, the Complementary Healthcare Council of Australia, the Australian Medical Association and Consumers Health Forum of Australia.

Representatives of most of the bodies listed in Schedule 1 of the Specification that were contacted by the TGA responded to that invitation, indicating their interest in participating.

Under the Specification the therapeutic goods information in relation to Australian recall actions in the SARA database prototype can be released by the Secretary to the bodies so listed and their members, agents and employees, for the purposes of obtaining their feedback about the functionality, suitability (in terms of informing the public about recall actions) and presentation, including any impacts on industry that might result from its launch.

The Specification is considered to be minor and machinery in nature.

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.

**ATTACHMENT**

1. Statement of compatibility for a legislative instrument that does not raise any human rights issues (Therapeutic Goods Information (Stakeholder Consultation on the System for Australian Recall Actions) Specification 2013).