EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (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 (System for Australian Recall Actions) 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.

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 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 (FRLI).

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.

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 to allow public access to databases of recall actions relating to therapeutic goods in both Australia and New Zealand. Initially, this will involve the provision of public access to a new database consisting of a sub-set of information held in TGA's existing database of Australian recall actions and, separately, a database of New Zealand recall actions operated by Medsafe.

The publicly accessible database in Australia will be known as the System for Australian Recall Actions (SARA), and is expected to provide a number of benefits for health-related

industries, consumers, patients and health care professionals by permitting them access to information about recall actions relating to therapeutic goods.

Public access to elements of TGA's database also addresses 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. A copy of the report is set out on the TGA's website at www.tga.gov.au. The Government agreed to the implementation of the recommendation in December 2011.

The purpose of the Specification is to provide a legal basis under the Act to support release to the public of information in the SARA database.

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 Specification made under subsection 61(5D) identifies the kinds of information about recall actions contained in the SARA database that the Secretary can then release by way of publication in the SARA database under subsection 61(5C) of the Act.

The information that will be released by the Secretary is set out at Schedule 1 to the Specification and 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 more information about that recall; or
- recall details – this search return will show summary information about a specific recall action that has been selected from a list, and provides greater detail than that which is viewable in the list of recalls.

The SARA database will contain information about recall actions for therapeutic goods supplied in Australia including prescription medicines, over the counter medicines, complementary medicines, medical devices (including in-vitro diagnostic medical devices) and biologicals.

Recall action is defined in the Specification 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 action.

The New Zealand Government, through Medsafe, has already made available a database of New Zealand recall actions on its website at www.medsafe.govt.nz. The TGA will release information about Australian recall actions on its website at www.tga.gov.au.

CONSULTATION

In December 2012 and January 2013, the TGA contacted a number of bodies that the TGA took the view would be in a position to provide useful feedback about the proposed SARA database and invited them to participate in testing a prototype. They included bodies representing specific industries relating to therapeutic goods, medical practitioners and consumers including Medicines Australia, the Generic Medicines Industry Association of Australia, the Australian Self Medication Industry Incorporated and the Complementary Healthcare Council of Australia, the Australian Medical Association and Consumers Health Forum of Australia.

A full list of these stakeholders is set out at Schedule 1 of the *Therapeutic Goods Information (Stakeholder Consultation on the System for Australian Recall Actions) Specification 2013* which was registered on FRLI on 30 January 2013. This earlier specification authorised release under the Act of therapeutic goods information to these bodies for the purposes of this testing, these bodies were given access to the prototype from 31 January 2013 to mid-February 2013. Feedback about the SARA database was sought on its functionality, suitability (in terms of informing the public about Australian recall actions) and presentation, including any impacts on industry that might result from its launch.

Comments from the stakeholders were considered by the TGA resulting in a number of changes being incorporated into the version of the SARA database that will be available to the public.

As noted above, the SARA database will involve 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 creation of the SARA database will allow access by the public to information about Australian recall actions more generally for the first 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 attached.

ATTACHMENTS

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