

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 whom 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 persons and bodies to whom the Secretary may release such information under subsection 61(5AA) and the purposes for which the Secretary may release that information to those persons.

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 (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.

As part of a staged approach to achieving that goal, 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 the establishment of a publicly accessible database of recall actions relating to therapeutic goods in both Australia and New Zealand. Initially, this will involve a TGA database of Australian recall actions and, separately, a database of New Zealand recall actions operated by Medsafe. The establishment of a database of Australian recall actions

is expected to provide a number of benefits for health-related industries and consumers, including permitting consumers to review recall actions relating to particular products.

The establishment of 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 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. The TGA proposes to release information about Australian recall actions on www.tga.gov.au.

The proposed database in which this information is to be released (the System for Australian Recall Actions or SARA) 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 persons and bodies that represent specific stakeholders (including industry) relating to therapeutic goods as set out in Schedule 1 of the Specification. These stakeholders include, for example, the Australian Medical Association, Medicines Australia, the Complementary Healthcare Council of Australia and the Consumers Health Forum.

The information proposed to be released by the Secretary through access to the prototype of the SARA database is set out in Schedule 1 of 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 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.

The Specification has the effect of permitting the Secretary to release to these specified persons and bodies, and their members, agents or employees, therapeutic goods information in relation to Australian recall actions, being information kept by the TGA in its prototype of the SARA database, for the purposes of obtaining feedback from those persons and bodies about the functionality, suitability (in terms of informing the public about recall actions) and presentation of the TGA's proposed SARA database, including any impacts on industry that might result from the launch of the database.

CONSULTATION

The release of therapeutic goods information in relation to recall actions for the purpose of testing a prototype of the SARA database is the proposed mechanism for consulting stakeholders on the database. It 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.

ATTACHMENTS

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).