EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014

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, 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 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 therapeutic goods information to the public under that section.

The Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014 (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.

The Specification has the effect of permitting the Secretary to release to the public therapeutic goods information of a kind mentioned 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

Early communication of information about current or anticipated shortages of prescription medicine assists health professionals to make informed decisions about the continuity of care of their patients.

To this end, the TGA, in partnership with Medicines Australia and the Generic Medicines Industry Association (GMiA), is implementing a Medicine Shortages Information Initiative (the Initiative).

The Initiative is aimed at collating and providing to the public and health professionals through publication on the TGA website, a range of information about shortages of registered prescription medicines that are occurring, or that are expected to occur, in Australia. The Initiative involves the development of a protocol that sets out the roles of sponsors and the TGA covering the provision of relevant information to the TGA and then

to the public, to assist in the management of shortages. Participation by sponsors is voluntary.

As part of the Initiative, the TGA has created a searchable database on its website (www.tga.gov.au) for health professionals and the public to access information about medicines shortages. The database contains information about the nature, anticipated duration and status of prescription medicine shortages, with links to additional information for health professionals and the public.

The kinds of information that the Secretary will be able to release for this purpose about a shortage of a prescription medicine are listed in Schedule 1 to the Specification and include, for example:

- the name of the medicine, and its strength and dosage form;
- contact details for the sponsor of the medicine;
- whether a shortage has been reported by the sponsor of the medicine to be an anticipated shortage (where supply is not reasonably likely to meet normal or projected consumer demand in Australia at a future date) or a current shortage (where supply is not reasonably likely to meet normal or projected consumer demand in Australia) or whether the sponsor is discontinuing the medicine's supply in Australia;
- the sponsor's advice as to the reasons for an anticipated or current shortage, for instance, a product recall, a manufacturing site problem, an unexpected increase in demand (for instance, because of the shortage of another medicine) or commercial reasons;
- the estimated date that an anticipated shortage might affect normal consumer demand in Australia and the date a current shortage is likely to be resolved, that is when supply is likely to meet normal consumer demand;
- information about the therapeutic classification of the medicine, inclusion of which in the database, will allow the application of the sort function to all medicines within the same therapeutic class that are experiencing a shortage or a discontinuation;
- information about substitute medicines (that is, medicines with the same active ingredient as the medicine the subject of the shortage, but which may have a different strength, dosage form or route of administration) and their supply arrangements and use;
- information about possible therapeutic alternatives (that is, other therapeutic options a health professional may consider as alternative treatments for a patient that may be affected by a shortage, and may involve options other than the use of medicines - for example, the use of radiotherapy for tumour reduction, or the use of neuromodulating medical devices for pain management) and their supply arrangements and use.

This information will principally be provided by the sponsor of the medicine. However, there may be other sources such as the TGA itself, the Commonwealth Chief Medical Officer or other public health officials. This information may include, for example, information about whether a medicine may only be available in limited care settings or circumstances (for instance, in hospitals).

The TGA will not be providing clinical advice to health professionals on substitute medicines or possible therapeutic alternatives to a medicine in relation to which there is a shortage. Rather, the TGA will in appropriate cases provide information as to where, for instance, health professionals can obtain further assistance or information (e.g. through

links to expert medical colleges and clinical advisory groups, the National Prescriber Service or sponsor's websites).

The purpose of the Specification is to provide a legal basis under the Act to support release to the public of therapeutic goods information via the searchable webpage on the TGA's website.

Subsection 61(5D) of the Act empowers the Minister to, by legislative instrument, specify kinds of therapeutic goods information that may be released to the public 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 kinds of information that the Secretary will be able to release in this manner are listed in Schedule 1 to the Specification.

CONSULTATION

The TGA, in partnership with Medicines Australia and GMiA, commenced work on the Initiative in October 2013, with the goal of improving the communication and thus the management of medicine shortages in Australia. This work reflects that of other countries, with the USA, Canada, the UK and European therapeutic goods regulators having launched similar initiatives during 2013.

The focus has been on drafting a Protocol for Australian sponsors and the TGA in relation to the operation of the Initiative, developing an electronic form to be completed by sponsors to use to notify the TGA of a shortage, and creating a searchable webpage for the public to access medicines shortages information.

The partnership established an Industry Working Group (the IWG) which, on 7 March 2014, released its work on the Initiative to that date for feedback from a broader range of stakeholders (inviting responses in the form of surveys, submissions or other comments about the Initiative and its proposed operation).

These stakeholders included 169 prescription medicines sponsors, 16 representatives of health professional and consumer organisations, and representatives of state and territory health departments.

A number of submissions and surveys were received in response, including 54 surveys and 14 submissions from sponsors, and a total of 325 feedback comments.

The feedback of sponsors included comments that:

- the Initiative was a sensible and constructive proposal and industry was supportive of the proposed risk based approach;
- the information requested for notifications appeared to be the standard type of information routinely provided to the TGA by sponsors by email and phone.

Approximately 80% of the sponsors indicated that they believed the Protocol would clearly support active and early notification, and 90% indicated that they believed it would assist in how medicine shortages are managed. Approximately 65% of them were satisfied with the proposed medicine shortages website overall.

The feedback of health professionals, state and territory departments and consumer groups included comments that the Initiative was an important first step in providing consolidated information about medicines shortages.

Approximately 85% of these respondents believed the Initiative would become a trusted source of information about medicine shortages in Australia, and approximately 90% expected to use the medicines shortage information available as a result of the Initiative to inform their decisions.

This feedback was reviewed and a summary of key outcomes prepared by the IWG. This feedback has also informed the detailed planning in readiness for implementation of the Initiative.

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 below.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

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

Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014

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 Legislative Instrument

The Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014 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 to release to the public specified kinds of information relating to prescription medicine shortages that is held by the Therapeutic Goods Administration under subsection 61(5C) of that Act.

The information authorised to be released by the Secretary includes, for example, information about whether a shortage of a prescription medicine is anticipated or current or whether a prescription medicine has been or is to be discontinued in the Australian market, the sponsor's advice as to the reasons for the shortage (in terms of whether, for instance, this is due to a product recall, manufacturing site problem, an unexpected increase in demand or commercial reasons), information about the medicine involved (e.g. its name, dosage form, strength and pack size, and the name of the sponsor of the

medicine). Other relevant information may also be published, including for example information about possible substitute medicines (these are medicines with the same active ingredient, but which may have different strengths, dosage forms or routes of administration) and about possible therapeutic alternatives (these are therapeutic options that a health professional may consider as an alternative treatment for a patient who may be affected by the shortage).

Human rights implications

As this instrument does not set out any measures other than providing the legal authority for the release of certain kinds of information relating to medicine shortages as outlined above, the instrument is not considered to 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.

Professor John Skerritt, delegate of the Minister for Health