EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information Specification 2017

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods that are used in Australia 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 and 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 Specification 2017* (the Specification) is made by a delegate of the Minister under subsection 61(5D) of the Act and specifies kinds of therapeutic goods information that may be released to the public by the Secretary 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 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 repeals the previous *Therapeutic Goods Information Specification 2015* (the 2015 Specification). The purpose of the Specification is to update the references in the 2015 Specification to the names of certain expert committees established under the *Therapeutic Goods Regulations 1990* (the Regulations), as these have recently changed following the introduction of a new, revised advisory Committee structure on 1 January 2017. This will ensure that the appropriate release of relevant information under the Specification may continue.

The Specification commenced on the day after it was registered on the Federal Register of Legislation.

BACKGROUND

Amendments to section 61 of the Act made in 2009, including the introduction of subsections 61(5C) and (5D), facilitated a more extensive release of therapeutic goods information by the Secretary. These amendments supported the making of the previous *Therapeutic Goods Information Specification 2009* (the 2009 Specification) which allowed the Secretary to release to the public a range of information, primarily relating to registered therapeutic goods.

The 2009 Specification and the 2015 Specification supported the publication on the TGA website of product information and consumer medicines information in relation to registered medicines. . Those Specifications also supported the publication (via the TGA website) of Australian Public Assessment Reports (AusPAR). AusPARs provide information about the

evaluation of medicines for which registration on the Australian Register of Therapeutic Goods (the Register) has been sought and include (where relevant) information such as the considerations that led to the TGA to approve, or not approve, the registration of the medicine. Currently published AusPARs can be found at http://tga.gov.au/browse-auspars-active-ingredient.

The purpose of the Specification is to replace the 2015 Specification, to reflect changes that have been made recently to TGA expert advisory Committees established under the *Therapeutic Goods Regulations 1990* (the Regulations) – these changes took effect on 1 January 2017. In particular, as the roles of the previous Advisory Committee on Prescription Medicines (ACPM) and the Advisory Committee on the Safety of Medicine (ACSOM) are now undertaken by the Advisory Committee on Medicines (ACM), and the role of the Advisory Committee on the Safety of Vaccines (ACSOV) is now undertaken by the broader Advisory Committee on Vaccines, appropriate updates are now needed to the references to the replaced committees in the Specification. Otherwise, the same matters are covered in the Specification as were covered in the 2015 Specification.

The kinds of therapeutic goods information that the Specification will continue to permit the Secretary to release to the public include the following:

- product information approved by the Secretary under subsection 25AA(1) or 25AA(4) of the Act in relation to a medicine and information required by the Regulations to be supplied with certain therapeutic goods (Consumer Medicine Information);
- information in documents prepared for the purpose of evaluating therapeutic goods under subsection 25(1) or subsection 9D(3) of the Act;
- information in relation to post-market pharmacovigilance requirements imposed as a condition on registration under the Act in relation to therapeutic goods, or by a regulation made for the purposes of paragraph 28(5)(e) of the Act;
- information in documents relating to assessments made as part of evaluation of the pharmacovigilance system, quality and non-clinical and clinical data of therapeutic goods under section 25 of the Act;
- information in documents included in a request of the Secretary for advice from the Advisory Committee on Medicines or its sub-committees , or the Advisory Committee on Vaccines, seeking advice in relation to the evaluation of a medicine under section 25 of the Act or for the purposes of subsection 9D(3) of the Act, including in relation to post-market pharmacovigilance requirements;
- information in the minutes or outcomes of those committees or subcommittees, about those matters, or of any other expert committee established by the Regulations about the suitability for registration or inclusion of therapeutic goods in the Register; and
- information in decisions of the Secretary under section 25 of the Act in relation to the registration of therapeutic goods, including the reasons for the decision.

The Specification also includes a reference to information in any written decision under section 60 of the Act on a review of a decision under subsection 25(3), subsection 9D(3) or subsection 25AA(1) or (4) of the Act. This will ensure that the Secretary can include information in an AusPAR about any decision under section 60 of the Act reviewing a decision about the registration of therapeutic goods, the variation of an entry in the Register in relation to registered therapeutic goods or a decision to approve product information in relation to registered goods.

The kinds of therapeutic goods information that the Secretary will be able to release to the public under the Specification are set out at Schedule 1 to the Specification.

CONSULTATION

The nature of the Specification is such that consultation was not considered to be necessary as the Specification is of a minor nature and does not substantially alter existing arrangements, as the only changes it introduces are to update the names of relevant advisory committees.
The Specification is a legislative instrument for the purposes of the *Legislation Act 2003*.

Statement of Compatibility with Human Rights for a legislative instrument that does not raise any human rights issues

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

Therapeutic Goods Information Specification 2017

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 Legislative Instrument

The *Therapeutic Goods Information Specification 2017* is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* (the Act) by a delegate of the Minister for Health. It replaces the *Therapeutic Goods Information Specification 2015* (the 2015 Specification) and updates references to certain statutory committees established under the *Therapeutic Goods Regulations 1990*, consistent with the new expert advisory Committee structure that was introduced on 1 January 2017 by the *Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016*. Otherwise, the same matters are covered in the Specification as were covered in the 2015 Specification.

It will permit the Secretary of the Department of Health to continue to release to the public under subsection 61(5C) of the Act therapeutic goods information held by the Therapeutic Goods Administration (TGA) in the form of Product Information, Consumer Medicine Information and Australian Public Assessment Reports (AusPAR) for prescription medicines, all currently published on the TGA's website (www.tga.gov.au).

Human rights implications

As this instrument does not include any measures other than providing for the release to the public of information outlined above, it 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.

Larry Kelly, delegate of the Minister for Health