

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017*

The *Therapeutic Goods Act 1989* (“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, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“TGA”) within the Australian Government Department of Health (“Department”).

Section 61 of the Act relevantly provides that the Secretary may release specified therapeutic goods information to the public and certain organisations, bodies or authorities, including the World Health Organisation, authorities of the Commonwealth, States or Territories, and national regulatory authorities of other countries with national responsibility for therapeutic goods.

For the purposes of that section, subsection 61(1) of the Act relevantly provides that therapeutic goods information means information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department’s functions.

Importantly, subsection 61(5C) provides that the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C).

The *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017* (“Specification”) is made under subsection 61(5D) of the Act to specify kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act.

The Specification will facilitate the publication of certain information relating to approvals granted by the Secretary under section 19A of the Act. Section 19A provides that the Secretary may grant an approval to import and supply specified therapeutic goods that are not included in the Australian Register of Therapeutic Goods (“Register”) when a registered medicine that may act as a substitute for the specified therapeutic goods is unavailable or in short supply, and when the availability of those goods is considered necessary in the interests of public health. Section 19A also provides that the Secretary may grant an approval to import and supply specified therapeutic goods that are in the process of being evaluated for inclusion in the Register when there are no other medicines included in the Register that may act as a substitute for the specified therapeutic goods, and availability of those goods is considered necessary in the interests of public health.

The Specification is intended to increase knowledge of approvals granted by the Secretary under section 19A of the Act for the benefit of consumers, patients, health professionals and industry. The publication of information specified in this instrument will be made available on a database on the Therapeutic Goods Administration website. The publication of this information will supplement the existing publication of information under the *Therapeutic Goods (Medicine Shortages Information Initiative) Specification 2014*. That information is voluntarily provided by industry to inform consumers and health care professionals about the unavailability or short supply of medicines. The publication of information specified in this instrument will not change the nature or extent of that publication. Rather, it will work together to ensure that consumers, patients and health practitioners, in particular, have immediate access to information identifying appropriate substitute medicines that may be lawfully supplied to patients to address the shortage or unavailability of registered medicines.

The database will primarily include information that is material to approvals under section 19A of the Act, such as information to adequately identify the medicines that may be supplied by health

professionals in substitution for, or in the absence of any, registered medicines of a similar nature. The database will not include information on applications under section 19A that have not been granted by the Secretary.

The information specified in this instrument will be published progressively on the database to reflect approvals granted under section 19A of the Act as contemporaneously as possible.

## **Background**

The Australian Government Department of Health is committed to ensuring that medicines, particularly those of critical importance, remain readily available to the public. In the event of any shortage or unavailability of a medicine included on the Register, section 19A of the Act enables the Secretary to receive and grant applications to import and supply substitute medicines.

The publication of information pursuant to this Specification will provide an important resource to consumers, patients and health professionals to identify appropriate substitute medicines that may be lawfully imported and supplied in Australia for the period of the approval under section 19A of the Act.

## **Consultation**

A regulation impact statement was not required in relation to the development of this Specification, as the matter of specifying kinds of therapeutic goods information under subsection 61(5D) of the Act is the subject of a standing exemption provided by the Office of Best Practice Regulation (OBPR ID 15070).

However, the Therapeutic Goods Administration conducted targeted consultation earlier this year with relevant stakeholders regarding its intention to publish information about approvals granted under section 19A of the Act on the Therapeutic Goods Administration website.

The stakeholders included all members of the pharmaceutical industry, who submitted applications to the Secretary under section 19A of the Act in recent years, and relevant peak industry and professional representative bodies, including the Australian Medical Association, the Royal Australian College of General Practitioners, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, Medicines Australia, the Generic and Biosimilar Medicines Association and the Consumers Health Forum. The measure was generally supported, and the submissions received assisted with the characterisation and clarification of the kinds of therapeutic goods information mentioned in this Specification.

The Therapeutic Goods Administration did not consider public consultation to be necessary in relation to the making of this Specification, given the significant benefit that the publication of this information specified in this Specification would provide consumers, patients and health professionals regarding the availability of therapeutic goods in Australia.

The feedback from the consultation, particularly the professional representative bodies, favoured the proposal to publish information relating to approvals under section 19A of the Act pursuant to this Specification. It is important to note that, as a result of this Specification, industry will not be required to provide any additional or different information to the Secretary beyond that which is required for the purposes of seeking approval under section 19A of the Act.

Details of the Specification are set out in [Attachment A](#).

The Specification is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in [Attachment B](#).

The Act specifies no conditions that need to be satisfied before the power to make this Specification may be exercised.

The Specification is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after registration on the Federal Register of Legislation.

**Details of the *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017***

**Section 1 – Name**

This section provides that the name of the Specification is the *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017*.

**Section 2 – Commencement**

This section provides that the Specification commences the day after it is registered on the Federal Register of Legislation.

**Section 3 – Authority**

This section provides that the legislative authority for making the Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* (“the Act”).

**Section 4 – Interpretation**

This section provides the interpretation of terms used in the Specification. Notably, the definition of active ingredient has the same meaning as given in the *Therapeutic Goods Regulations 1990*. Other terms used in the Specification are defined in the Act and therefore, as explained in the note, have the same meaning as given in the Act.

**Section 5 – Specified therapeutic goods information**

This section provides that the kinds of therapeutic goods information mentioned in Schedule 1 are specified under subsection 61(5D) for the purposes of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind mentioned in Schedule 1.

**Schedule 1 – Specified information**

This Schedule specifies the kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act. It includes information relating to the specified therapeutic goods approved under section 19A of the Act and information relating to the registered goods, which are unavailable or in short supply.

Specifically, Schedule 1 includes information that is specified in the relevant notice of approval under section 19A of the Act, such as the indications for which the specified therapeutic goods are approved for importation and supply, and the duration of the approval. It also includes information to assist consumers, patients and health professionals identify the specified therapeutic goods, which are the subject of the approval under section 19A of the Act, including images of the packaging and labelling in relation to those goods.

## Statement of compatibility with human rights

This statement is prepared in accordance with subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017*

The *Therapeutic Goods Information (Approvals relating to Medicine Shortages) Specification 2017* 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

This instrument is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to specify kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act.

The instrument will enable the publication of information relating to approvals granted by the Secretary under section 19A of the Act. The publication of this information is intended to increase knowledge and transparency of approvals granted by the Secretary under section 19A of the Act for the benefit of consumers, patients, health professionals and industry.

The specified information includes information that is material to approvals under section 19A of the Act, such as information to adequately identify the medicines that may be supplied by health professionals in substitution for, or in the absence of any, registered medicines of a similar nature. It includes the indications for which the specified therapeutic goods are approved for importation and supply, and the duration of the approval. It also includes information to assist consumers, patients and health professionals recognise the specified therapeutic goods, such as images of the packaging and labelling in relation to those goods.

In summary, the publication of information pursuant to this instrument will provide an important resource to consumers, patients and health professionals to positively identify appropriate substitute medicines that may be lawfully imported and supplied in Australia for the period of the approval under section 19A of the Act.

## Human rights implications

This instrument does not engage any of the applicable rights or freedoms.

## Conclusion

This instrument is compatible with human rights as it does not raise any human rights issues.

Larry Kelly, delegate of the Minister for Health