

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019*

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 Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health.

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.

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

Subsection 61(5C) relevantly 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) relevantly provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C).

The *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019* (“the Specification”) is made under subsection 61(5D) of the Act to specify kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The purpose of the Specification is to facilitate the publication of certain therapeutic goods information relating to complaints and investigations by the TGA in respect of the advertising of therapeutic goods and dissemination of generic information.

The Specification will repeal and replace the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018* (“the former Specification”), which commenced on 1 July 2018. The Specification specifies the same kinds of information that were included in the former Specification with minor changes to the instrument’s drafting, presentation and structure. The Specification clarifies that the following information is specified, consistent with the original policy intention:

- (a) the entirety of a complaint received by, or referred to, the TGA;
- (b) the notice or statement of reasons for a decision of the Secretary made under the Act or *Therapeutic Goods Regulations 1990* (“the Regulations”) in relation to the case;
- (c) the outcomes of a case, or subsequent related action or proceedings in relation to that case, including the findings that led to the outcomes, and a summary of, and reasons for, the outcomes.

The Specification also clarifies the definition of ‘complaint’ by including a complaint that was made to the Complaints Resolution Panel (“the Panel”) before that Panel was abolished, and led to a recommendation being made by the Panel to the Secretary under former regulation 42ZCAI of the Regulations.

The publication of therapeutic goods information specified in the instrument is intended to increase transparency of complaints and investigations conducted by the TGA in respect of advertising and the dissemination of generic information of therapeutic goods. It is also intended to promote consumer confidence in the regulation of therapeutic goods, and to encourage industry compliance with legislative requirements.

## **Background**

The advertising and dissemination of generic information in relation to therapeutic goods in Australia are subject to the requirements of the Act and Regulations, as well as other relevant laws, such as the *Competition and Consumer Act 2010*. The advertising and dissemination of generic information about therapeutic goods directed to consumers is also subject to the Therapeutic Goods Advertising Code (“the Code”) made under the Act.

The purpose of these requirements is to protect public health through the safe and proper use of therapeutic goods, and to ensure that therapeutic goods are accurately promoted as to their benefits, uses and effects.

The TGA has been solely responsible for dealing with complaints regarding the advertising and dissemination of generic information in relation to therapeutic goods since the abolition of the Complaints Resolution Panel and the Therapeutic Goods Advertising Code Council on 1 July 2018.

The publication of information relating to complaints received by the TGA, and investigations undertaken on its own initiative (where it reasonably suspects that an advertisement or dissemination of generic information contravenes the Act, the Regulations or the Code) serves the dual purpose of, first, open and transparent accountability for the actions that the TGA takes in relation to complaints and investigations and, second, guiding the behaviour of persons responsible for advertising and disseminating generic information in relation to therapeutic goods.

## **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 (OBPR ID 15070).

However, the TGA has previously undertaken detailed consultation with respect to the publication of information about advertising complaints in the context of the Review of Medicines and Medical Devices Regulation (“the Review”). During that process, the TGA consulted regarding the arrangements for handling complaints about advertising of therapeutic goods.

In response to the Review, the Government agreed that a single agency approach to complaints management had the potential to reduce complexity and encourage greater consistency in decision-making, benefiting consumers. The Government decided that the TGA would assume responsibility for handling all complaints about therapeutic goods advertisements directed to the public from 1 July 2018. A fact sheet included as part of the consultation announcement foreshadowed that the simplification of the advertising complaints mechanism would include improved transparency of complaint outcomes.

In addition, the TGA consulted the Therapeutic Goods Advertising Code Council prior to its abolition last year regarding the former Specification. As the Specification makes only minor clarifying and stylistic changes to the kinds of information previously specified under the former Specification, TGA considered that further consultation was not necessary in the making of this instrument.

Importantly, sponsors will not be required to provide any additional or different information to the TGA as a result of the Specification.

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 (Advertising Complaints and Investigations Information) Specification 2019***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019* (“the Specification”).

**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 – Definitions**

This section provides the definitions of certain terms used in the Specification. The section notes that a number of terms have the meaning given in section 3 of the Act, including ‘advertise’ and ‘Therapeutic Goods Advertising Code’. Other terms have been defined for the purposes of the Specification, including ‘case’, ‘complaint’ and ‘outcome’.

**Section 5 – Repeals**

This section provides that each instrument specified in Schedule 1 to the Specification is repealed. The purpose of this section is to repeal the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018*.

**Section 6 – Therapeutic goods information**

This section provides that the kinds of therapeutic goods information set out in column 2 of the table in Schedule 2 are specified for the purposes of subsection 61(5C) of the Act. The specified kinds of information are as described in column 3 of the corresponding item in the table. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in the table in Schedule 2.

**Schedule 1 – Repeals**

This Schedule repeals the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018*.

**Schedule 2 – Specified kinds of therapeutic goods 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.

## Statement of Compatibility with Human Rights

This statement is prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019*

This disallowable 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 (Advertising Complaints and Investigations Information) Specification 2019* (“the 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 facilitate the publication of certain therapeutic goods information relating to cases created by the Therapeutic Goods Administration (“the TGA”) in response to a complaint, or following a decision by the TGA to undertake an investigation on its own initiative, in relation to the advertising of therapeutic goods or the dissemination of generic information.

The kinds of therapeutic goods information that is specified include details of the relevant therapeutic goods, details of the complaint or reason for the investigation carried out by the TGA on its own initiative, and the outcomes of the case, including reasons for the outcome and any actions taken or decisions made in relation to the case.

The publication of therapeutic goods information specified in the instrument is intended to increase transparency of complaints and investigations conducted by the TGA in respect of advertising and the dissemination of generic information of therapeutic goods. It is also intended to promote consumer confidence in the regulation of therapeutic goods, and to encourage industry compliance with legislative requirements.

### Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“ICESCR”).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by helping to ensure the safe and proper use of therapeutic goods. The instrument seeks to protect and promote the health of all Australians by specifying therapeutic goods information in relation to complaints about, and investigations conducted by the TGA into, the advertising of therapeutic goods and dissemination of generic information that may contravene the Act, *Therapeutic Goods Regulations 1990* or Therapeutic Goods Advertising Code that may be released by the Secretary to the public.

Releasing such information to the public will assist to ensure that the benefits, uses and effects of therapeutic goods are accurately promoted. It will also act as a deterrent to behaviour that breaches requirements relating to advertising and disseminating generic information under the Act, Regulations and the Code.

### **Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

**Gillian Mitchell, delegate of the Minister for Health**