**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

**Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2015**

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 Organization 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 (Outcomes of Advertising Complaints Investigations) Specification 2015* (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**

The advertising of therapeutic goods to consumers and health professionals is controlled by a combination of statutory measures administered by the TGA, and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations.

Advertisements for therapeutic goods in Australia are subject to the requirements of the Act and the *Therapeutic Goods Regulations 1990* (the Regulations), as well as other relevant laws (such as the *Competition and Consumer Act 2010*). Advertisements for therapeutic goods directed to consumers must also comply with the *Therapeutic Goods Advertising Code 2015* (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 by ensuring that therapeutic goods are honestly promoted as to their benefits, uses and effects.

Complaints about advertisements directed to consumers in media such as newspapers, magazines, the Internet, radio and television are considered by the Complaints Resolution Panel (the Panel), a body established under the Regulations. If the Panel is satisfied that there has been a contravention of the Act or the Code in relation to an advertisement, they can request that the advertiser carry out certain actions. These include: withdrawing the advertisement or a particular claim or representation in it, publishing a retraction or correction, and seeking a written undertaking that a particular claim or representation will not be used in any other advertisement. These advertising complaint determinations are published on the Internet in the Panel’s complaints register (at [www.tgacrp.com.au](http://www.tgacrp.com.au)).

Where an advertiser does not fully comply with a request of the Panel within 14 days after the Panel’s request, or where an advertiser breaches an undertaking given, the Panel may recommend to the Secretary that the Secretary take a range of possible regulatory actions in relation to the advertisement including withdrawing approval for the advertisement, or suspending or cancelling the goods that are the subject of the advertisement from the Australian Register of Therapeutic Goods.

Upon receiving such a recommendation from the Panel, the TGA investigates the matter afresh, including liaising with the advertiser about the advertisement and consideration of whether an order under regulation 9 of the Regulations should be made.

The TGA currently publishes details where a decision has been made by the Secretary under regulation 9 of the Regulations, ordering an advertiser to take specific action to address breaches of the therapeutic goods advertising legislation (a Regulation 9 Order), on the recommendation of the Panel. This process will continue and is separate to publication under the Specification.

In practice, however, voluntary compliance by the advertiser with the Panel’s recommendations regarding the advertising complaint is often achieved in consultation with TGA during the investigation, without the need for a Regulation 9 Order.

The purpose of the Specification is to support the release to the public of therapeutic goods information about advertisement investigation outcomes in just such a circumstance – i.e. where, after the Panel has made recommendations to the Secretary and the TGA has started its own investigation and the advertiser has voluntarily complied with the Panel’s recommendations. The information will be made available on the TGA’s website.

The kinds of information that the Secretary will be able to release in this manner are listed in Schedule 1 to the Specification. These are the advertiser’s name, the name of the therapeutic goods involved and their Australian Register of Therapeutic Goods Register (ARTG) number (where relevant), the date the Panel’s recommendation relating to the advertisement was received and the date the TGA’s investigation into the complaint was finalised, as well as a summary of the complaint, a reference or link to the Panel’s determination of the complaint published in its complaint register and a summary of the outcome of TGA’s investigation into the advertisement, conducted after receipt of the Panel’s recommendation. The advertiser in almost all cases will be a registered business and/or corporation, and it is not intended to publish personal information in relation to advertisers as part of this initiative.

Publication of these outcomes is intended to improve the transparency of, and provide guidance to advertisers about, the TGA’s investigations into advertisements following recommendations from the Panel and where a Regulation 9 Order has not been necessary to achieve compliance.

**CONSULTATION**

The TGA has consulted with the Therapeutic Goods Advertising Code Council (the Council) about the Specification. The Council is a statutory body established under regulation 42A of the Regulations and is comprised of relevant stakeholders including the therapeutic goods industry, advertisers, health professionals and consumers. The Council was supportive of the approach taken in the instrument and no changes were recommended.

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 (Outcomes of Advertising Complaints Investigations) Specification 2015**

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 (Outcomes of Advertising Complaints Investigations) Specification 2015* 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, held by the Therapeutic Goods Administration (TGA) under subsection 61(5C) of that Act, relating to outcomes of TGA investigations into advertisements for therapeutic goods, following recommendations of the Complaints Resolution Panel (Panel) arising out of complaints about the advertisements.

The information authorised to be released by the Secretary includes the advertiser’s name, the name of the therapeutic goods involved and their ARTG number (where relevant), the date the Panel’s recommendation relating to the advertisement was received and the date the TGA’s investigation into the complaint was finalised, as well as a summary of the complaint, a reference or link to the Panel’s determination of the complaint published in its complaint register and a summary of the outcome of TGA’s investigation into the advertisement, conducted after receipt of the Panel’s recommendation.

**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.

**Lawrence Kelly, delegate of the Minister for Health**