Australian Government

Department of Health
Therapeutic Goods Administration

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

*Therapeutic Goods Act 1989*

I, Lawrence Kelly, a delegate of the Minister for Health, make this Specification under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

Dated this 26th day of November 2015

(Signed by)

Lawrence Kelly
Delegate of the Minister for Health

## 1 Name of Specification

This Specification is the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2015*.

## 2 Commencement

This Specification commences on the day after it is registered.

## 3 Interpretation

In this Specification:

***Act*** means the *Therapeutic Goods Act 1989*.

***advertiser,*** in relation to an advertisement, has the same meaning as "person apparently responsible" as in regulation 42ZCAA of the Regulations.

***ARTG*** means the Australian Register of Therapeutic Goods.

***complaint*** has the same meaning as in regulation 42ZCAA of the Regulations.

***complaint register*** means a register of complaints and related information published by the Complaints Resolution Panel on the Internet, under regulation 42ZCAL of the Regulations.

***Panel*** means the committee, known as the Complaints Resolution Panel, established under regulation 42R of the Regulations.

***recommendation*** means a recommendation of the Panel made under regulation 42ZCAI of the Regulations about an advertisement.

***Regulations*** means the Therapeutic Goods Regulations 1990.

***TGA*** means the Therapeutic Goods Administration, which is part of the Department of Health.

## 4 Therapeutic goods information

The kinds of therapeutic goods information mentioned in Schedule 1 are specified for the purposes of subsection 61(5D) of the Act.

# Schedule 1 Specified kinds of therapeutic goods information

(section 4)

The following kinds of therapeutic goods information:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

**Kinds of therapeutic goods information relating to outcomes of TGA investigations into advertisements for therapeutic goods, following recommendations from the Panel arising out of a complaint about that advertisement**

| Item | Information | Description |
|---|---|---|
| (a) | Advertiser name | The name of the advertiser in relation to the advertisement that is the subject of the complaint and the recommendation to the Secretary (the advertisement). |
| (b) | Name of therapeutic goods | The name of the therapeutic goods that are the subject of the advertisement. |
| (c) | ARTG number | The ARTG number of the therapeutic goods. |
| (d) | Date recommendation received | The date the Panel's recommendation relating to the advertisement was received by the Secretary. |
| (e) | Date investigation finalised | The date that the TGA's investigation into the advertisement, following the recommendation from the Panel, was finalised. |
| (f) | Complaint summary | A summary of the complaint relating to the advertisement. |
| (g) | Panel's determination | A reference, or link, to the Panel's determination relating to the complaint, containing details of the complaint as published in the complaint register. |
| (h) | Investigation outcome summary | A summary of the outcome of the TGA's investigation into the advertisement, conducted after receipt of the Panel's recommendation – this may also include a summary of any action taken by the advertiser in relation to the advertisement. |

## Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au