

Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2018

*Therapeutic Goods Act 1989*

I, Larry Kelly, a delegate of the Minister for Health, repeal the *Therapeutic Goods Information (Outcomes of Advertising Complaints Investigations) Specification 2015*, and make this Specification under subsection 61(5D) of the *Therapeutic Goods Act 1989*.

Dated this 27th day of June 2018

(Signed by)

Larry Kelly

Delegate of the Minister for Health

1 Name of Specification

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

2 Commencement

This Specification commences on 1 July 2018.

3 Definitions

Note 1: A number of expressions used in this Specification are defined in subsection 3(1) of the Act, including the following:

1. advertise;
2. Register;
3. therapeutic goods
4. Therapeutic Goods Advertising Code

In this Specification:

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

***advertiser*** means the person who advertises, by any means, therapeutic goods or causes the advertising, by any means, of therapeutic goods.

***complaint*** means a complaint:

1. made by a person to the TGA; or
2. made by a person to the Complaints Resolution Panel and that has been referred to the TGA; or
3. initiated by the TGA

alleging an advertisement or the dissemination of generic information contravenes the Act, Regulations or Therapeutic Goods Advertising Code.

***Complaints Resolution Panel*** means the committee previously established under section 42R of the Regulations and abolished by the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*.

***disseminator***means the person who disseminates, by any means, generic information about therapeutic goods to the public or a section of the public.

***generic information***has the same meaning as in section 42B of the Act.

***investigation***means a TGA investigation in response to a complaint.

***investigation outcome*** means the outcome of an investigation, including but not limited to:

1. a finding that there is no contravention, or insufficient evidence to support any finding of a contravention of, the Act, Regulations or Therapeutic Goods Advertising Code.
2. steps taken by a responsible entity in relation to a complaint to resolve it;
3. a decision or action taken by the Secretary under the Act or Regulations in relation to a complaint;
4. a decision of a Court that a person has committed an offence under Part 5-1 of the Act in relation to an advertisement or the dissemination of generic information;
5. a decision of a Court that a person has contravened a civil penalty provision under Part 5-1 of the Act in relation to an advertisement or the dissemination of generic information; and
6. a decision of a Court ordering an injunction under Part 5A-4 of the Act in response to an application by the Secretary in relation to an advertisement or the dissemination of generic informaton.

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

***responsible entity*** means the advertiser or the disseminator.

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

Note 2: The TGA is required to publish certain decisions or actions under Part 5-1 and Part 5A-3 of the Act.

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 3: 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 a complaint and the investigation outcome**

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| **Item** | **Information** | **Description** |
| (a) | Responsible entity | The name of the advertiser in relation to the advertisement, or the name of the disseminator in relation to the generic information, which is the subject of the complaint. |
| (b) | Therapeutic goods | The name of the therapeutic goods that are the subject of the complaint and any other information necessary to identify the therapeutic goods. |
| (c) | Register number | The Register number of the therapeutic goods the subject of the advertisement. |
| (d) | Complaint date | The date the complaint was received by the TGA. |
| (e) | Date investigation finalised | The date that the TGA’s investigation was finalised. |
| (f) | Complaint identifier | The unique identifier allocated to a complaint by the TGA identifying that complaint. |
| (g) | Complaint summary | A summary of the complaint relating to the advertisement or generic information, including how and where any therapeutic goods were advertised or how and where any generic information was disseminated, and of any alleged contravention of the Act, Regulations or Therapeutic Goods Advertising Code. |
| (h) | Investigation outcome summary | A summary of the outcome following the investigation. |
| (i) | Decision or action of the Secretary under the Act | A summary, reference, or link, to a decision or action taken by the Secretary under the Act in relation to a complaint that is required to be published under the Act. |
| (j) | Court decision | A reference, or link, to a Court decision in relation to a complaint. |