



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

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I, Gillian Mitchell, as delegate of the Minister for Health, make the following specification.

Dated 18 January 2019

Gillian Mitchell  
First Assistant Secretary  
Regulatory Practice and Support Division  
Health Products Regulation Group  
Department of Health



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## 1 Name

This instrument is the *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

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

## 4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) advertise;
- (b) device number;
- (c) listing number;
- (d) Register;
- (e) registration number;
- (f) Secretary;
- (g) therapeutic goods; and
- (h) Therapeutic Goods Advertising Code.

In this instrument:

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

*case* means a case created by the Therapeutic Goods Administration:

- (a) in response to a complaint; or
- (b) following a decision of the Therapeutic Goods Administration to undertake an investigation on its own initiative, where it reasonably

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

**case number** means any combination of numbers, symbols and letters assigned by the Therapeutic Goods Administration to a case.

**complaint** means a complaint alleging that an advertisement or the dissemination of generic information contravenes the Act, Regulations or Therapeutic Goods Advertising Code, which was:

- (a) made by a person to the Therapeutic Goods Administration; or
- (b) made by a person to the Complaints Resolution Panel and led to a recommendation being made by the Complaints Resolution Panel to the Secretary under regulation 42ZCAI of the old Regulations; or
- (c) referred to the Therapeutic Goods Administration by a body or an authority.

**Complaints Resolution Panel** has the same meaning as in the old Regulations.

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

**old Regulations** means the *Therapeutic Goods Regulations 1990* as in force immediately before the commencement of Part 3 of Schedule 4 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018*.

Note: Part 3 of Schedule 4 to the *Therapeutic Goods Legislation Amendment (2018 Measures No. 1) Regulations 2018* commenced on 1 July 2018.

**outcome** means the outcome of a case, or subsequent related action or proceedings in relation to that case, including:

- (a) a finding that there is no contravention of the Act, Regulations or Therapeutic Goods Advertising Code;
- (b) action taken by a responsible person in relation to the advertisement or dissemination of generic information;
- (c) action taken or a decision made by the Secretary in relation to the advertisement or dissemination of generic information;
- (d) a decision of a Court that a person has committed an offence, or contravened a civil penalty provision, under Part 5-1 of the Act in relation to the advertisement or the dissemination of generic information; and
- (e) 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 the advertisement or the dissemination of generic information.

**reference number** means any combination of numbers, symbols and letters assigned by the Therapeutic Goods Administration to a complaint or an investigation of the Therapeutic Goods Administration on its own initiative.

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

**responsible person** means the person who appears to be responsible for:

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- (a) advertising, by any means, therapeutic goods or causing the advertising, by any means, of therapeutic goods; or
  - (b) disseminating, by any means, generic information about therapeutic goods to the public or a section of the public.

*Therapeutic Goods Administration* has the same meaning as in the Regulations.

## **5 Repeals**

Each instrument that is specified in Schedule 1 to this instrument is repealed as set out in the applicable items in that Schedule.

## **6 Therapeutic goods information**

The kinds of therapeutic goods information set out in column 2 of the table in Schedule 2, as described in column 3 of the corresponding item, are specified for the purpose of subsection 61(5C) of the Act.

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

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## **Schedule 1—Repeals**

Note: See section 5.

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

#### **1 The whole of the instrument**

Repeal the instrument.



## Schedule 2—Specified kinds of therapeutic goods information

Note: See section 6.

Kinds of therapeutic goods information		
Column 1 Item	Column 2 Information	Column 3 Description
1	responsible person	the name of the responsible person in relation to the advertisement or dissemination of generic information that is the subject of the case
2	therapeutic goods	the name of the therapeutic goods relating to the advertisement or dissemination of generic information that is the subject of the case (the <i>relevant goods</i> ) and any other information necessary to identify the relevant goods
3	Register number	the device number, listing number or registration number of the relevant goods
4	reference number	the relevant reference number
5	case number	the relevant case number
6	risk category	the level of risk assigned to the relevant case by the Therapeutic Goods Administration
7	case details	<p>the details of the case, including:</p> <ul style="list-style-type: none"> <li>(a) the alleged breach of the Act, Regulations or Therapeutic Goods Advertising Code;</li> <li>(b) the circumstances in which the relevant goods were advertised or the generic information was disseminated, such as means and location;</li> <li>(c) the complaint, or a summary of the complaint, or reason for the investigation commenced by the Therapeutic Goods Administration on its own initiative, relating to the advertisement or dissemination of generic information; and</li> <li>(d) where the complaint led to a recommendation being made to the Secretary under regulation 42ZCAI of the old Regulations: <ul style="list-style-type: none"> <li>(i) a summary of, and website link to, the Complaints Resolution Panel's determination and recommendation; and</li> <li>(ii) any identifying number assigned to the complaint by the Complaints Resolution Panel</li> </ul> </li> </ul>
8	outcomes including actions and decisions	<p>the outcomes of the case, including:</p> <ul style="list-style-type: none"> <li>(a) the findings that led to the outcomes and a summary of, and reasons for, the outcomes;</li> <li>(b) actions taken and decisions made in relation to the case, including a summary of a decision made by</li> </ul>

Column 1 Item	Column 2 Information	Column 3 Description
		<p>the Secretary under the Act or Regulations, and any notice or statement of reasons given for that decision; and</p> <p>(c) a reference or website link to an Administrative Appeals Tribunal decision or Court decision in relation to an advertisement or dissemination of generic information that was the subject of the case</p>
9	relevant dates	<p>dates relating to the case, including:</p> <p>(a) the date that the complaint was received by the Therapeutic Goods Administration;</p> <p>(b) the date that the recommendation under regulation 42ZCAI of the old Regulations was made by the Complaints Resolution Panel to the Secretary;</p> <p>(c) the date that the investigation was commenced by the Therapeutic Goods Administration on its own initiative;</p> <p>(d) the date or dates of the alleged breach of the Act, Regulations or Therapeutic Goods Advertising Code;</p> <p>(e) the dates of the outcomes, including the dates that actions were taken and decisions were made in relation to the case; and</p> <p>(f) the date that the case was finalised by the Therapeutic Goods Administration</p>