

Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019

made under subsection 61(5D) of the

Therapeutic Goods Act 1989

Compilation No. 1

**Compilation date:** 28 September 2024

**Includes amendments:** F2024L01229

**About this compilation**

**This compilation**

This is a compilation of the *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019* that shows the text of the law as amended and in force on 28 September 2024 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

**Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

**Self‑repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name

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

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:

1. advertise;
2. device number;
3. listing number;
4. Register;
5. 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 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:

(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.

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).

Schedule 2—Specified kinds of therapeutic goods information

Note: See section 6.

| **Kinds of therapeutic goods information** |  |
| --- | --- |

| Column 1Item  | Column 2Information | Column 3Description |
| --- | --- | --- |
| 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 ***relevant goods)*** 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 | the details of the case, including:(a) the alleged breach of the Act, Regulations or Therapeutic Goods Advertising Code;(b) the circumstances in which the relevant goods were advertised or the generic information was disseminated, such as means and location;(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(d) where the complaint led to a recommendation being made to the Secretary under regulation 42ZCAI of the old Regulations:(i) a summary of, and website link to, the Complaints Resolution Panel’s determination and recommendation; and(ii) any identifying number assigned to the complaint by the Complaints Resolution Panel |
| 8 | outcomes including actions and decisions | the outcomes of the case, including:(a) the findings that led to the outcomes and a summary of, and reasons for, the outcomes; (b) actions taken and decisions made in relation to the case, including a summary of a decision made by the Secretary under the Act or Regulations, and any notice or statement of reasons given for that decision; and(c) a reference or website link to a decision of a court or tribunal in relation to an advertisement or dissemination of generic information that was the subject of the case |
| 9 | relevant dates | dates relating to the case, including:(a) the date that the complaint was received by the Therapeutic Goods Administration;(b) the date that the recommendation under regulation 42ZCAI of the old Regulations was made by the Complaints Resolution Panel to the Secretary;(c) the date that the investigation was commenced by the Therapeutic Goods Administration on its own initiative;(d) the date or dates of the alleged breach of the Act, Regulations or Therapeutic Goods Advertising Code;(e) the dates of the outcomes, including the dates that actions were taken and decisions were made in relation to the case; and(f) the date that the case was finalised by the Therapeutic Goods Administration |

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

**Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| ad = added or inserted | orig = original |
| am = amended | par = paragraph(s)/subparagraph(s) |
| amdt = amendment | /sub‑subparagraph(s) |
| c = clause(s) | pres = present |
| C[x] = Compilation No. x | prev = previous |
| Ch = Chapter(s) | (prev…) = previously |
| def = definition(s) | Pt = Part(s) |
| Dict = Dictionary | r = regulation(s)/rule(s) |
| disallowed = disallowed by Parliament | reloc = relocated |
| Div = Division(s) | renum = renumbered |
| exp = expires/expired or ceases/ceased to have | rep = repealed |
| effect | rs = repealed and substituted |
| F = Federal Register of Legislation | s = section(s)/subsection(s) |
| gaz = gazette | Sch = Schedule(s) |
| LA = *Legislation Act 2003* | Sdiv = Subdivision(s) |
| LIA = *Legislative Instruments Act 2003* | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment | SR = Statutory Rules |
| cannot be given effect | Sub‑Ch = Sub‑Chapter(s) |
| mod = modified/modification | SubPt = Subpart(s) |
| No. = Number(s) | underlining = whole or part not |
| o = order(s) | commenced or to be commenced |
| Ord = Ordinance |  |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| *Therapeutic Goods (Advertising Complaints and Investigations Information) Specification 2019* | 21 Jan 2019 (F2019L00050) | 22 Jan 2019 | — |
| *Therapeutic Goods (Advertising Complaints and Investigations Information) Amendment Instrument 2024* | 27 Sept 2024 (F2024L01229) | 28 Sept 2024 | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| s 2  | rep LA s 48D |
| s 5  | rep LA s 48C |
| Schedule 1  | rep LA s 48C |
| Schedule 2  | am F2024L01229 |