Therapeutic Goods Advertising Code (No.2) 2018

made under subsection 42BAA(1) of the

Therapeutic Goods Act 1989

Compilation No. 4

Compilation date: 28 July 2021

Includes amendments up to: F2021L01034

Prepared by the Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods Advertising Code (No.2) 2018* that shows the text of the law as amended and in force on 28 July 2021 (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 Legislation 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 series page on the Legislation 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 series page on the Legislation 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary

1 Name

This instrument is the *Therapeutic Goods Advertising Code (No.2) 2018*.

3 Authority

This instrument is made under subsection 42BAA(1) of the *Therapeutic Goods Act 1989*.

4 Definitions

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

(a) advertise;
(b) current Poisons Standard;
(c) directions for use;
(d) health practitioner;
(e) included in the Register;
(f) indications;
(g) Register;

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredients has the same meaning as in the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*.

advertiser means a person who:
(a) advertises, by any means, therapeutic goods; or
(b) causes the advertising, by any means, of therapeutic goods.

analgesic means a medicine for internal use, containing one or more of the following substances intended for the relief of aches and pains:
(a) salicylic acid, its salts, its derivatives (including aspirin) and their salts;
(b) other non-steroidal anti-inflammatory drugs;
(c) paracetamol;

not including such a medicine where:
(d) the condition for which it is designed is a self-limiting condition; and
(e) the substances mentioned in paragraphs (a)-(c) are combined with one or more other active ingredients; and
(f) the other ingredients have been included in the medicine for indications other than the relief of aches and pains.

approval number has the same meaning as in section 42B of the Act.

approved advertisement has the same meaning as in section 42B of the Act.

bench-mark price brand, in relation to a multi branded medicine, means the lowest priced product within the group of medicines that are listed on the Pharmaceutical Benefits Scheme as brands of the same medicine.

child means an individual under the age of 18.

complementary medicine has the same meaning as in the Regulations.

dispensing doctor means a medical practitioner approved under section 92 of the *National Health Act 1953*.

health professional means a person mentioned in section 42AA of the Act.

health warning means:

(a) in relation to a medicine that contains an ingredient mentioned in column 1 of an item in a table in Schedule 1, in the circumstances set out in column 2 of that item—the statement mentioned in column 3 of that item;

(b) in relation to a medical device or other therapeutic goods—a statement that is required under the Act, Regulations or Medical Devices Regulations to be included on the label, or in the instructions for use, of the device or goods, and is to the effect that:

  (i) a person who takes, or uses, the device or goods as intended may:
    (A) die; or
    (B) require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken, or used, the device or goods; or
    (C) require a medical practitioner to treat or prevent an injury, disability, incapacity, or impairment (the latter in relation to a bodily function, organ or structure), as a consequence of taking, or using, the device or goods; or

  (ii) the device or goods should not be taken, or used, in certain circumstances, which are described by reference to one or more of the following:
    (A) a serious form, within the meaning of subsection 28(1), of a disease, condition, ailment or defect;
    (B) an implantable device;
    (C) a specific class of persons;
    (D) pregnancy.

Note: A statement referred to in subparagraph (b)(ii) may be in the form of "DO NOT USE IF" followed by a reference to one of the matters mentioned in sub-subparagraphs (b)(ii)(A) to (D).

immediate family has the same meaning as in the Regulations.

ingredients means:

(a) active ingredients; and

(b) substances or groups of substances that are required to be on the label of the medicine under paragraph 8(1)(j) of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

other therapeutic goods means therapeutic goods that are not medicines, biologicals or medical devices.

patient information leaflet has the same meaning as in clause 13A.3 of Schedule 4 to the Medical Devices Regulations.

price information, in relation to prescription medicines and pharmacist-only medicines, means information about:

(a) the total purchase price of medicines that is to be paid by consumers of those medicines; and
(b) for medicines that are listed on the Pharmaceutical Benefits Scheme (or Repatriation Pharmaceutical Benefits Scheme), the price paid by the consumer when the prescription is dispensed.

prominently displayed or communicated, in relation to a statement in an advertisement, means:

(a) either:
    (i) for a visual statement—standing out so as to be easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
    (ii) for a spoken statement—able to be clearly heard and understood; and
(b) repeated as often as is necessary to ensure that it is likely to be noticeable for a viewer or listener.

public health campaign means a campaign about a public health matter that is conducted, approved or funded by:

(a) the Commonwealth; or
(b) a State or Territory; or
(c) a Commonwealth, State or Territory statutory authority.

Regulations means the *Therapeutic Goods Regulations 1990*.

specified media has the same meaning as in section 42B of the Act.

total purchase price, in relation to therapeutic goods, means the total cost of the goods to a consumer, including:

(a) the administration, handling and infrastructure fee, any mark-up payable to the pharmacist, dispensing fee, additional fee or allowable extra fee if applied by the pharmacist; and
(b) in relation to Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme prescriptions—any premium (such as a brand or therapeutic group premium or special patient contribution) that must be paid by the consumer.

unscheduled, in relation to a good, means not consisting of, or containing, a substance included in a schedule to the current Poisons Standard.

5 Object

The Object of this instrument is to ensure that the advertising of therapeutic goods to consumers is conducted in a manner that:

(a) promotes the safe and proper use of therapeutic goods by minimising their misuse, overuse or underuse; and
(b) is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance; and
(c) supports informed health care choices; and
(d) is not inconsistent with current public health campaigns.

6 Application

(1) Subject to subsection (2), this instrument applies to the advertising of therapeutic goods.

Note: In subsection 3(1) of the Act, ***advertise*** is defined as follows:

advertise, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:
(a) is on the label of the goods; or
(b) is on the package in which the goods are contained; or
(c) is on any material included with the package in which the goods are contained.

(2) This instrument does not apply to an advertisement that:
(a) is directed exclusively to health professionals; or
(b) is part of, or otherwise comprises, a public health campaign; or
(c) is made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021* made under section 42DK of the Act, as in force or existing on 28 July 2021.

Note: The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission (No. 3) 2021* is published at www.tga.gov.au.

(3) This instrument applies, in relation to a particular advertisement, by reference to its likely impact on a reasonable person to whom the advertisement is directed.

(4) In applying this instrument to an advertisement, the total presentation and context of the advertisement is to be taken into account.

(5) This instrument applies to any person who:
(a) advertises, by any means, therapeutic goods; or
(b) causes the advertising, by any means, of therapeutic goods.

(6) However, this instrument does not apply to genuine news that is broadcast or published in any medium by a person mentioned in subsection (7).

(7) For subsection (6), the persons are a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the Regulations for the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act.

Note 1: In subsections 42DLB(11) and 42MA(3), ***broadcaster, datacaster and SBS*** are defined as follows:

broadcaster has the meaning given by clause 3 of Schedule 2 to the *Broadcasting Services Act 1992*.

datacaster means a person who holds a datacasting licence (within the meaning of the *Broadcasting Services Act 1992*).

SBS has the same meaning as in the *Special Broadcasting Service Act 1991*.

Note 2: For the purposes of paragraphs 42DLB(10)(a) or 42DMA(2)(a) of the Act, the Regulations prescribe a publisher of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia.

6B Transitional arrangements

(1) In this section –

former Code means the *Therapeutic Goods Advertising Code 2015*, as in force immediately before the commencement of this instrument.

transition period, for an advertisement for therapeutic goods to which subsection (2) applies, means the period beginning on the commencement of this instrument, and ending on either of the following, whichever first occurs:

(a) the day on which the approval number for the advertisement expires, in accordance with subregulation 5J(3) of the Regulations; and

(b) for an advertisement for which approval is withdrawn in accordance with regulation 5L of the Regulations, the day on which approval is withdrawn.

(2) Despite the repeal of the former Code made by section 6A, the former Code continues to apply for the duration of the transition period in relation to advertisements for therapeutic goods that were approved under Division 2 of Part 2 of the Regulations before the commencement of this instrument.

7 Price information

(1) This instrument, other than Schedule 4, does not apply to advertising that consists solely of the dissemination of price information for medicines that are registered goods.

(2) For the purposes of subsections 42DL(10) and 42DLB(7) of the Act, to the extent that the dissemination of price information in relation to therapeutic goods mentioned in those subsections constitutes advertising, the dissemination is authorised if it complies with Schedule 4.

Part 2—General requirements for the advertising of therapeutic goods

Note: The rules in this Part apply generally in relation to advertisements for therapeutic goods. For advertisements for the particular therapeutic goods identified in Part 3, the rules in Part 3 may also apply.

8 Approved advertisements

(1) This section applies only to advertisements:

(a) that are approved advertisements to which Part 2 of the Regulations applies; and

(b) that are published in media referred to in paragraph (a) or (d) of the definition of ***specified media*** in section 42B of the Act.

(2) The advertisement must include the approval number allocated to the advertisement under the Regulations.

(3) The approval number must:
(a) stand alone; and
(b) be legible; and
(c) be located in the bottom right hand corner of the advertisement.

9 Accuracy

Advertising for therapeutic goods must satisfy the following:
(a) any claims made in the advertising are valid and accurate, and all information presented has been substantiated before the advertising occurs; and
(b) it is truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons; and
(c) any comparisons made in the advertising between therapeutic goods or classes of therapeutic goods do not directly or indirectly claim that the goods or class of goods being used as the comparator are harmful or ineffectual; and
(d) if the goods are included in the Register— it is consistent with the entry for the therapeutic goods in relation to that inclusion.

10 Effect

Advertising for therapeutic goods must:
(a) support the safe and proper use of therapeutic goods by:
(i) presenting the goods in accordance with directions or instructions for use; and
(ii) not exaggerating product efficacy or performance; and
(b) not be likely to lead to people delaying necessary medical attention or delaying the use of, or failing to use, treatment prescribed by a medical practitioner; and
(c) not encourage inappropriate or excessive use of the therapeutic goods; and
(d) not contain any claim, statement, implication or representation that:
(i) the therapeutic goods are safe or that their use cannot cause harm, or that they have no side-effects; or
(ii) the therapeutic goods are effective in all cases of a condition or that the outcome from their use is a guaranteed or sure cure; or
(iii) the therapeutic goods are infallible, unfailing, magical or miraculous; or
(iv) harmful consequences may result from the therapeutic goods not being used — unless the claim, statement, implication or representation is permitted under section 42DK of the Act or approved under section 42DF of the Act.

11 Therapeutic goods containing a Schedule 3 substance (required statement)

(1) This section does not apply to:
(a) a label or consumer medicine information; or
(b) a patient information leaflet; or
(c) an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, or any combination of these, provided the

advertisement does not contain or imply a claim relating to therapeutic use, or any other representation.

(2) An advertisement for therapeutic goods consisting of, or containing, a substance included in Schedule 3 of the current Poisons Standard and Appendix H of that Standard, must contain the following statement, prominently displayed or communicated:

ASK YOUR PHARMACIST—THEY MUST DECIDE IF THIS PRODUCT IS RIGHT FOR YOU

12 What must advertisements contain— therapeutic goods that are not available for physical examination before purchase

(1) This section applies to advertisements for therapeutic goods that are not available for physical examination by the consumer before or at the time of purchase, other than advertisements to which section 11 applies.

(2) This section does not apply to:
(a) a label or consumer medicine information; or
(b) a patient information leaflet.

(3) An advertisement for a medicine must contain the following:
(a) the name of the medicine, within the meaning of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
(b) the name of the dosage form, within the meaning of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
(c) the quantity of the medicine, within the meaning of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;
(d) at least one of the indications of the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label;
(e) a list of the ingredients;
(f) the requirements specified in the following table in relation to the type of medicine specified:

Type of medicine	Requirements
A medicine for which there are no health warnings	The following statement, prominently displayed or communicated: *ALWAYS READ THE LABEL*

A medicine for which there are health warnings	Either: (a) the following statement, prominently displayed or communicated, followed immediately by information about where the health warnings can be found: *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE*; or (b) both of the following, prominently displayed or communicated: (i) the following statement: *ALWAYS READ THE LABEL*; and (ii) the health warnings.

(g) the required statement mentioned in subsection 13(6) (as applicable), prominently displayed or communicated;
(h) the required statement or statements mentioned in subsection 13(7) (as applicable), prominently displayed or communicated;

(4) An advertisement for a medical device must contain the following:
(a) an accurate description of the device;
(b) either—
(i) if the trade name for the device is available—a reference to that name;
(ii) otherwise—a reference to another name for the device; or
(c) at least one of the intended purposes of, or indications for, the device, as the intended purpose or indication appears on the label or primary packaging of the device, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the device;
(d) a list of ingredients for the device, where relevant;
(e) the requirements specified in the following table in relation to the type of device specified:

Type of device	**Requirements**
A device for which there are no health warnings	One of the following statements, as appropriate for the packaging of the device, prominently displayed or communicated: (a) *ALWAYS READ THE LABEL*; or (b) *ALWAYS READ THE INSTRUCTIONS FOR USE*
A device for which there are health warnings	One of the following: (a) the following statement, prominently displayed or communicated, followed immediately by information about where the health warnings can be found: *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE*; or

	(b) both of the following, prominently displayed or communicated: (i) one of the following statements, as appropriate for the packaging of the device: (A) *ALWAYS READ THE LABEL*; or (B) *ALWAYS READ THE INSTRUCTIONS FOR USE*; and (ii) the health warnings.

(f) the required statement mentioned in subsection 13(6) (as applicable), prominently displayed or communicated;

(g) the required statement or statements mentioned in subsection 13(7) (as applicable), prominently displayed or communicated;

(5) An advertisement for other therapeutic goods must contain the following:

(a) an accurate description of the goods;

(b) either—

(i) if the trade name for the goods is available—a reference to that name; or

(ii) otherwise—a reference to another name for the goods;

(c) at least one of the intended purposes of, or indications for, the goods, as the intended purpose or indication appears on the label or primary packaging of the goods, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the goods;

(d) a list of ingredients for the goods, where relevant;

(e) the requirements specified in the following table in relation to the type of goods specified:

Type of goods	**Requirements**
Other therapeutic goods for which there are no health warnings	One of the following statements, as appropriate for the packaging of the goods, prominently displayed or communicated: (a) *ALWAYS READ THE LABEL*; or (b) *ALWAYS READ THE INSTRUCTIONS FOR USE*
Other therapeutic goods for which there are health warnings	One of the following: (a) the following statement, prominently displayed or communicated, followed immediately by information about where the health warnings can be found: *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE*; or (b) both of the following, prominently displayed or communicated: (i) one of the following statements, as appropriate for the packaging of the goods:

	(A) *ALWAYS READ THE LABEL*; or (B) *ALWAYS READ THE INSTRUCTIONS FOR USE*; and (ii) the health warnings.

(f) the required statement mentioned in subsection 13(6) (as applicable), prominently displayed or communicated;

(g) the required statement or statements mentioned in subsection 13(7) (as applicable), prominently displayed or communicated.

13 What must advertisements contain—general rules

(1) This section does not apply to:

(a) a label or consumer medicine information; or

(b) a patient information leaflet; or

(c) an advertisement that:

(i) displays only the name or picture of therapeutic goods or their price or point of sale, or any combination of these things; and

(ii) does not contain or imply a claim relating to therapeutic use; or

(d) an advertisement for a medicine to which section 11 applies; or

(e) an advertisement to which section 12 applies.

(2) An advertisement for a medicine must contain the following:

(a) a reference to the name of the medicine, within the meaning of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*;

(b) at least one of the indications for the medicine, as the indication appears on the medicine's label, or as modified in a manner that does not change the meaning or intent of the indication as it appears on the medicine's label;

(c) subject to subsections (2A) and (5)—the requirements specified in the following table in relation to the type of medicine specified:

Type of medicine	Requirements
A medicine that does not include any ingredients in Part 1 or Part 2 of Schedule 1 for which there are health warnings	The following statement, prominently displayed or communicated: *ALWAYS READ THE LABEL*
A medicine that includes an ingredient in Part 1 or 2 of Schedule 1 for which there are health warnings	Either: (a) the following statement, prominently displayed or communicated: *THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or (b) both of the following, prominently displayed or communicated: (i) the following statement: *ALWAYS READ THE LABEL*; and (ii) the health warnings.

(2A) If an advertisement relates to more than one medicine and:

(a) the advertisement does not relate to one or more other therapeutic goods or medical devices; and

(b) at least one of the medicines advertised includes an ingredient in Part 1 or Part 2 of Schedule 1 for which there is a health warning;

then the following statement may be prominently displayed or communicated in the advertisement instead of the applicable statements mentioned in the table in paragraph (2)(c):

(c) *THESE MEDICINES MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*.

(3) An advertisement for a medical device must contain the following:

(a) an accurate description of the device;

(b) either—

(i) if the trade name for the device is available—a reference to that name; or

(ii) otherwise—a reference to another name for the device;

(c) at least one of the intended purposes of, or indications for, the device, as the intended purpose or indication appears on the label or primary packaging of the device, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the device;

(d) subject to subsection (5)—the requirements specified in the following table in relation to the type of device specified:

Type of device	**Requirements**
A device for which there are no health warnings	One of the following statements, as appropriate for the packaging of the device, prominently displayed or communicated: (a) *ALWAYS READ THE LABEL*; or (b) *ALWAYS READ THE INSTRUCTIONS FOR USE*
A device for which there are health warnings	Where the label of the device is visible on the primary pack, one of the following: (a) the following statement, prominently displayed or communicated: *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or b) both of the following, prominently displayed or communicated: (i) *ALWAYS READ THE LABEL*; and (ii) the health warnings. Where the device does not have a label visible on the primary pack, one of the following: (a) the following statement, prominently displayed or communicated: *THIS PRODUCT MAY NOT BE RIGHT FOR*

	YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE; or b) both of the following, prominently displayed or communicated: (i) *ALWAYS READ THE INSTRUCTIONS FOR USE*; and (ii) the health warnings.

(4) An advertisement for other therapeutic goods must contain the following:

(a) an accurate description of the goods;

(b) either—

(i) if the trade name for the goods is available—a reference to that name; or

(ii) otherwise—a reference to another name for the goods;

(c) at least one of the intended purposes of, or indications for, the goods, as the intended purpose or indication appears on the label or primary packaging of the goods, or as modified in a manner that does not change the meaning or intent of the intended purpose or indication as it appears on the label or primary packaging of the goods;

(d) subject to subsection (5)—the requirements specified in the following table in relation to the type of goods specified:

Type of goods	**Requirements**
Other therapeutic goods for which there are no health warnings	One of the following statements, as appropriate for the packaging of the goods, prominently displayed or communicated: (a) *ALWAYS READ THE LABEL*; or (b) *ALWAYS READ THE INSTRUCTIONS FOR USE*
Other therapeutic goods for which there are health warnings	Where the label of the goods is visible on the primary pack, one of the following: (a) the following statement, prominently displayed or communicated: *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE*; or (b) both of the following, prominently displayed or communicated: (i) the following statement: *ALWAYS READ THE LABEL*; and (ii) the health warnings. Where the goods do not have a label visible on the primary pack, one of the following: (a) the following statement, prominently displayed or communicated: *THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE*; or (b) both of the following, prominently displayed

		or communicated: (i) the following statements: *ALWAYS READ THE INSTRUCTIONS FOR USE*; and (ii) the health warnings.

(5) Paragraphs (2)(c), (3)(d) and (4)(d) do not apply to radio advertisements that are 15 seconds or less in duration or to text only advertisements that consist of 300 characters or less for which there is no reasonable capacity to include pictures, logos or other imagery as part of the advertisement.

(6) An advertisement must contain either of the following statements as appropriate, prominently displayed or communicated:
(a) *FOLLOW THE DIRECTIONS FOR USE*; or
(b) *FOLLOW THE INSTRUCTIONS FOR USE*.

(7) Subject to subsection (7A), if an advertisement contains a claim relating to a symptom of a disease, condition, ailment or defect, the advertisement must contain either or both of the following statements as appropriate to the duration or recurrence of the symptoms, prominently displayed or communicated:
(a) *IF SYMPTOMS PERSIST, TALK TO YOUR HEALTH PROFESSIONAL*; or
(b) *IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTH PROFESSIONAL*

(7A) For an advertisement to which subsection (7) applies and which must contain both statements in that subsection, the statements may be shortened and combined into one statement, so as to avoid duplication.

(8) Subsection (7) does not apply to radio advertisements that are 15 seconds or less in duration or to text only advertisements that consist of 300 characters or less for which there is no reasonable capacity to include pictures, logos or other imagery as part of the advertisement.

14 Section 14 is intentionally not used.

15 Scientific or clinical representations

(1) This section does not apply to:
(a) a label or consumer medicine information; or
(b) a patient information leaflet.

(2) Where an advertisement makes a scientific or clinical representation:
(a) any scientific or clinical terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed; and
(b) any scientific or clinical representation must be consistent with the body of scientific or clinical evidence applicable to the advertised therapeutic goods.

(3) Where an advertisement contains a citation to scientific or clinical literature, either explicitly or impliedly:

(a) any research results must identify the researcher and financial sponsor of the research, where the advertiser knows, or ought reasonably to have known, that information; and
(b) the study must be sufficiently identified to enable consumers to access it.

16 Endorsements

(1) This section does not apply to:
(a) a testimonial to which section 17 applies; or
(b) in relation to a medicine that is listed under section 26AE of the Act or a complementary medicine that is registered under section 25 of the Act—a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority) under paragraphs 42DL(9)(b) and 42DLB(6)(b) of the Act, or prescribed by the Regulations for the purposes of paragraphs 42DL(9)(c) and 42DLB(6)(c) of the Act.

(2) Subject to subsection (2A), an advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by:
(a) a government authority, hospital or healthcare facility; or
(b) an employee or contractor of a government authority, hospital or healthcare facility; or
(c) a health practitioner, health professional, medical researcher or a group of such persons.

(2A) For the purposes of paragraph (2)(a), a healthcare facility does not include a community pharmacy.

(3) An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by:
(a) an organisation that:
(i) represents the interests of healthcare consumers; or
(ii) represents the interests of health practitioners, health professionals or medical researchers; or
(iii) conducts or funds research into any disease, condition, ailment or defect; or
(b) an employee or contractor of an organisation mentioned in paragraph (a), other than an individual mentioned in paragraph (2)(b) or (c);
unless the advertisement:
(c) names the organisation; and
(d) discloses:
(i) the nature of the endorsement; and
(ii) whether the organisation, or employee, has received, or will receive, any valuable consideration for the endorsement.

(4) For the purposes of subsection (3), an **organisation** means any group, association or body (whether incorporated or unincorporated).

17 Testimonials

(1) For the purposes of this section, a testimonial means a statement about a therapeutic good made by a person that claims to have used that good.

(2) A testimonial used in an advertisement for therapeutic goods must be:
- (a) made by a person:
  - (i) whose details are verified prior to the advertising occurring; and
  - (ii) who has used the goods for their intended purpose; and
  - (iii) who is not:
    - (A) involved with the production, sale, supply or marketing of the goods; or
    - (B) an employee or officer of a corporation that is involved with the production, sale, supply or marketing of the goods; or
    - (C) a corporation; or
    - (D) mentioned in subsection 16(2); and
- (b) verified as to the use of the goods and the claims made by the person prior to the advertising occurring; and
- (c) typical of the results to be expected from the use of the goods in accordance with the directions for use, or purpose, of the goods.

(3) A testimonial must disclose:
- (a) whether the person providing the testimonial has received, or will receive, any valuable consideration for the testimonial; and
- (b) where another person is taking the place in the advertisement of the person providing the testimonial; and
- (c) where the person providing the testimonial is an immediate family member of an individual who is involved with the production, sale, supply or marketing of the goods.

18 Incentives

An advertisement must not offer any personal incentive to a pharmacy assistant, or any retail sales person who is not a health professional, to recommend or supply therapeutic goods.

19 Advertising to children

(1) This section does not apply to labels.

(2) An advertisement for therapeutic goods must not be primarily directed to children under the age of 12 years in any circumstances.

(3) An advertisement for therapeutic goods must not be primarily directed to children aged 12 years or over.

(4) Subsection (3) does not apply where the goods are mentioned in Schedule 2 and advertised in accordance with any applicable conditions in that Schedule.

20 Samples

(1) An advertisement for therapeutic goods must not contain an offer of a sample.

(2) Subsection (1) does not apply where the goods are mentioned in Schedule 3 and advertised in accordance with any applicable conditions in that Schedule.

21 Consistency with public health campaigns

If a relevant public health campaign of which the advertiser knows, or ought reasonably to have known, is or will be current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign.

Part 3—Specific requirements for the advertising of particular therapeutic goods

Note: The rules in this Part apply in addition to the rules in Part 2, in relation to advertisements for the particular therapeutic goods mentioned in each section.

22 Application

This Part does not apply to:
(a) a label or consumer medicine information; or
(b) a patient information leaflet.

23 Complementary medicines

If an advertisement for a complementary medicine includes a claim or group of claims based on evidence of a history of traditional use, the reliance on this traditional use and paradigm must be disclosed in the advertisement and the disclosure must be prominently displayed or communicated in the advertisement.

24 Analgesics

(1) An advertisement for an analgesic must contain the following warning statement, prominently displayed or communicated:

INCORRECT USE COULD BE HARMFUL

(2) An advertisement for an analgesic must not imply that:
(a) analgesic consumption is safe; or
(b) analgesics will relax, relieve tension, sedate or stimulate.

25 Vitamins and minerals

An advertisement for vitamin or mineral supplements must not claim or imply that the supplements:
(a) are a substitute for good nutrition or a balanced diet; or
(b) are in any way superior to or more beneficial than dietary nutrients.

26 Therapeutic goods that are for weight management

(1) An advertisement for therapeutic goods containing any claim relating to weight management must balance the claims with the need for a healthy energy-controlled diet and physical activity.

(2) Advertising of therapeutic goods containing any claim relating to weight management must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over-consumption of any food or drink.

(3) An advertisement for therapeutic goods containing any claim relating to weight management must not:

(a) feature individuals in images or visual representations; or

(b) use individuals' statistics or testimonials;

unless the results achieved by those individuals from the use of the goods would be expected to be achieved on average by users of the goods.

(4) In this section:

weight management includes the following:

(a) weight loss;

(b) weight control;

(c) weight maintenance;

(d) measurement reduction;

(e) clothing size reduction;

(f) hunger suppression.

27 Sunscreens

(1) This section applies to an advertisement for a therapeutic good that is or contains a sunscreen that claims or implies that the good (the sunscreen) will prevent any of the following:

(a) sunburn;

(b) skin cancer.

(2) Advertising of sunscreens must:

(a) depict sunscreens as being only one part of sun protection; and

(b) include statements or visual representations, prominently displayed or communicated, to the effect that:

(i) prolonged high-risk sun exposure should be avoided; and

(ii) frequent re-application or use in accordance with directions is required for effective sun protection.

Part 4—Restricted representations and prohibited representations

28 Restricted representations—serious form of disease, condition, ailment or defect

(1) Subject to subsection (2), for the purposes of section 42DD of the Act, a form of a disease, condition, ailment or defect is a serious form if:

(a) it is medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional, except where the form has been medically diagnosed and medically accepted as being suitable for self-treatment and management; or

(b) there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up.

(2) A serious form of a disease, condition, ailment or defect does not include:

(a) pregnancy, other than pregnancy with a medical, obstetric or surgical complication; or

(b) any of the diseases mentioned in section 30.

Note 1: Section 42DD of the Act provides that a representation that refers to a serious form of a disease, condition, ailment or defect is a restricted representation.

Note 2: Sections 42DF and 42DK of the Act provide for the Secretary to approve or permit the use of a restricted representation in certain circumstances.

Note 3: See sections 42DL and 42DLB of the Act for offences and a civil penalty for advertising therapeutic goods, where the advertisement contains a restricted representation.

29 Restricted representations—public interest criteria

For the purposes of paragraph 42DF(4)(c) of the Act, the public interest criteria are as follows:

(a) whether the reference would be likely to take advantage of the vulnerability of consumers, or particular groups of consumers, when faced with the disease, condition, ailment or defect;

(b) whether the reference would be likely to result in consumers not seeking timely professional medical advice where required (such as where that advice is important to prevent negative health consequences, morbidity or mortality, or deterioration or progression of the disease, condition, ailment or defect);

(c) whether the reference would be likely (alone, through repetition or together with other references) to have a negative impact on public health (or to have an effect on persons other than those to whom the advertisement is directed);

(d) such other aspects of the public interest as may appear to be appropriate to the Secretary.

30 Prohibited representations

For the purposes of paragraph 6B(1)(b) of the Regulations, the following representations are prohibited representations:

(a) any representation regarding abortifacient action;

(b) any representation regarding the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to, the following diseases:

(i) neoplastic disease;

(ii) sexually transmitted diseases;

(iii) human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS);

(iv) hepatitis C virus (HCV);

(v) mental illness.

Note 1: Subsection 42DJ(1) of the Act provides that representations of a kind specified in Regulations made for the purposes of that subsection are prohibited representations about therapeutic goods of a kind specified in those regulations. Subregulation 6B(1) of the Regulations provides that the representations mentioned in this instrument are prohibited representations.

Note 2: Section 42DK of the Act provides for the Secretary to permit the use of a prohibited representation in certain circumstances.

Note 3: See sections 42DL and 42DLB of the Act for offences and a civil penalty for advertising therapeutic goods, where the advertisement contains a prohibited representation.

Schedule 1—Medicine ingredients with specific health warnings

Note: See section 4 (paragraph (a) of the definition of 'health warnings').

1 Table of medicine ingredients, circumstances and statements

The following Table lists ingredients, circumstances and statements for the purposes of paragraph (a) of the definition of 'health warnings' in section 4.

1. Ingredients	2. Circumstances	3. Health Warning
Part 1: Statements for ingredient(s) in registered medicines		
Aspartame	In preparations for oral use	Phenylketonurics - product contains aspartame (phenylalanine)
Aspirin	In preparations for oral use	Do not use if you have a stomach ulcer, are pregnant or allergic to anti-inflammatory medicines
Benzydamine	In preparations for topical use on mucosal surfaces, oral or dermal use	Do not use if you are allergic to benzydamine or other anti-inflammatory medicines
Butoconazole	In preparations for vaginal use	Do not use if pregnant
Chlorhexidine	In topical products including preparations for topical use on mucosal surfaces	Chlorhexidine can cause severe allergic reactions
Cold and Flu preparations containing the following: • Ammonia and ammonium salts, including: ○ ammonium chloride ○ ammonium bicarbonate	1. In preparations for oral use indicated for cough cold or flu which DO NOT include dosage instructions for children aged under	Either: Do not give to children under 12 years of age OR Do not give to children under 'x' years of age.

1. Ingredients	2. Circumstances	3. Health Warning
○ ammonium carbonate • Brompheniramine • Bromhexine • Clorphenamine (Chlorpheniramine) • Dexchlorpheniramine • Dextromethorphan • Dihydrocodeine • Diphenhydramine • Doxylamine • Guaifenesin (guaiphenesin) • Ipecacuanha • Oxymetazoline • Pentoxyverine • Pheniramine • Phenylephrine • Pholcodine • Promethazine • Pseudoephedrine • Senega • Triprolidine • Xylometazoline	12 years OR includes dosage instructions for children aged 'x' to 11 years (where 'x' is 6,7,8,9,10 or 11) 2. In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years OR includes dosage instructions for children aged 'x' to 11 years (where 'x' is 6,7,8,9,10 or 11)	
Diphenoxylate	In preparations for oral use	Do not give to children under 12 years of age
Famciclovir	In medicines for oral use	Do not use if you have problems with your immune system or allergic to famciclovir or penciclovir
Fluconazole	In medicines for oral use	Do not use if pregnant
Fluorides (1of 2)	In liquid preparations for topical use and containing 1000mg/kg or more of fluoride ion	Do not use in children under 6 years
Fluorides (2 of 2)	In preparations as oral fluoride supplements	Do not use if pregnant

1. Ingredients	2. Circumstances	3. Health Warning
Hydroquinone	In preparations for topical use	Do not use on children
Hydroxyanthracene derivatives such as those from: • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna	In preparations for oral use where the MRDD contains MORE than 10 mg	Do not use if you have abdominal pain, nausea, vomiting or diarrhoea
Ibuprofen/ Paracetamol combinations	In preparations for oral use	Do not use if you have a stomach ulcer, impaired kidney function, heart failure, allergic to anti-inflammatory medicines, pregnant or trying to become pregnant
Levocabastine	In topical eye or nasal preparations	Do not use if pregnant
Loperamide	In preparations for oral use	Do not use if you have a condition where constipation should be avoided or give to children under 12 years
Metoclopramide	In preparations for oral use	Do not use if you have epilepsy or give to children and adolescents under 18 years
Non-Steroidal Anti-inflammatory medicines: • Diclofenac • Flurbiprofen • Ibuprofen • Ketoprofen • Naproxen	In preparations for oral use	Do not use if you have a stomach ulcer, impaired kidney function, heart failure, are allergic to anti-inflammatory medicines, or in the last 3 months of pregnancy

1. Ingredients	2. Circumstances	3. Health Warning
• Mefenamic acid		
Phenylalanine	In preparations for oral use	Phenylketonurics - this product contains phenylalanine
Promethazine	In preparations for oral use	Do not use if pregnant or breastfeeding
Tioconazole	In preparations for vaginal use	Do not use if pregnant
Vasoconstrictor eye drops: • Naphazoline • Oxymetazoline • Phenylephrine • Tetrahydrozoline • Tramazoline • Tymazoline • Xylometazoline	In topical eye preparations	Do not use if you have glaucoma or other serious eye conditions
Part 2: Statements for ingredient(s) in listed medicines		
Actaea Racemosa including: • Black Cohosh Dry • Black Cohosh Powder	In preparations for oral use	Black Cohosh can harm the liver in some people
Aspartame	In preparations for oral use	Phenylketonurics - product contains aspartame (phenylalanine)
Azadirachta Indica (neem)	In preparations for dermal use	Do not use if pregnant or likely to become pregnant
Carthamus Tinctorius	In preparations for oral use	Do not use if pregnant or likely to become pregnant
Chelidonium Majus	In preparations for oral use	Greater Celandine may harm the liver in some people

1. Ingredients	2. Circumstances	3. Health Warning
Fallopia Multiflora	In preparations for oral use	Fallopia multiflora may harm the liver in some people
Fluorides including: • Sodium Fluoride • Sodium Monofluorophosphate	In liquid preparations for topical use and containing 1000mg/kg or more of fluoride ion	Do not use in children under 6 years
Foeniculum Vulgare including: • Fennel Bitter Seed Dry • Fennel Oil • Fennel Sweet Seed Dry	In preparations for oral use	Do not use if pregnant, likely to become pregnant or breastfeeding
Hydroxyanthracene derivatives including the following ingredients: • Aloe Ferox • Aloe Perryi • Aloe Vera • Aloes Cape • Cascara Dry • Cascara Powder • Cassia Fistula • Frangula Bark Dry • Frangula Bark Powder • Frangula Purshiana • Rhamnus Cathartica • Rhamnus Frangula • Rheum Officinale • Rheum Palmatum • Rheum Rhaponticum • Rheum Tanguticum • Rhubarb • Rhubarb Root Dry • Rhubard Root Powder • Senna Alexandrina • Senna Fruit Alexandrian Dry • Senna Fruit Alexandrian Powder • Senna Fruit Tinnevelly Dry • Senna Fruit Tinnevelly Powder	In preparations for oral use where the MRDD contains MORE than 10 mg	Do not use if you have abdominal pain, nausea, vomiting or diarrhoea

1. Ingredients	2. Circumstances	3. Health Warning
• Senna Leaf Dry • Senna Leaf Powder • Senna Occidentalis • Senna Tora		
Khaya Senegalensis	In preparations for oral use	Do not use if pregnant or likely to become pregnant
Larrea Tridentata	In preparations for oral use	Chaparral may harm the liver in some people
Methyl Salicylate including: • Betula Lenta • Betula Nigra • Betula Pendula • Birch Leaf Dry • Filipendula Ulmaria • Gaultheria Procumbens • Meadowsweet Herb • Nyctanthes Abortristis • Wintergreen oil	In preparations for topical use	Do not use if pregnant, likely to become pregnant or in children under 6 years
Phenylalanine	In preparations for oral use	Phenylketonurics - this product contains phenylalanine
Piper Methysticum	In preparations for oral use and containing more than 25 mg of kavalactones (of Piper methysticum)	Kava may harm the liver in some people
Pollen	In preparations for oral use	Pollen can cause severe allergic reactions
Propolis including: • Propolis Balsam • Propolis Dry Extract • Propolis LiquidExtract • Propolis Resin • Propolis Tincture	In preparations for oral use	Propolis can cause allergic reactions
Royal Jelly including:	In preparations for oral	Can cause severe

1. Ingredients	2. Circumstances	3. Health Warning
• Royal Jelly Fresh • Royal Jelly Lyophilised	use	allergic reactions, do not use if you have asthma or allergies
Part 3: Statements for ingredients(s) in either registered or listed medicines		
Aspartame	In preparations for oral use	Phenylketonurics - product contains aspartame (phenylalanine)
Alpha Casozepine Enriched Hydrolysed Milk Protein	In preparations for oral use	Derived from cow's milk
Arachis including: • Arachis Hypogaea • Arachis Oil • Peanut	In all preparations	Contains Peanut
Avena including: • Avena Fatua • Avena Sativa • Oat • Oat Bran • Oatmeal Collodial	In preparations for oral use	Contains Gluten
Benzoates including: • Benzoic acid • Sodium Benzoate	In all preparations	Contains benzoates Or Contains <insert name of benzoate used>
Bovine Colostrum Powder	In preparations for oral use	Contains cow's milk proteins and lactose
Bovine Lactoferrin	In preparations for oral use	Derived from cow's milk.
Bovine Whey Ig-Rich Fraction	In preparations for oral use	Derived from cow's milk.
Calcium Sodium Caseinate	In preparations for oral use	Derived from cow's milk
Canarium Indicum	In preparations for topical use	Derived from nuts

1. Ingredients	2. Circumstances	3. Health Warning
Euphausia Superba Oil	In preparations for oral use	Derived from seafood
Glucosamine including: • Acetyl Glucosamine • Glucosamine Hydrochloride • Glucosamine Sulfate • Glucosamine Sulfate Potassium Chloride • Glucosamine Sulfate Sodium Hydrochloride	In preparations for oral use and when derived seafood	Derived from seafood
Hydroxybenzoic acid esters including: • Ethyl hydroxybenzoate • Methyl hydroxybenzoate • Propyl hydroxybenzoate • Sodium Methyl hydroxybenzoate • Sodium Propyl hydroxybenzoate	In preparations for oral use	Contains Hydroxybenzoates Or Contains <insert name of Hydroxybenzoate used>
Hordeum including: • Hordeum Distichon • Hordeum Vulgare • Barley • Barley Bran • Barley Germ	In preparations for oral use	Contains Gluten
Lactitol including: • Lactitol Monohydrate	In preparations for oral use	Derived from cow's milk and contains lactose
Maltodextrin	In preparations for oral use and where ingredient is derived from gluten containing grains such as wheat, barley, rye and oats	Contains Gluten
Milk including: • Goat Milk • Nonfat Dry Milk • Whole Dry Milk	In preparations for oral use and contains Lactose	Contains Lactose
Phenylalanine	In preparations for oral	Phenylketonurics - this

1. Ingredients	2. Circumstances	3. Health Warning
	use	product contains phenylalanine
Poliglusam	In preparations for oral use	Derived from seafood
Secale including: • Secale Cereale • Rye	In preparations for oral use	Contains Gluten
Sorbic acid and Sorbic acid salts including: • Potassium Sorbate	In preparations for oral use	Contains Sorbates OR Contains <insert name of sorbate used>
Squid Oil including: • Concentrated Squid Omega-3 Triglycerides	In preparations for oral use	Derived from seafood
Lactose including: • Lactose Monohydrate	In preparations for oral use	Contains Lactose
Sulfite Salts including • Sodium Bisulfite • Sodium Metabisulfite • Sodium Sulfite • Sodium Bisulfite Heptahydrate • Sulfur Dioxide	In preparations for oral use	Contains Sulfites OR Contains <insert name of sulfite used>
Tartrazine	In preparation for oral use	Contains Tartrazine
Triticum including: • Triticum Aestivum • Triticum Durum • Hydrolysed Wheat Protein • Pregelatinised Wheat Starch • Wheat • Wheat Bran • Wheat Dextrin • Wheat Germ • Wheat Germ Glycerides • Wheat Starch	In preparations for oral use	Contains Gluten
Whey including: • Whey powder • Whey protein	In preparations for oral use	Contains Lactose

1. Ingredients	2. Circumstances	3. Health Warning
Part 4: Statements for ingredients(s) in either registered or listed medicines on and after 1 September 2020		
Egg, egg products including: • Egg Lecithin • Eggshell Membrane Hydrolysate • Eggshell Membrane Powder	In preparations for oral use	Contains Egg
Sesamum Indicum including: • Sesame Oil • Sesame Seed	In preparations for oral use	Contains Sesame
Soya beans and soya products including: • Glycine Max • Soya bean • Soya oil excluding: • fully refined soya oil, vitamin e (such as d-alpha tocopherol) from soya bean sources, • phytosterols from soya bean sources • plant stanol esters from soya bean sources.	In preparations for oral use	Contains Soya

Tree nuts and tree nut products including:
• Almond oil
• Anarcardium Occidentale
• Bertholletia Excelsa
• Brazil Nut
• Cashew
• Castanea spp including:
  ○ Castanea Mollisima
  ○ Castanea Sativa
• Chestnut Sweet
• Corylus spp including:
  ○ Corylus Avellana
  ○ Corylus Americana
• Hazelnut
	In preparations for oral use	Contains Nut

1. Ingredients	2. Circumstances	3. Health Warning

• Hazelnut Oil
• Juglans spp including:
  ○ Juglans Cinerea
  ○ Juglans Nigra
  ○ Juglans Regia
• Macadamia nut
• Macadamia nut oil
• Prunus dulcis
• Semecarpus Anacardium
• Walnut
• Walnut Oil		

Schedule 2—Advertising to children

Note: See subsection 19(4).

1 Goods that may be advertised to children

For the purposes of section 19, the following therapeutic goods may be primarily advertised to children aged 12 years or over:

(a) tampons;
(b) acne preparations;
(c) sunscreens SPF 15+;
(d) condoms and personal lubricants;
(e) bandages and dressings;
(f) Class 1 medical devices for management of chronic conditions under medical supervision;
(g) cold sore preparations;
(h) lip balm;
(i) unscheduled anti-dandruff preparations.

Schedule 3—Samples

Note: See section 20.

1 Goods that may be offered as samples

For the purposes of section 20, samples of the following therapeutic goods may be offered in advertisements:

(a) condoms;
(b) a therapeutic good that is or contains a sunscreen;
(c) stoma devices for self-management;
(d) continence catheter devices for self-management.

Schedule 4—Price Information

Note: See section 7.

1 Purpose

The purpose of this Schedule is to set out the conditions under which information about the price of prescription medicines and certain pharmacist-only medicines, that are registered goods, may be provided to the general public.

2 Application

(1) This Schedule applies to all price information directed to consumers of therapeutic goods that consist of, or contain, substances included in Schedules 3, 4 or 8 to the current Poisons Standard, but not included in Appendix H to that Standard.

(2) Price information may not be provided for Pharmaceutical Benefits Scheme medicines supplied through alternative arrangements under section 100 of the *National Health Act 1953*, other than dispensing fees for buprenorphine hydrochloride and methadone hydrochloride.

3 Who may provide price information

(1) Price information may only be provided by retail pharmacists, agents acting on behalf of retail pharmacists including pharmacy marketing groups, or dispensing doctors.

(2) Price information may not be provided by manufacturers, distributors or sponsors of medicines, other than pharmacy marketing groups acting in accordance with subclause (1).

4 Responsibility for compliance with this Schedule

(1) The following persons are responsible for ensuring compliance with this Schedule:
- (a) any person who publishes, by any means, price information for therapeutic goods to which this Schedule applies; or
- (b) any person who causes the publication, by any means, of price information for therapeutic goods to which this Schedule applies.

5 Methods for provision of price information

(1) Price information to which this Schedule applies may be provided by any method except:
- (a) transmission using radio or television; or
- (b) displays, including posters:
  - (i) in shopping malls (except inside individual shops); and
  - (ii) in or on public transport; and
  - (iii) on billboards; or
- (c) cinema advertising.

Online price information identified through a search function

(2) Where price information for the medicine is identified through a search function included in an electronic sales system, the results of the search must only include:
  (a) if the search is conducted using the name of the medicine or part thereof—a list of relevant medicines of that name;
  (b) if the search is conducted using an active ingredient or part thereof of the medicine—a list of relevant medicines in alphabetical order.

(3) The following provisions of this Schedule do not apply to price information identified in accordance with subclause (2):
  (a) subclause 6(1) and paragraph 6(3)(a);
  (b) clause 8;
  (c) clause 9.

6 General requirement restricting promotion

(1) Price information must not present or describe a medicine in a way that directs consumers to a particular medicine over and above any other medicine, whether or not that particular medicine is also referred to in the price information.

(2) Price information must not:
  (a) include or be presented with any promotional statement, picture or design; or
  (b) use:
    (i) adjectives or phrases that qualify the name of the medicine, sponsor's pack size or formula of the medicine; or
    (ii) terms indicating the predicted or recommended length of supply; or
  (c) promote the purchase of quantities or multiple packs that are not approved sponsor pack sizes or multiples of those sizes, except as provided under clause 7 of this Schedule; or
  (d) use comparative adjectives or terms to qualify the price of the medicine; or
  (e) give any prominence to the text of the name, description or price of a medicine compared to the remainder of the price information text; or
  (f) offer rewards or bonus points, or be included in association with any other advertising that promotes rewards or bonus points; or
  (g) limit or qualify the availability of the price, other than by including a statement of validity or expiry of the price; or
  (h) include any embellishment; or
  (i) be accompanied by, or located in proximity to, information (including implications or references to other sources of information) regarding approved or unapproved indications, diseases, conditions, ailments or defects so that a reasonable person could infer that the medicine will cure or alleviate those diseases, conditions, ailments or defects.

(3) Price information must:
  (a) include at least 25 medicines; and
  (b) be accompanied by the names and contact details of the retail suppliers from whom the medicine referred to in that price information may be obtained at the listed price.

(4) Paragraph (3)(a) does not apply to price information for medicines mentioned in subclause 5(2) of this Schedule.

7 Description of medicines

(1) Medicines must be described in price information using the name of the medicine within the meaning of whichever is relevant to the medicine:
  (a) the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines*; or
  (b) the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*.

(2) Price information must include, for each medicine:
  (a) if there is more than one strength of a form of the medicine—the strength of each active ingredient as it appears on the label of the medicine; and
  (b) the form in which the medicine is presented; and
  (c) the price for the relevant number of units of the sponsor's standard pack; and
  (d) the quantity contained in the sponsor's standard pack.

(3) For this section, the ***relevant number of units*** of the sponsor's standard pack is:
  (a) if the Pharmaceutical Benefits Scheme or Repatriation Benefits Scheme permit more than one unit of the sponsor's pack to be prescribed—the maximum number of units that may be prescribed under those schemes; and
  (b) otherwise—one.

(4) The need for a prescription for a particular medicine may also be indicated.

8 Presentation of price information

Alphabetical order

(1) Subject to subclause (2), medicines must be listed in alphabetical order by name, or by the names of active ingredients. Medicines must be set out in alphabetical order in each list according to only one of these classifications. More than one alphabetical list may be provided at the same time.

Medicine grouping

(2) Medicines may be grouped according to the Schedule in the current Poisons Standard in which they are included, provided that:
  (a) there are a sufficient number of medicines from each Schedule in each grouping so that consumers are not directed to a particular medicine over and above any other medicines; and
  (b) there are medicines from three or more sponsors included in the price information.

9 Pharmaceutical Benefits Scheme subsidised medicines

(1) Where a pharmacy marketing group publishes price information which includes both a Pharmaceutical Benefits Scheme subsidised medicine with a brand

premium or therapeutic group premium and their own generic medicine, that information must include at least one other bench-mark price brand of that medicine in addition to their own medicine (where such products exist).

(2) Medicines subsidised under the Pharmaceutical Benefits Scheme must be identified and the total purchase price must be clearly specified as the general or concessional price. Both prices may be provided.

(3) Price lists which include a Pharmaceutical Benefits Scheme subsidised medicine must include an indication that the price is subsidised by the Australian Government, and only applies when prescribed for the medical conditions listed in the Pharmaceutical Benefits Scheme Schedule for that medicine.

(4) The price information may include a statement that specified medicines are subsidised under the Pharmaceutical Benefits Scheme only for a limited range of diseases, conditions, ailments or defects.

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 the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

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

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Advertising Code (No.2) 2018	31 Oct 2018 (F2018L01524)	Sch 1 (Part 4): 1 Sept 2020 Remainder: 1 Jan 2019	s 6B
Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2019	29 July 2019 (F2019L01013)	30 July 2019	Sch 1 (item 22)
Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument 2021	4 June 2021 (F2021L00696)	5 June 2021	Sch 1 (item 2)
Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 2) 2021	9 July 2021 (F2021L00978)	10 July 2021	Sch 1 (item 3)
Therapeutic Goods Amendment (Therapeutic Goods Advertising Code) Instrument (No. 3) 2021	27 July 2021 (F2021L01034)	28 July 2021	Sch 1 (item 3)

Endnote 4—Amendment history

Provision affected	How affected
s 2	rep LA s 48D
s 3	am F2019L01013
s 4	am F2019L01013
s 6	am F2019L01013; F2021L00696; F2021L00978, F2021L01034
s 6A	rep LA s 48C
s 7	am F2019L01013
s 11 heading	am F2019L01013
s 11	am F2019L01013
s 12	am F2019L01013
s 13	am F2019L01013
s 16	am F2019L01013
s 28	am F2019L01013
Schedule 1	am F2019L01013
Schedule 4	am F2019L01013
Schedule 5	rep LA s 48C