Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

made under section 42BAA of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 20 December 2022

Includes amendments up to: F2022L01650

Prepared by Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* that shows the text of the law as amended and in force on 20 December 2022 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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

1 Name

This instrument is the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*.

3 Authority

This instrument is made under section 42BAA of the *Therapeutic Goods Act 1989*.

4 Therapeutic Goods Advertising Code

Schedule 1 constitutes the code relating to advertisements about therapeutic goods for the purposes of section 42BAA of the *Therapeutic Goods Act 1989*.

5 Transitional

(1) In this section:

former code means the *Therapeutic Goods Advertising Code (No.2) 2018*, as in force immediately before the commencement of this instrument.

transition period means the period beginning on the commencement of this instrument and ending on 30 June 2022.

(2) Despite the repeal of the former code made by this instrument, that code continues to apply for the duration of the transition period in relation to an advertisement about therapeutic goods, such that requirements specified in the former code may continue to be complied with, as an alternative to the requirements specified in Schedule 1.

Schedule 1—Therapeutic Goods Advertising Code

Note: See section 4.

Part 1—Preliminary

1 Name

This Code is the *Therapeutic Goods Advertising Code*.

2 Objects of this Code

The objects of this Code are to specify requirements for advertisements about therapeutic goods so that advertisements:

(a) promote the safe and proper use of the therapeutic goods by minimising misuse, overuse or underuse; and

(b) are ethical and do not mislead or deceive the consumer or create unrealistic expectations about the performance of the therapeutic goods; and

(c) support informed health care choices; and

(d) are not inconsistent with current public health campaigns.

3 Simplified outline of this Code

This Code specifies requirements for advertisements about therapeutic goods.

Part 1 deals with preliminary matters, including the definitions of key terms.

Part 2 specifies the advertisements to which the Code does, and does not, apply.

Part 3 specifies general requirements for advertisements about therapeutic goods.

Part 4 deals with mandatory statements and other required information that must be included in advertisements about therapeutic goods.

Part 5 specifies additional requirements for advertisements about analgesics, sunscreens and therapeutic goods for weight management.

Part 6 deals with testimonials and endorsements used in advertisements about therapeutic goods.

Part 7 deals with samples and incentives offered in advertisements about therapeutic goods.

Part 8 defines ***serious*** form of a disease, condition, ailment or defect, and specifies public interest criteria, for the purposes of restricted representations.

Part 9 deals with advertisements about therapeutic goods comprising price information.

4 Definitions

Note 1: A number of expressions used in this Code are defined in subsubsection 3(1) 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) label;
(h) medical device;
(i) medicine;
(j) Register;
(k) registered goods;
(l) supply.

Note 2: Other grammatical forms of a defined word have a corresponding meaning (see section 18A of the *Acts Interpretation Act 1901*), for example, ***advertise*** and ***advertisement***.

Note 3: The definition of ***advertise*** in the Act is 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.

Note 4: The definition of ***health practitioner*** in the Act is as follows:

health practitioner means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

(a) Aboriginal and Torres Strait Islander health practice;
(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);
(c) medical;
(d) medical radiation practice;
(e) nursing;
(f) midwifery;
(g) occupational therapy;
(h) optometry;
(i) pharmacy;
(j) physiotherapy;
(k) podiatry;
(l) psychology.

Note 5: The definition of ***indications*** in the Act is as follows:

indications, in relation to therapeutic goods, means the specific therapeutic uses of the goods.

Note 6: The definition of ***label*** in the Act is as follows:

label, in relation to therapeutic goods, means a display of printed information:

(a) on or attached to the goods; or
(b) on or attached to a container or primary pack in which the goods are supplied; or
(c) supplied with such a container or pack.

Note 7: The definition of ***registered goods*** in the Act is as follows:

registered goods means:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

Note 8: The definition of ***supply*** in the Act is as follows:

supply includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and

(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and

(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and

(d) supply by way of administration to, or application in the treatment of, a person.

In this Code:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

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;

but does not include 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) to (c) are combined with one or more active ingredients; and

(f) the other ingredients have been included in the medicine for indications other than the relief of aches and pains.

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

child means an individual who is under 18 years of age.

Class I medical device has the same meaning as in the Medical Devices Regulations.

complementary medicine has the same meaning as in the Regulations.

health professional means a person mentioned in paragraph 42AA(1)(a), (c) or (d), or subsection 42AA(2), of the Act.

***health warning*:**

(a) in relation to a medicine—has the meaning given by subsection 19(4);

(b) in relation to a medical device—has the meaning given by subsection 20(4);

(c) in relation to other therapeutic goods—has the meaning given by subsection 21(4).

immediate family has the same meaning as in the Regulations.

instructions for use has the same meaning as in the Medical Devices Regulations.

intended purpose has the same meaning as in the Medical Devices Regulations.

Note: The definition of ***intended purpose*** in the Medical Devices Regulations is as follows:

intended purpose, of a medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device; or

(b) the instructions for use of the device; or

(c) any advertising material applying to the device; or

(d) any technical documentation describing the mechanism of action of the device.

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 the Medical Devices Regulations.

pharmaceutical benefits scheme has the meaning given by section 99ZH of the *National Health Act 1953*.

pharmacy marketing group means an organisation that provides marketing or promotional services to community pharmacies that operate under the same pharmacy brand or banner.

price information, in relation to medicines that are registered goods and contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not a substance that is included in Appendix H of the current Poisons Standard), means information about:

(a) the total purchase price of medicines that is to be paid by consumers of those medicines; or

(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.

price information list has the meaning given by subsection 33(1).

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

(a) either:
(i) for a visual statement—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 be noticed by a viewer or listener.

public health campaign means a campaign about a public health matter that is conducted, approved or funded by one or more of the following:
(a) the Commonwealth;
(b) a state or territory;
(c) a Commonwealth, state or territory statutory authority.

Regulations means the *Therapeutic Goods Regulations 1990.*

Repatriation Pharmaceutical Benefits Scheme has the same meaning as in the *Veterans' Entitlements Act 1986.*

serious, in relation to a form of a disease, condition, ailment or defect, has the meaning given by section 28.

short form advertisement means:
(a) in relation to a radio advertisement—an advertisement that is 15 seconds or less in duration;
(b) in relation to a text only advertisement—an advertisement that consists of 300 characters or less for which there is no reasonable capacity to include a picture, logo or other imagery as part of the advertisement;
but does not include an advertisement that is published on social media.

TGO 91 means the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines.*

Note: TGO 91 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

TGO 92 means the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines.*

Note: TGO 92 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

total purchase price, in relation to therapeutic goods, means the total cost of the goods to a consumer, including but not limited to:
(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 a medicine listed in the pharmaceutical benefits scheme or Repatriation Pharmaceutical Benefits Scheme—any premium (such as a brand or therapeutic group premium or special patient contribution) that must be paid by the consumer.

trade name has the same meaning as in the Regulations.

traditional use has the same meaning as in the Regulations.

Part 2—Application of this Code

5 Advertisements to which this Code applies

(1) This Code applies to advertisements about therapeutic goods other than advertisements specified in section 6.

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

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

6 Advertisements to which this Code does not apply

(1) This Code does not apply to an advertisement that is:

(a) directed exclusively to a person mentioned in section 42AA of the Act; or

(b) part of, or otherwise comprises, a public health campaign; or

(c) made in accordance with the *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* made under section 42DK of the Act, as in force or existing on 20 December 2022.

Note: The *Therapeutic Goods (Restricted Representations—COVID-19 Vaccines) Permission 2022* is published on the Department's website at www.tga.gov.au.

Price information

(2) This Code, other than Part 9, does not apply to an advertisement about therapeutic goods that only contains price information about medicines that are registered goods and contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not a substance that is included in Appendix H of the current Poisons Standard).

Genuine news

(3) This Code does not apply to genuine news that is broadcast or published in any medium by:

(a) a broadcaster; or

(b) a datacaster; or

(c) the SBS; or

(d) 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: Subsections 42DLB(11) and 42DMA(3) of the Act, define ***broadcaster, datacaster*** and ***SBS*** 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) and 42DMA(2)(a) of the Act, regulation 7A of the Regulations prescribes 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.

Part 3—General requirements

7 Simplified outline of this Part

This Part specifies the general requirements for advertisements about therapeutic goods to ensure that advertisements are accurate, balanced and not misleading, promote the safe and proper use of the goods and are consistent with public health campaigns.

8 Accuracy

(1) An advertisement about therapeutic goods must:
  (a) be accurate, balanced and not misleading or likely to be misleading; and
  (b) only contain information that is substantiated by the advertiser prior to publication or dissemination.

(2) An advertisement about therapeutic goods included in the Register must not be inconsistent with any indication or intended purpose accepted in relation to the inclusion of the goods in the Register.

9 Safe and proper use

(1) An advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication, represents the goods to be:
  (a) safe, or without harm or side-effects; or
  (b) effective in all cases, or a guaranteed cure; or
  (c) infallible, unfailing, magical or miraculous.

(2) An advertisement about therapeutic goods must not:
  (a) cause, or be likely to cause, undue alarm, fear or distress; or
  (b) contain a representation to the effect that harmful consequences may result from the therapeutic goods not being used, unless the representation is the subject of an approval given under section 42DF of the Act or a permission made under section 42DK of the Act.

(3) An advertisement about therapeutic goods must not contain any statement, pictorial representation or design that, expressly or by implication:
  (a) is inconsistent with the label, directions for use, consumer medicine information, instructions for use, or patient information leaflet (as relevant) of the goods; or

(b) delays or discourages, or is likely to delay or discourage, persons from seeking necessary medical attention; or

(c) delays or discourages, or is likely to delay or discourage, persons from undertaking treatment prescribed by a medical practitioner; or

(d) exaggerates, or is likely to exaggerate, the efficacy or performance of the goods; or

(e) encourages, or is likely to encourage, inappropriate or excessive use of the goods; or

(f) compares the goods with other therapeutic goods, classes of therapeutic goods, or therapeutic services (***comparator goods or services***) where such comparison suggests that the comparator goods or services are harmful or ineffectual.

10 Consistency with public health campaigns

An advertisement about therapeutic goods must not be inconsistent with a current public health campaign.

11 Scientific or clinical representations

(1) This section does not apply in relation to:

(a) labels of therapeutic goods; or

(b) consumer medicine information; or

(c) instructions for use; or

(d) patient information leaflets.

(2) An advertisement about therapeutic goods that makes a scientific or clinical representation must:

(a) only contain scientific or clinical terminology that is clearly communicated and able to be readily understood by the audience to whom it is directed; and

(b) be consistent with the body of scientific or clinical evidence applicable to the goods.

(3) An advertisement about therapeutic goods that refers to scientific or clinical research, expressly or by implication, must:

(a) identify the researcher; and

(b) identify the financial sponsor of the research where the advertiser knows, or ought reasonably to have known, that information; and

(c) sufficiently identify the research by proper citation to enable consumers to access that research.

12 Advertising to children

(1) This section does not apply to labels of therapeutic goods.

(2) An advertisement about therapeutic goods must not be directed to children aged under 12 years.

(3) An advertisement about therapeutic goods may only be directed to children aged 12 years and over if:

(a) both of the following are satisfied:

(i) the goods are mentioned in an item in Annexure 1; and

(ii) the conditions (if any) for that item are met; and

(b) the goods do not contain a substance included in Schedule 2, 3, 4 or 8 to the current Poisons Standard.

Part 4—Mandatory statements and other required information

Division 1—Preliminary

13 Simplified outline of this Part

This Part deals with mandatory statements and other required information that must be included in advertisements about therapeutic goods.

Division 1 specifies the advertisements to which this Part does not apply.

Division 2 specifies mandatory statements that must be included in advertisements about therapeutic goods that are only available from pharmacists (section 15), advertisements about therapeutic goods that are not available for purchase by the general public (section 16), and short form advertisements about therapeutic goods (section 17).

Division 3 deals with other advertisements about medicines, medical devices and other therapeutic goods. It identifies the circumstances in which health warnings and other required information must be included in an advertisement.

14 Application of this Part

This Part does not apply in relation to:

(a) labels of therapeutic goods; or

(b) consumer medicine information; or

(c) instructions for use; or

(d) patient information leaflets; or

(e) advertisements about therapeutic goods that comprise one or more of the following:

(i) the name of the goods;

(ii) a pictorial representation of the goods;

(iii) the price of the goods;

(iv) the point of sale of the goods;

and does not refer, expressly or by implication, to a claim relating to therapeutic use.

Division 2—Mandatory statements for particular advertisements

Note: Advertisements mentioned in this Division do not need to comply with Division 3.

15 Advertisements—therapeutic goods only available from a pharmacist

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

ASK YOUR PHARMACIST ABOUT THIS PRODUCT

16 Advertisements—therapeutic goods not available for purchase by general public

Where:

(a) an advertisement about therapeutic goods is published or disseminated to the general public; and

(b) the goods are only available for supply through a health professional;

then the advertisement must contain the following statement, prominently displayed or communicated:

THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC

17 Advertisements—short form

An advertisement about therapeutic goods that is a short form advertisement must contain the following statement, prominently displayed or communicated:

ALWAYS FOLLOW THE DIRECTIONS FOR USE

Division 3—Mandatory statements and other required information for other advertisements

18 Application of this Division

This Division does not apply to an advertisement mentioned in Division 2.

19 Advertisements—medicines

General requirements

(1) An advertisement about a medicine must contain:

(a) the name of the medicine within the meaning of TGO 92; and

(b) one or more accepted indications for the medicine; and

(c) the following statement, prominently displayed or communicated:

ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE

Additional requirements for advertisements that facilitate directly the supply of medicines not able to be physically inspected before supply

(2) Where:

(a) an advertisement facilitates directly the purchase or other supply of a medicine; and

(b) the medicine is not able to be physically inspected by a consumer before the purchase or other supply;

Note: For paragraphs (a) and (b), an advertisement that facilitates directly the purchase or other supply of a medicine without prior physical inspection includes an advertisement that is published on a website, social media, or a software application, through which a transaction for the medicine may be conducted.

then the advertisement must also include:

(c) the name of the dosage form within the meaning of TGO 92; and

(d) the quantity of the medicine within the meaning of TGO 92; and

(e) each active ingredient; and

(f) if one or more health warnings apply in relation to the medicine—either of the following, prominently displayed or communicated:

(i) a list of the health warnings; or

(ii) a link to the health warnings.

(3) For subparagraph (2)(f)(ii), a link to health warnings in relation to a medicine must provide a consumer with direct access to the warnings or a document containing those warnings.

(4) In this section:

accepted indication means:

(a) in relation to a medicine that is included in the Register—an indication that is accepted in relation to the inclusion of the medicine; or

(b) in relation to a medicine that is not included in the Register and is not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication that is displayed on the label of the medicine.

Note: Regulation 7 of the Regulations prescribes therapeutic goods for the purposes of the offence and civil penalty provisions in subsections 42DL(12) and 42DLB(9) of the Act, respectively. Medicines prescribed in this regulation, and not included in the Register, must not be advertised to consumers. Medicines that are not prescribed, and not included in the Register, may be advertised to consumers.

health warning, in relation to a medicine (or an ingredient contained in the medicine), means a warning, contra-indication, precaution or restriction, that is:

(a) required under a relevant instrument to be included on the label of the medicine; and

(b) reasonably necessary to inform a decision of a consumer to purchase the medicine.

relevant instrument means one or more of the following:

(a) an instrument made under subsection 3(5A) of the Act relating to medicine advisory statements;
(b) a determination made under section 26BB of the Act relating to permissible ingredients;
(c) a determination made under section 26BF of the Act relating to permissible indications;
(d) a condition of registration or listing imposed under the Act in relation to the medicine;
(e) TGO 92.

Note 1: The instrument made under subsection 3(5A) of the Act that is in force at the commencement of this Code is the *Therapeutic Goods (Medicines Advisory Statements) Specification 2021*.

Note 2: The following determinations made under sections 26BB and 26BF of the Act, respectively, are in force at the commencement of this Code:
(a) *Therapeutic Goods (Permissible Ingredients) Determination (No. 3) 2021*;
(b) *Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021*.

Note 3: The instruments mentioned in notes 1 and 2 are legislative instruments published on the Federal Register of Legislation at www.legislation.gov.au.

20 Advertisements—medical devices

General requirements

(1) An advertisement about a medical device must contain:
(a) the trade name of the device; and
(b) an accurate description of the device; and
(c) one or more accepted intended purposes for the device; and
(d) either of the following statements, prominently displayed or communicated:

ALWAYS FOLLOW THE DIRECTIONS FOR USE

ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE

Additional requirements for advertisements that facilitate directly the supply of medical devices not able to be physically inspected before supply

(2) Where:
(a) an advertisement facilitates directly the purchase or other supply of a medical device; and
(b) the device is not able to be physically inspected by a consumer before the purchase or other supply;

Note: For paragraphs (a) and (b), an advertisement that facilitates directly the purchase or other supply of a medical device without prior physical inspection includes an advertisement that is published on a website, social media, or a software application, through which a transaction for the device may be conducted.

then the advertisement must also include:

(c) each ingredient of the device that is a substance included in a schedule to the current Poisons Standard, where relevant; and

(d) if one or more health warnings apply in relation to the device—either of the following, prominently displayed or communicated:

(i) a list of the health warnings; or

(ii) a link to the health warnings.

(3) For subparagraph (2)(d)(ii), a link to health warnings in relation to a medical device must provide a consumer with direct access to the warnings or a document containing those warnings.

(4) In this section:

accepted intended purpose means:

(a) in relation to a medical device that is included in the Register—an intended purpose that is accepted in relation to the inclusion of the device; or

(b) in relation to a medical device that is not included in the Register and is not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an intended purpose that is displayed on the label of the device, and otherwise communicated in the instructions for use for the device.

Note: Regulation 7 of the Regulations prescribes therapeutic goods for the purposes of the offence and civil penalty provisions in subsections 42DL(12) and 42DLB(9) of the Act, respectively. Medical devices prescribed in this regulation, and not included in the Register, must not be advertised to consumers. Medical devices that are not prescribed, and not included in the Register, may be advertised to consumers.

health warning, in relation to a medical device (or an ingredient contained in the device), means a warning, contra-indication, precaution or restriction, that is:

(a) required under a relevant instrument to be included on the label, or in the instructions for use, of the device; and

(b) reasonably necessary to inform a decision of a consumer to purchase the device.

relevant instrument means one or more of the following:

(a) the Medical Devices Regulations;

(b) a condition of inclusion imposed under the Act in relation to the device;

(c) the current Poisons Standard.

21 Advertisements—other therapeutic goods

General requirements

(1) An advertisement about other therapeutic goods must contain:

(a) the trade name of the goods; and

(b) an accurate description of the goods; and

(c) one or more accepted indications for the goods; and

(d) where there is a label on or attached to the goods—the following statement, prominently displayed or communicated:

ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE

(e) where there is no label on or attached to the goods—the following statement, prominently displayed or communicated:

ALWAYS FOLLOW THE DIRECTIONS FOR USE

Additional requirements for advertisements that facilitate directly the supply of other therapeutic goods not able to be physically inspected before supply

(2) Where:

(a) an advertisement facilitates directly the purchase or other supply of other therapeutic goods; and

(b) the goods are not able to be physically inspected by a consumer before the purchase or other supply;

Note: For paragraphs (a) and (b), an advertisement that facilitates directly the purchase or other supply of other therapeutic goods without prior physical inspection includes an advertisement that is published on a website, social media, or a software application, through which a transaction for the goods may be conducted.

then the advertisement must also include:

(c) each ingredient of the goods that is a substance included in a schedule to the current Poisons Standard, where relevant; and

(d) if one or more health warnings apply in relation to the goods—either of the following, prominently displayed or communicated:

(i) a list of the health warnings; or

(ii) a link to the health warnings.

(3) For subparagraph (2)(d)(ii), a link to health warnings in relation to other therapeutic goods must provide a consumer with direct access to the warnings or a document containing those warnings.

(4) In this section:

accepted indication means:

(a) in relation to other therapeutic goods that are included in the Register—an indication that is accepted in relation to the inclusion of the goods; or

(b) in relation to other therapeutic goods that are not included in the Register and are not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication that is displayed on the label of the goods.

Note: Regulation 7 of the Regulations prescribes therapeutic goods for the purposes of the offence and civil penalty provisions in subsections 42DL(12) and 42DLB(9) of the Act, respectively. Other therapeutic goods prescribed in this regulation, and not included in the Register, must not be advertised to consumers. Other therapeutic goods that are not prescribed, and not included in the Register, may be advertised to consumers.

health warning, in relation to other therapeutic goods (or an ingredient contained in the goods), means a warning, contra-indication, precaution or restriction, that is:

(a) required under a relevant instrument to be included on the label, or in the instructions for use, of the goods; and

(b) reasonably necessary to inform a decision of a consumer to purchase the goods.

relevant instrument means one or more of the following:

(a) a condition of listing imposed under the Act in relation to the goods;

(b) the current Poisons Standard.

Part 5—Additional requirements for advertisements about particular therapeutic goods

Note: This Part deals with additional requirements for advertisements about analgesics, sunscreens and therapeutic goods for weight management. The requirements in Part 5 apply in addition to the requirements in Part 4 (as applicable).

22 Application of this Part

This Part does not apply in relation to:

(a) labels of therapeutic goods; or

(b) consumer medicine information; or

(c) instructions for use; or

(d) patient information leaflets.

23 Additional requirements for particular therapeutic goods

Analgesics

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

INCORRECT USE COULD BE HARMFUL

Complementary medicines

(2) If an advertisement about a complementary medicine includes one or more claims based on evidence of traditional use, then a statement about the reliance on the traditional use must be prominently displayed or communicated in the advertisement.

Sunscreens

(3) An advertisement about a therapeutic good that is, or contains, a sunscreen and that claims or implies that the sunscreen will prevent sunburn or skin cancer, must:

(a) depict sunscreen as being only one component of sun protection; and

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

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

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

Therapeutic goods relating to weight management

(4) An advertisement about therapeutic goods that contains one or more claims relating to weight management:

(a) must include statements or visual representations, that are prominently displayed or communicated, which promote the need for a healthy energy-controlled diet and physical activity; and

(b) must not include any reference or depiction suggesting that the therapeutic goods will correct or reverse the effects of overeating or over-consumption of food or drink; and

(c) must not contain visual representations, statistics or testimonials of individuals that are not consistent with the results that would be expected to be achieved on average by consumers of the goods.

(5) 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.

Part 6—Testimonials and endorsements

24 Testimonials and endorsements

(1) A testimonial or endorsement used in an advertisement about therapeutic goods must comply with the requirements of this section, and all other applicable provisions of this Code.

(2) A testimonial or endorsement about therapeutic goods must not be inconsistent with:

(a) the label for the goods; and

(b) the directions for use or the instructions for use for the goods; and

(c) either of the following:

(i) in relation to goods that are included in the Register—an indication or intended purpose that is accepted in relation to the inclusion of the goods; or

(ii) in relation to goods that are not included in the Register and are not prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the Act—an indication or intended purpose that is displayed on the label of the goods, and otherwise communicated in the directions for use or the instructions for use for the goods.

Note: Regulation 7 of the Regulations prescribes therapeutic goods for the purposes of the offence and civil penalty provisions in subsections 42DL(12) and 42DLB(9) of the Act, respectively. Therapeutic goods prescribed in this regulation, and not included in the Register, must not be advertised to consumers. Therapeutic goods that are not prescribed, and not included in the Register, may be advertised to consumers.

(3) If a testimonial or endorsement about therapeutic goods refers, expressly or by implication, to a health benefit, then the health benefit must be typical of the benefit expected from the goods when used in accordance with the label, the directions for use or instructions for use, and the indication or intended purpose accepted in relation to the inclusion of the goods in the Register (where applicable).

(4) An advertisement about therapeutic goods must not contain a testimonial if the testimonial is made by any of the following:

(a) a person who is engaged in the production, marketing or supply of the goods (a ***relevant person***);

(b) a member of a relevant person's immediate family, unless the advertisement discloses that the person who made the testimonial is an immediate family member of the relevant person;

(c) a person or organisation mentioned in paragraphs (6)(a) to (e);

(d) a corporation.

Note: For paragraph (4)(a), a person who is engaged in the marketing or supply of therapeutic goods includes influencers, direct sellers and other persons who have, or will receive, valuable consideration for making the testimonial.

(5) An advertisement about therapeutic goods must not contain a testimonial, unless the advertiser has verified the content of, and identity of the person making, the testimonial.

(6) An endorsement about therapeutic goods must not be given, whether expressly or by implication, by any of the following:

(a) a government or government authority, unless otherwise permitted by the Act or Regulations;

(b) a hospital, or healthcare facility, other than a community pharmacy;

(c) employees or contractors of a body mentioned in paragraphs (a) or (b);

(d) a current or former health practitioner, health professional or medical researcher;

(e) a person who represents themselves as being qualified or trained to diagnose, treat or prevent disease, ailment, defect or injury in persons;

(f) an organisation that represents the interests of healthcare consumers, or represents the interests of persons mentioned in paragraph (d), unless the advertisement discloses:

(i) the name of the organisation; and

(ii) whether the organisation has received, or will receive, any valuable consideration for the endorsement.

Part 7—Samples and incentives

25 Samples

(1) An advertisement about therapeutic goods must not contain or consist of a sample, or an offer of a sample, of therapeutic goods, unless:

(a) the goods are mentioned in an item in Annexure 2; and

(b) the conditions (if any) for that item are met; and

(c) the goods do not contain a substance included in Schedule 2, 3, 4 or 8 to the current Poisons Standard; and

(d) in relation to goods included in the Register—the goods are supplied in a pack accepted in relation to the inclusion of the goods.

Note: It is an offence or contravention of a civil penalty provision in subsections 42DL(12) and 42DLB(9) of the Act respectively to offer or supply a sample of therapeutic goods that are prescribed in regulation 7 of the Regulations for the purposes of subsections 42DL(12) and 42DLB(9) of the Act, and not included in the Register.

(2) In this section:

sample, in relation to therapeutic goods, means any goods given for free.

Note: A sample does not include therapeutic goods offered under a 'buy one, get one free' arrangement, provided the free therapeutic goods are the same as the purchased therapeutic goods.

26 Incentives

An advertisement about therapeutic goods must not offer any personal incentive or commission to a pharmacy assistant, or any retail salesperson who is not a health professional, in exchange for recommending or supplying the goods.

Part 8—Restricted representations

27 Simplified outline of this Part

This Part deals with restricted representations for the purposes of section 42DD of the Act. It identifies the circumstances in which a disease, condition, ailment or defect is considered to be a serious form, and mentions the public interest criteria for deciding whether to approve or refuse the use of restricted representations under section 42DF of the Act.

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

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 health practitioner who is suitably qualified, 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;

but does not include:

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

Note 1: 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 2: 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.

Note 3: A restricted representation in the form of a warning or contra-indication that is required by a legislative instrument to be included in an advertisement may be used without prior approval (under section 42DF of the Act), permission (under section 42DK of the Act) or authorisation (for the purposes of sections 42DL and 42DLB of the Act).

Note 4: See Part 5-1 of the Act and Part 2 of, and Schedule 2 to, the Regulations for requirements relating to restricted representations and prohibited representations.

29 Restricted representations—public interest criteria

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

(a) whether the representation would be likely to exploit, or take advantage of, vulnerable consumers, or particular groups of consumers, impacted by the disease, condition, ailment or defect; and

(b) whether the representation would be likely to delay or discourage consumers from seeking timely medical attention, where the attention is necessary to prevent negative health consequences, morbidity or mortality, or deterioration or progression of the disease, condition, ailment or defect; and

(c) whether the representation (itself or together with other representations) would be likely to have a negative impact on public health; and

(d) any other public interest criteria that the Secretary considers relevant.

Note: This section mentions the public interest criteria that the Secretary must consider when deciding to approve or refuse the use of a restricted representation under section 42DF of the Act.

Part 9—Price information

Note: To avoid doubt, the publication or dissemination of price information made in accordance with this Part is authorised by the Department for the purposes of subsections 42DL(10) and 42DLB(7) of the Act.

30 Simplified outline of this Part

This Part sets 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.

31 Application of this Part

This Part applies to an advertisement about therapeutic goods that is, or comprises, price information:

(a) in relation to medicines that are registered goods and contain a substance included in Schedule 3, 4 or 8 to the current Poisons Standard (but not included in Appendix H of the current Poisons Standard); and

(b) published or disseminated to the general public.

32 Publication or dissemination of price information

(1) Price information may only be published or disseminated by a retail pharmacy, an agent acting on behalf of a retail pharmacy (including a pharmacy marketing group), or a medical practitioner approved under section 92 of the *National Health Act 1953*.

(2) Price information must not be published or disseminated in relation to a medicine listed in the pharmaceutical benefits scheme, and supplied through alternative arrangements under section 100 of the *National Health Act 1953*, other than dispensing fees for buprenorphine hydrochloride and methadone hydrochloride.

(3) Price information may be published or disseminated by any means, other than the following:

(a) radio or television transmission, including pay and streaming services;

(b) digital or non-digital displays, including but not limited to displays:

(i) in shopping malls outside individual pharmacies;

(ii) in or on public transport;

(iii) on billboards;

(c) cinema advertising.

Online price information published or disseminated through a search function

(4) Where price information for a medicine is published or disseminated 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; or

(b) if the search is conducted using an active ingredient or part thereof of the medicine—a list of relevant medicines in alphabetical order.

(5) The following provisions of this Part do not apply to price information published or disseminated in accordance with subsection (4):
(a) paragraph 33(1)(a) and subsections 33(2) and (3); and
(b) paragraph 35(a); and
(c) section 36.

33 Presentation of price information

List of medicines

(1) Price information in relation to a medicine must be:
(a) published or disseminated in a list containing not less than 25 medicines (the ***price information list***); and
(b) accompanied by the name and contact details of the retail supplier from whom each medicine mentioned in the price information list may be purchased at the list price.

Alphabetical order

(2) Subject to subsection (3), a price information list must specify medicines in alphabetical order with reference to trade name or active ingredient.

Medicine grouping

(3) Medicines may be grouped in a price information list according to the schedule in the current Poisons Standard in which the medicines are included, provided that the price information list contains three or more:
(a) medicines from each schedule in each grouping; and
(b) persons in whose names the medicines are included in the Register.

34 Description of medicines

(1) A medicine in a price information list must be specified with reference to the name of the medicine within the meaning of TGO 91 or TGO 92, as applicable.

(2) A price information list must include, in relation to each medicine:
(a) if there is more than one strength of the medicine—the strength of each active ingredient as it appears on the label of the medicine; and
(b) the dosage form in which the medicine is presented; and
(c) the purchase price of the relevant number of units of the standard pack accepted in relation to the inclusion of the medicine in the Register (***standard pack***); and
(d) the quantity contained in the standard pack.

(3) For this section, the ***relevant number of units*** of a standard pack is:
(a) if the pharmaceutical benefits scheme or Repatriation Pharmaceutical Benefits Scheme permit more than one unit of the standard pack to be

prescribed—the maximum number of units that may be prescribed under those schemes; and

(b) otherwise—one.

(4) A price information list may include a reference to the requirement to obtain a prescription for a particular medicine.

35 General restrictions

A price information list must not:

(a) 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 mentioned in the price information list; or

(b) be accompanied by any promotional statement, pictorial representation or design; or

(c) include:

(i) an adjective or phrase that qualifies the name, formulation or pack size of the medicine; or

(ii) a term indicating the predicted or recommended length of supply; or

(iii) any embellishment; or

(d) promote the purchase of quantities or multiple pack sizes that are not accepted in relation to the inclusion of the goods in the Register, except as provided under section 34; or

(e) use a comparative adjective or term to qualify the purchase price of the medicine; or

(f) give any prominence to the text of the name, description or purchase price of a particular medicine compared to any other medicine in the price information list; or

(g) offer rewards or bonus points, or be associated with any other advertising that promotes rewards or bonus points; or

(h) limit or qualify the availability of the price, other than by including a statement of validity or expiration of the purchase price; or

(i) be accompanied by, or located in proximity to, information (including implications or references to other sources of information) regarding indications, diseases, conditions, ailments or defects, so that a reasonable person might infer that the medicine would cure or alleviate those diseases, conditions, ailments or defects.

36 Medicines listed in the pharmaceutical benefits scheme

(1) If:

(a) a pharmacy marketing group publishes or disseminates a price information list that includes price information for a medicine listed in the pharmaceutical benefits scheme that is a brand premium or therapeutic group premium; and

(b) the price information list mentioned in paragraph (a) includes price information for the pharmacy marketing group's own generic medicine that is listed in the pharmaceutical benefits scheme;

then the price information list must also include price information for at least one other bench-mark price brand of that medicine, where such medicine exists.

(2) A price information list that includes a medicine listed in the pharmaceutical benefits scheme must clearly:

(a) indicate that the medicine is listed in the pharmaceutical benefits scheme; and

(b) specify the total purchase price with reference to the general price or concessional price or both.

(3) A price information list that includes a medicine listed in the pharmaceutical benefits scheme must indicate that the purchase price:

(a) is subsidised by the Australian Government; and

(b) only applies when the medicine is prescribed for the medical conditions listed in the pharmaceutical benefits scheme schedule for that medicine.

(4) A price information list may include a statement that particular medicines are listed in the pharmaceutical benefits scheme only in relation to certain diseases, conditions, ailments or defects (without specifying those diseases, conditions, ailments or defects).

Annexure 1—Advertising to children

Note: See section 12.

Therapeutic goods that may be advertised to children aged 12 years and over		
Column 1	**Column 2**	**Column 3**
Item	**Therapeutic goods**	**Conditions**
1	acne preparations	
2	anti-dandruff preparations	
3	Class I medical devices for the management of chronic conditions under medical supervision	
4	cold sore preparations	
5	condoms and personal lubricants	
6	face masks and gloves for preventing the transmission of diseases between persons	
7	hand sanitisers	
8	lip balm	
9	oral hygiene products, including toothpaste, mouthwash and interdental brushes	
10	oral rehydration products	
11	sunscreens with a sun protection factor of more than 15	
12	tampons and menstrual cups	
13	wound care dressings for superficial wounds, including first aid items and antiseptics	

Annexure 2—Samples

Note: See section 25.

Therapeutic goods that may be offered as samples		
Column 1	**Column 2**	**Column 3**
Item	**Therapeutic goods**	**Conditions**
1	condoms and personal lubricants	
2	continence catheter devices for self-management	
3	COVID-19 rapid antigen tests for self-testing	
4	disinfectants	
5	face masks and gloves for preventing the transmission of disease in persons	
6	hand sanitisers	
7	lancets and blood glucose strips for use in connection with measuring blood glucose	
8	nicotine replacement therapies administered by oromucosal or transdermal means, including sprays, patches, gums, lozenges, sachets and tablets	
9	oral hygiene products, including toothpaste, mouthwash and interdental brushes	
10	oral rehydration products	
11	stoma devices for self-management	
12	sunscreens and other therapeutic goods containing sunscreen	
13	tampons and menstrual cups	
14	wound care dressings for superficial wounds, including first aid items and antiseptics	

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

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 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 (Therapeutic Goods Advertising Code) Instrument 2021	1 Dec 2021 (F2021L01661)	1 Jan 2022	s 5
Therapeutic Goods (Therapeutic Goods Advertising Code) Amendment (2022 Measures No. 1) Instrument 2022	15 Dec 2022 (F2022L01650)	20 Dec 2022	Sch 1 (item 2)

Endnote 4—Amendment history

Provision affected	How affected
s 2…….	rep LA s 48D
s 6…….	rep LA s 48C
Schedule 1	
Part 2	
s 6…….	am F2022L01650