



Therapeutic Goods Advertising Code 2018

I, John Skerritt, Deputy Secretary, a delegate of the Minister for Health for the purposes of section 42BAA of the *Therapeutic Goods Act 1989*, make the following Code under that section.

Dated June 29, 2018

(Signed by)

John Skerritt
Delegate of the Minister for Health

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Part 1—Preliminary

1 Name

This instrument is the *Therapeutic Goods Advertising Code 2018*.

2 Commencement

This instrument commences on 1 January 2019.

3 Repeal of previous Advertising Code

The *Therapeutic Goods Advertising Code 2015* is repealed.

4 Definitions

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

- (a) advertise;
- (b) directions for use;
- (c) health practitioner;
- (d) included in the Register;
- (e) indications;
- (f) label;
- (g) medical device;
- (h) medicine;
- (i) presentation;
- (j) primary pack;
- (k) Register;
- (l) sponsor;
- (m) State;
- (n) State law;
- (o) supply;
- (p) therapeutic goods;
- (q) therapeutic use.

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*.

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*.

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

- (a) in the case of 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; and
- (b) in the case of a spoken statement—able to be clearly heard and understood.

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

health warning, in relation to therapeutic goods, means a statement that is required on the label or instructions for use that warns that a person who takes or uses the goods 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 goods; or
- (c) require a medical practitioner to treat or prevent any of the following as a consequence of taking or using the goods:
 - (i) injury;
 - (ii) disability;
 - (iii) incapacity;
 - (iv) impairment of any bodily function, organ or structure.

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 1 to the Medical Devices Regulations.

Poisons Standard means the Standard in force under section 52D of the Act at the commencement of this Code.

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) in relation to 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) having the same prominence as the most noticeable representations or statements in the advertisement; and
- (b) in the case of 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; and
- (c) in the case of a spoken statement—able to be clearly heard and understood; and
- (d) in the case of a visual advertisement not designed to be viewed all at once—repeated as often as is necessary to ensure that is likely to be seen by a viewer.

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 Poisons Standard.

5 Object

The Object of this Code 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 of the Code

- (1) Subject to subsection (2), this Code 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 Code does not apply to advertisements directed exclusively to health professionals.
 - (3) This Code is to be applied, 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 Code to an advertisement, the total presentation and context of the advertisement is to be taken into account.
 - (5) This Code 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 Code 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.

7 Price information

- (1) This Code, other than Schedule 1, does not apply to advertising that consists solely of the dissemination of price information.
- (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 1.

Part 2—Requirements for advertising therapeutic goods— general

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 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 displaying only the name or picture of therapeutic goods or their price or point of sale, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation; or
 - (d) an advertisement that is covered by section 12; or
 - (e) an advertisement for a medicine that is covered by section 14.
- (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) a reference to the indications for the medicine;
 - (c) subject to subsection (5)—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, displayed or communicated: <i>ALWAYS READ THE LABEL</i> |

| | |
|--|---|
| A medicine for which there are health warnings | <p>Either:</p> <p>(a) the following statement, prominently displayed or communicated: <i>THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE</i>; or</p> <p>(b) both of the following, displayed or communicated:</p> <p>(i) the following statement: <i>ALWAYS READ THE LABEL</i>; and</p> <p>(ii) the health warnings.</p> |
|--|---|

- (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) a reference to the intended purpose of, or indications for, 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 | <p>One of the following statements, as appropriate for the packaging of the device, displayed or communicated:</p> <p>(a) <i>ALWAYS READ THE LABEL</i>; or</p> <p>(b) <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i></p> |
| A device for which there are health warnings | <p>Where the label of the device is visible on the primary pack, one of the following:</p> <p>(a) the following statement, prominently displayed or communicated: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE</i>; or</p> <p>b) both of the following, displayed or communicated:</p> <p>(i) <i>ALWAYS READ THE LABEL</i>; and</p> <p>(ii) the health warnings.</p> <p>Where the device does not have a label visible on the primary pack, one of the following:</p> <p>(a) the following statement, prominently displayed or communicated: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE</i>; or</p> <p>b) both of the following, displayed or communicated:</p> |

-
- (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) a reference to the intended purpose of, or indications for, 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, displayed or communicated: <ul style="list-style-type: none"> (a) <i>ALWAYS READ THE LABEL</i>; or (b) <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i> |
| 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: <ul style="list-style-type: none"> (a) the following statement, prominently displayed or communicated: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE</i>; or (b) both of the following, displayed or communicated: <ul style="list-style-type: none"> (i) the following statement: <i>ALWAYS READ THE LABEL</i>; and (ii) the health warnings. Where the goods do not have a label visible on the primary pack, one of the following: <ul style="list-style-type: none"> (a) the following statement, prominently displayed or communicated: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE</i>; or (b) both of the following, displayed or communicated: <ul style="list-style-type: none"> (i) the following statements: <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i>; and (ii) the health warnings. |

- (5) Paragraphs (2)(c), (3)(d) and (4)(d) do not apply to radio commercials that are 15 seconds or less in duration or to written advertisements that consist of 300 characters or less.

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

- (1) This section applies to advertisements for goods that are not available for physical examination by the consumer before or at the time of purchase.
- Note: This section does not apply to advertisements covered by section 11.
- (2) This section does not apply to:
- (a) a label or consumer medicine information; or
 - (b) a patient information leaflet.
- (3) For the purposes of this section, a statement that is required to be prominently displayed or communicated must be displayed in close proximity to either:
- (a) the first use of the name of the medicine in the advertisement; or
 - (b) where the name of the medicine is not used—the first image of the primary pack of the medicine in the advertisement; or
 - (c) where the name and image of the medicine is not used—at the beginning of the advertisement.
- (4) 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) the indications for the medicine;
 - (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, displayed or communicated: <i>ALWAYS READ THE LABEL</i> |

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

- (g) as applicable, the required statements mentioned in subsection 13(3) and sections 24 and 27, prominently displayed or communicated;
- (h) as applicable, the required statements mentioned in subsection 13(2) and section 23, displayed or communicated;
- (i) any other mandatory warnings or advisory statements that are required to be included on the label for the medicine, displayed or communicated.

(5) 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) the intended purpose of, or indications for, 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 | <p>One of the following statements, as appropriate for the packaging of the device, displayed or communicated:</p> <p>(a) <i>ALWAYS READ THE LABEL</i>; or</p> <p>(b) <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i></p> |
| A device for which there are health warnings | <p>One of the following:</p> <p>(a) the following statement, prominently displayed or communicated, followed immediately by information about where the health warnings can be found: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE</i>; or</p> <p>(b) both of the following, displayed or communicated:</p> |

-
- (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 statements mentioned in subsection 13(3) (as applicable), prominently displayed or communicated;
 - (g) the required statements mentioned in subsection 13(2), displayed or communicated ;
 - (h) any other mandatory warnings or advisory statements that are required to be provided with the device, displayed or communicated .
- (6) 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) the intended purpose of, or indications for, 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, displayed or communicated: <ul style="list-style-type: none"> (a) <i>ALWAYS READ THE LABEL</i>; or (b) <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i> |
| Other therapeutic goods for which there are health warnings | One of the following: <ul style="list-style-type: none"> (a) the following statement, prominently displayed or communicated, followed immediately by information about where the health warnings can be found: <i>THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE</i>; or (b) both of the following, displayed or communicated: <ul style="list-style-type: none"> (i) one of the following statements, as appropriate for the packaging of the goods: <ul style="list-style-type: none"> (A) <i>ALWAYS READ THE LABEL</i>; or (B) <i>ALWAYS READ THE INSTRUCTIONS FOR USE</i>; and (ii) the health warnings. |

- (f) the required statements mentioned in subsection 13(3) (as applicable) prominently displayed or communicated;
- (g) the required statements mentioned in subsection 13(2), displayed or communicated;
- (h) any other mandatory warnings or advisory statements that are required to be provided with the good, displayed or communicated.

13 Required statements

- (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, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation; or
 - (d) an advertisement that is covered by section 12; or
 - (e) an advertisement for a medicine that is covered by section 14.
- (2) An advertisement must contain either of the following statements as appropriate, displayed or communicated:
 - (a) *FOLLOW THE DIRECTIONS FOR USE*; or
 - (b) *FOLLOW THE INSTRUCTIONS FOR USE*.
- (3) If an advertisement contains a claim relating to a symptom of a disease, condition, ailment or defect, the advertisement must contain either 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 HEALTHCARE PROFESSIONAL*; or
 - (b) *IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL*
- (4) Paragraph (3) does not apply to radio commercials that are 15 seconds or less in duration or to written advertisements that consist of 300 characters or less.

14 Required statement—pharmacist-only medicines

- (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, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation; or
 - (d) an advertisement that is covered by section 12.
- (2) An advertisement for a medicine consisting of, or containing, a substance included in Schedule 3 of the 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

15 Scientific 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 claim:
 - (a) any scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed; and
 - (b) any scientific representation must be consistent with the body of scientific evidence applicable to the advertised therapeutic goods.
- (3) Where an advertisement contains a citation to scientific literature, either explicitly or impliedly:
 - (a) any research results must identify the researcher and financial sponsor of the research; and
 - (b) if a specific research study is cited—the study must be sufficiently identified to enable consumers to access it.

16 Endorsements

- (1) This section does not apply to a testimonial covered by section 17.
- (2) An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by:
 - (a) a government agency, hospital or healthcare facility; or
 - (b) an employee or contractor of a government agency, hospital or healthcare facility; or
 - (c) a health practitioner, health professional, medical researcher or a group of such persons.
- (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.

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 or supply of the goods; or
 - (B) an employee or officer of a corporation that is involved with the production, sale or supply of the goods; or
 - (C) a body corporate; 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:
 - (a) disclose where any valuable consideration has been given to the person providing the testimonial; and
 - (b) disclose where another person is taking the place in the advertisement of the person providing the testimonial; and
 - (c) disclose where the person providing the testimonial is a relative or associate of an individual who is involved with the production, sale or supply 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) Advertising must not be primarily directed to children under the age of 12 years in any circumstances.
- (3) Advertising 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 is current at the time of advertising therapeutic goods, the promotion of the goods must not be inconsistent with the public health campaign and the other objects of this Code.

Part 3—Rules relating to particular therapeutic goods

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

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 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 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 sunscreen that claims or implies that 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) 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.

- 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.

(2) Subsection (1) does not apply to the diseases mentioned in section 30.

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 Code 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—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 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 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 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.

Schedule 2—Advertising to children

Note: See section 19.

1 Goods that may be advertised to children

For the purposes of section 19, the following therapeutic goods may be 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) sunscreens.