Therapeutic Goods Advertising Code 2015

made under section 42BAA of the *Therapeutic Goods Act 1989*

Compilation No. 1

Compilation date: **1 July 2018**

Includes amendments up to: **F2018L00977**

Prepared by Department of Health

About this compilation

This compilation

This is a compilation of the Therapeutic Goods Advertising Code 2015 that shows the text of the law as amended and in force on 1 July 2018 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

1 Object of the Code

(1) The Object of the Therapeutic Goods Advertising Code 2015 (the Code) is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.

(2) The Code is generally consistent with the *World Health Organisation (WHO): Ethical Criteria for Medicinal Drug Promotion 1988* (refer **Appendix 1**). In the event of any inconsistency between the Code and the WHO criteria, the Code prevails.

(3) In interpreting the Code, emphasis will be placed on the Object and the Principles of the Code and the total presentation and context of the advertisement.

2 Definitions

Act means the *Therapeutic Goods Act 1989*.

Advertisement is defined in section 3 of the Act.

Broadcast media is defined in section 42B of the Act.

Complaints Resolution Panel means the committee established by regulation 42R of the Regulations.

Current Poisons Standard is defined in section 52A of the Act

Designated therapeutic goods is defined in regulation 2 of the Regulations.

Label is defined in section 3 of the Act.

Mainstream media is defined in section 42B of the Act.

Price Information Code of Practice means the document of the same name that is published on the website of the Therapeutic Goods Administration (see http://www.tga.gov.au/publication/price-information-code-practice).

Regulations means the Therapeutic Goods Regulations 1990.

Specified media is defined in section 42B of the Act.

Sponsor is defined in section 3 of the Act.

Therapeutic goods is defined in section 3 of the Act.

Therapeutic Goods Advertising Code Council means the committee established by regulation 42A of the Regulations.

***Therapeutic* use** is defined in section 3 of the Act.

Typical means that which reflects the characteristic of a group i.e. a result obtained from the use of a product which would be likely to be attained by most people using the product within the audience to which the advertisement is directed.

3 Compliance with, and application of, the Code

(1) All advertisements for therapeutic goods are subject to the Act, the Regulations, the Australian Consumer Law under the *Competition and Consumer Act 2010* and other relevant laws. Compliance with this Code does not exempt advertisements from the application of those laws.

(a) Advertisements for therapeutic goods directed to consumers must comply with the Code.

(b) Advertisements for therapeutic goods directed exclusively to health professionals referred to in section 42AA of the Act, are not subject to this Code.

(c) This Code does not apply to bona fide news, public interest or entertainment programs; or information material which complies with the *Price Information Code of Practice*.

(2) The conformity of an advertisement with this Code should be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.

(3) Advertisements for designated therapeutic goods published or inserted, or intended to be published or inserted, for valuable consideration, in specified media must be approved under regulation 5G of the Regulations by the relevant delegate of the Secretary for compliance with the Code (Appendix 3 refers) prior to publication or broadcast, other than:

(a) advertisements for designated therapeutic goods that may be advertised and which comply with the requirements set out in subregulation 5C(2) of the Regulations; or

(b) information material that complies with the *Price Information Code of Practice*.

(4) Information about appeals and complaints is set out in **Appendix 4**.

4 General Principles

(1) An advertisement for therapeutic goods *must*:

(a) comply with the statute and common law of the Commonwealth, States and Territories; and

(b) contain correct and balanced statements only and claims which the sponsor has already verified.

(2) An advertisement for therapeutic goods *must not*:

(a) be likely to arouse unwarranted and unrealistic expectations of product effectiveness;

(b) be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;

(c) mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions;

(d) abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;

(e) contain any matter which is likely to lead persons to believe:
  (i) that they are suffering from a serious ailment; or
  (ii) that harmful consequences may result from the therapeutic good not being used.

  Sunscreen preparations are exempted from (ii) if the claims made in the advertisement are consistent with current public health messages.

(f) encourage, or be likely to encourage, inappropriate or excessive use;

(g) contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;

(h) contain any claim, statement or implication that it is effective in all cases of a condition;

(i) contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects; or

(j) be directed to minors, **except** the therapeutic goods listed in **Appendix 5**.

(3) Incentives to pharmacy assistants and other non-healthcare professional sales persons

An advertisement must not offer any personal incentive to a pharmacy assistant, or other non-healthcare-professional sales person at retail, to recommend or supply therapeutic goods.

(4) Scientific Information

Any scientific information in an advertisement should be presented in a manner that is accurate, balanced and not misleading. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed. Publication of research results must identify the researcher and financial sponsor of the research.

(5) Comparative Advertising

Comparative advertisements must be balanced and must not be misleading or likely to be misleading, either about the therapeutic goods advertised or the therapeutic goods, or classes of therapeutic goods, with which it is compared. Points of comparison should be factual and reflect the body of scientific evidence. Comparisons should not imply that the therapeutic goods, or classes of therapeutic goods, with which comparison is made, are harmful or ineffectual.

(6) Professional Recommendation

(a) Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and is not presented as an endorsement of a therapeutic good.

(b) Advertisements must not contain or imply endorsement by:

(i) any government agency;

(ii) hospitals and other facilities providing healthcare services;

(iii) individual or groups of health professionals referred to in section 42AA of the Act or any other person or group of persons represented directly or indirectly to be health professionals, other than where the emphasis is on the availability, which may include the price of therapeutic goods through his/her retail business; or

(iv) by individuals, who are health professionals by way of their representation in advertisements or academic qualifications, and/or who are likely to be known as health professionals by the reasonable person.

(c) Advertisements must not contain or imply endorsement of the goods by bodies or peak health professional associations that:

(i) represent the interests of health consumers;

(ii) conduct or fund research into a disease, condition disorder or syndrome; or

(iii) represent health professionals;

unless:

(iv) the advertisement names the body or association;

(v) the endorsement is authenticated;

(vi) the nature of the endorsement is clearly disclosed; and

(vii) the endorsement is based upon an objective assessment of available scientific data supporting the use of that product. Where this is not the case and where the body or association has received valuable consideration for the endorsement, the advertisement must acknowledge that consideration.

(7) Testimonials

Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.

(8) Samples

An advertisement for therapeutic goods (other than therapeutic devices and sun screening preparations) must not contain an offer of a sample.

5 Prohibitions

(1) An advertisement for therapeutic goods must not contain, expressly or by implication, a representation specified in **Part 1** of **Appendix 6**.

(2) An advertisement for therapeutic goods must not refer, expressly or by implication, to serious forms of diseases, conditions, ailments or defects specified in **Part 2** of **Appendix 6**, unless prior approval is given under the Act.

6 Minimum Requirements

(1) This section, other than paragraph (3)(b), does not apply to:

(a) advertisements for unbranded therapeutic goods; or

(b) labels.

(2) This section does not apply to retail advertisements displaying only the name/picture of the goods and/or price and/or the point of sale, provided the advertisement does not contain a claim for therapeutic use.

(3) An advertisement for therapeutic goods shall contain:

(a) the trade name of the goods;

(b) a reference to the approved/permitted indication(s) for the use of the goods; and

(c) where applicable, a list of ingredients or the following statement prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

ALWAYS READ THE LABEL

except:

(i) in the case of direct marketing and internet marketing, which must contain:

- a full list of the active ingredients. (Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement); and
- the mandatory warning statements prominently displayed on each page of the catalogue or internet that features therapeutic goods; and
- any mandatory advisory statements required to be included on the product label, prominently displayed on each page that features the relevant medicine(s); and
- if the medicine, when used according to the directions:
  - has known serious adverse effects (in terms of severity and clinical importance); or
  - is contraindicated for a known group of people because it could cause serious adverse effects which are reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI);

an appropriate warning of those effects must be given, prominently displayed on each page that features the relevant medicine(s); and

(ii) radio commercials which are 15 seconds or less.

(d) words to the following effect, prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

USE ONLY AS DIRECTED

and, in all advertisements other than radio commercials that are 15 seconds or less, for claims relating to symptoms of diseases or conditions,

IF SYMPTOMS PERSIST SEE YOUR DOCTOR/HEALTHCARE PROFESSIONAL

(e) or, in the case of Schedule 3 therapeutic goods listed in *Appendix H* of the current *Poisons Standard*, either :

(i) words to the effect of:

YOUR PHARMACIST'S ADVICE IS REQUIRED; or

(ii) the following statement:

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

Note: the *Poisons Standard* is also known as the *Standard for Uniform Scheduling of Medicines and Poisons*.

(f) and, in the case of therapeutic goods that are able to be lawfully advertised and are available only directly from, or on the recommendation of, a health professional (except in the case of S2 and S3), the following statements should be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

YOUR [APPROPRIATE HEALTHCARE PROFESSIONAL] WILL ADVISE YOU WHETHER THIS PREPARATION [PRODUCT NAME] IS SUITABLE FOR YOU/YOUR CONDITION.

(4) Print media advertisements for therapeutic goods must include the approval number which is to stand alone, be prominently displayed and located in the bottom right hand corner of the advertisements.

7 Specific Categories

(1) Analgesics

(a) Analgesics are those preparations for internal use containing one or more of the following substances intended for the relief of minor aches and pains:

(iii) salicylic acid, its salts, its derivatives (including aspirin) and their salts;
(iv) codeine;
(v) other non-steroidal anti-inflammatory drugs; or
(vi) paracetamol.

(b) This excludes preparations for internal use in self-limiting conditions and which contain an analgesic in combination with one or more other active ingredients such as cough mixtures and cold tablets.

(c) An advertisement for analgesics (other than product labels and radio advertisements which are 15 seconds or less) must contain the following warning statement, prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or heard and understood:

Use only as directed. Incorrect use could be harmful. Consult your healthcare professional if symptoms persist

(d) Radio advertisements which are 15 seconds or less must include the following:

Always read the label. Use only as directed by a healthcare professional

(e) An advertisement for analgesics must not imply that:

(i) analgesic consumption is safe; or
(ii) analgesics will relax, relieve tension, sedate or stimulate.

(2) Vitamins

An advertisement for vitamins shall not imply that vitamin 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 or that normal health may be affected by not taking vitamin supplements.

(3) Weight management

Advertisements for therapeutic goods containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between the claims and references to healthy energy-controlled diet and physical activity.

Appendix 1
(Subsection 1(2) refers)

World Health Organisation (WHO): Ethical Criteria for Medicinal Drug Promotion 1988

WHO's *Ethical Criteria for Medicinal Drug Promotion 1988* are underpinned by the following main principles, cited verbatim:

(a) ***Promotion*** refers to all informational activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products.

(b) All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or give rise to undue risks.

(c) Comparison of products should be factual, fair and capable of substantiation.

(d) Advertisements to the general public should help people to make rational decisions on the use of drugs determined to be legally available without prescription. While they should take into account people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health, nor mislead the consumer into unwisely relying on medicines to solve physical, emotional or mood problems.

(e) The provision of free samples to the general public for promotional purposes is difficult to justify from a health perspective.

(f) Advertisements may claim that a drug can cure, prevent or relieve an ailment only if this can be substantiated.

(g) Language which brings fear or distress should not be used.

(h) Advertisements should not be allowed for certain serious conditions that can be treated only by qualified health practitioners.

Appendix 2

This Appendix deliberately left blank.

Appendix 3
(Subsection 3(3) refers)

Approval of mainstream advertisements

Advertisements for complementary medicines in specified media (other than broadcast media) that are required to be approved under regulation 5C of the Regulations must be submitted to:

The Office of Advertising Compliance
Complementary Healthcare Council of Australia
PO Box 820
MAWSON, ACT 2607

Ph: (02) 6260 4066
Fax: (02) 6260 4122
Email: advertising@chc.org.au

Advertisements for complementary medicines in broadcast media and all other therapeutic goods (other than goods that are not designated therapeutic goods) advertised in specified media that are required to be approved under regulation 5C of the Regulations, must be submitted to:

Advertising Services
Australian Self Medication Industry
PO Box 764
NORTH SYDNEY NSW 2059

Ph: (02) 9955 7205
Email: asmiadvertising@asmi.com.au

All advertisements for therapeutic goods that are required to be pre-approved prior to publication in specified media, other than broadcast media, must display the current approval number allocated to that advertisement as required by subsection 42C(4) of the Act.

Minimum requirements for the submission of advertisements

1. Typed copy (no smaller than 10 point), black copy on white background.
2. Draft layout or clear description of layout
3. For TVC's, copy of script with storyboard
4. For radio, copy of script to include sound-effect descriptions
5. Copy of appropriate documentation
   A – Certificate of Listing/Registration
   B – Label (enlarged for legibility)
   C – Approved indications of use (where applicable)
   D – Copy of any research/surveys/data referenced in advertisement (Note: further evidence to be provided if requested).
   E – Copy of documentation supporting professional recommendations and testimonials (Note: further evidence to be provided if requested)

Note:

1. Substantiation of therapeutic claims to be provided upon request
2. Substantiation, in line with levels of evidence required to be held by the sponsor at the time of listing or registration, may be required by the advertising services manager
3. Notwithstanding the above, further substantiation may also be requested
4. Listing or registration of a claim does **not** automatically mean that the claim may be advertised

Appendix 4
(Subsection 3(4) refers)

Appeals and Complaints Mechanisms

Review of a decision not to approve an advertisement (refer to regulation 5M of the Regulations)

In the event of an advertisement not gaining approval, a request to review the decision can be submitted to the Minister for Health in writing and must be made within 30 days after notice of the decision is given to the applicant.

The applicant must, at the same time, send a copy of the request for review of the decision to the Therapeutic Goods Advertising Code Council (the TGACC) (subregulation 5M(3) of the Regulations).

Level 13 Macquarie House
167 Macquarie Street
SYDNEY NSW 2000
Phone: (02) 8667 3026 or (02) 8667 3025
Email: jbrimer@tgacc.com.au

Complaints about advertisements or generic information (refer Subdivision 2, Division 3 of Part 6 of the Regulations)

A person may complain in writing about an advertisement or generic information to the Complaints Resolution Panel as set out in regulation 42ZCAB of the Regulations. Complaints may be lodged online at http://www.tgacrp.com.au/index.cfm?pageID=12 or by writing to:

Complaints Resolution Panel

Level 13 Macquarie House
167 Macquarie Street
SYDNEY NSW 2000

Complaints about other advertisements must be directed to the appropriate industry association or to the TGA. See http://www.tga.gov.au/regulation-therapeutic-goods-advertising-australia.

Appendix 5
(Paragraph 4(2)(j) refers)

Goods that may be advertised to minors

In considering whether or not to make a recommendation to the Secretary to amend Appendix 5 so as to permit therapeutic goods to be advertised to persons under the age of 18, the TGACC will satisfy itself on the following factors (which are not exhaustive):

1. That the likely audience could be expected to have the knowledge and maturity to self-diagnose and self-manage the condition(s) for which the goods are to be advertised;
2. That the advertising of the goods to the likely audience could reasonably be expected to deliver to them significant health benefits or significant improvements to their quality of life;
3. That the risk of over-use, misuse or inappropriate use in the likely audience is insignificant;
4. That over-use, misuse or inappropriate use of the goods is unlikely to cause significant harm;
5. That the advertising of the goods can be confined to the intended audience.

The following are not subject to paragraph 4(2)(j):

- Tampons
- Acne preparations
- Sunscreens SPF 15 +
- Condoms and personal lubricants
- Bandages and dressings
- Devices for management of chronic conditions under medical supervision
- Cold sore preparations
- Lip balm
- Unscheduled anti-dandruff preparations

Appendix 6
(Section 5 refers)

Prohibited, Restricted and Permissible Representations

Part 1 – Prohibited Representations

A prohibited representation is defined as:

(i) any representation regarding abortifacient action; or
(ii) any representation regarding the treatment, cure or prevention of the following diseases:
- Neoplastic
- Sexually Transmitted Diseases (STD)
- HIV AIDS and/or HCV; or
- Mental illness;

except for the following representations which are to become restricted representations:

(i) prevention of skin cancer through the use of sunscreens; or
(ii) devices used in contraception or in the prevention of transmission of disease between persons.

Part 2 – Restricted Representations

An advertisement for therapeutic goods may refer, expressly or by implication, to a disease, condition, ailment or defect specified in **Table 1**, provided that prior approval for such a reference is obtained from the Secretary of the Department of Health.

Approval may be given by a delegate of the Secretary in the TGA, taking into consideration any recommendation from the TGACC and appropriate expert committee or committees.

Table 1. Diseases, conditions, ailments and defects for which the advertising of serious forms is restricted

- Cardiovascular diseases
- Dental and periodontal diseases
- Diseases of joint, bone, collagen, and rheumatic disease
- Diseases of the eye or ear likely to lead to blindness or deafness
- Diseases of the liver, biliary system or pancreas
- Endocrine diseases and conditions including diabetes and prostatic disease
- Gastrointestinal diseases or disorders
- Haematological diseases
- Infectious diseases
- Immunological diseases
- Mental disturbances
- Metabolic disorders
- Musculoskeletal diseases
- Nervous system diseases
- Poisoning, venomous bites and stings
- Renal diseases

- Respiratory diseases
- Skin diseases
- Substance dependence
- Urogenital diseases and conditions

Serious in the context of this table will mean forms of those diseases, conditions, ailments or defects which are:

- Generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or
- Generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

Public interest criteria to be applied
In considering an application for approval to include in an advertisement a reference to a disease, condition, ailment or defect specified in Part 2 of **Appendix 6**, the Secretary may consult the TGACC. In making a recommendation to the Secretary, the TGACC must take into account:

1. Consumers', or certain groups of consumers', vulnerability when faced with the disease, condition, ailment or defect;
2. Whether the reference would be likely to result in consumers not seeking timely professional advice where appropriate (such as where timely professional advice is important to prevent negative health consequences or irrevocable deterioration or progression of disease);
3. Whether the reference would be likely (alone or 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); and
4. Such other aspects of the public interest as may appear to be appropriate.
5. The World Health Organization notes that responsible self-medication can:
    - Help prevent and treat symptoms and ailments that do not require medical consultation;
    - Reduce the increasing pressure on medical services for the relief of minor ailments, especially when financial and human resources are limited;
    - Increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult; and
    - Enable patients to control their own chronic conditions.

Additional Note: If this were to apply to products that require prescribing following initial diagnosis, the Code would apply to the advertising of such products.

Endnotes

Endnote 1—About the endnotes

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

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

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

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

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

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

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods Advertising Code 2015	13 November 2015 F2015L01787	14 November 2015	none
Therapeutic Goods Advertising Code 2015 Amendment No. 1 of 2018	30 June 2018 F2018L00977	1 July 2018	none

Endnote 4—Amendment history

Provision affected	How affected
Paragraph 6(3)(e)	am F2018L00977