



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods Advertising Code 2005

I, David Graham, National Manager, Therapeutic Goods Administration and delegate of the Minister for Health and Ageing for the purposes of the exercise of the Minister's powers under subsection 3(1) of the *Therapeutic Goods Act 1989* and acting under that subsection, hereby:

- 1) **REVOKE** the Therapeutic Goods Advertising Code of 16 July 2003 as amended by the Therapeutic Goods Advertising Code: Amendments (20/01/05); (the superseded Code) and;
- 2) **REPLACE** the superseded Code with the Therapeutic Goods Advertising Code 2005.

The Therapeutic Goods Advertising Code 2005 commences on the day after it is registered in the Federal Register of Legislative Instruments.

Dated this nineteenth day of August 2005

David Graham
Delegate of the Minister for Health and Ageing

Therapeutic Goods Act 1989

Therapeutic Goods Advertising Code 2005

1 Object of the Code

- (1) The Object of the Therapeutic Goods Advertising Code 2005 (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

Advertisement in relation to therapeutic goods as defined in the *Therapeutic Goods Act 1989* includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods”.

Broadcast media in relation to an advertisement or generic information, means any means (other than a means declared in the Therapeutic Goods Regulations to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms.

Healthcare Professional includes a person that meets the description of a healthcare professional in subsection 42AA(1), (2), (3) of the *Therapeutic Goods Act 1989* (see Appendix 2) and any other person represented directly or indirectly to be a healthcare professional.

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.

Mainstream media means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

Specified media in relation to an advertisement or generic information, means:

- (a) mainstream media, within the meaning of s.42B of the Act; or
- (b) broadcast media, within the meaning of s.42B of the Act; or
- (c) cinematograph films; or
- (d) displays about goods, including posters:
 - (i) in shopping malls (except inside individual shops);
 - (ii) in or on public transport; and
 - (iii) on billboards.

Sponsor in relation to therapeutic goods, means:

- (a) a person who exports, or arranges the exportation of, the goods from Australia; or
- (b) a person who imports, or arranges the importation of, the goods into Australia; or
- (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

- (d) exports, imports or manufactures the goods; or
- (e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

Therapeutic goods are defined in the *Therapeutic Goods Act 1989* as goods:

- (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a) (ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- (c) goods declared not to be therapeutic goods under an order of force under section 7; or
- (d) goods in respect of which an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised or presented for supply in the way specified in the order where the goods are used, advertised or presented for supply in that way; or
- (e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the *Australia New Zealand Food Standards Code* as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or
- (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Therapeutic use is defined in the *Therapeutic Goods Act 1989* as meaning use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- (b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- (c) testing the susceptibility of persons or animals to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons or animals.

3 Compliance with, and application of, the Code

- (1) All advertisements for therapeutic goods are subject to the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations, the *Trade Practices Act 1974* 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 healthcare professionals are governed by industry codes of practice and are not subject to this Code. (**Appendix 2** refers).
 - (c) This Code does not apply to bona fide news, public interest or entertainment programs.
- (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 therapeutic goods appearing in specified and broadcast media must be approved by the appropriate Advertising Services Manager for compliance with the Code (**Appendix 3** refers) prior to publication or broadcast, other than:
- (a) therapeutic devices, and
 - (b) advertisements for those therapeutic goods that may be advertised and which display only name, picture and/or price and /or point of sale, without therapeutic claims.
- (4) Appeals and complaints shall be dealt with as 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 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 inappropriate or excessive consumption;
 - (g) contain any claim, statement or implication that it is infallible, unailing, 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 may contain or imply an endorsement by individual, or individual groups of, healthcare professionals in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing healthcare professionals, provided that the endorsement does not imply endorsement by any government agency, hospital or other facility providing healthcare services.

Such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the name of the endorser and acknowledgement of any valuable 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 *Therapeutic Goods Act 1989*.

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
- (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 *Standard for the Uniform Scheduling of Drugs and Poisons*, words to the effect of -

YOUR PHARMACIST'S ADVICE IS REQUIRED; and

- (f) 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:
 - (i) salicylic acid, its salts, its derivatives (including aspirin) and their salts;
 - (ii) codeine;
 - (iii) other non-steroidal anti-inflammatory drugs; or
 - (iv) 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

(Section 2 – Definitions – *Healthcare Professional* and Subsection 3(1)(b) refer)

Section 42AA of the *Therapeutic Goods Act 1989*

42AA This Part not to apply to advertisements directed at health professionals etc.

- (1) This Part does not apply to advertisements directed exclusively to:
 - (a) medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, scientists working in medical laboratories or nurses; or
 - (b) persons who are:
 - (i) engaged in the business of wholesaling therapeutic goods; or
 - (ii) purchasing officers in hospitals; or
 - (c) herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths registered under a law of a State or Territory.
- (2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies prescribed for the purposes of this subsection.
- (3) For the purposes of subsection (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.
- (4) This Part does not apply to advice or information given directly to a patient by a person referred to in paragraph (1)(a) or (c) or paragraph (2) above in the course of treatment of that patient.

Refer to Schedule 1 of the Regulations for a full list of bodies currently covered by subsection 42AA(2).

Appendix 3

(Subsection 3(3) refers)

Approval of mainstream advertisements

Advertisements for complementary healthcare products (other than devices) in specified media, other than broadcast media and cinematograph films are required under the Therapeutic Goods Act and Regulations to be submitted to:

Advertising Services
Complementary Healthcare Council
PO Box 104
DEAKIN WEST ACT 2600

Ph: (02) 9542 5860
Fax: (02) 6260 4122
Email: advertising@chc.org.au

Advertisements for complementary healthcare products advertised in broadcast media or cinematograph films, and all other therapeutic goods (other than devices) advertised in specified media, are required under the *Therapeutic Goods Act 1989* and Regulations to be submitted to:

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

(Suite 2202
Level 22, 141 Walker Street
NORTH SYDNEY NSW 2060)

Ph: (02) 9955 7205
Fax: (02) 9957 6204
Email: cath@asmi.com.au

All specified media advertisements, other than broadcast media advertisements, for therapeutic goods must display the current approval number allocated to that advertisement as required under s.42C(4)(b) of the *Therapeutic Goods Act 1989*.

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

In the event of an advertisement not gaining approval, a request to review the decision must be submitted to the Minister for Health & Ageing (refer Regulation 5M).

The request must be made within 30 days after notice of the decision.

For a decision not to approve a print media advertisement, the applicant must, at the same time, send a copy of the request to the Therapeutic Goods Advertising Code Council.

Complaints about advertisements (refer Part 6, Division 3 of the Therapeutic Goods Regulations)

A person may complain in writing to the Complaints Resolution Panel about an advertisement for a designated therapeutic good or therapeutic device that is published or inserted in specified media that the person believes to be in breach of the Therapeutic Goods Advertising Code (TGAC) or the *Therapeutic Goods Act 1989* or Regulations (refer Regulation 42ZCAB).

Complaints about other advertisements must be directed to the appropriate industry association, i.e. CHC for complementary medicines and ASMI for non-complementary OTC medicines.

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

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

- (i) prevention of skin cancer through the use of sunscreens
- (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 is obtained for such a reference. Approval may be obtained from the TGA, upon 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
 - Musculo-skeletal diseases
 - Nervous system diseases
 - Poisoning, venomous bites and stings
 - Renal diseases
 - Respiratory diseases
 - Skin diseases
- (cont. over)*

- 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 by TGACC

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 must 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.