Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Advertising Code 2018

Guidance on applying the Code when advertising therapeutic goods to the public

Version 0.1, March 2018

TGA Health Safety Regulation

Contents

Introduction

The Therapeutic Goods Advertising Code 2018 (the Code) is the cornerstone of the therapeutic goods advertising framework. It exists to ensure that the marketing and advertising of therapeutic goods to public is conducted in a manner that:

- promotes the safe and effective use of therapeutic goods by minimising misuse, overuse or underuse of the goods;
- is ethical and does not mislead or deceive the consumer or create unrealistic expectations about product performance;
- supports informed health care choices; and
- is consistent with current public health campaigns.

This document is designed to be read in conjunction with the Code to provide further information about the understanding, interpretation and application of the Code provisions.

This document should also be considered in the context of the *Therapeutic Goods Act 1989.*

This document is divided into three broad sections:

- Background
- Guidance on specific provisions of the Code, and
- Other guidance on the application of the Code in specific circumstances.

This document is also supplemented by fact sheets on key topics. The availability (or proposed availability) of these fact sheets is indicated throughout the document.

This document provides examples of the application of the Code and, where relevant, includes 'decision highlights' from the Complaints Resolution Panel (CRP). The CRP was responsible for the handling of many complaints about advertisements for therapeutic goods from 1999 to 2018.

Key concepts – advertise

The Act defines:

> *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.*

The intent referred to in this definition is not the intent of the advertiser, but what a reasonable viewer would consider the intent of the advertisement was. The test of whether material is intended to promote a particular product is an

objective one; that is, the question is whether the material or format, on its face and without reference to the actual intentions of those concerned with its circulation, publication, transmission, or dissemination, appears to be designed or calculated to draw public attention to and to promote the supply, sale or use of the particular therapeutic good.

The definition of 'advertise' encompasses only material of a promotional character. However, the definition is also intended to maintain a wide compass, in that, even if the material or the format of advertising can be said to promote the use or supply of relevant goods only in an indirect way, the material or format will still be an 'advertisement'.

Background

Legal basis

Section 42BAA of the *Therapeutic Goods Act 1989* (the Act) allows the Minister, or their delegate, to make a code relating to advertisements about therapeutic goods in the form of a legislative instrument.

It is a criminal offence under section 42DM of the Act to advertise a therapeutic good to consumers in a way that does not comply with the Code. Section 42DMA provides for corresponding civil penalties.

When preparing to advertise therapeutic goods to the public, you will need to consider other legal requirements as well as those set out in the Code. There are additional advertising requirements specified in the Act (including Part 5-1). In addition, the Australian Consumer Law and state or territory legislation may apply to your advertising. For further information about these requirements, see the "Other Requirements" section below.

The Act also provides for a range of compliance and enforcement tools that the TGA may employ to address non-compliant advertising. (A fact sheet this range of tools and their use by the TGA is currently under development.)

Certain sections of the Code also apply to generic information. See Generic information below.

Jurisdiction

Section 6 of the Act limits the operation of the Act, and therefore the Code, to

(a) activities by corporations; and

(b) activities by natural persons:

(i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or

(ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or

(iii) in relation to the Commonwealth

As such, neither the Act, nor the Code, apply to sole traders that operate solely within the state or territory in which they are based. However, advertisers should be aware that the promotion of therapeutic goods online may be considered trade or commerce across state/territory borders and therefore the Act and Code may apply. Sole traders operating solely intrastate should also be aware that some states and territories have adopted the advertising requirements in the Act and the Code.

The advertising requirements in the Act and the Code only apply to the advertising of therapeutic goods, as defined in section 3 of the Act. The advertising of goods that are not therapeutic goods, including foods and goods excluded from the operation of the Act under sections 7 or 7AA, is not subject to the requirements of the Act and the Code. However, some goods, when advertised with therapeutic claims, may be considered therapeutic goods. See Complementary Medicines Interface Issues for more information.

Other requirements

In addition to the Act and the Code, there are other Commonwealth and state and territory laws that the advertising of therapeutic goods to the public must comply with. These include:

- Australian Consumer Law
- National Health Practitioner Law (where the advertiser is a regulated health practitioner)
- State and territory poisons legislation.

Depending on a range of factors, including the advertising medium used, there may also be self-regulatory requirements that apply. For example:

- Advertisements to appear on free-to-air television require clearance by FreeTV Australia's Commercial Advice
- Advertisements to the public from sponsors of therapeutic goods may be captured by their industry organisations' respective self-regulatory codes. For example:
  - Australian Self Medication Industry Code of Practice;
  - Complementary Medicines Australia Marketing & Supply Code of Practice: Complementary Medicines;
  - Medical Technology Association of Australia Code of Practice; and
  - IVD Australia Code of Conduct.

Other relevant policies

The Code draws on concepts used in the World Health Organisation: Ethical Criteria for Medicinal Drug Promotion 1988[1], namely:

> *(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.*

[1] See http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf

(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.

The Code is also grounded in the Quality Use of Medicines (QUM) framework[2]:

Quality Use of Medicines means:

- *Selecting management options wisely by:*
  - *considering the place of medicines in treating illness and maintaining health, and*
  - *recognising that there may be better ways than medicine to manage many disorders.*
- *Choosing suitable medicines if a medicine is considered necessary so that the best available option is selected by taking into account:*
  - *the individual*
  - *the clinical condition*
  - *risks and benefits*
  - *dosage and length of treatment*
  - *any co-existing conditions*
  - *other therapies*
  - *monitoring considerations*
  - *costs for the individual, the community and the health system as a whole.*
- *Using medicines safely and effectively to get the best possible results by:*
  - *monitoring outcomes,*
  - *minimising misuse, over-use and under-use, and*
  - *improving people's ability to solve problems related to medication, such as negative effects or managing multiple medications.*

Under the QUM framework, consumers should be able to select management options wisely; choose suitable medicines (if a medicine is considered necessary); and use medicines safely and effectively. Similar considerations apply to other therapeutic goods (such as certain medical devices) that may be appropriate for self-selection by consumers for use in the care of themselves or their family.

To support the principles of the QUM framework, industry should be able to provide truthful information to potential consumers about the nature and benefits of therapeutic goods. They should be able to do so through responsible advertising, where this will enhance the health outcomes of the Australian people.

Aspects of the WHO criteria and QUM framework can equally apply to medical devices and other therapeutic goods that are advertised to the public.

In this context, the Code is pivotal to establishing a robust and effective system for regulating advertising of all therapeutic goods to the public. It aids in giving consumers confidence that the claims they read and hear are well-founded, and it should provide a level playing field for industry.

In the event of any inconsistency between the Act or the Code and these other policies, the Act and the Code prevail.

[2] See http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm

Complaints about advertisements and price lists

Complaints about advertisements to the public for therapeutic goods and prescription medicine price lists can be sent to the TGA.

More information about the TGA's processes for complaints handling is available from the TGA website.

Further information about where and how to lodge a complaint, including how the complaint will be handled is still under development.

Guidance on specific Code sections

For ease of reference, the numbering in this section aligns with the relevant parts, sections and paragraphs of the Code.

Part 1 - Preliminary

2 Commencement

3 Repeal of previous Advertising Code

The *Therapeutic Goods Advertising Code 2018* (the Code) is expected to be effective from 1 July 2018. The *Therapeutic Goods Advertising Code 2015* will be repealed at the same time.

Applications for pre-approval considered on or after 1 July 2018 will be considered against this Code. For advertisements requiring pre-approval before this date, they will be assessed against the Therapeutic Goods Advertising Code 2015 (2015 Code). Any complaints about such advertisements will be considered in the context of the relevant Code. (A fact sheet on 'Current advertising pre-approval requirements to remain unchanged until 2020' is currently under development.)

Guidance on transition arrangements for all other advertisements currently under development.

4 Definitions

Where a term or concept has not been defined in the Code, any definition of that term in the Act will apply. In the absence of a definition in the Act or Code, the normal meaning, as derived from the current edition of the Macquarie Dictionary, will apply.

Stakeholder feedback indicated that users would benefit from a consolidated list of definitions in the guidance, including definitions made under the Act and Code. This list needs to be developed and inserted into this guideline as an appendix.

The section below, providing further information on definitions also needs to be expanded on.

Further information on Code definitions

Analgesics

Products excluded from the definition of "analgesic" for the purposes of the Code are medicines for internal use in self-limiting conditions and that contain an analgesic in combination with one or more other active ingredients such as cough and cold medicines.

Prominently displayed or communicated

What needs to be "prominently displayed or communicated"

The Code requires a range of information to be prominently displayed or communicated in advertising to the public for therapeutic goods, including:

- Warnings regarding persistence or worsening of symptoms and the need to consult a healthcare professional
- Warnings regarding serious allergies
- For direct marketing or internet marketing for medicines, warnings regarding known serious adverse effects and/or contraindications
- Statements required for the advertising of Schedule 3 medicines and analgesics
- The appropriate use of sunscreens.

The Code does not require all mandatory information in an advertisement to be prominently displayed or communicated.

Practical application

Objectively, information forms part of the main message for the intended audience of the advertisement if it stays in the minds of viewers. How this is achieved may depend on the reasonable consumer to whom the advertisement is directed – for example, an advertisement directed to people with eyesight difficulties may require special consideration to ensure the message received in its entirety.

For visual statements, this may require:

- the information be provided in a similar font (including colour, size etc) to that used for the name of the therapeutic goods advertised
- For online advertising including social media, mobile phone apps and e-mails:
  - the information needs to be available in the same locale as the advertising content (i.e. the viewer must be able to view it without having to scroll or click through to a separate tab or page)
  - a pop-up may provide such information to consumers (provided that it cannot be disabled).

For spoken statements, this may require:

- Using a similar volume and delivery (e.g. pitch, speed) to the name of the therapeutic goods advertised.

Ensuring that such information is part of the main message is highly dependent on the media used for the advertising. For example, for a television or internet advertisement that relies heavily on an actor to impart the therapeutic representations, it may be necessary for any mandatory statements to also be presented by the actor to ensure that they are part of the main message.

Advertisers should ensure that they choose advertising mediums that provide sufficient scope to meet the requirement to prominently display or communicate the required information for advertisements for therapeutic goods. (A fact sheet on 'Prominently displayed or communicated' is currently under development.)

Reason for requirement

Information required by the Code to be "prominently displayed or communicated" is critical for consumers to:

- identify where a particular therapeutic good may not be suitable for them and/or
- be provided with the information to assist them in the safe and responsible use of the therapeutic goods advertised.

The requirement for a "prominently displayed or communicated" statement to form part of the main message of the advertisement is to provide important consumer information about the advertised therapeutic good .

An advertisement for therapeutic goods that fails to draw consumers' attention to the most likely situations in which the good may not be suitable (e.g. serious allergies, adverse events and /or contraindications) may potentially be misleading. In order to ensure consumers are aware of such information, it is important that it forms part of the overall main message of the advertising.

The diversity of contemporary advertising channels and media is such that it would be inappropriate to specify precise requirements (e.g. 12 point font at the top of the advertisement) for the communication of such information.

5 Object

The object outlines the underlying purposes of the Code. It sets out general aims or principles to help readers interpret the Code and may assist in resolving uncertainty or ambiguity around the application of the other provisions in the Code.

6 Application of the Code

In applying this Code to an advertisement, the total presentation and context of the advertisement and its likely impact on a reasonable person to whom the advertisement is directed will be taken into account. This includes the spirit and the intent of the Code.

6(1) Definition of 'advertise'

Advertising is not limited to a specific type, or types, of media. It includes articles published in journals, magazines and newspapers, displays on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and material posted on the internet. Point-of-sale materials, leaflets, booklets and other promotional materials that include specific product claims and which are supplied separately from the product may also be advertisements. Words forming part of a soundtrack or video recording are within the definition of advertisement as is the spoken word.

Depending on the content and the context in which such material is provided to the public, some documents and content may not be considered advertisements for the purposes of the Code. For example:

- reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make therapeutic or promotional claims;
- information relating to human health or diseases where there is no reference to therapeutic goods;
- advertising for health services that does not refer, either directly or indirectly, to therapeutic goods;

- correspondence, possibly accompanied by material of a non-promotional nature, to answer a specific unsolicited question about a therapeutic good.

(A fact sheet providing more information on the differences between advertising and other activities is currently under development.)

The Code applies to digital communications channels such as social networking sites, blogs and discussion forums when these are used to promote therapeutic goods. Website providers should ensure that materials posted on the internet do not contravene the Code. Material posted on Australian websites or websites registered to an Australian entity is subject to the Act and the Code.

The labelling and package leaflet of a product, even if they comply fully with the labelling requirements of the Act, the Regulations, the Devices Regulations and the Labelling Orders, may still be an advertisement. If a label is an advertisement, it needs to comply with the Code (other than those specific sections that have an exemption for labels).

6(2) Advertisements exclusively to health professionals

The Code applies to all advertising of therapeutic goods to the public. Advertisements directed exclusively to health professionals (within the meaning of s.42AA of the Act) are not subject to the requirements of the Code. The definition of 'health professional' in section 42AA of the Act includes:

- medical practitioners,
- psychologists,
- pharmacists,
- optometrists,
- chiropractors,
- physiotherapists,
- nurses and midwives,
- dentists, dental hygienists, dental prosthetists, and dental therapists
- osteopaths;
- the following practitioners, provided they are registered under a law of a State or Territory:
  - herbalists,
  - homoeopathic practitioners,
  - naturopaths,
  - nutritionists,
  - practitioners of traditional Chinese medicine
  - podiatrists
- a person who is a member of an Australian branch of one of the bodies prescribed in Schedule 1 of the Therapeutic Goods Regulations 1990.

In order for an advertisement to be considered to be directed exclusively to health professionals, the content must not be available to consumers at all. For example:

- Content provided online must be behind a secure firewall and can only be accessed once the AHPRA or other professional accreditation of the individual requiring access has been established
- Content provided via email is only provided once the AHPRA or other accreditation of the individual has been established. Emails are sent to a personal email address and not a group email (e.g. manager@practice.com).

6(3) Impact on reasonable person to whom the advertisement is directed

Some advertisements are directed to specific population groups e.g. diabetics, carers of small children. Other advertisements are directed more broadly – e.g. to adults who get colds. In each case, the characteristics of the audience will differ, including any particular vulnerabilities or stresses, disabilities and health literacy levels. These factors can influence the audience's perception of advertising.

Only once the target audience for an advertisement is identified can an assessment be made as to the likely 'reasonable consumer' in that audience, what that person is likely to make of the advertisement and how they are likely to be impacted by it.

This aspect needs to be considered before an advertisement is considered for compliance with the Code.

For example, an advertisement for therapeutic goods that targets older people with sight difficulties may be unbalanced if it does not present all of the information with sufficient prominence, allowing for the abilities of the target audience.

6(4) Total presentation and context of advertising

When considering the application of the Code to advertising, the total context of the advertising must be considered, not just specific claims. For example, an advertisement that states a particular therapeutic good is for the relief of pain associated with mild arthritis but uses an image of a person that is debilitated with pain from arthritis is likely to represent to the viewer that the goods may assist with pain relief for more serious forms of arthritis.

Representations can be made in a variety of ways, as indicated by case law:

- A statement, made orally or in writing or by implication from words or conduct, relating to a matter of fact and may be made by plans and drawings, maps, pictures and photographs or made by gestures, demeanour or other conduct (*Given v Pryor 1979*)
- A statement must be communicated in order to amount to a representation, but does not mean that it must be communicated to any particular person (*Thompson v Riley McKay Pty Ltd* (No 2] [1980]).
- The placing of an article on display in a shop window is sufficient (*Weitmann v Katies Ltd* 1977).

6(5) Who the Code applies to

6(6) Who the Code does not apply to

Subject to the jurisdictional requirements set out above, the Code applies to any person who advertises, by any means, therapeutic goods; or causes the advertising, by any means, of therapeutic goods. Examples of persons who might advertise, or cause the advertising of, therapeutic goods include the following:

- the sponsor of the goods;

- the person in relation to whom the goods are included in the Australian Register of Therapeutic Goods (the Register);
- any person in the supply chain for the therapeutic goods (e.g. manufacturers, wholesalers, retailers, franchisees, multi-level marketers) who advertises the good.
- a publisher, broadcaster, datacaster, internet or mobile service provider, or any other media service provider;
- the advertising agency involved in creating an advertisement for goods if the agency undertakes advertising on behalf of the sponsor of the goods or the person in relation to whom the goods are included in the Register;
- any person who receives valuable consideration for advertising or promoting the goods (including influencers, bloggers and product ambassadors);
- any person publicly endorsing, or making a testimonial for, the goods;
- a journalist, print or broadcast organisation;
- a health practitioner advertising therapeutic goods or promoting services that require the use of a specific therapeutic good.

Bona fide news would not be considered advertising where it is just that i.e. a balanced news story that does not promote any specific therapeutic good or goods. News that is considered advertising will be subject to the provisions of the Act, but not the Code, due to the specific exemption in section 6(6) of the Code. Other programs, such as public interest and entertainment programs, are more likely to be considered promotional as there is no requirement for such programs to be balanced. (A fact sheet on advertising, bona fide news and related activities will be developed.)

The TGA considers that the responsibility for compliance of an advertisement lies with the advertiser; that is the person who paid for or otherwise authorised the advertising or in some other way was directly responsible for the public dissemination of the advertisement. For example, in the case of a shelf wobbler in a pharmacy, the primary responsibility for compliance lies with the pharmacy owner who authorised public display of the item. However, if the owner demonstrated that they had received the shelf wobbler in good faith from the sponsor of the goods and had undertaken reasonable steps to ensure the content of the wobbler was compliant, and continued to be compliant, the sponsor is likely to be considered liable.

CRP decision highlight – Information on retailer websites is the responsibility of the website publisher

Publishers of websites should be aware that they are responsible for the material they publish, regardless of whether they have copied that material from product packaging or other websites. Some online retailers appear to be of the view that it is acceptable to duplicate information from such sources for the purposes of advertising products for sale, but take no responsibility for the publication of the information. In complaint 4-0707, an online retailer and advertiser argued that they had "absolutely no way of knowing whether [the product sponsor is] in fact justified in what they say about " the advertised product, and explained that "text on our website is originally all copied from the respective manufacturer's websites and other publicity they provide when the product is launched". In its determination the Panel noted as follows:

> 12. In the view of the Panel, it is an extraordinary proposition that a

publisher of a commercial website could publish information regarding therapeutic goods that are for sale by means of that website, and disavow any responsibility for the accuracy of that information, or publish information when by their own acknowledgment they have "absolutely no way of knowing whether [the product sponsor is] in fact justified in what they say" about the advertised therapeutic goods.

13. Where an advertiser publishes information regarding a product in an advertisement, it is a prima facie presumption that the advertiser is the person responsible for publishing that information even where it has been copied from material published by the product sponsor. Material that has been compiled from sources such as product packaging or other material may not be current, may not have been provided with the intention that it be reproduced in advertising by others, or may in some other way be deficient. Such material may have been reproduced without the consent, control, or authorisation of the product sponsor.

14. If, therefore, the product sponsor or some other party is to be considered responsible for the information contained in the advertisement, rather than the advertiser, it would (at a minimum) be necessary for the advertiser to provide documentary evidence that the information was provided to the advertiser expressly for the purpose of advertising the product. This is not to say that retailers must hold evidence in the same way that product sponsors must. It is simply to say that if a retailer is in the business of advertising and selling therapeutic goods, it is not unreasonable to expect that retailer to take on the responsibility, at a minimum, of instituting a process whereby the accuracy of advertising claims is explicitly warranted by the product sponsor, and this warranty is documented.

7 Price information

Prescription medicines, as listed in schedules 4 and 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard), cannot be advertised to the public as it is an offence to do so under section 42DL of the Act. The same prohibition applies to pharmacist only medicines that are not listed in Appendix H of the Poisons Standard.

However, for the reasons set out in the Galbally Review[3], price lists for such medicines can be issued to the public.

To ensure that price lists do not promote the use of particular prescription medicines, it is essential that price lists comply with Schedule 1 of the Code. If a price list does not comply with Schedule 1 of the Code, it is considered an advertisement for prescription medicines and/or pharmacist only medicines and the TGA may take action to ensure compliance.

[3] *COAG Review of Drugs Poisons & Controlled Substances Legislation (2001)*

Part 2—Requirements for advertising therapeutic goods—general

8 Approved advertisements

Approval number

Those approved advertisements that appear in mainstream media or are displays about goods must include the approval number. The approval number must stand alone, be legible and be located in the bottom right hand corner of approved print advertisements.

Advertisements that need approval

Advertisements for medicines that are to appear in specified media require approval under regulation 5G of the Regulations before being published or broadcast. Specified media is defined in section 42B of the Act as:

(a) mainstream media; or
(b) broadcast media; or
(c) cinematograph films; or
(d) displays about goods, including posters:
    (i) in shopping malls (except inside an individual shop); and
    (ii) in or on public transport; and
    (iii) on billboards.

Mainstream media is also defined in section 42B as "any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions".

This requirement arises from section 42C of the Act, which provides a range of offences relating to the publication or broadcast of an advertisement for medicines in specified media. These include publishing or broadcasting an advertisement:

- without prior approval (ss.42C(1));
- that differs from the approved advertisement (ss.42C(2)); and
- that does not comply with any conditions of approval (ss.42C(6)).

Advertisers will need to obtain approval from the TGA for any restricted representations that appear in the proposed advertisement prior to lodging an application for pre-approval.

Seeking pre-approval of advertising

Advertisements for medicines in specified media that are required to be approved under regulation 5G of the Regulations must be submitted to:

Type of advertisement/medicine	Submit application to
Advertisements for complementary medicines to appear in specified media (other than broadcast media)	The Office of Advertising Compliance Complementary Healthcare Council of Australia PO Box 820 MAWSON, ACT 2607 Ph: (02) 6260 4066

Type of advertisement/medicine	Submit application to
	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) to appear in specified media.	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 and section 8 of the Code.

Minimum requirements for the submission of advertisements for pre-approval

1. Typed copy (no smaller than 10 point), black copy on white background.
2. Draft layout or clear description of layout.
3. For television commercials, copy of script with storyboard.
4. For radio, copy of script to include sound-effect descriptions.
5. Copies of appropriate documentation:
    a. Certificate of Listing/Registration, showing the indications for use
    b. Label (enlarged for legibility)
    c. Copy of any research/surveys/data referenced in advertisement (Note: further evidence to be provided if requested).
    d. Copy of documentation supporting any testimonials and/or endorsements(Note: further evidence to be provided if requested)

Applicants should note that:

- Evidence to substantiate therapeutic claims needs to be provided to the Advertising Services Manager upon request.
- 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.
- Notwithstanding the above, further substantiation may also be requested
- Inclusion of a claim in the Register entry for the medicine to be advertised (listed or registered) does not automatically mean that the claim may be advertised.

Review of a decision not to approve an advertisement

A request to review a decision made under Regulation 5G can be submitted to the Minister for Health in writing (see Regulation 5M of the *Therapeutic Goods Regulations 1990*). The request must be made within 30 days after notice of the decision is given to the applicant.

Further information on how to request a review of a decision is still under development.

9 Accuracy

(a) Valid and substantiated advertising claims

Claims (both therapeutic and non-therapeutic) must be verified before use in advertising. The kind and amount of information required to substantiate advertising will depend on the type claims made (including any implied claims).

Therapeutic use claims

For therapeutic-use claims, the appropriate evidence requirements apply. These requirements should also be considered in the context of the requirements for claims to be truthful, balanced and not misleading (see (b) below).

This section is still under development. When complete, it will identify the evidence requirements to support advertising, including any particular requirements for certain types of therapeutic goods. The content will link to any existing evidence requirements (e.g. Evidence guidelines for complementary medicines.

Other types of claims

Claims other than therapeutic use claims can be made about therapeutic goods and these also require substantiation. Such claims fall into two categories:

- Scientific (e.g. relief in just an hour, non-drowsy)
- Non-scientific (e.g. 4 out of 5 people prefer this brand)

The type of evidence needed to substantiate such claims will vary depending on the claim.

(b) Truthful, balanced and not misleading or likely to be misleading

In addition to being substantiated, advertising for therapeutic goods must be truthful, balanced and not misleading (including any implied claims).

In order to be truthful and not misleading, the strength of claims made in advertising must be consistent with the strength and type of available evidence. The strength of the claim should also reflect the whole body of evidence. For example, a claim that a medicine is "clinically proven to relieve headaches", supported only by a preliminary clinical trial of 20 patients with tension headaches, would not be considered truthful and will mislead consumers.

A claim can be substantiated and accurate but still mislead people. For example, an imaging device that is advertised as producing 500% less radiation than other common imaging devices but fails to provide that information in the context that the amount of radiation produced by such devices is very small is likely to mislead consumers into thinking other imaging devices are harmful. It is also likely to mislead consumers as to the order of magnitude of the difference in radiation produced by the advertised device and other similar devices – even if the claim is substantiated.

Similarly, the claims in an advertisement can be verified but presented in a way that lacks balance.

CRP decision highlight - The use of the words "clinically proven" should be carefully considered

The Panel is concerned at the growing use of the words "clinically proven" in advertisements for therapeutic goods, when these words are not supported by an adequate and appropriate body of evidence that relates to the specific product (and not merely to a similar product or ingredient) to which the advertisement relates. In complaint 2008-02-005, the Panel noted as follows:

> The Panel also noted the use of the words "clinically proven" in relation to the product. Given the strength of this claim and the clear potential for it to mislead and deceive consumers, the Panel considers that its use in advertising should not even be contemplated unless unequivocally supported by robustly designed, published, peer-reviewed clinical trials which have been conducted upon the actual product being advertised or an identical formulation (as a minimum). Even where such evidence is available, the claim must also reflect the weight of all available evidence and not just the specific research being relied upon.

A related point has been made in recent determinations regarding undue emphasis on the weight of scientific evidence in relation to products. For example, in 16-0907, the Panel stated:

> When advertisers of therapeutic goods make representations regarding the efficacy of those therapeutic goods, they must ensure that the strength of the evidence is reflected in the strength of the representations. Where evidence is very strong, strong claims may be justified. Where the evidence is of modest quality (but nonetheless supports claims of product efficacy), advertisers must take care not to overstate the quality and nature of the evidence when making claims about the product. To do otherwise is likely to mislead the public and breach sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code.

Claims that an advertised therapeutic good is natural, or contains natural ingredients, can suggest that a product is safe or more efficacious because it is natural. In addition, the 'natural' claim itself can mislead consumers (A fact sheet on the use of 'natural' claims will be developed.)

(c) Consistency with Register entry

Advertising needs to be consistent with the Register entry or entries for the advertised therapeutic goods, unless the goods are exempt from inclusion in the Register. Consistency must be gauged from the total context of the advertisement.

The need for consistency extends to all aspects of the full Register entry (not just the information provided in the public view). This includes:

- The dosage form (e.g. tablets, capsules, topical liquid) or, in the case of medical devices, the GMDN code;
- The name of the goods;
- The formulation of the goods;

- Indications / intended purpose;
- Any conditions applied to the Register entry (including those that may constrain the way in which the goods can be promoted); and
- Any warnings or contraindications.

For example, an advertisement that promoted a complementary medicine as having "the healing powers of aloe vera" where the formulation of the medicine in the Register listing did not include aloe vera as an active ingredient would contravene this requirement. Further, if the medicine did not contain aloe vera at all, the advertisement would be misleading (see above). If the medicine did include aloe vera that was not declared in the Register listing, this would raise additional regulatory issues under the Act.

Being consistent with the Register entry does not require all of the Register information to be replicated in the advertisement.

Note that special care is needed when advertising a range of goods under an umbrella name, especially where the individual goods may not have the same indications.

The Act defines an 'indication' as a specific therapeutic use. For example, the claim "helps relieve constipation" is an indication. However, qualifying the indication with a timeframe results in an advertising claim being appended to the indication – namely, "helps relieve constipation within 24 hours". Advertising claims are not required to be included in the Register entry for the goods.

10 Effect

(a) Support the safe and proper use of the goods

(i) Present the goods in accordance with directions or instructions for use

Advertising must only present therapeutic goods in accordance with:

- the directions for use on the labelling approved by the TGA (for registered medicines and disinfectants);
- the directions for use prescribed by the sponsor (for listed medicines); and
- the instructions for use prescribed by the manufacturer (for medical devices and other therapeutic goods).

For example, an advertisement that portrays a medicine as being able to be used by children under 12 for the relief of pain when there are no approved dosage instructions for children on the label of the medicine is likely to contravene this provision. Such a representation could also lead to the inappropriate use of the advertised medicine and would also be misleading (see above).

(ii) Don't exaggerate product efficacy or performance

This section is still under development.

(b) Delaying medical attention and/or treatment

This section is still under development.

(c) Encouraging inappropriate or excessive use

This section is still under development. Once complete, it should provide guidance to advertisers on the operation of this provision, including whether promotions such as two-for-one, heavy discounting and similar offers are likely to contravene this section (as this is a common question from stakeholders).

(d) Other prohibited effects in advertising

(i) Safe, cannot cause harm, no side effects

Therapeutic goods exert a therapeutic effect on the human body. As such, the use of a therapeutic good affects the human body and may have unintended consequences or trigger an adverse event.

For these reasons, this section of the Code specifically prohibits the advertising of a therapeutic good as safe or having no side-effects, even for specific patient populations or particular dosages. This requirement applies even if there is evidence to substantiate such a claim.

Advertising claims that imply a therapeutic good is safe are also prohibited. Examples of such claims include:

- "[the therapeutic good] has a safe mode of action"
- "No known side effects"
- "Safe, natural alternative"
- "Non-toxic amounts of [ingredient]"
- "Safe alternative to prescription medicines without the debilitating side effects"

Claims that a therapeutic good is "natural" should be used with caution as they may imply that a therapeutic good is safe or has no side effects, in addition to being misleading about the nature of the therapeutic good. Care is also needed to ensure that comparisons with other therapeutic goods do not mislead consumers to think that competing therapeutic goods are harmful.

(ii) Effective in all cases of a condition, guaranteed, sure cure

(iii) Infallible, unfailing, magical or miraculous

These sections are still under development.

(iv) Harmful consequences may result from not using the goods

This section prohibits the advertiser from claiming that harmful consequences may result from the therapeutic goods not being used, unless that claim is permitted under s.42DF or s.42DK of the Act. However, to receive such an approval, the claim would need to refer to a restricted or prohibited representation and the Secretary must be satisfied that the use of the representation was in the public interest (e.g. prevention of skin cancer through sunscreen use).

11 What must advertisements contain – general rules

Refer to "prominently displayed" in the Definitions section above.

(1) Things this section does not apply to

The requirements in this section do not apply to labels, consumer medicine information, internet marketing or direct marketing as these must comply with other specific requirements.

These requirements do not apply where the advertisement displays only the name or picture of the therapeutic goods and their price or point of sale. However, a trade name could be a therapeutic claim in itself.

(2) General rules for medicines advertisements

Mandatory information for medicines advertising

Section 11(2)(a) requires an advertisement for a medicine to include a reference to the name of the medicine, as required under other therapeutic goods legislation. A reference to the name of the medicine will be satisfied by the inclusion of one of the following in the advertisement:

- The trade name of the medicine
- The trade name for a group of medicines.

Section 11(2)(b) requires an advertisement for a medicine to include a reference to the intended purpose for the medicine. Establishing the intended purpose for a medicine varies depending on the type of medicine:

- For medicines that are exempt from inclusion in the Register, the indications should be established from the information provided by the sponsor of the medicine, including the medicine label and the sponsor's website.
- For medicines included in the Register, the intended purpose should be established from:
  - the indications included in the Register entry for the medicine; and
  - for registered medicines only, the approved label for the medicine.

For medicines included in the Register, the use of other indications not included in the Register entry in the advertisement is an offence under subsection 22(5) of the Act.

There is no requirement for the reference to the indications in the advertisement to be presented word-for-word as they appear in the Register. However, the meaning and intent must not differ. For example:

- A medicine is entered in the Register with the indication "For the relief of colds". Advertising the medicine for the relief of ear aches would not align with the meaning or intent of the indication in the Register for the medicine.

Where a medicine is included in the Register with multiple indications, it is not necessary to refer to all of these indications in the advertisement.

Mandatory information for advertising of medical devices and therapeutic goods that are neither medicines medical devices or biologicals

Section 11(3)(a) requires an advertisement for a medical device or therapeutic goods that are neither a medicine, a medical device or a biological to include a reference to the trade name and to the intended purpose of the goods.

Key concepts – 'Intended purpose' for medical devices

Paragraph 11(2)(b) of the Code requires an advertisement for a medical device to include a reference to the intended purpose for that device.

Under section 41BD of the Act, the intended purpose needs to be ascertained from the information supplied by the manufacturer of the device, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

Mandatory information for advertising of all therapeutic goods

Both sections 11(2) and (3) requires the advertisement to contain the required statement *ALWAYS READ THE LABEL*. This statement must be displayed or communicated in accordance with the definition included in section 4 of the Code. Short form advertisements (such as radio commercials that are 15 seconds or less or written advertisements that consist of 256 characters or less) are exempt from this requirement.

This section is still under development.

12 What must advertisements contain - direct marketing and internet marketing

Internet marketing is where a consumer can buy a therapeutic good, sight unseen, through a website or mobile phone app. Direct marketing is where a consumer can buy a therapeutic good, sight unseen, through other means (for example, a mail-order catalogue or telemarketing).

As consumers can purchase therapeutic goods through such channels without the opportunity to pick up the goods and read all the information available on the label and/or packaging to establish whether it is suitable for their needs, it is important that internet and direct marketing contain a greater level of information (e.g. contraindications, warnings) than other advertising.

Section 12 is still under development.

13 Required statements

This section sets out further required statements for therapeutic goods advertisements which must be displayed or communicated, such as:

- FOLLOW THE DIRECTIONS FOR USE. (for medicines); or
- FOLLOW THE INSTRUCTIONS FOR USE (for medical devices or other therapeutic goods that are not a medicine or medical device).

This section is still under development.

(4) Symptom claims

An advertisement for therapeutic goods that refers to symptoms of a disease, ailment, condition or defect is required to prominently display or communicate the statement:

> *IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL.*

This statement is not required for prevention, health maintenance or wellbeing claims.

14 Required statement – pharmacist-only medicines

Like other mandatory statements, this statement must be 'prominently displayed or communicated'.

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

As such, the main message of an advertisement for a pharmacist-only medicine must include the concept that consumers must know they have to talk to a pharmacist in order to obtain the medicine.

Advertisements for pharmacist-only medicines are not required to carry any of the statements required under sections 12 and 13.

15 Scientific representations

A scientific or clinical representation, in the context of advertising therapeutic goods to the public, is one that:

- Is referenced to a supporting study, and/or
- Contains scientific or clinical terminology that does not appear in the everyday language of the audience to whom the advertisement is directed.

This section is still under development to include examples of what is and isn't acceptable, including in relation to:

- how the identification of the "sponsor of the scientific study" should be made in the advertisement;
- whether the endorsement provisions would be breached by identifying the sponsor of a clinical study as government or NHMRC research grant.

Key concepts – sponsorships, endorsements and testimonials

The dictionary definitions for 'sponsorship', 'endorsement' and 'testimonial' indicate that these terms overlap considerably.

- An endorsement is made where a person, or corporation, sanctions a particular therapeutic good but there is no indication as to the outcome(s) from the use of the good. For example, "Company X recommends Brand Y disinfectant".
- A testimonial is made where a person, or corporation, has used a therapeutic good and has testified as to the outcome(s) they experienced from the use of the good. For example, "Football club X uses product A to aid the muscle recovery of its players", "I use Brand Z cream on my eczema as it helps soothe the itch and inflammation" or "Brand A liquid helped ease my daughter's discomfort during teething".
- A sponsorship is where a person, or corporation, receives funding or other valuable consideration from a sponsor or retailer of a therapeutic good. For example, "Organisation X receives 10 cents from the sale of every bottle of Brand Y disinfectant".

Sponsorships, testimonials and endorsements can all influence consumer choices and therefore there are certain requirements that must be met when they are used in the advertising of therapeutic goods.

16 Endorsements

If the details of a sponsorship arrangement are not clearly communicated in an advertisement (e.g. the only detail is the use of the third party logo in advertising without qualification), it will be considered a product endorsement by the sponsored party.

CRP decision highlight – "TGA Approved" claims

In complaint 2008-02-018, the Panel noted as follows:

> Section 4(6)(b) of the Code prohibits representations that goods are endorsed by government bodies. While in one sense the words "Listed with the Therapeutic Goods Administration as a herbal medicine" may constitute an attempt to indicate compliance with the Act, they are likely to convey an implication that the goods so listed are approved by

an Australian government agency to a degree that is not factually correct, particularly as regards the efficacy of the product. The complaint was therefore justified. However, for the advertiser's benefit, the Panel noted that s.42DL(1)(e)(i) of the Act, whilst prohibiting "a reference to the Act", does permit a statement to the effect that "Product X is listed in the ARTG, AUST L 123". The Panel also noted that such a statement makes no reference to any government agency.

Care is needed with endorsements as they have the potential to promote a therapeutic good for purposes that may not be accepted in relation to particular therapeutic goods. For example, advertising a cough and cold medicine as being endorsed by a migraine patient group may imply to viewers that the medicine can also prevent or relieve migraines.

Valuable consideration

Valuable consideration includes, but is not necessarily, a monetary exchange. It may be an exchange of services in-kind, or a promise to engage services in the future or any other return in kind.

Professional endorsement vs availability

References to business names (e.g. the name of a chain of a pharmacy) are commonly used in the naming of therapeutic goods to signify availability. However, this is not necessarily considered professional endorsement of the goods.

This section is still under development to include examples of what is and isn't acceptable.

Other considerations

This section is still under development.

When complete, it should address a number of common questions, including:

- How and what needs to be disclosed in an advertisement in relation to endorsements?
- What makes an implied endorsement?
- Does the advertiser have to disclose valuable consideration even if the actor doesn't say anything?
- Celebrity social media accounts and application of requirements.

17 Testimonials

Testimonials must comply with all applicable aspects of the Code, not just the requirements set out in section 17. Testimonials can be advertisements themselves or may form part of a broader advertisement for the therapeutic goods referenced.

This section only applies to testimonials from persons (or corporations) not captured under section 16 (endorsements).

Only testimonials from people (or corporations) whose details are verifiable can be used in advertising for therapeutic goods. Details include name, age and address, in addition to any other information needed to identify the testifier.

This section is still under development. It will be expanded to explain how testimonials might be verified and what 'typical results' means.

The testifier either needs to have used the advertised goods, or administered the goods and been able to observe the results (e.g. to a child) – otherwise it would be considered an endorsement.

For a testimonial with claims regarding the health outcomes from the use of the good to be used in an advertisement, the claims must be typical of the results to be expected from the use of the goods (paragraph 17(1)(c)).

A statutory declaration in relation to a testimonial should be made (and therefore dated) before the advertisement featuring it.

Advertisers using testimonials can amend testimonials to ensure compliance with Code but where this has been done, it must be noted in the advertisement (e.g. testimonial has been truncated, altered or paraphrased). However, it is recommended that advertisers speak with the testifier before making such changes.

In addition to the requirements set out in this section of the Code, the use of testimonials must not contravene the other provisions of the Code. For example, a testimonial must not present the advertised good as miraculous (paragraph 10(d)(iii)), even if there is robust scientific evidence to support excellent results from the use of the good. Caution is also needed to ensure that the use of testimonials does not result in promoting the advertised goods for a different indication or intended use that that accepted in relation to the inclusion of the goods in the Register as this would contravene the Act.

Advertisers are responsible for ensuring the compliance of any testimonials that are publically posted to by third parties to Facebook, Twitter, Instagram or any other social media accounts where the advertiser has control of the content. Non-compliant testimonials should be modified so that they are complaint or removed. As indicated above it must be noted where a testimonial has been altered.

18 Incentives to pharmacy assistants and other non-healthcare professional sales persons

Pharmacy assistants and retail staff (e.g. health food shop staff) who are not covered by section 42AA of the Act are considered members of the public in terms of the application of Part 5-1 of the Act and the advertising requirements prescribed in the Code. As such, advertising for

therapeutic goods to be included in pharmacy or other retail content directed to pharmacy assistants and other retail staff needs to comply with the Act and Code.

As the advice that retail staff give can influence consumer choices of therapeutic goods and they generally do not have the educational qualifications or experience of trained health professionals, such as a pharmacist, the Code prohibits advertising to retail staff from containing incentives to recommend or supply the advertised goods. While the risk of inappropriate recommendations from retail staff members should also be managed through professional interventions in pharmacies, there may not be similar protections in place in other retail sectors. In addition, the historically low number of complaints regarding this requirement may suggest that it is a well-known and accepted standard.

Given there are a significant number of retail staff under the age of 18 years that work in retail outlets that sell therapeutic goods, advertisers should also consider the application of the advertising to children provision (see section 19 and Schedule 2 below).

19 Advertising to children

This section is still under development.

20 Allergies

It is important for health consumers to know if a therapeutic good has a history of causing a serious allergic reaction in a known patient group prior to purchase. Such a warning must be 'prominently displayed or communicated' in the advertisement. The following is an example of an appropriate warning:

This product may cause reactions in persons with an allergy to shellfish.

Warnings could also focus on other potential allergies such as to nuts or bee stings.

21 Consistency with public health campaigns

Advertising for therapeutic goods must not undermine current public health campaigns. Public health messages are an investment by the Government in the promotion of public health and safety. The Government's priorities in public health messaging change, depending on trends and needs within the community. However, a 'current' campaign does not necessarily have to be active at the time of the advertisement. For example, an advertisement for a cold and flu medicine must not undermine the most recent government respiratory health public messaging even if the advertising occurs outside of the cold and flu season.

The existence and details of current public health campaigns can be established through an internet search. Examples of relevant current public health campaigns include:

- for sunscreens—sun safety campaigns;
- for cough and cold products—campaigns relating to the management of respiratory diseases and hygiene;
- smoking cessation;
- vaccination/immunisation.

Part 3—Rules relating to particular therapeutic goods

22 Application

This section is still under development.

23 Complementary medicines

Referring to indications that are supported by evidence of traditional use inappropriately in advertising for complementary medicines has the potential to mislead consumers about the type of supporting evidence for the medicine.

For this reason, where the advertiser is relying on traditional evidence to support an indication referenced in an advertisement, the advertiser must clearly disclose to the viewer that this is the case and identify the paradigm of the traditional use. This information must be clearly disclosed in the advertisement.

Paradigms include, but are not limited to:

- Traditional Chinese Medicine
- Ayurvedic medicine
- Western herbal medicine.

Where evidence from multiple paradigms is relied upon, the advertisement needs to clearly disclose this and link the appropriate paradigm to the appropriate indication, and if needed, the ingredient. For example:

Medicine	Appropriate	Inappropriate
Single ingredient medicine	Traditionally used in Ayurvedic medicine to relieve sleeplessness. Traditionally used in western herbal medicine to soothe restlessness.	Traditionally used to relieve sleeplessness and restlessness.
Multiple ingredient medicine for different indications	Ingredient X is traditionally used in Ayurvedic medicine to relieve sleeplessness. Ingredient Y is traditionally used in western herbal medicine to soothe restlessness.	Ingredient X is traditionally used in Ayurvedic and western herbal medicine to soothe sleeplessness and restlessness.

For further information, refer to the Guidelines on the evidence required to support indications for listed complementary medicines.

24 Analgesics

Analgesic advertisements must prominently display or communicate the following warning statement:

INCORRECT USE COULD BE HARMFUL

This section is still under development.

25 Vitamins and minerals

Advertisements for vitamins and minerals must not claim or imply that they are a substitute for good nutrition or a balanced diet, or that they are in any way superior to, or more beneficial than, dietary nutrients. Note also the required representations relating to vitamins and minerals in Schedule 2 of Therapeutic Goods Regulations 1990.

26 Weight Management

Consumers seeking to lose weight, especially morbidly obese consumers, are considered vulnerable and their vulnerabilities can leave them highly susceptible to marketing. For these reasons, there are special requirements for the advertising of goods for weight management.

Weight management is defined in paragraph (4) of this provision as including claims about weight loss, weight control and measurement reduction and hunger suppression.

For an advertisement for a weight management good to convey the balance required by paragraph (1) in this provision, the need for a healthy energy controlled diet and physical activity must receive adequate prominence in the advertisement in relation to the weight management claims. For a visual advertisement, the inclusion of statements expressing the need for a healthy energy controlled diet and physical activity are unlikely to provide the balance required. For such advertisements, the messaging around these requirements should form part of the main message of the advertisement.

Claims that are likely to contravene paragraph (2) of this provision include claims that a therapeutic good can eliminate some or all of an individual's calorific intake.

Advertisers should also consider guidance from the TGA and NHMRC in relation to weight loss products and what can constitute typical results.

27 Sunscreens

Consistent with the requirement that advertising of therapeutic goods must not be undermine public health messaging, there are special requirements around the advertising of sunscreens. It is also essential that, given Australia has one of the highest incidences of skin cancer in the world, consumers are aware that sunscreen use is only one element of sun protection and other protections (like a hat, shirt, sunglasses and the use of shade) are necessary, as is the regular re-application of sunscreen.

This approach is also consistent with the permitted indications for sunscreens, which requires sunscreens labels to carry a message to the effect that "Prolonged exposure to the sun should be avoided, it is important to wear protective clothing, hats and eyewear when exposed to the sun".

Part 4—Restricted representations and prohibited representations

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

This section provides a definition for the serious form of a disease, condition ailment or defect (i.e. restricted representations) through a series of criteria – if a reference to a disease, condition, ailment or defect meets one of the criteria, it is considered a serious form of a disease, and will be classified as a restricted representation for the purposes of section 42DD of the Act.

However, if a reference to a disease, condition, ailment or defect is qualified in such a way that it does not meet any of the criteria, it will not be considered a serious form of the disease, and will not be a restricted representation.

This section is still under development.

CRP decision highlight – Arthritis claims

The word "arthritis" can refer to a number of conditions including osteoarthritis and rheumatoid arthritis and, less commonly, other conditions such as gout. The word "arthritis", when used without clear qualification in an advertisement directed to consumers, may refer to joint disease of any severity or type. Because such a reference is not specific as to the type of arthritis, it is likely to be taken to refer to cases of arthritis that have not yet been diagnosed by a qualified healthcare professional. The Panel is of the view that, where arthritis is referred to without qualification in an advertisement, the reference can refer to forms of joint disease that are:

- generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitable healthcare professional; and,
- 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.

Furthermore, where an unqualified reference to arthritis is made, it is likely that a consumer will interpret the reference as extending to serious forms of arthritis, including rheumatoid arthritis. This interpretation is less likely to occur if a reference is confined to osteoarthritis and is qualified by words such as "mild" or "minor". Where a reference is confined to osteoarthritis, the context in which a claim is made, including images and language used, and whether or not a claim is qualified by "temporary" or "symptomatic" relief, will be relevant

For information on approval to use restricted representations, please refer to: https://www.tga.gov.au/restricted-representations

29 Restricted representations—public interest criteria

Section 42DF of the Act requires that the Secretary (or delegate) take into consideration the public interest criteria set out in the Therapeutic Goods Advertising Code when deciding whether to approve or refuse to approve the use of a restricted representation in advertising.

The public interest criteria ask whether the reference to a serious form of a disease in an advertisement would

- be likely to take advantage of the vulnerability of consumers;
- be likely to result in consumers not seeking medical advice at an appropriate time;
- be likely to have a negative impact on public health; or

The Secretary can also take into account other aspects of the public interest that appear to be appropriate.

The public interest criteria provide a framework against which the Secretary (or delegate) can assess the suitability of the restricted representation for use in advertising to consumers.

An application for approval to use restricted representations should include a statement from the applicant setting out how the public interest criteria apply to their advertisement and goods. See https://www.tga.gov.au/form/application-approval-use-restricted-representation-advertising for more information.

30 Prohibited representations

Section 42D of the Act and Subregulation 6B(1) of the Regulations enable the Code to specify which representations are prohibited representations. The Code states that representations relating to the treatment, cure, prevention or diagnosis of:

- neoplastic diseases (i.e. all types of cancer)
- sexually transmitted diseases
- HIV/AIDS
- Hepatitis C virus and
- mental illness

are prohibited representations. Any representation about abortifacient action is also a prohibited representation.

The Secretary may authorise the use of prohibited representations in some circumstances under section 42DK of the Act.

This section is still under development.

Schedule 1 – Price Information

1 Purpose

This Schedule is intended to set out the requirements as to how information about the prices of prescription medicines can lawfully be provided to the public.

2 Application

The requirements set out in Schedule 1 of the Code apply to the provision, to the public, of price information for prescription medicines and some pharmacist-only medicines..

Provision of price information for Highly Specialised Drugs

These medicines are supplied through specific arrangements for special needs access or specialised drugs and include Highly Specialised Drugs. Price information on dispensing fees for buprenorphine hydrochloride and methadone hydrochloride should be available in support of the treatment of opiate dependence.

3 Who may provide price information

Price information may only be made available by retail pharmacists or their agents, pharmacy marketing groups, and dispensing doctors. This is consistent with the purpose of this Schedule of providing price information for consumers to consider when purchasing their medicine. It also prevents manufacturers or sponsors from providing price information about their range of medicines. Pharmacy marketing groups, who are also sponsors of therapeutic goods, are permitted to provide price information on behalf of nominated pharmacists, subject to meeting all applicable requirements.

4 Responsibility for compliance with this schedule

Persons who distribute price information are not responsible for its compliance with this Schedule unless they are also the suppliers of the price information. For example, dispensing doctors or pharmacists who provide patients or customers with price information pamphlets that identify other suppliers of the medicines referred to in that information are not responsible for ensuring that the information complies with this Schedule. Those identified in the information as the suppliers of the medicine are responsible for compliance.

Where a pharmacy marketing group prepares and arranges for the publication of price information on behalf of a group of pharmacists, the pharmacists identified in the price information will be responsible for its compliance with the Schedule.

5 Methods for provision of price information

Methods by which price information may be provided include newspapers, magazines, leaflets, and the Internet. Special requirements are specified for online price information identified through a search function.

Suppliers are not precluded from generally advertising their services and indicating that price lists are available on request, provided that the advertisement does not mention particular prescription medicines or classes of medicine, or the substances that they contain.

6 General requirement restricting promotion

6(2)(a) Promotional statements and designs

Price information on medicines cannot be accompanied by, or be located near, pictures, photographs or illustrations of any of the medicines to which this Schedule applies. Examples of the location of pictures, photographs or illustrations that would contravene this paragraph are:

a) A picture of a medicine listed in price information (eg of a pill, bottle or pack) that is in the same catalogue put out by a group of pharmacists as the price information list.

b) A photograph of a medicine listed in price information in a newspaper that is on the adjacent page or the next page following the list.

c) A price information list located within a 'background collage' of illustrations of medicines to which this Schedule applies.

This does not preclude price information from being accompanied by pictures or graphics in relation to medicines to which this Schedule does not apply where those pictures or graphics:

a) comply with all the relevant legislative requirements; and

b) are not positioned so that it is implied/ imply that they are pictures of the medicines included in the price information or that they relate to those medicines.

6(2)(b) Adjectives and qualifications

This section prohibits the use of adjectives or phrases that qualify the name of the medicine, sponsor's pack size or formula of the medicine; or terms indicating the predicted or recommended length of supply.

Examples of adjectives and qualifications prohibited by this section include:

- adjectives describing the medicine, including "new" and "improved"
- describing the pack size like "small", "large", "jumbo"
- "one month's supply", "thirty normal doses"

6(2)(c) Promoting the purchase of particular quantities

6(2)(d) Comparative objectives to qualify the price of the medicine

Examples of presentations prohibited by these sections include:

- "two for one",
- wording that indicates the price of the medicine is particularly cheap – "now only", "save on 100 tablet pack"

This provision needs to be considered in the context of requirements around presenting pack sizes – see section 7(2).

6(2)(e) Giving prominence to an aspect of a medicine

This section prohibits giving any prominence to the text of the name, description or price of a medicine compared to the remainder of the price information text.

Examples of presentations prohibited by this section include providing the name, description or price of a medicine in text that is:

- bolded or italicized;
- a different colour;
- a different font or size;
- surrounded by a border, highlighting; or
- in any other way distinguished from the remainder of the price information list.

6(2)(g) Qualifying the availability of the price

This section prohibits limiting or qualifying the availability of the price of the medicines in the list, other than by including a statement of validity or expiry of the price.

Acceptable representations include:

- Prices current as at 1 March 2018
- Prices expire 30 August 2018.

Any expiry date included in a price list must allow for a reasonable period in which consumers can purchase the medicine at the listed price. Otherwise, the price list is likely to encourage consumers to seek out their medicines before they are needed, which would be considered advertising.

Examples of presentations prohibited by this section include:

- "today only";
- listing a normal price and "members price";
- use of tag lines and other information that would be likely to encourage the promotion of price comparisons, including between retail pharmacy outlets, such as "we are the cheapest", "we will not be beaten on price".

6(2)(h) Use of embellishments

The content of a price list must be limited to the medicines (including the descriptions), the price for each medicine and where the medicines can be obtained (see section 7). As such, the use of embellishments is prohibited under this provision.

6(2)(i) Other information

This section prohibits price information from being accompanied by (or located in proximity to) other information that would lead a consumer to infer that a medicine in the price list will cure or alleviate particular diseases, conditions ailments or defects.

Examples of arrangements prohibited by this provision:

- A pharmacy catalogue with a price list on one page, which includes various strengths and brands of metformin, and an article on the opposite page about how metformin works to reduce blood glucose levels in diabetics.

6(3) Other requirments

Price information must include at least 25 medicines and be accompanied by name and contact details for the pharmacy.

7 Description of medicines

The two options for describing medicines by brand name or sponsor's name are provided because some medicines (e.g. some generic medicines) may not have a brand name, but all medicines on the Register will have a sponsor. The names of the active ingredients of the medicine will need to be provided where the medicine is described by the name of its sponsor. This does not preclude also describing branded medicines using the names of active ingredients.

The form in which the medicine is presented is the dosage form – e.g. tablets, capsules.

8 Presentation of price information

Medicines must be listed in alphabetical order using their brand name, or names of their 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. To allow a price list of medicines in order by sponsor name would circumvent that requirement.

9 Pharmaceutical Benefits Scheme subsidised medicines

Where a pharmacy marketing group publishes price information which includes both a PBS 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). This requirement is intended to prevent any misleading implication that the pharmacy marketing group's medicine is the only bench-mark price medicine.

Schedule 2 – Advertising to children

1 Goods that may be advertised to children

This section is still under development.

Other guidance on application of Code

This section is still under development, including the development of information about the application of the Code in other scenarios.

The information intended to be included in this section of the document may be better published as fact sheets, other guidance or web statements.

Comparative advertising

Although there are no specific provisions in the Code for comparative advertising, the other advertising provisions still apply.

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.

Samples

Although there are no specific requirements relating to the offer of a sample through an advertisement, the other advertising provisions will still apply to such offers. For example – an advertisement for a topical cold sore relief product that contains an offer of a sample of a magnesium supplement may potentially contravene section 10(c) of the Code as it could be seen as encouraging someone with no established need for such a magnesium supplement to try it.

Promotion of goods for use by specific populations

Promotion of goods for use by specific populations e.g. infants and neonates is likely to be considered misleading unless specific information on the use of the advertised good in the referenced population is available to support the claims made.

Foreign language advertising

The Code applies to advertising in Australia that uses languages other than English.

Advertisers should be aware that literal translations between English and other languages (and vice versa) often distort the take out messages.

Care is also needed for mixed language advertising (where one language is usually English) as the juxtaposition of the two different languages can alter the main message.

Where the TGA receives a complaint about an advertisement that contains a language other than English, the TGA will request an expert accredited (NAATI) translator to certify the messaging.

Generic information

Definition of generic information

Generic information is defined in section 42B of the Act as including "…any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include:

(a) an advertisement about the goods; or

(b) generic information included in an advertisement about the goods; or

(c) bona fide news."

Further information about generic information is in section 42DN of the Act. Section 42DP of the Act requires generic information to comply with certain sections of the Code, as defined in Regulation 8[4].

(A fact sheet providing more information on the differences between advertising, generic information and other activities is currently under development.)

Unbranded advertising

An unbranded advertisement promotes the use or supply of a particular type of good or an ingredient of a good by inviting the consumer to seek further information about symptoms or conditions and/or their treatment or management while not referring overtly to any particular branded product.

Unbranded advertising is still considered an advertisement for therapeutic goods and therefore is subject to the requirements in the Act and Code. Care is needed to ensure unbranded advertising does not contravene the Code, including section 11, which requires a reference to the name of the therapeutic good. Unbranded advertising is not considered generic information as it is promotional.

Provision of price information for medicines other than prescription medicines

This section is still under development.

[4] In the transition from the 2015 Code to the 2018 version, the numbering of the Code sections has changed. This will require a further change to Regulation 8.

Version history

Version	Description of change	Author	Effective date
V0.1	Original publication – draft for consultation	Advertising Compliance Unit	29 March 2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #