Australian Government
Department of Health
Therapeutic Goods Administration

Advertising to the public

Complying with the Therapeutic Goods Advertising Code (No. 2) 2018

Version 1.4, July 2020

TGA Health Safety Regulation

Contents

Therapeutic goods are not usual items of commerce. Advertising of therapeutic goods requires a higher ethical standard than may apply for ordinary consumer goods. Consumers rely on therapeutic goods for their health. Determining the appropriateness of a therapeutic good can be difficult for a consumer and it is important that promotional material is truthful, balanced and not misleading. Advertising should give adequate information on the risks and cautions around a product and recommend to seek health professional advice where appropriate. As a result there is specific legislation that applies to the advertising of therapeutic goods to consumers (over and above Australian Consumer Law, which regulates advertising generally) and applies to therapeutic goods through the requirements under the *Therapeutic Goods Act 1989* and subordinate regulation. The regulation of advertising reflects the importance of consumers being properly informed so that they can select treatment options appropriately for use in their own and their family's healthcare.

When advertising therapeutic goods to the public, advertisers must comply with the *Therapeutic Goods Advertising Code (No 2) 2018* (the Code), which is the cornerstone of the therapeutic goods advertising regulatory framework. Not all therapeutic goods are allowed to be advertised to the public including biologicals, goods containing a Schedule 4 or Schedule 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Poisons Standard), and goods containing a Schedule 3 substance not included in Appendix 8 of the Poisons Standard. More information is available on these restrictions and others in: Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG).

The ARGATG also has information on:

- advertising and the *Therapeutic Goods Act 1989*
- activities that represent advertising
- sanctions and penalties for addressing non-compliant advertising
- lodging an advertising complaint

About the Code and this guidance

The Code sets out minimum requirements for advertisements about therapeutic goods directed to the public. It is a legislative instrument made by the Minister or their delegate under section 42BAA of the *Therapeutic Goods Act 1989* (the Act). There are criminal offences and civil penalties for advertising to the public that does not comply with the Code.

Object of the Code

The Code exists to ensure that the advertising of therapeutic goods to the public is conducted in a manner that:

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

Reading the Code

In the event of any inconsistency between the Act, the Regulations or the Code and this guidance or other published policies, the Act, the Regulations and the Code prevail.

This guidance is designed to be read in conjunction with the Code and its Explanatory Statement to provide further information about the understanding, interpretation and application of the Code provisions. Unless otherwise stated, the Code requirements apply to all elements of advertising (including both therapeutic claims and non-therapeutic claims) and all types of advertising to the public.

The Act, the *Therapeutic Goods Regulations 1990* (the Regulations) and the Code contain explicit definitions for certain terms. Where a term is not defined the normal meaning, derived from the current edition of the Macquarie Dictionary, applies.

In reading the Code provisions, note that the conjunctions 'and', 'or' have different meanings:

- the conjunction 'and' signifies that each paragraph set out in the provision applies
- the conjunction 'or' puts each paragraph as an alternative such that only one of the paragraphs needs to be satisfied in order for the provision to apply
- where no conjunction is used, 'and' is implied unless the wording is clear that each itemised paragraph is an alternative

A reference to a noun that is singular is taken to include plural forms, for example 'medicine' also includes 'medicines'.

A reference to 'person' in the Act, the Regulations or the Code includes individuals, organisations and corporate entities.

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

This guidance 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 June 2018. This guidance is supplemented by fact sheets on major topics.

Examples provided in this guidance are provided to illustrate the information provided and are not intended to be either comprehensive or exhaustive in relation to the application of the Code.

With the exception of CRP matters, all examples used in this guidance have been compiled to demonstrate the application of the legislation. They should not be taken to be a reference to any particular advertisement.

Other relevant policies and principles

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

- 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
- all promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, and 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
- comparison of products should be factual, fair and capable of substantiation
- 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
- the provision of free samples to the general public for promotional purposes is difficult to justify from a health perspective
- advertisements may claim that a drug can cure, prevent or relieve an ailment only if this can be substantiated
- language which brings fear or distress should not be used
- 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. 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 medical devices and other therapeutic goods that may be appropriate for self-selection by consumers for their care or their family's care.

To support the principles of QUM, advertisers should provide truthful information to potential consumers about the nature and benefits of therapeutic goods. They should be able to do so through responsible advertising.

Guidance on specific Code provisions

The numbering of the sections corresponds to the numbering of the Code provisions for ease of cross-reference. However, this guidance does not cover all sections of the Code so the numbering may not be sequential.

Part 1 - Preliminary

2 Commencement

The Code is effective from 1 January 2019. However Part 4 of Schedule 1 of the Code does not commence until 1ST of September 2020.

4 Definitions

A consolidated list of definitions from the Act, the Regulations, the Code and any other legislative instruments that are relevant to the Code is provided.

5 Object

The object outlines the underlying purposes of the Code.

The object reflects the responsibility that advertisers have to ensure that the content and presentation of their advertisement promotes responsible use of therapeutic goods through encouraging consumers to select management options wisely, to choose suitable therapeutic goods and to use them safely and effectively.

Generally, in applying this Code to an advertisement, advertisers should take into account the Code's object to protect public health by ensuring therapeutic goods are honestly promoted as to their benefits, uses and effects.

6 Application

6(1) Code applies to the advertising of therapeutic goods

The Code applies to the advertising of therapeutic goods, except for:

- content that is outside of TGA's jurisdiction
- advertising directed exclusively to health professionals
- genuine news in particular situations

The Code does not apply to the advertising of products that are not therapeutic goods, including food and cosmetics. However, making therapeutic claims in advertising for such products may in some circumstances make these products a therapeutic good. See the Australian Regulatory Guidelines on Advertising Therapeutic Goods for more information on these "interface products".

Public health messages that do not promote an identifiable therapeutic good (for example, mammography services, or vaccination services) are not advertisements for therapeutic goods. Disease awareness initiatives that may be undertaken by companies to encourage consumers to seek health professional advice in relation to certain health symptoms are also unlikely to be considered advertisements for therapeutic goods (in cases where no product is identifiable).

The marketing of therapeutic goods can include the name of the good, the name and logo of the sponsor and tag lines or catch-phrases which are often used in a similar fashion to logos to identify a good or advertising as belonging to the sponsor. Similarly, a range of goods may have a common or 'umbrella' name or brand to tie them together and differentiate them from similar ranges of goods marketed by competitors. Depending on the nature and context of these elements when used within advertising of therapeutic goods, they may be interpreted as claims about the advertised therapeutic goods.

Further information on Forms an advertisement may take is available in the ARGATG.

Therapeutic goods advertising material posted on a website owned by or registered to an Australian entity, or where the contact for the website is an Australian individual or corporate entity (Australian websites) are subject to the Act and the Code. Overseas websites containing material promoting therapeutic goods that are linked to or where the entered URL for these websites redirects the user to another website, or promotional material incorporated by any other means into an Australian website must either be compliant with the Code or the link, content or redirection must be removed from the Australian website.

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. See Definitions for more information on the types of health professionals that are subject to this exemption.

Directing advertising exclusively to health professionals

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 for health professional should be secured in some way to ensure that it can only be accessed by those persons who are listed as health professionals under section 42AA of the Act. The mechanism for achieving this outcome is up to individual advertisers and could include having the material password protected, and/or by a declaration that the user is a healthcare professional and/or by a requirement to provide a current healthcare professional (AHPRA) registration number.
- content provided via email should only be provided once the professional credentials (e.g. AHPRA or other accreditation) of the individual has been established
- an advertisement that appears in magazine directed to a specific health professional group such as the Australian Journal of Pharmacy or Australian Doctor

Factual information (for example scientific/medical information) meant for health professionals does not need to be secured provided that it is not directly or indirectly promotional. For example, a medicines sponsor website that provides access to product information documents for all of their prescription medicines that is accessed via an index ordered solely by medicine name would be unlikely to be considered promotional. However, providing broad public access to the same documents via an index grouped by medical condition, or allowing searching of such documents by medical conditions would be considered promotional. Providing factual information publically in other promotional contexts may also result in that information being considered part of an advertisement to the public.

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

This section requires the Code to be applied to an advertisement by reference to its likely impact on a reasonable person to whom the advertisement is directed.

Reasonable person

Therapeutic goods differ from normal consumer goods. Consumers are making choices about their health and considering goods that are intended to have a therapeutic effect. In some cases, this may place them in a more vulnerable position than if they were making choices about ordinary consumer items. There are additional requirements for advertising therapeutic goods over and above Australian Consumer Law in recognition of the potential vulnerability of consumers who may have limited capacity to properly evaluate the information presented in advertisements.

Therefore, advertisers should be aware that a 'reasonable person' for the purposes of the application of the Code may include a consumer of therapeutic goods who may be more vulnerable than a prospective purchaser of ordinary consumer goods and who:

- purchases therapeutic goods for personal use or use by family members
- has sufficient capacity to discern where a health claim is being made by taking into account any representation or claim about the goods, and
- bears some responsibility for taking care in relation to their interests and the interests of those in their care

All reasonable interpretations of advertising claims must be considered in assessing compliance of advertisement with the Code (noting this may include messages the advertiser had not directly intended to convey).

Target audience

Advertisements for therapeutic goods may be directed to particular audiences. depending on the nature of the therapeutic goods being advertised. Some advertisements are directed (either explicitly or by implication) to specific subpopulation groups for example diabetics, carers of infants and children. Other advertisements are directed more broadly – for example to adults who may have a cold. In each case, the characteristics of the audience may 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, how that person is likely to interpret the advertisement and how they are likely to be impacted by it.

The target audience should be taken into account for an advertisement in order to properly assess the advertisement's compliance with the Code.

For example:

- the reasonable consumer assessing an advertisement for a Type I diabetes product, is likely to have some knowledge of diabetes, perhaps gleaned from having the condition and from interactions with health professionals
- an advertisement in which a medicine to improve memory is represented as having been 'clinically trialled' would lead the reasonable person within an all-adult target audience to the view that the effectiveness of the medicine has been proven through credible clinical trials

- an advertisement for therapeutic goods that targets older people with eyesight difficulties may be unbalanced if the reduced vision capacity of the target audience is not taken into account in displaying information, such as advisory or warning statements, in the advertisement

6(4) Total presentation and context of advertisement

When considering the application of the Code to advertising, the 'takeout message' that is likely to be imparted from the total context of the advertising must be considered, not just specific claims. The words (whether written or spoken) and the emphasis given to them, images and presentation of the advertisement (including the medium) will all need to be considered in determining whether the advertisement is compliant with the Code.

Advertisements can be presented in a variety of ways, including by a statement (orally or in writing), images and pictures and shop displays. Advertisements can be presented by actors, who may make promotional claims through their words, gestures and demeanour.

For example, an advertisement that states a particular therapeutic good is (only) for the relief of pain associated with mild arthritis but uses images of a person that is debilitated with pain from arthritis is likely to leave the viewer with the 'takeout message' that the product may provide pain relief for serious forms of arthritis.

Additionally, compliance with the Code is required for pack-shot images (and the wording contained thereon) when they are included in consumer advertising.

6(5) Who the Code applies to

Subject to the jurisdictional constraints set out in Section 6 of the Act, the Code applies to any person who advertises, by any means, therapeutic goods; or causes the advertising, by any means, of therapeutic goods to the public. Examples of persons who might advertise, or cause the advertising of, therapeutic goods include the following:

- the sponsor of the goods - i.e. the person in relation to whom the goods are included in the ARTG
- any person in the supply chain for the therapeutic goods (for example 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
- an advertising agency involved in creating and disseminating advertisement for goods
- any person who receives valuable consideration for advertising or promoting the goods (including influencers, bloggers and product ambassadors)
- any person publicly endorsing the goods
- a print or broadcast organisation
- a health practitioner advertising therapeutic goods or promoting services that require the use of a specific therapeutic good

6(6) and (7) Genuine news

Genuine news must be accurate, balanced, factual, impartial and non-promotional, otherwise it would be considered to be advertising. News that promotes the use or supply of a therapeutic good is advertising and would be subject to the provisions of the Act and the Code. Media releases about therapeutic goods may either be considered to be genuine news or advertising depending upon both their content and context.

The Code does not apply to genuine news that is broadcast or published in any medium by:

- broadcasters, datacasters and the SBS (Special Broadcasting Service)
- publishers of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia

Public interest and entertainment programs (including current affairs programs) that are non-promotional and presented in an accurate, factual, balanced and impartial way are unlikely to be considered advertising. However, as these types of programs are more likely to take a particular stance on issues (see section 3.4.3 of the Commercial Television Industry Code of Practice 2018[1]), steps should be taken to ensure they are either not advertising therapeutic goods or, if they do advertise therapeutic goods, do so in a compliant manner.

The republication of *genuine* news in certain contexts by parties other than those identified in section 6(7) could render the content part of an advertisement for therapeutic goods for example if the news segment was posted on an advertiser's website or social media account and was associated in any way with a therapeutic good.

All parties involved in advertising therapeutic goods to the public have responsibilities to ensure compliance with the Code.

For example, in the case of a shelf "wobbler" in a pharmacy chain or buying group, the responsibility for compliance may lie with that pharmacy chain or group. However, where the pharmacy chain or group or a pharmacist sole trader 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 (such as receiving documented assurance that the wobbler is compliant with the Code), the sponsor is likely to be considered the responsible advertiser.

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. 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

[1] http://www.freetv.com.au/content_common/pg-code-of-practice.seo

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.

6A & 6B Repeal and Transitional arrangements

While the Therapeutic Goods Advertising Code 2015 (2015 Code) and the Therapeutic Goods Advertising Code 2018 will be repealed at the same time the Code comes into force on 1 January 2019 (see Schedule 5 to the Code), the 2015 Code will continue to apply for the duration of the transition period **in relation to advertisements for therapeutic goods that were approved** under Division 2 of Part 2 of the Regulations before the commencement of the Code. The transition period means the period beginning on the commencement of the Code (1 January 2019) and continues to apply until either:

- the day on which the approval number for the advertisement expires, in accordance with the Regulations; or
- for an advertisement for which approval is withdrawn in accordance with the Regulations, the day on which approval is withdrawn.

Therefore advertisements approved under the pre-approval arrangements in the Regulations that were assessed against the 2015 Code, will continue to be subject to the 2015 Code in accordance with the conditions specified above.

For all other advertisements (those not requiring pre-approval under the Regulations), they should comply with the Code from 1 January 2019. However 'enforcement discretion' in relation to new requirements for mandatory information will be utilised throughout 2019, in particular in the first half of 2019 – see Therapeutic goods advertising changes. For information on the changeover to the Code from the 2015 Code, also see Changeover to Therapeutic Goods Advertising Code 2018.

Note: The information in this section is now historical and currently under review since the requirement for advertising pre-approval ceased on 1 July 2020.

7 Price information

Prescription medicines, as listed in Schedules 4 and 8 of the Poisons Standard cannot be advertised to the public as it is an offence to do so under subsection 42DL(1) (or subsection 42DLB(7) for the corresponding civil offence) of the Act. The same prohibition applies to pharmacist only (Schedule 3) medicines that are not listed in Appendix H of the Poisons Standard. However, price lists for such medicines can be issued to the public.

To ensure that dissemination of price information does not promote the use of particular prescription medicines, it is essential that price lists comply with Schedule 4 of the Code.

Part 2 – General requirements for the advertising of therapeutic goods

8 Approved advertisements

This section only applies to medicine advertisements which:

- have received pre-approval from the Secretary's delegate under Part 2 of the Regulations
- are published in mainstream media or in displays about goods (including posters in shopping malls, in or on public transport, and on billboards, as required by paragraphs (a) and (d) of the definition of 'specified media' in section 42B of the Act)

Information on how to obtain pre-approval for medicines advertising in specified media is available in the ARGATG.

Approval number

An approved advertisement that appears in mainstream media or is a display about therapeutic goods must include its distinguishing approval number allocated in accordance with regulation 5J. The approval number must stand alone, be legible and be located in the bottom right hand corner of approved print advertisements, displays about goods such as posters in shopping malls, in or on public transport and on billboards.

Note: The information in this section is now historical and currently under review since the requirement for advertising pre-approval ceased on 1 July 2020.

9 Accuracy

This section of the Code is an overarching specification of the fundamental truthfulness requirements for therapeutic goods advertising.

9(a) Valid, accurate and substantiated advertising claims

The Code requires that claims must be valid and accurate as well as substantiated.

'Advertising claims' refers to all claims made in advertising material – that is, claims of therapeutic effect and all other claims. A claim can be an explicit or implicit statement describing the positive effect or attribute of a product. All elements of an advertisement must be considered in identifying claims, including text, product name, pictorial representations etc. Further, all claims must be consistent with the advertised goods' indication or intended purpose as it is recorded on the ARTG (see section 9(d) below).

A 'valid' claim is one that is authoritative, sound or well-founded, while an 'accurate' claim conforms to the truth and is free from error (refer to the Macquarie Dictionary). An accurate claim is a truthful claim and is correct.

All claims (both therapeutic or non-therapeutic) made in therapeutic goods advertising must have been substantiated prior to the advertising of the product. This means that evidence must held that can demonstrate the accuracy of every claim that is made in the advertisement. The kind and amount of information required to substantiate a claim will depend on the type of claims made (including any implied claims - see below).

Therapeutic use claims

For therapeutic use claims, (see definition of 'therapeutic use' in the Definitions section of these Guidelines) 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 section 9(b) below).

Therapeutic claims (as well as other types of claims detailed below) must be capable of substantiation. The advertiser must hold evidence at the time of the advertisement that adequately demonstrates the claim is accurate and valid and it must be commensurate with the level and kinds of evidence needed to substantiate the inclusion of the good in the ARTG. Such evidence, depending on the nature of the therapeutic use claim and the good(s) being advertised may comprise:

- clinical study reports on the actual therapeutic good being advertised
- if clinical data is not available on the actual therapeutic good, a justification and reference to ingredients (for medicines) or to similar devices (for medical devices)
- literature reviews
- objective critical review of all data presented by an independent clinical expert

Guidelines setting out the principles on how to demonstrate evidence of efficacy or performance are available for:

- Australian Regulatory Guidelines for Medical Devices, (see Principle 14)
- Clinical evidence guidelines documents for medical devices
- Australian Regulatory Guidelines for OTC Medicines
- Australian Regulatory Guidelines for Complementary Medicines
- Guidelines on the evidence required to support indications for listed complementary medicines
- Permitted indications for listed medicine guidance
- Assessed listed medicines

These guidelines should be taken as a minimum standard for evidence requirements to underpin therapeutic claims in an advertisement. Advertisers should take care that the supporting evidence for the therapeutic claims in an advisement must be commensurate with the level of the claim.

For example, a product is listed on the ARTG for the temporary relief of heartburn based on a single small clinical trial of adults of all age ranges assessing relief over 2 hours. An advertising claim such as 'clinically proven to relieve heartburn in the elderly for 8 hours' would require the sponsor to have based the claim on additional supporting evidence demonstrating this outcome in the specific patient population for the claimed timeframe. They would need to supply this evidence to the TGA if required.

Regardless of the level of the claim, each therapeutic use claim must be consistent with the accepted indication (medicine) or intended purpose (medical devices) of the therapeutic good(s) being promoted.

Other types of claims

Claims other than therapeutic use claims can be made about therapeutic goods and these also must be substantiated, valid, accurate, truthful, balanced and not misleading.

For example:

- marketing statements unrelated to the therapeutic use of the goods (for example gluten free, 20% off this week, 4 out of 5 people prefer this brand, improved flavour)
- claims related to effectiveness or performance (for example relief in just an hour, non-drowsy)

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

9(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. This includes any implied claims.

In order to be truthful and not misleading, the strength of claims made in advertising must be consistent with the level 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 would be seen as misleading consumers for a number of reasons:

- a preliminary trial would be unlikely to meet TGA evidence requirements for medicine indications
- a single trial of only 20 subjects would also be unlikely to meet TGA evidence requirements for medicine indications
- the claim relates to 'headaches' generally, yet the trial only related to a specific kind of headache

A claim can be truthful but still mislead people. For example, an imaging device that is advertised as producing 5 times 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 only very small, is likely to mislead consumers into thinking other imaging devices are harmful.

Similarly, claims in an advertisement that can be verified, but the advertisement is presented in a way that lacks balance can also mislead. The term 'balance' embraces the overall balance of statements, claims, implications or representations made within an advertisement. The inclusion of health warnings where required, can, for example assist to lend balance to an advertisement.

An advertisement that omits or minimises important information and/or emphasises certain information about a product would be unbalanced and could also mislead.

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:

- 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 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.

9(c) Comparative advertising

Comparative advertising is advertising that identifies a competing product and may make or imply certain claims about the competing product. Consumers can be particularly susceptible to comparative advertising for therapeutic goods. They are unlikely to have sufficient knowledge to comprehend the subtleties of this type of advertising and their lack of knowledge can easily be exploited. An advertisement which compares the advertised good with one or more competitor or other goods must not expressly or by implication lead the consumer to a view that the comparator goods are harmful or ineffectual.

Comparative statements can include therapeutic (for example efficacy) and non-therapeutic (for example attribute) claims. Comparative advertising should be factual and substantiated and should not discredit other products either directly or by implication. Hanging comparatives such as 'higher strength' or 'better absorbed' should not be used unless it is clear to the audience to which product(s) comparison is being made. Comparative advertising, like all advertising, must comply with all relevant Code provisions and must not mislead the consumer about the benefits of the advertised good in comparison with the other products including by taking advantage of consumers' lack of knowledge. Advertisers should ensure such advertisements are balanced and fair.

Examples:

Ü The claim made of a liquid vitamin preparation 'alternative to gummies' is a comparative claim. However it is unlikely to mislead or imply that the therapeutic goods with which comparison is made are harmful or ineffectual.

Û An advertisement for a complementary medicine product contains claims such as 'natural anti-inflammatory'. The advertisement makes comparisons between the advertised good and other therapeutic goods such as cortisone. This advertisement would be likely to be in breach of this Code provision because of the implication that the comparator good is harmful.

9(d) Consistency with Register (ARTG) entry

Advertising needs to be consistent with the ARTG entry or entries for the advertised therapeutic goods, unless the goods are exempt from inclusion in the ARTG. Where the goods are exempt from inclusion in the ARTG, the advertising must be consistent with the labelling (medicines, other therapeutic goods and most devices) or packaging (some devices where they are not labelled) to avoid being misleading. Consistency must be gauged from the total context of the advertisement.

The need for consistency extends to all aspects of the full ARTG entry. This includes (but should not be interpreted to mean the reproduction of this information):

- the name (noting that the "name of the medicine" defined by TGO 92 will always be consistent with the name entered on the ARTG) or description of the goods (for medical devices)

- the dosage form (for example tablets, capsules, topical liquid) or, in the case of medical devices, the GMDN code
- the formulation of the goods (noting that the advertising of excipients as having or enhancing a therapeutic use would not be consistent with the entry. This may also breach other provisions of the Act.)
- the intended purpose (for the purposes of this provision, this includes indications, for example, for medicines) (Note that this id discussed further below in relation to adverting an intended purpose that is not included on the labelling or packaging of the good)
- any conditions applied to the ARTG entry (including those that may constrain the way in which the goods can be promoted)
- particular 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 ARTG 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).

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

Particular 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 and a therapeutic use claim. However, qualifying the indication with a timeframe in which the therapeutic results are expected to be achieved, but which is not a therapeutic claim, is nevertheless a claim which would need to be substantiated for example 'helps relieve constipation within 24 hours'. Advertising claims that are not indications are not required to be included in the ARTG entry for the goods but they must still be consistent with the ARTG entry and must be valid, accurate, truthful, balanced and not misleading.

While therapeutic claims made in an advertisement need to be consistent with the indication or the intended purpose of the therapeutic good, they do not need to replicate it exactly. Qualifying or clarifying information attached to the therapeutic claim can be used if such information is supported by evidence.

For example, a medicine indicated for the relief of hay fever symptoms may be advertised to 'provide relief of hay fever symptoms' along with the provision of further information such as 'will not cause drowsiness'. So while the claim 'will not cause drowsiness' is not a part of the medicine's indication, it can be used if the advertiser holds sufficient evidence to substantiate it. Conversely to imply an antihistamine was suitable for use at night when driving for example setting the advertisement in the interior of a vehicle at night while moving, would not be consistent with the entry if it included information that it may cause drowsiness.

However, if an indication in the ARTG entry has been qualified (for example to limit it to a specific population), that information must also be used whenever the indication is used in advertising.

In certain circumstances a claim may be consistent with the ARTG entry but still not compliant with the Code. Particular care should be taken if a therapeutic claim is consistent with an indication or intended purpose entered on the Register but that use is not included on the label or packaging of the good. While the claim may be consistent with entry it may be confusing at best and misleading at the worst where the consumer relies on the claim in the advertisement but cannot find a matching claim on the good.

Being consistent with the ARTG entry does not guarantee an advertisement complies with all the requirements of the Code.

10 Effect

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

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

Advertising must 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 as they appear on the medicine's label (for listed medicines)
- the instructions for use prescribed by the manufacturer (for medical devices and other therapeutic goods)

For example, an advertisement that shows a medicine being administered to children 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 be misleading (see above).

10(a)(ii) Not exaggerate product efficacy or performance

Exaggerating product efficacy or performance in advertising will generate unrealistic consumer expectations, and could mislead and be inaccurate.

Exaggeration of product efficacy or performance can occur in various ways and may include:

- omitting important information – for example that the product's efficacy has only been established in a particular population group
- through the use of explicit or implied claims that the advertised good offers therapeutic effects which exceed the indication/intended purpose of the good
- through the use of overstated terminology such as 'powerful', 'strong', 'certain' or 'proven', which may be acceptable in relation to specific claims where there is evidence
- through the use of testimonials which refer to unrealistic or unusual therapeutic effects

10(b) Not likely to delay medical attention or failing to use prescribed treatment

Claims in an advertisement which state or imply that a particular health condition (either expressly named or implied by reference to a symptom or group of symptoms) can be adequately treated or managed by using the advertised therapeutic good could result in consumers placing undue trust in the good. They could also delay seeking medical attention when such attention is necessary for the proper treatment or management of the condition.

For example:

- a claim like 'Itchy rash down there? This will fix it! Get it at your supermarket!' in advertising for a barrier cream could result in consumers attempting to self-manage a condition for which timely health professional treatment is necessary
- an advertisement that refers to the negative side-effects of a class of prescription medicines (for example antibiotics) while promoting the advertised goods as an alternative could result in consumers failing to use prescribed treatment (as well as being non-compliant with 9(c) of the Code).

10(c) Not encouraging inappropriate or excessive use

Advertisements which make therapeutic claims that exceed, or are inconsistent with the advertised good's indication or intended purpose could encourage inappropriate use (as well as exaggerate product effectiveness).

For example, advertisements for:

- a medicine containing caffeine with claims like can 'help you study all night' would encourage inappropriate use
- a sunscreen that represents the product as 'giving long lasting protection' could give consumers the impression that the sunscreen could be relied upon for extended periods without reapplication, thereby encouraging inappropriate use
- a medical device which has the intended purpose of alleviating snoring that promotes the use of the device for the more serious condition of sleep apnoea would be likely to encourage inappropriate use

10(d) Other prohibited effects in advertising

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

Therapeutic goods 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 at particular dosages. This requirement applies even if it is considered that there is evidence to substantiate such a claim.

Similarly, advertising claims that imply a therapeutic good is "safe" are also prohibited. Examples of such prohibited claims include:

- û '[the therapeutic good] has a safe mode of action'
- û 'No known side effects'
- û 'Safe alternative'
- û 'Non-toxic amounts of [ingredient]'

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

Individual responses to therapeutic goods vary. Therefore advertisements for therapeutic goods must not contain any claim, statement, implication, or representation that the use of the goods will be effective in every case of a condition. Further, while it may be permissible to offer a money back or satisfaction guarantee, the Code also prohibits claims which state or imply that a product is guaranteed to work in regards to its therapeutic action.

For example:

- 'Lose 3 kilos in 3 days'
- 'No more arthritis'
- 'Say goodbye to sick days forever'
- 'Clinically proven to get rid of your abdominal fat'
- '100% guaranteed to eradicate head lice and nits'

10(d)(iii) Infallible, unfailing, magical or miraculous

Individual responses to therapeutic goods vary even when such individuals are afflicted with the same or similar health condition. Efficacy will depend on a number of factors which can be specific to individuals. No therapeutic good will be effective in all cases of a condition.

The use of exaggerated language such as 'revolutionary', 'amazing', 'incredible' is unlikely to be acceptable in advertisements for therapeutic goods. Apart from such terminology being in breach of 10(d)(ii) and/or (iii) of the Code it will also invariably be unable to be substantiated. Such terminology will present consumers with an unbalanced impression of the therapeutic good(s) being advertised and as such also likely to be misleading.

For example:

- an advertisement for a multi-vitamin and mineral product which was represented in an advertisement as 'the holy grail of good health' may give the reasonable consumer the impression that the product had a miraculous or infallible quality
- an advertisement for a magnesium supplement which contained the claim 'a revolutionary solution for your health' is likely to give the reasonable consumer the impression that the product is infallible

10(d)(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 approved under s.42DF or permitted under s.42DK of the Act (provisions relating to the use of 'restricted representations').

Advertisers must not use 'scare-mongering' to promote the use of the good. An advertisement could do this by:

- implying that the consumer's health may suffer by not using the advertised good
- exaggerating adverse consequences of not treating a health condition
- implying that the use of an advertised good is essential for normal health
- implying that a health condition will become more serious if the advertised good is not used

11 Pharmacist-only medicines (required statement)

Section 11 recognises the professional responsibility of pharmacists for providing access to pharmacist-only medicines (medicines that are included in Schedule 3 of the Poisons Standard). Only those medicines listed in Appendix H of the current Poisons Standard can be advertised to the public.

Section 11 does not apply to:

- labels, patient information leaflets or Consumer Medicine Information (CMI)
- an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation

This section requires the use of the statement:

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

which must be 'prominently displayed or communicated'.

This statement is to ensure that consumers understand that they have to talk to a pharmacist who can assess the suitability of the medicine for the individual. Factors the pharmacist may need to take into account include the use of other medicines by the consumer and type and duration of their symptoms.

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

Consumers can purchase therapeutic goods through certain channels without the opportunity to physically examine the goods and thus be able to read information available on the label and/or packaging to establish whether it is suitable for their needs. Therefore, it is important that advertising that promotes supply through these channels contains a greater level of information than other advertising.

Examples of channels through which a consumer could purchase a therapeutic good without being able to physically examine it first include:

- internet marketing
- direct marketing (for example, a mail-order catalogue or telemarketing)
- digital and other direct marketing sources where the consumer is able to directly purchase within an advertisement.

Section 12 sets out the minimum requirements for advertising for therapeutic goods that are not available for physical examination before purchase. It refers to Schedule 1 - Medicine ingredients with specific health warnings.

This Schedule sets out when a health warning, or alternately, the statement "This medicine may not be right for you. Read the warnings before purchase" must be used. However not all warnings required on the label are also required in advertising – Schedule 1 sets out the minimum requirements only. When considering the advertising of goods that are not available for examination before purchase, consideration may also be given to whether any other (non-mandatory) information or warnings would be of benefit to the consumer in making their decision to purchase.

Please note however that all parts (that is parts 1 - 4) of Schedule 1 apply to section 12. In effect this means, for example, that certain allergen warnings that are not required in advertisements set out in section 13 are required in advertisements where the physical product is not available for examination before purchase. This additional requirement for advertisements covered by section 12 is to ensure that allergy sufferers do no inadvertently purchase a product that would be dangerous to their health. This requirement does not extend to advertisements through which the product cannot be directly purchased as allergy sufferers are usually well aware of what substances they are allergic to and are accustomed to searching for this information on the medicine label before they purchase the product.

12(1) Application of this section

Section 12(1) sets out the information which must be included in an advertisement for a medicine, where the physical product is not available for examination before purchase.

12(2) Things this section does not apply to

Section 12 does not apply to:

- advertisements covered by section 11
- labels
- Consumer Medicine Information
- patient information leaflets

12(3) Things advertisements for a medicine must contain

Section 12(3) sets out that required statements which must be prominently displayed or communicated must be displayed in close proximity to one of the following:

- the first use of the name of the goods in the advertisement
- (except for a medicine) where the name of the good is not used—the first image of the primary pack of the medicine in the advertisement
- (except for a medicine) where the name and image of the good is not used—at the beginning of the advertisement

Name of the medicine

Section 12(3)(a) requires an advertisement for a medicine to include a reference to the 'name of the medicine' as defined by the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (TGO 92).

- where the medicine to be advertised is entered in the ARTG, use the name of the medicine appearing on the Certificate of Registration or Certificate of Listing in relation to the medicine (with exclusions specified in TGO 92)
- where a medicine is not entered in the ARTG, use either:
  - the registered trade mark for the medicine

    OR
  - a unique, invented, common or scientific name, assigned to the medicine by the sponsor and appearing on the label
- where a medicine is advertised as part of a range of medicines, use the trade name for that group of medicines. However, advertisers must ensure that any individual medicine advertised as part of the range must also comply with all the requirements of Section 12

Dosage form and quantity

Sections 12(3)(b) and (c) require an advertisement for a medicine to also contain respectively:

- the name of the dosage form of the medicine, within the meaning of TGO 92
- the quantity of the medicine, within the meaning of TGO 92

Indications for the medicine

Section 12(3)(d) requires an advertisement for a medicine to include the indications for the medicine as they appear on the medicine's label.

There is no requirement for the reference to the indications made in the advertisement to be presented word-for-word as they appear on the medicine's label. However, the meaning and intent must not differ. See examples given for section.

Medicine ingredients

Section 12(3)(e) requires an advertisement for a medicine to contain a list of the active ingredients and any other ingredient required to appear on the label of the medicine.

Health warnings

Some therapeutic goods, particularly certain medicines may have significant contraindications. An example is medicines that should not be used by individuals with particular conditions, for example pregnant or lactating women.

Where these contraindications are sufficiently serious that particular individuals should not use the product they are required to be included on the label or in the instructions for use for the good. In this situation, they are collectively referred to in the Code as 'health warnings'. The definition of 'health warning' is set out in section 4 of the Code.

It is essential to bring health warnings to the consumer's attention before they purchase the goods as these warnings are critical to their decision to purchase. Consistent with this aim, statements alerting the consumer to the existence of health warnings are required to be prominently displayed or communicated in any advertising.

Prominently displayed or communicated

The requirement for 'prominently displayed or communicated' is consistent with the requirement for 'displayed or communicated' from the 2015 Code, that is, 'standing out so as to be easily read from a normal viewing distance, and/or heard and understood'.

Essentially, 'prominently displayed or communicated' information is information that is conspicuously or noticeably displayed. It must be clear and stand out so that it is easily noticed by a consumer. Factors which need to be taken into consideration include font size, clarity and contrast, and duration (pace). The Australian Competition and Consumer Commission (ACCC) provides the following advice[2].

> What is 'prominent' may vary on a case-by-case basis and you should consider factors such as the advertising medium, size, placement, colour and font of the price, as well as the background of the advertisement.

[2] See www.accc.gov.au/publications/advertising-selling/advertising-and-selling-guide/pricing/component-pricing

Free TV has also provided advice about prominently displaying information specific to television advertisements[3].

The onus is on the advertiser to ensure mandatory information can be read or heard clearly such that it can be readily noticed by the audience to whom it is directed.

Care must be taken in internet and other digital advertising that the required information is readily available to the consumer without the need to click tabs to locate the information. Further information is available under Prominently displayed or communicated examples.

Required statements for medicines

Section 12(3)(f) sets out the required statements in an advertisement for a medicine based on whether there are health warnings (as defined in Section 4 of the Code) for the medicine or not.

- if there are no health warnings for the medicine:
  - the statement ALWAYS READ THE LABEL must be prominently displayed or communicated
- if there are health warnings for the medicine, either
  - the statement THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE must be prominently displayed or communicated and followed immediately by information about where the health warnings can be found. The health warnings must be provided within the advertisement. The information about the location could be explicit directions, a link or any other means appropriate to the medium in which the advertisement appears

    OR
  - both the statement ALWAYS READ THE LABEL together with the health warnings must be prominently displayed or communicated

Section 12(3)(g) also requires the additional statements in the provisions listed below to be prominently displayed or communicated:

- section 13(6), regarding following the directions or instructions for use

Section 12(3)(h) requires the additional statements mentioned in:

- section 13(7), regarding changes to symptoms

12(4) Mandatory information for advertising of medical devices where the physical product is not available for examination

Section 12(4) sets out the information which must be included in an advertisement for a medical device where the physical product is not available for examination before purchase.

Sections 12(4)(a), (b), (c) and (d) require an advertisement for a medical device to contain the following information respectively:

- an accurate description of the device
- if a trade name is available, a reference to it; or otherwise, a reference to another name for the device
- the intended purpose of, or indications for, the device
- a list of ingredients for the device, where relevant.

[3] www.freetv.com.au/media/CAD/Info_Sheets/Disclaimers_&_Other_Text.pdf

Advertisers should note that some medical devices include medicines while others may have substances on or in the device that may be required to be shown on the label. The "dictionary" definition of active ingredient is applicable for devices. That is any biologically active ingredient included in or with a device that is essential for the intended purpose of the device. In particular, "relevant" ingredients are these active ingredients and any other ingredients referred to in a warning required to be displayed on the label or packaging of the device under Essential Principle 13. Advertisers may note this requirement does not extend to additional ingredients that are required to be displayed on the label or packaging by the Poisons Standard.

Intended purpose

Further information about the intended purpose for medical devices is available in section 11.

Required statements

Section 12(4)(e) sets out the required statements for an advertisement for a medical device based on whether there are health warnings for the medical device or not. The required statement will depend on the packaging of the device.

- if there are no health warnings for the medical device:
  - either of the statements ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE, as appropriate to the primary pack for the device, and the statement must be prominently displayed or communicated
- if there are health warnings for the medical device, either
  - the statement THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE must be prominently displayed or communicated and followed immediately by information about where the health warnings can be found. The information about the location could be explicit directions, a link or any other means appropriate to the medium in which the advertisement appears.

    OR

  - alternatively either the statement ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE, as appropriate to primary pack for the device, accompanied by the health warnings with both the statement and health warnings prominently displayed or communicated

The following additional statements are also required in the advertisement:

- section 12(4)(f) requires the additional statements required by section 13(3) regarding changes to symptoms to be prominently displayed or communicated (as applicable)
- section 12(4)(g) requires the additional statements required by section 13(2) regarding following the directions or instructions for use to be prominently displayed or communicated

12(5) Mandatory information for advertising of other therapeutic goods where the physical product is not available for examination

Section 12(5) sets out the information which must be included in an advertisement for other therapeutic goods where the physical product is not available for examination before purchase.

Sections 12(5)(a), (b), (c) and (d) requires an advertisement for an "Other Therapeutic Good" to contain the following information respectively:

- an accurate description of the goods
- if a trade name is available a reference to it; or otherwise, a reference to another name for the goods
- the intended purpose of, or indications for, the goods
- a list of ingredients for the goods, where relevant

Required statements

Section 12(5)(e) sets out the required statements in an advertisement for Other Therapeutic Goods based on whether there are health warnings for the good or not. The required statement will depend on the packaging of the good.

If there are no health warnings for the other therapeutic goods:

- either of the statements ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE, as appropriate to primary pack for the good, must be prominently displayed or communicated

If there are health warnings for the good, either

- the statement THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE must be prominently displayed or communicated and followed immediately by information about where the health warnings can be found. The information about the location could be explicit directions, a link or any other means appropriate to the medium in which the advertisement appears.

OR

- Both the statement ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE (as appropriate to primary pack for the good) accompanied by the health warnings with both the statement and health warnings to be prominently displayed or communicated

The following additional statements are also required in the advertisement:

- section 12(5)(f) requires the additional statement required by section 13(6) regarding following the directions or instructions for use to be prominently displayed or communicated
- section 12(5)(g) requires the additional statement required by section 13(7) regarding changes to symptoms to be prominently displayed or communicated (as applicable)

13 What advertisements must contain – general rules

Section 13 sets out the information which advertisements for medicines, medical devices and other therapeutic goods must contain where the goods will be physically available to be examined by the consumer before purchase.

This information includes describing the goods, their use and alerting consumers through advertising to any health warnings for the product.

13(1) Things this section does not apply to

Section 13 does not apply to:

- advertisements which provide for the purchase of the advertised good directly (such that the consumer is unable to physically examine the good before purchase) as these types of advertisements have requirements for the inclusion of additional information section 12) when compared with section 13
- labels, patient information leaflets or CMIs
- advertisements for pharmacist-only medicines (section 11)
- an advertisement displaying only the name or picture of therapeutic goods or their price or point of sale, provided the advertisement does not contain or imply a claim relating to therapeutic use, or any other representation

A sponsor's name, umbrella brand, trade name, or tag line could be a therapeutic claim in itself - in particular, where it includes:

- the name of a disease, ailment, condition or defect
- a sign or a symptom of a disease, ailment, condition or defect, and/or
- a verb

It is likely to be a therapeutic claim or indication for the therapeutic good. For example, the Cold Relief People, Cold Relievers Pty Ltd, Company X Cold & Flu Relief, Rapid Itch Help.

13(2) Mandatory information for advertising of medicines

Name of the medicine

Section 13(2)(a) requires an advertisement for a medicine to include a reference to the 'name of the medicine' as defined by the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (TGO 92):

- where the medicine to be advertised is entered in the ARTG, use the name of the medicine as specified in TGO 92)
- where a medicine is not entered in the ARTG, use either:
  - the registered trade mark for the medicine; or
  - a unique, invented, common or scientific name, assigned to the medicine by the sponsor and appearing on the label
- where a medicine is advertised as part of a range of medicines, use the trade name for that group of medicines

Indications for the medicine

Section 13(2)(b) requires an advertisement for medicines to include a reference to the indication(s) for each medicine included in the advertisement as the indication(s) appear on the label of the good.

For medicines entered in the ARTG, promoting an indication that has not been accepted in relation to the ARTG entry for that medicine in an advertisement is an offence under subsections 22(2), (3) and (5) of the Act. Subsection 21B(4) provides a corresponding civil penalty.

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

- in a case where a medicine is entered in the ARTG with the indication 'For the relief of colds'. Advertising the medicine for the relief of ear aches associated with a cold would not align with the meaning or intent of the indication in the ARTG for the medicine.
- Similarly a claim for the product as 'Prevention of colds' would not be acceptable.

Where a medicine's label contains multiple indications, it is not necessary to refer to all of these indications in the advertisement. However advertisers should exercise care if advertising a specific subset of an indication if it could be taken to mean that the product has specificity in its actions which is not supported by evidence.

Required statements for medicines

Section 13(2)(c) sets out the required statements in an advertisement for a medicine based on whether there are health warnings (as defined in Section 4 of the Code) for the medicine or not.

- if there are no health warnings for the medicine:
  - the statement ALWAYS READ THE LABEL must be prominently displayed or communicated **or**
- if there are health warnings for the medicine, either
  - the statement THIS MEDICINE MAY NOT BE RIGHT FOR YOU. READ THE LABEL BEFORE PURCHASE must be prominently displayed or communicated; **or alternatively**
  - both:
    - § the statement - ALWAYS READ THE LABEL prominently displayed or communicated

      AND
    - § the health warnings prominently displayed or communicated

13(3) Mandatory information for advertising of medical devices

Sections 11(3)(a), (b) and (c) require an advertisement for a medical device to contain the following information respectively:

- an accurate description of the device
- if a trade name is available a reference to it; or otherwise, a reference to another name for the device
- a reference to the intended purpose of, or indications for the device

Intended purpose

For medical devices included in the ARTG, promoting a purpose that is not accepted in relation to the ARTG entry for that device is an offence under section 41ML of the Act. Section 41MLB provides a corresponding civil penalty.

The intended purpose for a device or class of devices can be much broader than an indication for a medicine. Establishing the intended purpose for a device varies depending on the type of device:

- for devices that are exempt from being entered in the ARTG, the indications should be consistent with the label, the instructions for use, any advertising by the manufacturer and the manufacturer's website
- for devices entered in the ARTG, the purpose should be consistent with the intended purpose entered in the ARTG entry for the device or class of devices as well as the label, the instructions for use, any advertising by the manufacturer and the manufacturer's website

There is no requirement for the reference to the intended purpose made in the advertisement to be presented word-for-word as recorded in the ARTG. However, the meaning and intent must be consistent with that purpose. Where a device is entered in the ARTG for more than one purpose, it is not necessary to refer to all of those purposes in the advertisement. However advertisers should exercise care if advertising a specific subset of a broader intended purpose if it could be taken to mean that the product has specificity in its intended purpose which is not supported by evidence.

Key concepts – 'Intended purpose' for medical devices

Section 13(3)(c) 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

Required statements for medical devices

Section 13(3)(d) sets out the required statements for an advertisement for a medical device based on whether there are health warnings for the medical device or not. The required statement will depend on the packaging of the device and whether the label of the device, or its instructions for use, are visible on the pack in which the device is to be supplied to consumers (primary pack).

- if there are no health warnings for the medical device:
  - either of the statements ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE, as appropriate to the primary pack for the device, must be prominently displayed or communicated

- if there are health warnings for the medical device, one of the following sets of statements:
  - the statement THIS PRODUCT MAY NOT BE RIGHT FOR YOU with either READ THE LABEL BEFORE PURCHASE or READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE (as appropriate to primary pack for the device), with both statements being prominently displayed or communicated

    OR
  - either READ THE LABEL BEFORE PURCHASE or READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE (as appropriate to primary pack for the device), accompanied by the health warnings with both the statement and the health warnings prominently displayed or communicated

13(4) Mandatory information for advertising of other therapeutic goods

Sections 13(4)(a), (b) and (c) require an advertisement for Other Therapeutic Goods (defined in section 4 of the Code as therapeutic goods which are not medicines, biologicals or medical devices), to contain the following information:

- an accurate description of the goods
- if a trade name is available a reference to it, otherwise a reference to another name for the goods
- a reference to the intended purpose of, or indications for the goods

Indications/intended purpose

For information on the indications/intended purpose for other therapeutic goods, see the information on indications for medicines.

Like medicines, for other therapeutic goods that are entered in the ARTG, promoting an indication that has not been accepted in relation to the ARTG entry for that good in an advertisement is an offence.

Required statements

Section 13(4)(d) sets out the required statements in an advertisement for other therapeutic goods based on whether there are health warnings for the goods or not. The required statement will depend on the packaging of the good and whether the label of the good or its instructions for use are visible on the pack in which the good is to be supplied to consumers (primary pack).

- if there are no health warnings for the other therapeutic good:
  - either of the statements ALWAYS READ THE LABEL or ALWAYS READ THE INSTRUCTIONS FOR USE (as appropriate to primary pack for the good) must be prominently displayed or communicated
- if there are health warnings for the good, one of the following:
  - the statement THIS PRODUCT MAY NOT BE RIGHT FOR YOU with either of the statements READ THE LABEL BEFORE PURCHASE or READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE (as appropriate to primary pack for the device) with both statements being prominently displayed or communicated

    OR
  - either of the statements READ THE LABEL BEFORE PURCHASE or READ THE INSTRUCTIONS FOR USE BEFORE PURCHASE (as appropriate to primary pack for the good) accompanied by the health warnings themselves with both the statement and the health warnings prominently displayed or communicated

13(5) Exemption for short-form advertising

Subsection 13(5) exempts the application of the required statements and/or health warnings (as set out in sections 13(2)(c), 13(3)(d) and 13(4(d)) from applying to both:

- radio advertisements that are 15 seconds or less in duration
- written advertisements that are 300 characters or less for which there no reasonable capacity to include pictures, logos or other imagery as part of the advertisement

This means that these requirements do not apply to short formats like a 15 second radio commercial, a tweet and classified advertisements. It is not intended to provide a general exemption for all social media such as Facebook and Instagram, as these are capable of containing a greater number of words.

Short form written advertisements must only contain text and must not contain audio, video or still pictures including pack-shots. If a short form written advertisement includes pictures, videos or any other types of representations it is expected that the requirement to include the mandatory statements could be fulfilled.

This exemption would apply to text based 'Google advertisements' which have been paid for by the advertiser as long as the written advertisement consisted of 300 characters or less.

This exemption is not intended to apply to television advertisements which may contain written text, pictures, logos, or other imagery, and so are capable of including the required statements and health warnings even in a short duration advertisement. However, the required statements in a short form TV advertisement can either be provided in text or in a voiceover. However, the manner in which short duration television advertisements must comply with the obligations in the Code to include mandatory statements is not prescribed and compliance may be achieved, for example, through the inclusion of either text or spoken word statements (or both).

Any web link (if used) must lead to content that meets all the mandatories required by the Code. Similarly, the radio commercial, in its entirety must be 15 seconds or less in duration to qualify for the exemption and any reference to a website in a radio or television advertisement must meet the same requirements.

13(6) Use statements

Section 13(6) requires that advertisements must contain (as appropriate to the goods), one of the following statements prominently displayed or communicated:

- FOLLOW THE DIRECTIONS FOR USE
- FOLLOW THE INSTRUCTIONS FOR USE

Broadly, 'directions' are used for medicines and 'instructions' for devices and other therapeutic goods.

13(7) Symptom claims

An advertisement for therapeutic goods that contains a claim relating to one or more symptoms of a disease, ailment, condition or defect is required to prominently display or communicate one of the following statements as appropriate to the duration or recurrence of the symptoms:

- IF SYMPTOMS PERSIST, TALK TO YOUR HEALTHCARE PROFESSIONAL
- IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL

The appropriate statement to use will depend on:

- the disease(s), ailment(s), condition(s) or defect(s) concerned
- any possible differential diagnosis from the symptoms
- the expected natural progression of the condition
- the expected duration of recurrence of the symptoms and
- any other relevant factors

For example:

- for a medicine for the relief of symptoms associated with medically diagnosed benign prostatic hypertrophy, some symptoms may be reasonably expected to persist. However, an unexpected change and/or deterioration in symptoms are likely to indicate disease progression that requires re-evaluation by a healthcare professional. Thus, the second statement "IF SYMPTOMS WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL" is appropriate
- for a medicine for the relief of symptoms associated with medically diagnosed irritable bowel syndrome, some symptoms may be reasonably expected to persist. However, an unexpected change and/or deterioration in symptoms could indicate the development of a different, possibly more serious condition and therefore needs re-evaluation by a healthcare professional. Again, the second statement is appropriate
- for a medical device used to assist in the healing of minor muscle injuries, symptoms would be ordinarily expected to improve with time and the use of the device. Therefore, if symptoms persist, healing may be impaired and require medical assessment. In this case the first statement "IF SYMPTOMS PERSIST, TALK TO YOUR HEALTHCARE PROFESSIONAL" may be more appropriate

For listed medicines, the ARTG entry for the medicine will generally indicate which statement is the most appropriate, based on the permitted indications selected for the medicine.

The use of a symptoms statement is not required for prevention, health maintenance or wellbeing claims.

Section 13(7A) clarifies that where the advertisement must contain both the statements in subsection (7), the statements may be shortened and combined into one statement, so as to avoid duplication.

Section 13(8) provides an exemption from the requirement to include any of the statement(s prescribed by sections 13(6) and (7) for radio commercials that are 15 seconds or less in duration, or for written advertisements that are 300 characters or less for which there is no reasonable capacity to include pictures, logos or other imagery as part of the advertisement. See advice on short-form advertisements above.

14 Section 14 is intentionally not used

Section 14 of this instrument is intentionally not used. This is because the Regulations will, from 1 January 2019, contain a number of references to specific provisions of the Code which, if section 14 were to be used and subsequent sections renumbered, would require consequential amendment.

15 Scientific representations

Section 15 does not apply to:

- labels
- Consumer Medicine Information
- patient information leaflets

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 terminology or clinical terminology (covering concepts such as diseases, treatments and medicines) that does not appear in the everyday language of the audience to whom the advertisement is directed

Broadly, scientific studies constitute research through the systematic collection, interpretation and evaluation of data. The type of scientific research most relevant to therapeutic goods is 'clinical studies', in particular studies on the use of therapeutic goods in the treatment or alleviation of diseases and/or symptoms.

Referencing scientific studies (including clinical studies) to support representations made in advertisements gives credibility to the representations. This credibility could be misplaced for a number of reasons including:

- the study has not been peer reviewed
- the study does not have sufficient subject numbers
- inadequate inclusion and exclusion criteria for subjects have been applied
- the study has inadequate 'blinding' (masking)
- the study results are inconsistent with the broader body of evidence reflected in systematic reviews and meta-analyses

Where claims are validated by a reference to scientific (including clinical) studies the consumer should have available to them enough information in the advertisement to locate the referenced study.

The majority of scientific studies require funding. Where it is reasonable possible to identify the researcher and the financial sponsor of the research, their identity (where the advertiser knows or ought to reasonably to have known that information) should be clearly disclosed in the advertisement. This is particularly important when the source of funding is, or is associated with, the therapeutic good's sponsor or advertiser.

When the sponsor of a scientific study that the advertiser is using to support the veracity of a therapeutic claim is a government department or agency, the advertiser must ensure that endorsement of the therapeutic good by that government agency is not implied. However, merely stating the name of the source of funding (such as the Australian National Health and Medical Research Council (NHMRC)) for the study is unlikely to imply government endorsement of the good.

For example:

[Therapeutic ingredient] has been the subject of a scientific study* funded by the National Health and Medical Research Council (NHMRC).

*Author, Name of study and publication details

16 Endorsements

Endorsements can be made by a person or a corporation expressing their support for a product. An endorsement can be made explicitly or indirectly.

Endorsements and testimonials

The dictionary definitions for 'endorsement' and 'testimonial' overlap considerably. A 'testimonial' is a type of 'endorsement'.

- An **endorsement** is made where a person, or corporation, sanctions (approves of) a particular therapeutic good but there is no indication as to the outcome(s) from the use of the good by any individual. For example, 'Company X recommends Brand Y disinfectant'
  - The endorsement can be based on evidence which demonstrates the value of the endorsed good in relation to the health condition with which the endorsing organisation is concerned (in which case the evidence must be available for provision to the TGA if required)

    OR
  - The endorsement can be based on the endorser receiving funding or other 'valuable consideration' from a sponsor or retailer of the endorsed therapeutic good. For example, 'Organisation X receives 10 cents from the sale of every bottle of Brand Y disinfectant'. This arrangement is sometimes referred to as a '**sponsorship'**, however for the purposes of the Code it is taken to be a form of endorsement
  - A testimonial is made where an individual person, has used a therapeutic good and has testified as to the outcome(s) they experienced from the use of the good. For example, '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'

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

Section 16(2) prohibits any endorsement of therapeutic goods in advertisements by:

- a government authority, hospital or healthcare facility (does not include a community pharmacy)
- an employee or contractor of one of these bodies
- a health practitioner, health professional, medical researcher or a group of any of these persons

Such endorsements are prohibited so as to avoid a consumer being unduly influenced to purchase a therapeutic good by the weight they may give to statements made by these organisations and individuals.

Section 16(3) allows an endorsement by the following organisations and individuals where the advertisement names the organisation, discloses the nature of the endorsement, and also discloses whether the organisation, employee or contractor has received or will receive valuable consideration for the endorsement:

- an organisation representing the interests of healthcare consumers
- an organisation representing the interests of health practitioners, health professionals, or medical researchers
- an organisation which conducts or funds research into any disease condition, ailment or defect
- an employee or contractor of any of these bodies (unless they are of an individual prohibited from making an endorsement under section 16(2))

Note that organisation is defined in the Code for the purposes for section 16 only to mean any group, association or body (whether incorporated or unincorporated). This requirement ensures that consumers are aware of the details of the endorsement and if the endorsing organisation has been remunerated or in way has been compensated for their endorsement.

While testimonials can be viewed as a type of endorsement, this section does not apply to testimonials covered under section 17.

CRP decision highlight – 'TGA Approved' claims and Government endorsement

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[4] , 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, while most often a monetary exchange, can be non-monetary. For example, it may be an exchange of services in-kind, provision of product, or a promise to engage services in the future or any other return in kind.

[4] On 6 March 2018, this changed to s.42DL(9).

Professional endorsement vs availability

References to business names (for example 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 health professional endorsement of the goods.

For example a catalogue from a pharmacy that bears the name of the pharmacist owner **would not** be a professional health endorsement if it contains an article written by the pharmacist, with their picture and signature, about hayfever season that highlights selected products for hayfever relief would be considered an endorsement by a health professional.

However, a catalogue from a pharmacy that bears the name of the pharmacist owner would be a professional health endorsement if it contains pages of therapeutic goods images, with visible claims and prices, for hayfever relief. While these pages would be considered advertising, they convey availability of the goods through the pharmacy rather than the pharmacist's endorsement.

17 Testimonials

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

Section 17 only applies to testimonials from individuals who claim to have actually used that good. Testimonials are not captured under section 16 (endorsements). Corporations may not make testimonials as it would be very difficult or impossible to verify that every employee or individual associated with a particular corporation has used the particular therapeutic good and is prepared individually to provide a testimonial along the required lines.

Only testimonials from people whose details have been verified prior to the use of the advertisement and who have used the product or who have administered the goods and observed the results (e.g. in a child) can be used in advertising for therapeutic goods. Details may include name, age, employer and address. However, a testimonial cannot be made by a person who is:

- involved with the production, sale, supply or marketing of the goods
- an employee or officer of a corporation that is involved with the production, sale, supply or marketing of the goods
- a corporation
- an employee or contractor of a government agency, hospital or healthcare facility, a health practitioner, health professional, or medical researcher

Disclosures about the testimonial are required in the following circumstances:

- where the person providing the testimonial has received, or will receive any valuable consideration for providing the testimonial
- where another person takes the place of the person who provided the testimonial
- where the person providing the testimonial is an immediate family member of an individual involved in the production, sale, supply or marketing of the goods

These disclosures are required as the consumer is entitled to know:

- if a testimonial may have been influenced by the fact that the testimonial provider has received, or will receive, valuable consideration
- if a testimonial may have been influenced by the fact that the testimonial provider is an immediate family member of an individual who is involved with the production, sale, supply or marketing of the goods

In both these circumstances, the weight the consumer gives testimonial may be impacted.

As it may be important for the consumer to know the nature of the 'valuable consideration' provided in order to be able to assess whether, and to what extent, the testimony might have been influenced, it is recommended to disclose the nature of the 'valuable consideration'.

The disclosure, in order for it to have the effect of providing the consumer with the required information, must be noticeable and placed beneath or very close to the testimonial.

Testimonials must be consistent with the goods' accepted indication or intended purpose. For example a testimonial for a hay fever medicine must not indicate the medicine proved helpful for headache relief.

A reasonable standard for verification of a testimonial is a statutory declaration. A statutory declaration in relation to a testimonial should be made before the advertisement featuring the testimonial is published or broadcast.

Care should be taken if truncating, altering or paraphrasing a testimonial in an advertisement to ensure that it is not misleading.

The use of testimonials must also 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 than that accepted in relation to the inclusion of the goods in the ARTG as this would contravene the Act.

Advertisers are responsible for ensuring the compliance of any testimonials that are publically posted by third parties to Facebook, Twitter, Instagram or any other social media accounts and blogs where the advertiser has control of the content. Advertisers should monitor testimonials and remove non-compliant testimonials.

However, whether an unsolicited post or comment on the website, social media site, internet blog or other medium of an advertiser is a testimonial subject to the requirements of section 17 turns on whether it is 'used' in that advertisement. Section 17 is intended to ensure that consumers are aware of important facts about the testimonials as presented in the advertising, which will assist them to weigh the importance of the testimonial.

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

Pharmacy assistants and retail salespeople (for example health food shop staff) who are not health professionals 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. Therefore, advertising for therapeutic goods directed to pharmacy assistants and other retail salespeople 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 also prohibits advertising to retail staff from containing incentives to these staff to recommend or supply the advertised goods.

19 Advertising to children

In the main, advertisements for therapeutic goods must not be primarily directed to children.

Many children are unlikely to have developed sufficient knowledge or reason to make responsible choices in relation to therapeutic goods or to understand the generally persuasive intent of advertising. Choices about when and how therapeutic goods may be appropriate for them are typically made by the adult who looks after the interests of the child. It would therefore not be responsible to target children in advertisements for therapeutic goods. There are exceptions in relation to particular therapeutic goods for children 12 years and over, consistent with their increasing independence from adults.

These requirements do not apply to labels, on which characters, colouring, fonts and other artefacts may be used to identify therapeutic goods which are suitable for use in children, including to differentiate children's dosage forms from adult preparations.

20 Samples

Even where an offer of a sample in advertising is not prohibited, advertisers should note that other advertising provisions may still apply to such offers.

Advertisers should be aware that the act of giving a sample could be an advertisement that would also need to comply with the Code.

The types of therapeutic goods that may be offered as a sample in an advertisement have been selected because of their important role in public or individual health.

21 Consistency with public health campaigns

Advertising must not be inconsistent with public health campaigns because to do so could undermine important current public health and safety messages.

Public health messages are based on considerable research and expert advice. The objective of this provision is to ensure that that advertising of therapeutic goods does not undermine or otherwise diminish the message contained in government public health campaigns.

Government priorities in public health messaging change depending on needs within the community and developments in health policy. 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.

Advertisers should remain abreast of public health campaigns that are relevant to the type of therapeutic goods they advertise, so as to identify any existing advertising that may be inconsistent with new campaigns. When preparing new advertising, advertisers need to ensure that it is not inconsistent with a relevant public health campaign of which they know, or ought reasonably to have known, will be taking place at the time of the advertisement.

Information about Australian public health campaigns is available from a range of websites, including:

- Australian Government campaigns and Health promotion pages
- The Australian Government Department of Health Programs & Campaigns page
- Queensland Department of Health campaigns
- VicHealth campaigns

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

An example of advertising that would be considered inconsistent with public health campaigns include advertising a therapeutic good that is claimed to be able to prevent and reverse the lung damage caused by smoking.

This requirement is unlikely to impact the majority of advertisements for therapeutic goods.

Part 3 - Requirements relating to particular therapeutic goods

22 Application

This part of the Code, which sets out requirements relating to particular types of therapeutic goods, does not apply to:

- labels
- consumer medicine information
- patient information leaflets for implantable medical devices

23 Complementary medicines

To simplify the discussion of this section a "claim" is limited to being a therapeutic claim in an advertisement about an indication that is supported by evidence of traditional use by a particular paradigm (see below for examples). Where an advertiser is relying on traditional evidence to support a claim in an advertisement, the fact that it is "traditionally used" and the paradigm applicable to that claim must be prominently displayed or communicated in the advertisement. Otherwise the consumer may be misled about the type of supporting evidence for the medicine. While this section of the Code does not prescribe the inclusion of the ingredient in the disclosure, it may be misleading not to do so for certain medicines. Particular care in this respect must be taken with the presentation and content of the disclosure for multi-ingredient, multi-paradigm medicines. Making broad disclosures of paradigms for these types of listed medicine medicines apart from misleading the consumer, can also lead to the advertising of actual or implied indications that are not included in the entry for the medicine which may breach applicable sections e.g. sub section 22(5) of the Act.

The form of the disclosure is not prescribed by this section of the Code, however the language and content must carry the intent of the disclosure for the intended audience of the advertisement. Words to the same effect are acceptable as it is not the intent of the Table to prescribe how the claims and disclosures should be combined or presented.

Paradigms include, but are not limited to:

- traditional Chinese medicine
- Ayurvedic medicine
- western herbal medicine

Where evidence from multiple paradigms is relied upon for a single ingredient and claim, the advertisement needs only to disclose one of those paradigms. This applies to both single or multi ingredient medicines. This does not prevent the advertiser from disclosing more than one paradigm for that claim should they wish.

Where the medicine being advertised contains multiple ingredients and claims then the paradigm(s) must be linked to the appropriate claim and where needed to avoid being misleading, the ingredient.

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

24 Analgesics

Analgesic medicines can pose particular risks to consumers, and so must prominently display or communicate the following warning statement:

- INCORRECT USE COULD BE HARMFUL

Such advertisements are prohibited from implying that the consumption of analgesics is safe, or that analgesics have relaxing, tension-relieving, sedative or stimulating effects. This recognises the particular harms that inappropriate or excessive use of analgesics have caused in the past and can continue to cause.

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 or that supplementation is necessary for the maintenance of normal health when the diet is not inadequate.

Advertisers should also be aware of the requirements relating to vitamins in Schedule 2 of the Regulations. Part 1, item 3 of Schedule 2 of the Regulations prohibits certain representations in relation to vitamins. Only the substances listed in Part 3 of Schedule 2 may be referred to as vitamins and then may only be referred to by the names specified in that part. Further, Schedule 2, Part 1, item 9 prohibits certain representations about the recommended daily or dietary intake or allowance of a vitamin or mineral.

26 Therapeutic goods that are for weight management

Consumers seeking to lose weight are may be susceptible to marketing. For these reasons, there are special requirements for the advertising of goods for weight management.

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

For an advertisement for a weight management good to convey the balance required by subsection (1), the need for a healthy energy controlled diet and physical activity must receive adequate prominence in relation to the weight management claims.

Claims that are likely to contravene subsection (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 TGA and NHMRC in relation to weight loss products and what can constitute typical results.

For listed medicines, see Evidence guidelines - Part B: Further technical guidance.

For listed assessed medicines, see Assessed listed medicines evidence guidelines - 5. Evidence requirements and standards

27 Sunscreens

Consistent with the requirement that advertising of therapeutic goods must not undermine public health messaging, there are special requirements around the advertising of sunscreens that claim or imply that the sunscreen will prevent any of sunburn or skin cancer. 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. Other protections (like a hat, shirt, sunglasses and the use of shade) are necessary, as is the regular re-application of sunscreen.

Statements or visual representations to the effect that prolonged high-risk sun exposure should be avoided and frequent re-application or use in accordance with directions is required for effective sun protection must be prominently displayed or communicated.

This approach is also consistent with the permitted indications for sunscreens, which require sunscreen 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 identifies a serious form of a disease, condition, ailment or defect 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 (for example mild osteoarthritis).

Under certain circumstances, the use of 'restricted representations' may be appropriate, however, the use of such representations requires detailed consideration by the TGA to ensure such use does not compromise individual or public health and to ensure the representations are accurate, balanced and not misleading. Consumers who know, or suspect they have, a serious disease or who may be the primary carer for such a person, are particularly vulnerable. See Restricted representations and advertising for more information.

Conditions that must be medically diagnosed that can be self-treated and self-managed

The definition of a serious form of a disease, condition, ailment or defect (collectively, 'condition') specifically excludes those conditions that, although must be medically diagnosed, are medically accepted as being suitable for self-treatment and management.

If a form of a condition is medically accepted as a form that can be self-treated and managed after diagnosis by a health professional, the onus is on the advertiser to ensure the form is represented in the advertising as having been already medically diagnosed, otherwise the representation would meet the definition of a restricted representation. For example, while plantar fasciitis (heel pain caused by inflammation of the tissue along the bottom of the foot) can generally be self-treated and managed, if the advertisement did not make it clear that the good was only suitable for use by consumers that have already been diagnosed with the condition, the representation containing the reference to plantar fasciitis would be a restricted representation and could not be used without prior approval from TGA. However, a reference to 'medically diagnosed plantar fasciitis' would not be considered a restricted representation.

The requirement to clearly qualify such a condition in advertising is especially important for conditions that, while medically accepted to be suitable for self-treatment and self-management, share symptoms and signs with other conditions that might be more serious and require medical treatment (for example plantar fasciitis requires medical diagnosis to rule out serious underlying conditions like ankylosing spondylitis). This can be achieved by ensuring the reference to the condition is made in a way which makes it clear to the consumer that the condition must have already been definitively medically diagnosed (for example qualifying references to the condition as 'medically diagnosed').

There is a risk to consumers from attempting to self-manage a condition that they might think is a particular condition but in fact requires a medical diagnosis – this could come about due to the use of representations that did not qualify the condition as medically diagnosed.

A failure to clearly identify the need for medical diagnosis in advertising would also be likely to contravene:

- subsection 10(b), which prohibits advertisements that would be likely to lead to people delaying necessary medical attention and/or
- subsection 10(c) which prohibits advertising that encourages inappropriate use of the therapeutic goods

Examples of applying the definition of 'serious'

Condition	s. 28(1)(a) - medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional	s. 28(1)(a) – exclusion for forms that have been medically diagnosed and medically accepted as being suitable for self-treatment and management	s. 28(1)(b) - there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up	Restricted representation status
Arthritis	"Arthritis" can cover a wide variety of forms and severities, like debilitating osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. These are forms that require medical diagnosis.	Management is variable but likely to involve prescription medicines. The appropriate treatment must be determined by a health professional.		Arthritis meets the definition of 'serious'. Representations in advertising that include unqualified references to arthritis are restricted representations.
Mild arthritis	The more serious forms of arthritis detailed above are excluded by the qualifier 'mild'.	Not applicable		'Mild arthritis' does not meet the definition of 'serious'. Representations in advertising that include references to 'mild arthritis' are not restricted representations, as long as the mild nature is not contradicted by images, testimonials or any other aspect of the advertising.

Condition	s. 28(1)(a) - medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional	s. 28(1)(a) – exclusion for forms that have been medically diagnosed and medically accepted as being suitable for self-treatment and management	s. 28(1)(b) - there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up	Restricted representation status
Autism spectrum disorder (ASD)	Clinically accepted that an experienced paediatrician or a child psychiatrist should confirm the diagnosis	Management may involve prescription psychotropic medicines. Allied health professionals may also be needed.	Not applicable	ASD meets the definition of 'serious'. Representations in advertising that include references to ASD are restricted representations.
Cystic fibrosis (CF)	A serious condition that requires diagnostic tests ordered by a specialist medical practitioner for its definitive diagnosis.	Management of CF includes antibiotic therapy and other prescription medicines and treatment by physiotherapist.	In Australia, CF is usually detected through a newborn screening test and/or a sweat test. The results require medical interpretation and follow-up.	CF meets the definition of 'serious'. Representations in advertising that include references to CF are restricted representations.
Headlice	It is generally medically accepted that headlice infestations can be self-diagnosed and self-treated.	Not applicable	Not applicable	Headlice does not meet the definition of 'serious'. Therefore, representations in advertising that include references to headlice are not restricted representations.

Condition	s. 28(1)(a) - medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional	s. 28(1)(a) – exclusion for forms that have been medically diagnosed and medically accepted as being suitable for self-treatment and management	s. 28(1)(b) - there is a diagnostic (including screening), preventative, monitoring, susceptibility or pre-disposition test available for the form (including a self-administered test), which requires medical interpretation or follow-up	Restricted representation status
Irritable bowel syndrome (IBS)	Clinically accepted to require medical diagnosis to rule out serious conditions like malignancy, inflammatory bowel disease and Coeliac disease	There are no long-term sequelae from IBS without medical treatment and it can be self-managed.		While people can self-manage IBS following medical diagnosis, to attempt to manage symptoms that have not been definitively diagnosed as IBS puts the consumer at risk. For that reason, representations that refer to unqualified references to IBS are restricted representations.
Medically diagnosed Irritable bowel syndrome	Clinically accepted to require medical diagnosis to rule out serious conditions like malignancy, inflammatory bowel disease and Coeliac disease	There are no long-term sequelae from IBS without medical treatment and it can be self-managed.		The ability to self-manage IBS following diagnosis excludes it from meeting the definition of 'serious'. However, it must be qualified as medically diagnosed in advertising, as medical diagnosis is required to rule out serious forms of diseases which would require medical treatment.

29 Restricted representations - public interest criteria

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

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

- be likely to take advantage of the vulnerability of consumers or particular groups of consumers, when faced with the disease, condition, ailment or defect
- be likely to result in consumers not seeking medical advice at an appropriate time (also refer to section 10(b) of the Code)
- be likely to have a negative impact on public health

The Secretary (or their delegate) 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 their 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 Application for approval to use a restricted representation in advertising for more information.

30 Prohibited representations

Section 42DJ of the Act and subregulation 6B(1) of the Regulations enable the Code to specify which representations are prohibited representations. The Code provides that representations relating to the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to:

- 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 (or their delegate) may permit the use of a prohibited representation under section 42DK of the Act where it is necessary for one of the following:

- public health interests
- the appropriate use of the goods (applies to packaging and/or labelling only)

In addition, advertisers should be aware that there are other prohibited representations specified in Schedule 2, Part 1 of the Regulations, including the following:

- antiseptics and disinfectants – certain representations about bacteriostatic activity and other claims about activity and tests are prohibited representations
- goods that are, or contain, vitamins or minerals – representations such as expressing the quantity of a vitamin or a mineral contained in a preparation as a percentage or proportion of the recommended daily or dietary intake or allowance are prohibited representations
- analgesics – representations that analgesic consumption is safe; or will relax, relieve tension, sedate or stimulate are prohibited representations

Schedule 1 – Medicine ingredients with specific health warnings

This Schedule includes a table of medicine ingredients, circumstances and statements for the purposes of paragraph (a) of the definition of 'health warnings' in section 4. That paragraph provides that 'health warning', for a medicine that contains an ingredient mentioned in column 1 of the table in Schedule 1, in the circumstances set out in column 2 of that table, means the statement mentioned in column 3 of the table in Schedule 1.

The health warning statements listed in this Schedule 1 must be included in advertisements for a medicine containing an ingredient this schedule, in the circumstances required by sections 12(3)(f) and 13(2)(f) of the Code.

Parts 3 and 4 of Schedule 1 include health warnings for allergenic ingredients in registered or listed medicines. It is appropriate that advertisements for medicines containing these ingredients include the health warnings specified in those Parts of Schedule 1 when the medicine is not available for physical examination before purchase. Accordingly, only advertisements to which section 12 of the Code applies must, where relevant, include the health statements listed in Parts 3 and 4 of Schedule 1. In practical effect, the whole of Schedule 1 is potentially applicable to advertisements regulated by section 12.

However, it is not considered necessary to include the health warnings for medicines including allergenic ingredients in other advertisements where the consumer will be able to examine the goods before purchase and can read its label. The health warning statements for the allergenic ingredients listed in Parts 3 and 4 of Schedule 1 are therefore not required to be included in advertisements regulated by section 13 of the Code. Accordingly, only Parts 1 and 2 of Schedule 1 are potentially applicable to advertisements regulated by section 13.

This schedule reflects a set of the most serious warning statements that sponsors of principally registered over the counter medicines and listed (mostly complementary) medicines are or will be required to include on the labels of their products under a number of other requirements under the Act (for example, for listed medicines - the Therapeutic Goods (Permissible Ingredients) Determination No.3 of 2018, and for registered over the counter medicines - the Medicines Advisory Statement Specification 2017 and for both categories of medicine – Therapeutic Goods Order No.69 – General Requirements for Labels for Medicines 2017 and Therapeutic Goods Order No.92 – Standard for labels of non-prescription medicines). The statements in Schedule 1 have, where possible, been condensed, for suitability for inclusion in therapeutic goods advertisements, focussing on the most important health information for consumers to be aware of when considering buying a medicine, e.g. for Chlorhexidine, "Chlorhexidine can cause severe allergic reactions", or for Ibuprofen "Do not use if you have a stomach ulcer, impaired kidney function, heart failure, are allergic to anti-inflammatory medicines, or in the last 3 months of pregnancy".

Schedule 2 - Advertising to children

Goods that may be advertised to children

Certain therapeutic goods may be advertised to children over the age of 12 years. These are goods where the likely audience could be expected to have the maturity to make responsible decisions in relation to the advertised goods.

However, advertising must never be directed to children under the age of 12 years. Media clearly directed to young children, such as childrens' magazines and childrens' television programs, must not include advertisements for therapeutic goods.

See also section 19 – Advertising to children.

Schedule 3 - Samples

Goods that may be offered as samples

This clause advises that for the purposes of section 20, samples of the following goods may be offered as samples:

- condoms
- sunscreens
- Stoma devices for self-management
- Continence catheter devices for self-management

See also section 20 – Samples.

Schedule 4 - Price Information

Allowing the inclusion of price information for prescription and certain other medicines in advertisements benefits consumers by providing additional information to assist in their choice of what medicines to purchase and allows consumers to select the 'best buy'. The availability of price information for prescription medicines also promotes greater competition amongst suppliers with associated price reductions.

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. Schedule 4 of the Code replaces the Price Information Code of Practice 2006.

2 Application

The requirements set out in Schedule 4 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.

Price information cannot be provided for medicines listed on the Pharmaceutical Benefits Scheme (PBS) which are supplied through these kinds of alternative arrangements under section 100 of the *National Health Act 1953*.

However, 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 can only be made available to the public by retail pharmacists or their agents, pharmacy marketing groups, and dispensing doctors. Other medical practitioners and health professionals cannot provide price information. 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 can 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. For more information on advertising services, see Advertising therapeutic goods with a related service in the ARGATG.

6 General requirement restricting promotion

Advertisers should note that the inclusion of any representation, whether explicit or implied, about the therapeutic use of a medicine in price information will always be considered to be promotional and therefore incompatible with Schedule 4.

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 picture of a medicine listed in price information (for example of a pill, bottle or pack) that is in the same catalogue put out by a group of pharmacists as the price information list
- 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
- a price information list located within a 'background collage' of illustrations of medicines to which this schedule applies

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 adjectives to qualify the price of the medicine

Price information must not:

- promote the purchase of particular quantities or multiple packs, except as provided under Clause 7 of the Schedule
- use comparative adjectives or words to qualify the price to be paid for 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 italicised
- a different colour
- a different font or size
- surrounded by a border, highlighting
- in any other way distinguished from the remainder of the price information list

6(2)(f) Rewards

This section prohibits price lists from:

- including the offer of rewards or bonus points, or
- being included with any other advertising that promotes such rewards or bonus points

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, for example:

- prices current as at 1 March 2019
- prices expire 30 August 2019

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.

An example of arrangements prohibited by this provision:

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

6(3) Other requirements

Price information must include at least 25 medicines. However, this does not apply to price information for medicines provided in accordance with clause 5(2) of this schedule – that is, where prices are identified through a search function included in an electronic sales system (for example through the pharmacy website).

This section also requires that price information be accompanied by name and contact details for the pharmacy at which the medicines listed can be obtained at the listed price.

7 Description of medicines

Medicines must be described in price information using the name of the medicine as defined in *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines*, or *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*, as appropriate to the Schedule of the Poisons Standard for the medicine. Label standards and the Poisons Standard can be accessed at www.legislation.gov.au.

Price information must include, for each medicine:

- if there is more than one strength of a form of the medicine - the strength of each active ingredient as it appears on the label of the medicine
- the form in which the medicine is presented and
- the price for the relevant number of units of the sponsor's standard pack

The relevant number of units of the sponsor's standard pack is either:

- the maximum number of units that may be prescribed under the Pharmaceutical Benefits Scheme or Repatriation Benefits Scheme, where they permit more than one unit of the sponsor's pack to be prescribed, or
- one unit

It also provides that the need for a prescription for a particular medicine may also be indicated in the price information.

8 Presentation of price information

Medicines must be listed in alphabetical order by either:

- name

  OR

- the names of active ingredients

Medicines can also be grouped according to the schedule of the Poisons Standard in which they are included. However, there must be sufficient numbers of medicines from each schedule so that consumers are not directed to a particular medicine and there are medicines from three or more sponsors included. Within each group of scheduled medicines, the medicines must still be listed in alphabetical order as set out above.

9 Pharmaceutical Benefits Scheme subsidised medicines

If a pharmacy marketing group publishes price information which includes both a PBS subsidised medicine with a brand premium or therapeutic group premium, and the group's 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 ensures that 'house brands' sold by a retail supplier cannot be given prominence over other comparable brands.

Medicines subsidised under the PBS must be identified and the total purchase price must be clearly identified as the general or concessional price. Both prices may be provided.

Price lists which include a PBS subsidised medicine must include an indication that the price is subsidised by the Australian Government, and only applies when prescribed for the medical conditions listed in the PBS Schedule for that medicine. Note however, that the actual condition must not be mentioned.

Definitions

These definitions are current as at 31 October 2018. Advertisers are encouraged check the source of the definition for the current definition as legislation is amended from time to time and may, on occasions, be replaced or new instruments made.

In the absence of a definition in the Act, the Regulations or the Code, the relevant normal meaning, as derived from the current edition of the Macquarie Dictionary, will apply.

Term	Definition	Source
Act	the *Therapeutic Goods Act 1989*	*Therapeutic Goods Advertising Code 2018*
active ingredients	means a therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action	*Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines*
analgesic	a medicine for internal use, containing one or more of the following substances intended for the relief of aches and pains: a. salicylic acid, its salts, its derivatives (including aspirin) and their salts; b. other non-steroidal anti-inflammatory drugs; c. paracetamol; not including such a medicine where: d. the condition for which it is designed is a self-limiting condition; and e. the substances mentioned in paragraphs (a)-(c) are combined with one or more other active ingredients; and f. the other ingredients have been included in the medicine for indications other than the relief of aches and pains	*Therapeutic Goods Advertising Code 2018*

Term	Definition	Source
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	Subsection 3(1) of the Act
bench-mark price brand	in relation to a multi branded medicine, means the lowest priced product within the group of medicines that are listed on the Pharmaceutical Benefits Scheme as brands of the same medicine	*Therapeutic Goods Advertising Code 2018*
broadcaster	in relation to an advertisement for therapeutic goods, means a person (other than a person who is required to enter those goods on the ARTG) who undertakes, as a business activity in its own right: a. the broadcasting of the advertisement in broadcast media; or b. the placement of the advertisement for such broadcasting	Section 42B of the Act
broadcast media	in relation to an advertisement or generic information, means any means (other than a means declared in the 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	Section 42B of the Act
child	means an individual under the age of 18	*Therapeutic Goods Advertising Code 2018*
complementary medicine	means a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use	Regulation 2 in the Regulations

Term	Definition	Source
directions for use	in relation to therapeutic goods, includes information on: a. appropriate doses of the goods; and b. the method of administration or use of the goods; and c. the frequency and duration of treatment for each indication of the goods; and d. the use of the goods by persons of particular ages or by persons having particular medical conditions	Subsection 3(1) of the Act
dispensing doctor	means a medical practitioner approved under section 92 of the *National Health Act 1953*	*Therapeutic Goods Advertising Code 2018*
generic information	in relation to therapeutic goods, includes 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	Section 42B of the Act
health practitioner	means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions: a. Aboriginal and Torres Strait Islander health practice; b. dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist); c. medical; d. medical radiation practice; e. nursing; f. midwifery; g. occupational therapy; h. optometry; i. pharmacy; j. physiotherapy; k. podiatry; l. psychology	Subsection 3(1) of the Act

Term	Definition	Source
health professional	The kinds of 'health professionals' covered by section 42AA of the Act include: • 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*	*Therapeutic Goods Advertising Code 2018* Section 42AA of the Act

Term	Definition	Source
health warning	a. for a medicine that contains an ingredient mentioned in column 1 of the table in Schedule 1, in the circumstances set out in column 2 of that table, means the statement mentioned in column 3 of the table in Schedule 1; b. for a medical device or other therapeutic goods, means a statement that is required under the Act or the Regulations to be included on the label or instructions for use that warns that a person who takes or uses the device or goods as intended may: i. die; or ii. require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken or used the device or goods; or iii. require a medical practitioner to treat or prevent any of the following as a consequence of taking or using the device or goods: (A) injury; (B) disability; (C) incapacity; (D) impairment of any bodily function, organ or structure	*Therapeutic Goods Advertising Code 2018*
immediate family	in relation to a person, means the parents, grandparents, spouse, de facto spouse, child or ward of that person.	Part 1(2) of the Regulations
included in the Register	a. in relation to a biological—means included in the Register under Part 3 2A of the Act; and b. in relation to a medical device to which Chapter 4 applies—means included in the Register under Chapter 4 of the Act	Subsection 3(1) of the Act
indications	in relation to therapeutic goods, means the specific therapeutic uses of the goods	Subsection 3(1) of the Act

Term	Definition	Source
ingredients	a. active ingredients; and b. substances or groups of substances that are required to be on the label of the medicine under paragraph 8(1)(j) of the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*	*Therapeutic Goods Advertising Code 2018*
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	Subsection 3(1) of the Act
mainstream media	means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions	Section 42B of the Act

Term	Definition	Source
medical device	a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: i. diagnosis, prevention, monitoring, treatment or alleviation of disease; ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; iii. investigation, replacement or modification of the anatomy or of a physiological process; iv. control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or aa. any instrument, apparatus, appliance, material or other article specified under subsection (2A); or ab. any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or b. an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab)	Subsection 41BD(1) of the Act
Medical Devices Regulations	means the *Therapeutic Goods (Medical Devices) Regulations 2002*	*Therapeutic Goods Advertising Code 2018*

Term	Definition	Source
medicine	means: a. therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and b. any other therapeutic goods declared by the Secretary, for the purpose of the definition of ***therapeutic device***, not to be therapeutic devices	Subsection 3(1) of the Act
other therapeutic goods	therapeutic goods that are not medicines, biologicals or medical devices	*Therapeutic Goods Advertising Code 2018*
patient information leaflet	In relation to an implantable device, means: 1. A leaflet (a patient information leaflet) that meets the requirements of subclauses (2) to (4) and clause 13A.4 must be provided with the medical device 2. The leaflet must include the following information: a. information identifying the device, or the kind of device b. the intended purpose of the device c. information explaining how to use the device safely d. other information about the device as specified in Clause 13A.3 that the manufacturer considers would be useful for patients 3. In particular, the leaflet must include the information specified in subclause (3)	Clause 13A.3 of Schedule 1 to the Medical Devices Regulations 2002 (as they will be amended in December 2018)
Poisons Standard	means the Standard in force under section 52D of the Act at the commencement of this Code	*Therapeutic Goods Advertising Code 2018*
presentation	in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods	Subsection 3(1) of the Act

Term	Definition	Source
price information	information about: a. the total purchase price of medicines that is to be paid by consumers of those medicines; and b. for medicines that are listed on the Pharmaceutical Benefits Scheme (or Repatriation Pharmaceutical Benefits Scheme), the price paid by the consumer when the prescription is dispensed	*Therapeutic Goods Advertising Code 2018*
primary pack	the complete pack in which the goods, or the goods and their container, are to be supplied to consumers	Subsection 3(1) of the Act
prohibited representation	a representation referred to in subsection 42DJ(1) Note: subregulation 6B(1) in the Regulations provides further details.	Section 42B of the Act
prominently displayed or communicated	In relation to a statement in an advertisement, means: a. either: i. for a visual statement—standing out so as to be easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or ii. for a spoken statement—able to be clearly heard and understood; and b. repeated as often as is necessary to ensure that is likely to be noticeable for a viewer or listener	*Therapeutic Goods Advertising Code 2018*
public health campaign	a campaign about a public health matter that is conducted, approved or funded by: a. the Commonwealth; or b. a State or Territory; or c. a Commonwealth, State or Territory statutory authority	*Therapeutic Goods Advertising Code 2018*

Term	Definition	Source
publisher	in relation to an advertisement for therapeutic goods, means a person (other than a person who is required to enter those goods on the ARTG) who undertakes, as a business activity in its own right: a. the publishing of the advertisement in specified media other than broadcast media; or b. the placement of the advertisement for such publication	Section 42B of the Act
publishing	in relation to an advertisement, includes inserting material within the pages of an item of mainstream media	Section 42B of the Act
Register	the Australian Register of Therapeutic Goods maintained under section 9A of the Act Also referred to as the '**ARTG'**.	Register
Regulations	the *Therapeutic Goods Regulations 1990*	*Therapeutic Goods Advertising Code 2018*
required representation	a representation referred to in subsection 42DJ(2)	Section 42B of the Act
restricted representation	a representation referred to in section 42DD	Section 42B of the Act
specified media	in relation to an advertisement or generic information, means: 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	Section 42B of the Act

Term	Definition	Source
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	Subsection 3(1) of the Act
State	includes the Australian Capital Territory and the Northern Territory	Subsection 3(1) of the Act
State law	a law of a State, of the Australian Capital Territory or of the Northern Territory	Subsection 3(1) of the Act
supply	includes: a. supply by way of sale, exchange, gift, lease, loan, hire or hire purchase; and b. supply, whether free of charge or otherwise, by way of sample or advertisement; and c. supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and d. supply by way of administration to, or application in the treatment of, a person	Subsection 3(1) of the Act

Term	Definition	Source
therapeutic goods	means 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 biologicals, 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 in force under section 7; or d. goods in respect of which such 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 standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or f. goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented; or g. goods covered by a determination under subsection 7AA(1) (excluded goods); or h. goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination	Subsection 3(1) of the Act

Term	Definition	Source
therapeutic use	means use in or in connection with: a. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or b. influencing, inhibiting or modifying a physiological process in persons; or c. testing the susceptibility of persons 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	Subsection 3(1) of the Act
total purchase price	in relation to therapeutic goods, means the total cost of the goods to a consumer, including: a. the administration, handling and infrastructure fee, any mark-up payable to the pharmacist, dispensing fee, additional fee or allowable extra fee if applied by the pharmacist; and b. in relation to Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme prescriptions—any premium (such as a brand or therapeutic group premium or special patient contribution) that must be paid by the consumer	*Therapeutic Goods Advertising Code 2018*
traditional use	for a designated active ingredient, means use of the designated active ingredient that: a. is well documented, or otherwise established, according to the accumulated experience of many traditional health care practitioners over an extended period of time; and b. accords with well established procedures of preparation, application and dosage	*Therapeutic Goods Regulations 1990*
unscheduled	in relation to a good, means not consisting of, or containing, a substance in a schedule to the current Poisons Standard	*Therapeutic Goods Advertising Code 2018*

Other guidance on the application of the Code

Further information on 'prominently displayed or communicated'

The Code requires certain information to be 'prominently displayed or communicated' in advertisements:

- required statements for medicines and devices, described in sections 12(3), 12(4) and 12(5), which may include health warnings for specific substances
- warnings regarding persistence or worsening of symptoms and the need to consult a healthcare professional
- statements required for the advertising of Schedule 3 medicines
- statements required for the advertising of analgesics (see Section 24)
- statements required for the appropriate use of sunscreens (see Section 27)

The 'prominently displayed or communicated' requirement has been restricted to those provisions which require important mandatory information to be communicated in advertising- i.e. the messages that are critical to the consumer when self-selecting a product for self-treatment. Advertisers should be aware that the target audience of the advertisement should be considered. For example, to meet the requirement to be prominently displayed or communicated, an advertisement directed to people with eyesight difficulties may require special consideration to ensure the message is received in its entirety.

Examples of prominently displayed and communicated mandatory information

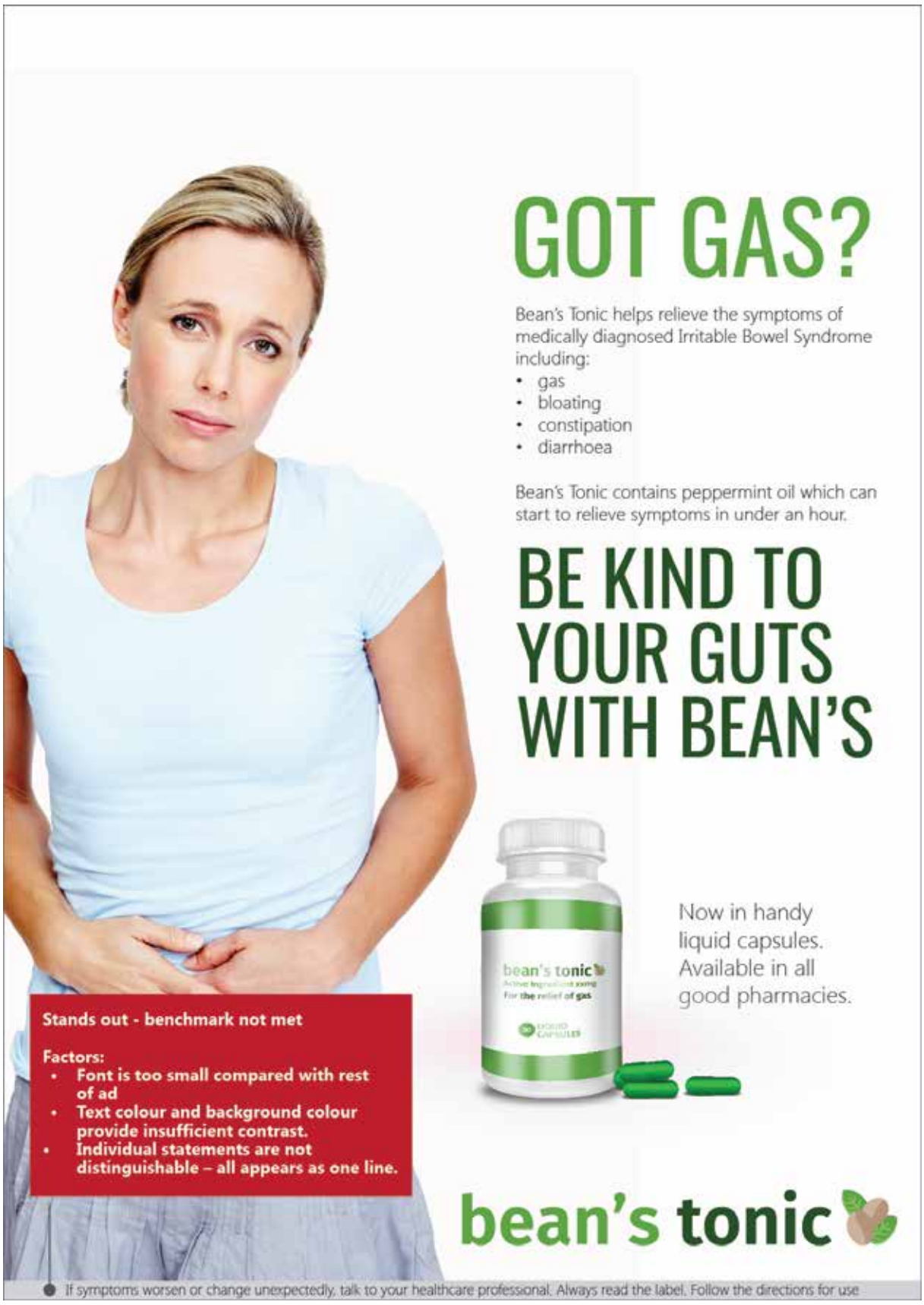
Mandatory statements are not required to be in any particular font style, size or format when included as visual statements in an advertisement, as long as they are 'prominently displayed or communicated' within the meaning of that term as defined in section 4 of the Code. For example, font embellishments (including serifs, italicised, cursive, shadowed, calligraphic, poster) and other fancy or irregular fonts, may affect the extent to which the required statement stands out so as to be easily read and understood.

The following examples are indicative of the requirements for ensuring mandatory statements are prominently displayed or communicated:


GOT GAS?
Bean's Tonic helps relieve the symptoms of medically diagnosed Irritable Bowel Syndrome including:
• gas
• bloating
• constipation
• diarrhoea
Bean's Tonic contains peppermint oil which can start relieving symptoms in under an hour.
BE KIND TO YOUR GUTS WITH BEAN'S
Now in handy liquid capsules. Available in all good pharmacies.
Stands out - benchmark met.
Factors:
• Font size and type similar to the main representations in the ad.
• Good contrast from background.
• Good separation of individual warning statements assists
Always read the label. If symptoms worsen or change unexpectedly, talk to your healthcare professional.
Follow the directions for use
bean's tonic


GOT GAS?
Bean's Tonic helps relieve the symptoms of medically diagnosed Irritable Bowel Syndrome including:
• gas
• bloating
• constipation
• diarrhoea
Bean's Tonic, with peppermint oil and ibuprofen can start to relieve symptoms in under an hour.
BE KIND TO YOUR GUTS WITH BEAN'S
Now in handy liquid capsules. Available in all good pharmacies.
Stands out - benchmark met
Factors:
• Font size and type similar to the main representations in the ad
• Not buried under pictures.
• Good contrast from background.
This medicine may not be right for you. Read the label before purchase. If symptoms worsen or change unexpectedly, talk to your healthcare professional. Follow the directions for use.
bean's tonic


GOT GAS?
Bean's Tonic helps relieve the symptoms of medically diagnosed Irritable Bowel Syndrome including:
• gas
• bloating
• constipation
• diarrhoea
Bean's Tonic contains peppermint oil and ibuprofen, which work together to start relieving symptoms in under an hour.
BE KIND TO YOUR GUTS WITH BEAN'S
Now in handy liquid capsules. Available in all good pharmacies.
Stands out - benchmark met
Factors:
• Font size and type similar to the main representations in the ad.
• Good contrast from background.
Separation of individual warning statements may also assist
Always read the label. Do not use if you have a stomach ulcer, impaired kidney function, heart failure, allergic to non-steroidal anti-inflammatory medicines, pregnant or trying to become pregnant. If symptoms worsen or change unexpectedly, talk to your healthcare professional. Follow the directions for use.
bean's tonic


GOT GAS?
Bean's Tonic helps relieve the symptoms of medically diagnosed Irritable Bowel Syndrome including:
• gas
• bloating
• constipation
• diarrhoea
Bean's Tonic contains peppermint oil which can start to relieve symptoms in under an hour.
BE KIND TO YOUR GUTS WITH BEAN'S
Now in handy liquid capsules. Available in all good pharmacies.
bean's tonic
Stands out - benchmark not met
Factors:
• Font is too small compared with rest of ad
• Text colour and background colour provide insufficient contrast.
• Individual statements are not distinguishable – all appears as one line.
bean's tonic
If symptoms worsen or change unexpectedly, talk to your healthcare professional. Always read the label. Follow the directions for use

Prominently displaying or communicating information in social media

To satisfy the requirement to be 'prominently displayed or communicated' in online advertising including social media, mobile phone apps and emails:

- the information needs to be available in the same locale as the advertising content
- a pop-up may provide such information to consumers

For spoken statements, this may require:

- using a similar volume and delivery (for example pitch, speed) to the name of the therapeutic goods advertised

Ensuring that such information satisfies the requirement to be prominently displayed is dependent on the media used for the advertising. For example, for a television or internet advertisement that relies on an actor to impart the therapeutic representations including the 'main claim', 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.

In the case of visual advertisements not designed to be viewed at once (for example, a printed brochure or a webpage that will be scrolled through) the mandatory information must be repeated as often as necessary to ensure the likelihood that it will be seen by a viewer.

Promotion of goods for use by specific populations

Where a good as being promoted for use in specific populations (for example infants and neonates), the representations are likely to be misleading unless there is specific evidence on the use of the advertised good in the referenced population 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, an expert accredited (NAATI) translator certified translation for the advertising will be required to be provided by the advertiser.

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:

- an advertisement about the goods; or
- generic information included in an advertisement about the goods; or
- bona fide news'

Division 4 of Part 5-1 of the Act requires that generic information for therapeutic goods used as an ingredient or component in the manufacture of other therapeutic goods (for example, information about fish oil that is principally factual rather than promotional) must comply with any sections of the Code that are identified in the Regulations for that purpose (section 42DO of the Act refers).

The relevant sections of the Code are set out in regulation 8 of the *Therapeutic Goods Regulations 1990* (currently these refer to sections of the Therapeutic Goods Advertising Code 2015), and from 1 January 2019 an updated regulation 8 will take effect that will refer to the following sections of the Code in relation to such generic information- sections 9 (Accuracy), 10 (Effect), 15 (Scientific or clinical representations), 16 (Endorsements), 18 (Incentives), 19 (Advertising to children) and 21 (Consistency with public health campaigns).

- Further information about generic information is in section 42DN of the Act.

In the transition from the 2015 Code to the Therapeutic Goods Advertising Code (No 2) 2018, the numbering of the Code sections has changed. This will be reflected in regulation 8, from 1 January 2018.

Provision of price information for medicines other than prescription medicines

The Act prohibits advertising to the general public of a substance, or a therapeutic good containing a substance, included in Schedule 3 (Pharmacist-Only medicine), 4 (Prescription-Only medicine) or 8 (Controlled Drug) of the current Poisons Standard . Substances which are listed in Schedules 3, 4 or 8 of the current Poisons Standard are, collectively referred to as, restricted scheduled substances.

Schedule 3 substances listed in Appendix H to the current Poisons Standard are permitted to be advertised directly to consumers.

A positive or promotional statement about a therapeutic good, preparation or substance that contains or is a restricted scheduled substance that is published or broadcast to the public is likely to be considered an advertisement under the Act.

Subject to certain exclusions, therapeutic goods that do not contain restricted scheduled substances can be advertised to consumers, provided that the advertising complies with the requirements under the Act, the Regulations and the Code.

If price advertising of OTC medicines is to be published in conjunction with price information for restricted scheduled substances, care is needed as there are more restrictive requirements set out in the Price Code (for example note in particular that any photographs or other reproductions of the medicine are prohibited). Combined price advertising of restricted scheduled substances and OTC/complementary medicines often fails to meet the requirements of the Price Code.

Under the Act, it is an offence to advertise to any person a therapeutic good for an indication that is not entered in the ARTATG for that medicine (that is, 'off-label' use).

Puffery

Puffery is defined by the Macquarie Dictionary as the 'act of praising unduly' or 'exaggerated commendation'.

The ACCC states:

> 'Puffery' is a term used to describe wildly exaggerated or vague claims about a product or service that no one could possibly treat seriously. For example, a restaurant claims they have the 'best steaks on earth'. These types of statements are not considered misleading.

While puffery may be permitted in Australian Consumer Law (to the extent such claims would not be considered misleading), and there is no express prohibition on its use in the Code, there are additional requirements for advertising therapeutic goods (over and above the requirements for advertising in Australian Consumer Law) which effectively prohibit the use of puffery. For example, section 9 of the Code requires advertisements for therapeutic goods to be valid, accurate, substantiated and truthful. Section 10 of the Code prohibits the use of statements that exaggerate product efficacy or performance.

Puffery by its nature is not truthful. It is exaggerated, inaccurate and unsubstantiated and should not be used in advertisements for therapeutic goods.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication – draft for first consultation	Advertising Compliance Unit	29 March 2018
V1.1	Draft for second consultation Incorporated changes following first public consultation Some information was relocated to the Australian Regulatory Guidelines for Advertising Therapeutic Goods	Advertising Compliance Unit	August 2018
V1.2	Guidance incorporating changes following second public consultation and consultative committee feedback	Advertising Compliance Unit	October 2018
V1.3	Corrected links to the Therapeutic Goods Advertising Code (No.2) 2018	Advertising Compliance Unit	January 2019
V1.4	Changes to reflect the requirement for advertising pre-approval in specified media ending on 30 June 2020	Advertising Education and Assurance Section	July 2020

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Reference/Publication #