



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Consultation draft: Advertising to the public

## Complying with the Therapeutic Goods Advertising Code 2018

Version 1.1, August 2018

**TGA** Health Safety  
Regulation

Historical consultation document

**Copyright**

© Commonwealth of Australia 2018

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <[tga.copyright@tga.gov.au](mailto:tga.copyright@tga.gov.au)>

**Confidentiality**

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submissions made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Historical consultation document

# Contents

|   |           |
|---|-----------|
| <b>About the Code and this guidance</b>   | <b>6</b>  |
| Purpose of the Code   | 6         |
| Reading the Code  | 6         |
| Key differences from the previous Code  | 7         |
| About this guidance   | 7         |
| Other relevant policies   | 8         |
| <b>Guidance on specific Code provisions</b>   | <b>9</b>  |
| <b>Part 1 - Preliminary</b>   | <b>9</b>  |
| 2 Commencement and 3 Repeal of previous Advertising Code  | 9         |
| 4 Definitions   | 9         |
| 5 Object  | 10        |
| 6 Application of the Code   | 10        |
| 7 Price information   | 15        |
| <b>Part 2 - Requirements for advertising therapeutic goods - general</b>                                    | <b>15</b> |
| 8 Approved advertisements   | 15        |
| 9 Accuracy  | 16        |
| 10 Effect   | 20        |
| 11 What must advertisements contain - general rules   | 24        |
| 12 What must advertisements contain - goods that are not available for physical examination before purchase | 29        |
| 13 Required statements  | 34        |
| 14 Required statement - pharmacist-only medicines   | 36        |
| 15 Scientific representations   | 36        |
| 16 Endorsements   | 37        |
| 17 Testimonials   | 39        |
| 18 Incentives to pharmacy assistants and other non-healthcare professional sales persons                    | 41        |
| 19 Advertising to children  | 41        |
| 20 Samples  | 41        |
| 21 Consistency with public health campaigns   | 41        |
| <b>Part 3 - Rules relating to particular therapeutic goods</b>  | <b>43</b> |
| 22 Application  | 43        |
| 23 Complementary medicines  | 43        |
| 24 Analgesics   | 44        |

|   |           |
|---|-----------|
| 25 Vitamins and minerals  | 44        |
| 26 Weight Management  | 44        |
| 27 Sunscreens   | 44        |
| <b>Part 4 - Restricted representations and prohibited representations</b>             | <b>45</b> |
| 28 Restricted representations - serious form of disease, condition, ailment or defect | 45        |
| 29 Restricted representations - public interest criteria                              | 51        |
| 30 Prohibited representations   | 51        |
| <b>Schedule 1 - Price Information</b>   | <b>52</b> |
| 1 Purpose   | 52        |
| 2 Application   | 52        |
| 3 Who may provide price information   | 52        |
| 4 Responsibility for compliance with this schedule                                    | 53        |
| 5 Methods for provision of price information  | 53        |
| 6 General requirement restricting promotion   | 53        |
| 7 Description of medicines  | 55        |
| 8 Presentation of price information   | 56        |
| 9 Pharmaceutical Benefits Scheme subsidised medicines                                 | 56        |
| <b>Schedule 2 - Advertising to children</b>   | <b>56</b> |
| 1 Goods that may be advertised to children  | 56        |
| <b>Schedule 3 - Samples</b>   | <b>57</b> |
| 1 Goods that may be offered as samples  | 57        |
| <b>Attachment A - Definitions</b>   | <b>58</b> |
| <b>Attachment B – Other guidance on the application of the Code</b>                   | <b>68</b> |
| Prominence of mandatory information   | 68        |
| Prominently displayed or communicated   | 68        |
| Displayed or communicated   | 70        |
| Legible   | 70        |
| Promotion of goods for use by specific populations                                    | 70        |
| Foreign language advertising  | 70        |
| Generic information   | 70        |
| Definition of generic information   | 70        |
| Unbranded advertising   | 71        |

|   |           |
|---|-----------|
| <b>Provision of price information for medicines other than prescription medicines</b> | <b>71</b> |
| <b>Natural claims</b>   | <b>72</b> |
| <b>Therapeutic goods cannot be promoted as entirely natural</b>                       | <b>72</b> |
| <b>Claims about natural and naturally derived ingredients</b>                         | <b>73</b> |
| <b>Organic claims</b>   | <b>73</b> |
| <b>Puffery</b>  | <b>74</b> |

Historical consultation document

Therapeutic goods are not usual items of commerce - there are potential adverse consequences to individuals and the broader public from their accidental or deliberate misuse. In addition, the relative merits of products may not be apparent to consumers. As a result there is particular legislation that applies to the advertising of therapeutic goods to consumers. This legislation reflects the importance of consumers being fully informed so that they can select treatment options appropriately for use in the care of themselves or their family.

When advertising therapeutic goods to the public, advertisers must comply with the [Therapeutic Goods Advertising Code 2018](#) (the Code), which is the cornerstone of the [therapeutic goods advertising regulatory framework](#). However, not all therapeutic goods are allowed to be advertised to the public, and there are a number of other restrictions, that are described 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](#)
- [lodging a 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.

## Purpose 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

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 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 e.g. 'medicine' also includes 'medicines'.

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

Certain sections of the Code also apply to generic information. See [Generic information](#) below.

## Key differences from the previous Code

There are a number of key differences in the Code from the previous version (2015), including:

- advertising must not undermine [public health campaigns](#)
- changes to the mandatory statement required in advertising for [Schedule 3 \(pharmacist-only\) medicines](#)
- changes in mandatory statements needed for the advertising of other therapeutic goods (altered wording and requirements regarding prominence). This affects both [advertising for goods that are not available for physical examination before purchase](#) and [other advertising](#)
- a revised definition for 'serious' for use in determining whether a representation about a disease, condition, ailment or defect is a [restricted representation](#)
- special requirements that apply to the advertising of [sunscreens](#)

## About this guidance

This guidance is supplemented by fact sheets on major topics. The availability (or planned availability) of these fact sheets is indicated throughout the document.

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 2018.



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

The Code draws on concepts used in the World Health Organisation: 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.

The Code is pivotal to giving consumers confidence that the claims they read and hear are well-founded and it should provide a level playing field for industry.

In the event of any inconsistency between the Act, the *Therapeutic Goods Regulations 1990* (the Regulations) or the Code and this guidance or other published policies, the Act, the Regulations and the Code prevail.

## Guidance on specific Code provisions

The following content provides guidance on specific provisions in the Code. The numbering of the sections corresponds to the numbering of the Code provisions for ease of cross-reference. However, these guidelines do not cover all sections of the Code and, as such, the numbering may not be sequential.

### Part 1 - Preliminary

#### 2 Commencement and 3 Repeal of previous Advertising Code

The *Therapeutic Goods Advertising Code 2018* (the Code) is effective from 1 January 2019. The *Therapeutic Goods Advertising Code 2015* (2015 Code) will be repealed at the same time.

While the *Therapeutic Goods Advertising Code 2015* will be in force until 31 December 2018, the Code was registered and [made available](#) to stakeholders on 1 July 2018. The transition period of 6 months enables advertisers to familiarise themselves with the Code, undertake training offered by the TGA and to bring existing advertising material into compliance with the Code before it comes into effect on 1 January 2019.

For information on the changeover to the Code from the 2015 Code, see [Changeover to Therapeutic Goods Advertising Code 2018](#).

#### 4 Definitions

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

## 5 Object

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

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 of the Code

### 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 [exclusively to health professionals](#)
- [genuine news](#) in some situations

The Code does not apply to the advertising of products that are not therapeutic goods, including food and cosmetic goods. However, sometimes advertising such products with therapeutic claims can render them therapeutic goods (interface products). See the [Australian Regulatory Guidelines on Advertising Therapeutic Goods](#) for more information on 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.

The definition of 'advertise' is very broad. Further information on [Forms an advertisement may take](#) is available in the Australian Regulatory Guidelines for Advertising Therapeutic Goods.

The marketing of therapeutic goods can comprise many elements, including the name and logo of the sponsor, tag lines (a catch-phrase) 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.

### 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 must be behind a secure firewall and must only be able to be accessed once the AHPRA registration details or other professional accreditation of the individual requiring access has been established
- content provided via email is only provided once the AHPRA or other accreditation of the individual has been established. Emails should be sent to a personal email address for the health professional and not a group email (e.g. [manager@practice.com](mailto:manager@practice.com))

Factual information (e.g. scientific information) meant for health professionals does not necessarily need to be contained behind a firewall provided that it is not directly or indirectly promotional. For example, a sponsor website that provides access to product information documents for all of their prescription medicines that is accessed via an index ordered alphabetically solely by medicine name would be unlikely to be considered promotional. However, providing 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 indirectly 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***

The therapeutic goods market is a complex product market. Vulnerability to, or detriment suffered from, inadequate or difficult to understand information in this market is increased because of Australians' low health literacy levels<sup>1</sup>. Additionally, serious conditions and/or chronic ill health can adversely affect a consumers' capacity to make rational decisions.

A 'reasonable person' for the purposes of the application of the Code is a consumer who must therefore always be considered as being 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

It is possible that reasonable responses to advertising claims may differ. However, responses that are extreme or fanciful and not held by a significant number of consumers could not be regarded as responses held by the reasonable person.

#### ***Target audience***

Advertisements for therapeutic goods necessarily are directed to particular audiences, depending on the nature of the therapeutic goods being advertised.

<sup>1</sup> See [National womens health policy - health literacy](#) and [Health literacy - taking action to improve safety and quality](#)

Some advertisements are directed (either explicitly or by implication) to specific population groups e.g. diabetics, carers of infants and children. Other advertisements are directed more broadly – e.g. 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, what that person is likely to make of the advertisement and how they are likely to be impacted by it.

You must take into account the likely target audience for your advertisement in order to properly assess the advertisement’s compliance with the Code.

For example:

- the reasonable consumer from a metropolitan area, assessing an advertisement for a Type I diabetes product, is likely to be a consumer who has 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 the target audience (all adults) 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 sight difficulties may be unbalanced if the reduced vision capacity of the target audience is not taken into account in displaying certain information, such as required advisory or warning statements, in the advertisement

TGA generally expects purchasers of Traditional Chinese Medicines (TCM) to have an understanding of the particular terminology used in relation to the indications for such medicines as they are likely to be under the care of a TCM practitioner. A similar approach would also be taken with Anthroposophic and Ayurvedic remedies. However, as there are important differences in the evidence required for traditional and scientific claims, the Code requires the inclusion of the tradition of use and paradigm where appropriate in advertisements, to ensure all consumers are aware of that evidence. If the basis of a claim is ‘tradition of use’ evidence, this fact must be clearly conveyed in the advertisement:

- product x (or ingredient x) has been traditionally used in Ayurvedic medicine for the relief of ...

NOT

- product x (or ingredient x) is used for the relief of ...

#### **6(4) Total presentation and context of advertising**

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), images (if any) and general presentation of the advertisement will all need to be considered in determining whether the advertisement is consistent with the Code.

Advertisements can be presented in a variety of ways, including by a statement (orally or in writing), images and pictures (including moving 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 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 goods may assist with pain relief for more serious forms of arthritis.

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

*Genuine news* must be accurate, balanced and factual otherwise it could be considered advertising. The Code does not apply to genuine news that is broadcast or published in any medium by:

- broadcasters
- datacasters
- the SBS
- publishers of a print edition of a newspaper or magazine that is or was available to the public by way of purchase in Australia

However, 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.

Public interest and entertainment programs (including current affairs programs) that are non-promotional and presented in an accurate, factual and balanced way are unlikely to be considered advertising. However, as these types of programs are more likely to take a particular

stance on issues<sup>2</sup>, steps must be taken to ensure they are either not advertising therapeutic goods or, if they do advertise therapeutic goods, do so in a compliant manner. (Information sheets on the differences between advertising, genuine news and related activities will be developed soon.)

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 were posted on a sponsor's website or social media account.

All parties involved in advertising therapeutic goods to the public have responsibilities to ensure compliance with the Code. The party or parties responsible for the advertisement are considered on a case by case basis.

For example, in the case of a shelf wobblers in a pharmacy, responsibility for compliance may lie with the pharmacy owner who authorised public display of the item. However, if the owner demonstrated that they had received the shelf wobblers in good faith from the sponsor of the goods and had undertaken reasonable steps to ensure the content of the wobblers was compliant, and continued to be compliant (such as ensuring the wobblers is placed in front of the corresponding product, in full and unamended and avoiding the placement of health information near the wobblers that might have the effect of extending the product's indications), 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. Some online retailers appear to be of the view that it is acceptable to duplicate information from such sources for the purposes of advertising products for sale, but take no responsibility for the publication of the information. In complaint [4-0707](#), an online retailer and advertiser argued that they had “absolutely no way of knowing whether [the product sponsor is] in fact justified in what they say about” the advertised product, and explained that “text on our website is originally all copied from the respective manufacturer’s websites and other publicity they provide when the product is launched”. In its determination the Panel noted as follows:

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

13.) Where an advertiser publishes information regarding a product in an advertisement, it is a prima facie presumption that the advertiser is the person responsible for publishing that information even where it has been copied from material published by the product sponsor. Material that has been compiled from sources such as product packaging or other material may not be current, may not have been provided with the intention that it be reproduced in advertising by others, or may in



<sup>2</sup> See section 3.4.3 of the [Commercial Television Industry Code of Practice 2018](#)

some other way be deficient. Such material may have been reproduced without the consent, control, or authorisation of the product sponsor.

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

## 7 Price information

Prescription medicines, as listed in Schedules 4 and 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (the [Poisons Standard](#)), cannot be advertised to the public as it is an offence to do so under section 42DL (or section 42DLB 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, for the reasons set out in the [Review of drugs, poisons and controlled substances legislation \(the Galbally Review\)](#), 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 1 of the Code. If the price information does not comply with Schedule 1 of the Code, it would contravene the relevant offence and civil penalty provisions in the Act.

## Part 2 - Requirements for advertising therapeutic goods - general

### 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 Australian Regulatory Guidelines for Advertising Therapeutic Goods.

## Approval number

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

## 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

Noting that all claims must be consistent with the advertised goods' indication or intended purpose as it is recorded on the ARTG, you must hold evidence that can demonstrate the accuracy of every claim (including non-therapeutic claims) made in an advertisement. The kind and amount of information required to do this will depend on the type of claims made (including any implied claims). An accurate claim is a truthful claim and is correct.

All claims made in therapeutic goods advertising must have been substantiated prior to the advertising. 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 (relying on the ordinary meanings of these words in the Macquarie Dictionary).

#### *Therapeutic use claims*

For therapeutic use claims, (see definition of 'therapeutic use' in Schedule 3) evidence requirements apply. These requirements should also be considered in the context of the requirements for claims to be truthful, balanced and not misleading (see (b) below).

Therapeutic claims (as well as other types of claims detailed below) must be capable of substantiation. This means the advertiser must hold evidence at the time of the publication or broadcast of the advertisement that adequately demonstrates the claim is accurate and valid and 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 a clinical expert

It should be noted that even when a claim can be substantiated by evidence, it may nevertheless be deemed to be misleading and/or unbalanced or, in the case of goods included in the ARTG, may not be consistent with the entry for the good in relation to that inclusion.

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 Complementary Medicines](#)



- [Guidelines on the evidence required to support indications for listed complementary medicines](#)
- [Assessed listed medicines](#)

These should be taken as a minimum standard for evidence requirements. However, you should be aware that the evidence needed to support your product's inclusion in the ARTG may not be sufficient to support all of your advertising claims for the product. (Further guidance on evidence requirements in such cases will be developed.) For all therapeutic goods, the evidence for therapeutic use claims 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, who 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 and not misleading.

For example:

- marketing statements unrelated to the therapeutic use of the goods (e.g. natural ingredients, 20% off this week, 4 out of 5 people prefer this brand, improved flavour)
- claims related to effectiveness or performance (e.g. 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.

For listed medicines, more information is available in the [Permitted indications for listed medicines guidance](#) and [Guidelines on the evidence required to support indications for listed complementary medicines](#).

## **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 (including 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 will mislead 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 substantiated and accurate 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 very small in any event, is likely to mislead consumers into thinking other imaging devices are harmful. It is also likely to mislead consumers as to the order of magnitude of the difference in radiation produced by the advertised device and other similar devices – even if the claim is substantiated.

Similarly, claims in an advertisement where they can be verified but the advertisement 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.

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 as follows:

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

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

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

Information on the application of these provisions to ‘natural’ claims about therapeutic goods can be found [below](#).

### 9(c) Comparative claims

While it may be acceptable for an advertisement to make a comparison between therapeutic goods or classes of therapeutic goods the advertiser must ensure that comparative claims do not expressly or by implication lead the audience to a view that the comparator goods are harmful or ineffectual. This applies to both therapeutic and non-therapeutic comparative claims, as well as hanging comparators. When considering the potential impact of a comparator claim on the viewer, the viewers' level of knowledge needs to be taken into consideration.

For example, in Australia listed complementary medicines must be manufactured in a Good Manufacturing Practice (GMP) licensed facility (there are some limited exceptions). However, the concept of GMP and GMP licensing, and when it is required, is unlikely to be familiar to most consumers. Advertising such a medicine with:

- ✘ the claim "This medicine is manufactured in a GMP licensed facility to ensure highest quality" may be accurate but would not be balanced and could imply that comparator products are harmful or of lesser quality because they haven't been manufactured in such a facility
- ✓ a statement to the effect that all complementary medicines commercially supplied in Australia must be manufactured in a GMP licensed facility would be accurate, balanced and would not undermine comparator products

A further example is the use of '[organic](#)' claims. While it may be acceptable to claim the ingredients of a product are 'organic' if that can be substantiated, it is not acceptable to compare such a product with a non-organic counterpart product in a way that states or implies the comparator product could cause harm to the consumer.

### 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. Consistency must be gauged from the total context of the advertisement.

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

- the dosage form (e.g. tablets, capsules, topical liquid) or, in the case of medical devices, the GMDN code
- the name or description of the goods
- the formulation of the goods
- the intended purpose (for the purposes of this provision, this includes indications, for example, for medicines)
- any conditions applied to the ARTG entry (including those that may constrain the way in which the goods can be promoted)
- any warnings or contraindications

For example, an advertisement that promoted a complementary medicine as having "the healing powers of aloe vera" where the formulation of the medicine in the 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). If the medicine did include aloe vera that was not declared in the ARTG listing, this would raise additional regulatory issues under the Act.



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

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

The Act defines an ‘indication’ as a specific therapeutic use. For example, the claim “helps relieve constipation” is an indication and a therapeutic claim. However, qualifying the indication with a timeframe in which the therapeutic results are expected to be achieved, 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.

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.

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

## 10 Effect

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

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

Advertising must only present therapeutic goods in accordance with:

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

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

#### *10(a)(ii) Don't 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’, ‘proven’, ‘clinically proven’ which may be acceptable in relation to specific claims (where there is evidence) but which are unlikely to be acceptable in relation to the therapeutic good itself
- through the use of testimonials which refer to unrealistic 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 (which may be 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 and delaying medical attention when medical attention is necessary for the proper treatment and/or management of the consumer’s 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 to prevent negative health consequences for the consumer
- a claim that a complementary medicine may help a child who ‘worries excessively’ may result in the child’s parent or guardian delaying seeking health professional advice in relation to the child’s symptoms

### **10(c) 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 clearly encourage inappropriate use
- a sunscreen that represents the product as ‘giving 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 intending purpose of alleviating snoring that promotes the use of the device for sleep apnoea would be likely to encourage inappropriate use
- a weight loss medicine that binds dietary fat that contains claims that people can adjust the dosage depending on their fat intake, with no upper limit, would encourage excessive use

- an advertisement that suggests that the advertised good should be used by the general population but is not suitable for some sub-populations like children, would be likely to encourage inappropriate use and be inconsistent with the QUM framework

While it is permissible to offer discounted prices and engage in other similar promotional activity of a commercial nature, the onus is on the advertiser to ensure that such offers would be unlikely to result in consumers using the good inappropriately or excessively as may happen if, for example, medicines which are close to their 'use by' date are offered at greatly reduced prices.

## **10(d) Other prohibited effects in advertising**

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

Therapeutic goods exert a therapeutic effect on the human body. Therefore, the good may also have unintended consequences or trigger an adverse event.

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

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

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

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

Individual responses to therapeutic goods are always variable. Accordingly, 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:

- an 'antioxidant product' advertised with claims such as:
  - 'essential for normal metabolism'
  - 'the solution' for good health
  - 'proven to protect against oxidative stress'

would be likely to give the 'reasonable person' the impression that the product is guaranteed to work in all cases of oxidative stress and a sure cure.

- weight-loss products that claim to completely prevent the absorption of fats

- a headache product advertised with claims like “100% Guaranteed to eradicate headache and migraines” and “90 day money back guarantee” represents the product as being effective in all cases of a condition and a guaranteed and sure cure

### **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 great number of factors which can be specific to individuals. No therapeutic good will be effective in all cases of a condition.

The use of ‘hype’ language such as ‘revolutionary’, ‘amazing’, ‘incredible’ is not acceptable in advertisements for therapeutic goods. Apart from such terminology being in clear 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.

For example:

- an advertisement for a multi-vitamin and mineral product which was represented in an advertisement as “the holy grail of good health” is likely to give the reasonable consumer the impression that the product had a magical quality

Additionally, as testimonials used in an advertisement form part of that advertisement (or can on their own be an advertisement) and must therefore comply with the Code, care must be taken by advertisers to ensure testimonials, in addition to being genuine, do not, for example, use language which overstates the accepted and validated efficacy of the good, which state or imply the good is safe, or which state or imply the good is infallible, unfailing, magical or miraculous.

For example:

- a testimonial for a therapeutic good when the indication for that good is for the temporary relief of mild pain, and which read:

I was at the end of the road with pain that kept me awake all night. Product X took that pain right away and for the first time in years I managed to sleep through the night – pain free and with no side effects. I was so amazed I just wanted to share my experience. Try it. It really works.

would be in breach of the sections 10(a)(ii), (d)(i) and (iii) of the Code.

Additionally, images used to depict before and after product results, should accurately reflect the results that can be obtained from product use.

For example:

- an image of skin affected with extensive, inflamed eczema in a ‘before product use’ photo accompanied with an image of completely healed skin in an ‘after product use’ photo taken 2 days after use of the product started could be considered to be portraying the advertised product as miraculous

### **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 permitted under s.42DF or s.42DK of the Act. However, to receive such an approval, the claim would need to refer to a restricted or prohibited representation and the Secretary must be satisfied that the use of the representation was in the public interest (e.g. prevention of skin cancer through sunscreen use).

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
- imply that a health condition will become more serious if the advertised good is not used

## 11 What must advertisements contain - general rules

### Health Warnings

Some therapeutic goods, particularly certain medicines, may cause unintended side effects or adverse events even when taken or used according to the directions or instructions for use. Similarly, some goods may have contraindications. Where these effects on health are sufficiently serious 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 will be 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.

### Mandatory information for advertising of all therapeutic goods

Section 11 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.

The mandatory statements are required to be either 'prominently displayed or communicated' or 'displayed or communicated' depending on the importance of this information. Attachment B – Other guidance on the application of the Code contains details about [the prominence of mandatory information](#).

### 11(1) Things this section does not apply to

Section 11 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 to section 11
- labels, patient information leaflets or CMIs
- advertisements for pharmacist only medicines (section 14)
- 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.

The exclusions from the operation of section 11 are strictly limited to those situations set out in subsection 11(1). The remainder of the Code still applies to the content and presentation of this type of advertising (unless there is an explicit exclusion similarly worded to 11(1)).

## 11(2) Mandatory information for advertising of medicines

### *Name of the medicine*

Section 11(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 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

### *Indications for the medicine*

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

- for medicines that are exempt from being entered in the ARTG, the indications should be consistent with the medicine label and the sponsor's website
- for medicines entered in the ARTG, the indications should be consistent with the indications entered in the ARTG entry for the medicine (including any qualifications)

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 recorded in the ARTG. However, the meaning and intent must not differ. For example:

- 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 an alteration to “Prevention of colds” would not be acceptable

Where a medicine is entered in the ARTG with 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 instance or subset of an indication.

### ***Required statements for medicines***

Section 11(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 [displayed or communicated](#) (which is consistent with the long standing public health campaigns on labelling of therapeutic goods); 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 [displayed or communicated](#), and
    - the health warnings [displayed or communicated](#)

### **11(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 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 instance or subset of a broader purpose.

### Key concepts – 'Intended purpose' for medical devices

Section 11(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 11(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, which must be 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 [displayed or communicated](#)

### **11(4) Mandatory information for advertising of other therapeutic goods**

Sections 11(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 11(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) which must be 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 [displayed or communicated](#)

### **11(5) Exemption for short-form advertising**

Subsection 11(5) exempts the application of the required statements and/or health warnings (as set out in sections 11(2)(c), 11(3)(d) and 11(4)(d)) from applying to:

- radio commercials that are 15 seconds or less in duration, and

- written advertisements that are 300 characters or less

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.

For clarity, short form written advertisements must not contain audio, video or still pictures. If a short form written advertisement included pictures, videos or any other types of representations, the TGA would assume that the requirement to include the mandatory statements could be fulfilled as they could be included in the picture or video.

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

## **12 What must advertisements contain - goods that are not available for physical examination before purchase**

### **12(1) Application of the section**

Consumers can purchase therapeutic goods through certain channels without the opportunity to physically examine the goods and read all the information available on the label and/or packaging to establish whether it is suitable for their needs. Therefore, it is important that advertising promoting supply through these channels contains a greater level of information (e.g. contraindications, warnings) 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, where a consumer can buy a therapeutic good, through a website, social media platform or mobile phone app
- direct marketing, where a consumer can buy a therapeutic good, sight unseen, through other means (for example, a mail-order catalogue or telemarketing)
- digital and other direct marketing sources where the consumer is able to directly purchase within that advertisement

This section of the Code ensures that all of the information that would normally be available to the consumer by way of the packaging and labelling is made available through the advertisement.

Where an advertisement does not allow for the purchase of the advertised goods, the requirements at [section 11](#) also apply.

### ***Health Warnings***

Some therapeutic goods, particularly certain medicines, may cause unintended side effects or adverse events even when taken or used according to the directions or instructions for use. Similarly, some goods may have contraindications. Where these effects on health are sufficiently serious they are required to be included on the label on 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.

## 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) Prominence of statements

Further to the requirements set out in the definition for '[prominently displayed or communicated](#)', section 12(3) imposes additional requirements as to the location or timing of such statements.

Statements required to be [prominently displayed or communicated](#) for advertisements covered by section 12 must be displayed in close proximity to either:

- the first use of the product's name in the advertisement, or
- if the name of the product is not used, to the first image of the product's primary pack in the advertisement

If neither the name nor the image of the product is used, such statements must appear at the beginning of the advertisement.

## 12(4) Mandatory information for advertising of medicines 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 medicine where the physical product is not available for examination before purchase.

### ***Name of the medicine***

Section 12(4)(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*.

- 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(4)(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 *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*
- the quantity of the medicine, within the meaning of *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*

### ***Indications for the medicine***

Section 12(4)(d) requires an advertisement for a medicine to include the indications for the medicine. Establishing the indications for a medicine varies depending on the type of medicine:

- for medicines that are exempt from being entered in the ARTG, the indications should be consistent with the medicine label
- for medicines entered in the ARTG, the indications should be consistent with the indications entered in the ARTG entry for the medicine (including any qualifications)

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.

There is no requirement for the reference to the indications made in the advertisement to be presented word-for-word as recorded in the ARTG. However, the meaning and intent must not differ. See examples given for [section 11](#).

Where a medicine is entered in the ARTG with 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 instance or subset of an indication.

### ***Medicine ingredients***

Section 12(4)(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.

### ***Required statements for medicines***

Section 12(4)(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 [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 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.

- both the statement ALWAYS READ THE LABEL together with the health warnings themselves [displayed or communicated](#)

Section 12(4)(g) also requires the additional statements in the provisions listed below to be prominently displayed or communicated:

- [section 13\(3\)](#), regarding changes to symptoms
- [section 24](#) for analgesics (where the advertised good is an analgesic)
- [section 27](#) for sunscreens (where the advertised good is a sunscreen)

Section 12(4)(h) requires the additional statements mentioned in:

- [section 13\(2\)](#), regarding following the directions or instructions for use
- [section 23](#) for complementary medicines

as applicable to the advertisement to be [displayed or communicated](#).

Section 12(4)(i) requires any other mandatory warnings or advisory statements that are required to be included on the label for the medicine to be [displayed or communicated](#). These warnings or advisory statements may be imposed by:

- the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Poisons Standard))
- the 'Required Advisory Statements for Medicine Labels' (set out as the schedules to the *Medicines Advisory Statements Specification 2017*)
- by the conditions of registration of a medicine

## **12(5) Mandatory information for advertising of medical devices where the physical product is not available for examination**

Section 12(5) 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(5)(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. Advertisers should note that some devices include medicines while others may have substances on or in the device that may be required to be shown on the label

### ***Intended purpose***

Further information about the intended purpose for medical devices is available in [section 11](#).

### ***Required statements***

Section 12(5)(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 [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 [displayed or communicated](#)

The following additional statements are also required in the advertisement:

- section 12(5)(f) requires the additional statements required by [section 13\(3\)](#) regarding changes to symptoms to be [prominently displayed or communicated](#) (as applicable)
- section 12(5)(g) requires the additional statements required by [section 13\(2\)](#) regarding following the directions or instructions for use to be [displayed or communicated](#)
- section 12(5)(h) requires any other mandatory warnings or advisory statements that are required to be provided with the device (e.g. on any label or within instructions) to be [displayed or communicated](#). These warnings or advisory statements may be imposed by the Therapeutic Goods (Medical Devices) Regulations 2002 or the Poisons Standard

## **12(6) Mandatory information for advertising of other therapeutic goods where the physical product is not available for examination**

Section 12(6) 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(6)(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(6)(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 [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.

- 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 [displayed or communicated](#)

The following additional statements are also required in the advertisement:

- section 12(6)(f) requires the additional statement required by [section 13\(3\)](#) regarding changes to symptoms to be [prominently displayed or communicated](#) (as applicable)
- section 12(6)(g) requires the additional statement required by [section 13\(2\)](#) regarding following the directions or instructions for use to be [displayed or communicated](#)
- section 12(6)(h) requires any other mandatory warnings or advisory statements that are required to be provided with the good (e.g. on any label or within instructions), to be [displayed or communicated](#). Such warnings or advisory statements may be imposed by the *Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilant*, the *Therapeutic Goods Order No. 82 - Standard for Tampons – Menstrual* and the *standard AS/NZS 2869:2008 Tampons – Menstrual*

## 13 Required statements

Section 13 sets out further required statements for therapeutic goods advertisements that are in addition to the requirements set out in section 11.

### 13(1) Things this section does not apply to

Section 13 does not apply to:

- labels, patient information leaflets or CMI's
- advertisements covered by section 12 (noting however, that the statements required under sections 13(2) and (3) are also specified requirements (as applicable) within section 12)
- advertisements for pharmacist-only medicines (section 14 refers)
- advertisements 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 also be a therapeutic claim or indication for the therapeutic good.

The exclusions from the operation of section 13 are strictly limited to those situations set out in subsection 13(1). The remainder of the Code still applies to the content and presentation of the advertising.

### **13(2) Use statements**

Section 13(2) requires that advertisements must contain (as appropriate to the goods), either of the following statements [displayed or communicated](#):

- FOLLOW THE DIRECTIONS FOR USE. or
- FOLLOW THE INSTRUCTIONS FOR USE

Broadly 'directions' are used for medicines and 'instructions' for devices and other therapeutic goods. However this may not be universally true.

### **13(3) and (4) 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, symptoms may be reasonably expected to persist (if improved with the use of the medicine). 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 is appropriate
- for a medicine for the relief of symptoms associated with medically diagnosed irritable bowel syndrome, symptoms may be reasonably expected to persist (if improved with the

use of the medicine). 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 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.

These statements do not apply to radio commercials that are 15 seconds or less in duration, or to written advertisements that are 300 characters or less. See advice on [short-form advertisements](#) above.

## 14 Required statement - pharmacist-only medicines

Section 14 recognises the professional responsibility of pharmacists for providing access to pharmacist-only medicines; i.e. those medicines that are included in Schedule 3 of the current [Poisons Standard](#). Only those medicines listed in Appendix H of the current Poisons Standard can be advertised to the public.

Section 14 does not apply to:

- labels, patient information leaflets or CMIs
- 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 important to ensure that consumers understand that they have to talk to a pharmacist in order for the suitability of the medicine to be determined and for the medicine to be supplied if the pharmacist considers it appropriate.

## 15 Scientific representations

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

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

Referencing scientific studies to support claims made in advertisements gives credibility to the claims. This credibility could be misplaced if:

- the scientific study has not been peer reviewed
- the scientific study results are inconsistent with the body of evidence (the body of evidence can be reflected in systematic reviews and evidence based assessments)

Where claims are validated by a reference to scientific 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. The financial sponsor of the research should be clearly disclosed in the advertisement in the same way certain mandatory information must be displayed or communicated. 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. Merely stating the name of the source of funding 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 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.



### Sponsorships, endorsements and testimonials

The dictionary definitions for 'sponsorship', 'endorsement' and 'testimonial' overlap considerably.

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

For example, “Organisation X receives 10 cents from the sale of every bottle of Brand Y disinfectant”

Sponsorships, testimonials and endorsements can each 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 agency, hospital or healthcare facility
- an employee or contractor of one of these bodies, or
- 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 the listed organisations and individuals.

Section 16(3) allows an endorsement by the following listed organisations and individuals where; the advertisement names the organisation; discloses the nature of the endorsement, and 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, or
- an employee or contractor of any of these bodies (unless they are of an individual prohibited from making an endorsement under section 16(2))

This requirement ensures that consumers are aware of the details of the endorsement and if they are remunerated for their endorsement.

Testimonials may be viewed as a type of endorsement. However, this section does not apply to testimonials covered under section 17.

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

#### CRP decision highlight – ‘TGA Approved’ claims

In complaint [2008-02-018](#), the Panel noted as follows:

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



Australian government agency to a degree that is not factually correct, particularly as regards the efficacy of the product. The complaint was therefore justified. However, for the advertiser's benefit, the Panel noted that s.42DL(1)(e)(i) of the Act<sup>3</sup>, whilst prohibiting 'a reference to the Act', does permit a statement to the effect that "Product X is listed in the ARTG, AUST L 123". The Panel also noted that such a statement makes no reference to any government agency

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

### Valuable consideration

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

### Professional endorsement vs availability

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

For example, a catalogue from a pharmacy that bears the name of the pharmacist owner:

- 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
- 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

## 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.

<sup>3</sup> On 6 March 2018, this changed to s.42DL(9).

Only testimonials from people whose details have been verified prior to the advertisement occurring and have used the product can be used in advertising for therapeutic goods. Details include name, age and address, in addition to any other information needed to identify the testifier. However, a testimonial cannot be made by a person who is:

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

The testimonial must be verified prior to the advertisement occurring as to the use of the goods and the claims made by the person. It must also be typical of the results which can be expected from using the goods in accordance with the directions for use or intended purpose of the goods.

Disclosures about the testimonial are required in following circumstances:

- where the person providing the testimonial has received any valuable consideration
- where another person takes the place of the person who provided the testimonial
- where the person who provided the testimonial is related to or associated with an individual involved in the production, sale or supply of the goods

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.

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

The gold standard for verification of a testimonial is a statutory declaration. A statutory declaration in relation to a testimonial should be made (and therefore dated) before the advertisement featuring the testimonial.

Where a testimonial, as made, does not comply with the Code, it should not be used. Care should be taken if truncating, altering or paraphrasing a testimonial in an advertisement to ensure that it is not misleading. If the original testimonial has been truncated, altered or paraphrased in the advertisement this must be documented.

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

Advertisers are responsible for ensuring the compliance of any testimonials that are publically posted to by third parties to Facebook, Twitter, Instagram or any other social media accounts where the advertiser has control of the content. Non-compliant testimonials must be removed.



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

Pharmacy assistants and retail salespeople (e.g. 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 to be included in pharmacy or other retail content directed to pharmacy assistants and other retail salespeople needs to comply with the Act and Code. This is intended to recognise the pre-eminent responsibility of specified health professionals for the actions and conduct of their staff and to prevent the intrusion of other commercial parties into that relationship.

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

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

## 19 Advertising to children

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

Children are a particularly vulnerable population group in terms of advertising. 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 rightly made by the adult who looks after the interests of the child. It would therefore not be ethical or socially responsible to target children in advertisements for therapeutic goods. There are exceptions in relation to specific 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 for use in children, including to differentiate children's dosage forms from adult preparations.

## 20 Samples

Where it is possible under this provision to include an offer of a sample in advertising, advertisers should note that other advertising provisions may still apply to such offers.

Advertisers should be aware that a sample itself, or the giving of a sample, could be an advertisement that would also need to comply with the Code. (However, this would not capture samples provided by health professionals to patients as part of a course of treatment.)

## 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 an investment by the Government to improve public health and safety and 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.

The Government's priorities in public health messaging change and may be adapted, depending on trends, 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.

It is recommended that you update yourself on a regular basis on new public health campaigns so that you can identify any existing advertising that may be inconsistent with new campaigns. When preparing new advertising, you should specifically consider it in the context of public health campaigns.

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

- The 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

Examples of advertising that would be considered inconsistent with public health campaigns include advertising:

- for a hangover relief product that encourages excessive alcohol intake (e.g. get rid of that hangover so you can go out again tonight and do it all again...) is contrary to government campaigns to reduce excessive alcohol consumption
- for a therapeutic good that claims 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. However, it is important that the Code reflects the principle that advertising for therapeutic goods not trivialise or conflict with public health messages.

## Part 3 - Rules 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 (which come into force on 1 December 2018)

These documents are exempted from these Code requirements as other legislation and regulation requires the inclusion of such information.

### 23 Complementary medicines

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

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

Paradigms include, but are not limited to:

- traditional Chinese medicine
- Ayurvedic medicine
- western herbal medicine

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

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

For further information, refer to the [Guidelines on the evidence required to support indications for listed complementary medicines](#).

## 24 Analgesics

Analgesic medicines can pose particular risks to consumers. As such, analgesic advertisements 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 use of 'analgesics' have caused in the past.

## 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. In addition, advertisers should also be aware that of the requirements relating to vitamins in Schedule 2 of *Therapeutic Goods Regulations 1990*.

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 Weight Management

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

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

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

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

Advertisers should also consider guidance from the TGA<sup>4</sup> and NHMRC in relation to weight loss products and what can constitute typical results.

## 27 Sunscreens

Consistent with the requirement that advertising of therapeutic goods must not be undermine public health messaging, there are special requirements around the advertising of sunscreens 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,

---

<sup>4</sup> 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](#).

consumers are aware that sunscreen use is only one element of sun protection and other protections (like a hat, shirt, sunglasses and the use of shade) are necessary, as is the regular re-application of sunscreen.

This approach is also consistent with the permitted indications for sunscreens, which 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 provides a definition for the forms of diseases, conditions ailments or defects which are considered to be serious forms, through a series of criteria. Representations that refer to a serious form of a disease, condition, ailment or defect are restricted representations (see 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 (e.g. 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 (e.g. 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 (e.g. 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’**

| <b>Condition</b> | <b>s. 28(1)(a) - medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional</b>   | <b>s. 28(1)(a) - exclusion for forms that have been medically diagnosed and medically accepted as being suitable for self-treatment and management</b> | <b>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</b> | <b>Restricted representation status</b>  |
|------------------|--|--|--|--|
| Arthritis        | Arthritis is an umbrella term that 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’.<br><br>As such, 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’.<br><br>As such, representations in advertising that include references to ‘mild arthritis’ are not restricted representations, as long as the mild nature is not contradicted by images, |

| 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   |
|--------------------------------|---|---|---|--|
|                                |   |   |   | testimonials or any other aspect of the advertising.   |
| Autism spectrum disorder (ASD) | Clinically accepted that an experienced paediatrician or a child psychiatrist should confirm the diagnosis <sup>5</sup>                   | Management may involve prescription psychotropic medicines (if warranted). Allied health professionals may also be needed.                      | Not applicable  | ASD meets the definition of 'serious'.<br><br>Therefore, representations in advertising that include references to ASD are restricted representations. |
| Cystic fibrosis (CF)           |   | 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. <sup>1</sup>   | CF meets the definition of 'serious'.<br><br>As such, representations in advertising that include references to CF are restricted                      |

<sup>5</sup> eTG complete accessed 12 July 2018



| 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   |
|--------------------------------|--|---|---|--|
|                                |  |   |   | representations.   |
| Headlice                       | It's 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'.<br><br>Therefore, representations in advertising that include references to headlice are not restricted representations.                         |
| Irritable bowel syndrome (IBS) | Clinically accepted to require medical diagnosis to rule out serious conditions like malignancy, inflammatory bowel disease and Coeliac disease <sup>6</sup> | There are no long-term sequelae from IBS without medical treatment and it can be self- managed.   |   | While people can self-manage IBS following diagnosis to attempt to manage symptoms that have not been definitively diagnosed as IBS puts the consumer at risk. For that reason, representations that |

<sup>6</sup> Lucak, S. (2004). Diagnosing Irritable Bowel Syndrome: What's Too Much, What's Enough? Medscape General Medicine, 6(1), 17.

| 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  |
|--|--|---|---|---|
|  |  |   |   | 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 <sup>7</sup> | 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’.<br><br>However, it must qualified as medically diagnosed in advertising, as medical diagnosis is required to rule out serious forms of diseases which would require medical treatment. |

<sup>7</sup> Lucak, S. (2004). Diagnosing Irritable Bowel Syndrome: What’s Too Much, What’s Enough? Medscape General Medicine, 6(1), 17.

## 29 Restricted representations - public interest criteria

Section 42DF of the Act requires that the Secretary (or delegate) take into consideration the public interest criteria set out in the *Therapeutic Goods Advertising Code 2018* 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
- be likely to result in consumers not seeking medical advice at an appropriate time
- be likely to have a negative impact on public health

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

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

An application for approval to use restricted representations should include a statement from the applicant setting out how the public interest criteria apply to their advertisement and goods. See [Application for approval to use a restricted representation in advertising](#) for more information.

## 30 Prohibited representations

Section 42D of the Act and subregulation 6B(1) of the Regulations enable the Code to specify which representations are prohibited representations. The Code states that representations relating to the treatment, cure, prevention, 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 may authorise the use of a prohibited representation under section 42DK of the Act where it is necessary for either:

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

In addition, you 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 - 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 1 of the Code replaces the Price Information Code of Practice 2006.

### 2 Application

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

#### Provision of price information for Highly Specialised Drugs

These medicines are supplied through specific arrangements for special needs access or specialised drugs.

Price information cannot be provided for medicines listed on the Pharmaceutical Benefits Scheme 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<sup>8</sup>. 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.

---

<sup>8</sup> A dispensing doctor is a medical practitioner approved under section 92 of the *National Health Act 1953*.

## 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 Australian Regulatory Guidelines for Advertising Therapeutic Goods.

## 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 1.

### 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 (e.g. 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 objectives 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 italicized
- 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:

- prices current as at 1 March 2018
- prices expire 30 August 2018

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

Examples of presentations prohibited by this section include:

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

### **6(2)(h) Use of embellishments**

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

### **6(2)(i) Other information**

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

Examples of arrangements prohibited by this provision:

- a pharmacy catalogue with a price list on one page, which includes various strengths and brands of metformin, 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 – i.e. where prices are identified through a search function included in an electronic sales system (e.g. 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. Both label standards and the Poisons Standard can be accessed at [www.legislation.gov.au](http://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 Pharmaceutical Benefits Scheme 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 Pharmaceutical Benefits Scheme 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 Pharmaceutical Benefits Scheme subsidised medicine must include an indication that the price is subsidised by the Australian Government, and only applies when prescribed for the medical conditions listed in the Pharmaceutical Benefits Scheme Schedule for that medicine. Note however, that the actual condition must not be mentioned.

# Schedule 2 - Advertising to children

## 1 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 children's magazines and television shows, must not include advertisements for therapeutic goods.

See also [section 19 – Advertising to children](#).

## **Schedule 3 - Samples**

### **1 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

See also [section 20 – Samples](#).

Historical consultation document

## Attachment A - Definitions



These definitions are current as at 1 July 2018. We encourage you to 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 Code, the relevant normal meaning, as derived from the current edition of the Macquarie Dictionary, will apply.

| Term               | Definition  | Source  |
|--------------------|---|---|
| Act                | the <i>Therapeutic Goods Act 1989</i>   | <i>Therapeutic Goods Advertising Code 2018</i>  |
| Active ingredients | means a therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action  | <i>Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines</i> |
| Analgesic          | a medicine for internal use, containing one or more of the following substances intended for the relief of aches and pains:<br>(a) salicylic acid, its salts, its derivatives (including aspirin) and their salts;<br>(b) other non-steroidal anti-inflammatory drugs;<br>(c) paracetamol;<br>not including such a medicine where:<br>(d) the condition for which it is designed is a self-limiting condition; and<br>(e) the substances mentioned in paragraphs (a)-(c) are combined with one or more other active ingredients; and<br>(f) the other ingredients have been included in the medicine for indications other than the relief of aches and pains | <i>Therapeutic Goods Advertising Code 2018</i>  |
| 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:<br>(a) is on the label of the goods; or<br>(b) is on the package in which the goods are contained; or<br>(c) is on any material included with the package in which the  | Subsection 3(1) of the Act  |

| Term                   | Definition  | Source   |
|------------------------|---|--|
|                        | goods are contained   |  |
| Approval number        | means the distinguishing number allocated to an approved advertisement by the Secretary under regulation 5J of the Therapeutic Goods Regulations  | Section 42B of the Act                                   |
| Approval number        | a distinguishing number given to each approved advertisement  | Regulation 5J, <i>Therapeutic Goods Regulations 1990</i> |
| Approved advertisement | means an advertisement:<br>(a) approved under regulation 5G, or taken to be approved by the Secretary under subregulation 5H(2), or approved by the Minister on review under regulation 5M, of the Therapeutic Goods Regulations; and<br>(b) the approval of which has not been withdrawn   | Section 42B of the Act                                   |
| Bench-mark price brand | in relation to a multi branded medicine, means the lowest priced product within the group of medicines that are listed on the Pharmaceutical Benefits Scheme as brands of the same medicine   | <i>Therapeutic Goods Advertising Code 2018</i>           |
| 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 Register) who undertakes, as a business activity in its own right:<br>(a) the broadcasting of the advertisement in broadcast media; or<br>(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   | <i>Therapeutic Goods Advertising Code</i>                |
| 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                          |
| Directions for         | in relation to therapeutic goods, includes information on:  | Subsection 3(1) of the                                   |

| Term                      | Definition  | Source                                    |
|---------------------------|---|---|
| use                       | (a) appropriate doses of the goods; and<br>(b) the method of administration or use of the goods; and<br>(c) the frequency and duration of treatment for each indication of the goods; and<br>(d) the use of the goods by persons of particular ages or by persons having particular medical conditions  | Act                                       |
| Dispensing doctor         | means a medical practitioner approved under section 92 of the <i>National Health Act 1953</i>   | <i>Therapeutic Goods Advertising Code</i> |
| Displayed or communicated | in relation to a statement in an advertisement, means:<br>(a) in the case of a visual statement—standing out so as to be easily read from a reasonable viewing distance; and<br>(b) in the case of a spoken statement—able to be clearly heard and understood   | <i>Therapeutic Goods Advertising Code</i> |
| 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:<br>(a) an advertisement about the goods; or<br>(b) generic information included in an advertisement about the goods; or<br>(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:<br>(a) Aboriginal and Torres Strait Islander health practice;<br>(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);<br>(c) medical;<br>(d) medical radiation practice;<br>(e) nursing;<br>(f) midwifery;<br>(g) occupational therapy;<br>(h) optometry;<br>(i) pharmacy;<br>(j) physiotherapy;<br>(k) podiatry;<br>(l) psychology | Subsection 3(1) of the Act                |
| Health professional       | The kinds of 'health professionals' covered by section 42AA of the Act include: <ul style="list-style-type: none"> <li>• medical practitioners</li> </ul>   | <i>Therapeutic Goods Advertising Code</i> |

| Term                     | Definition   | Source  |
|--------------------------|--|---|
|                          | <ul style="list-style-type: none"> <li>• psychologists</li> <li>• pharmacists</li> <li>• optometrists</li> <li>• chiropractors</li> <li>• physiotherapists</li> <li>• nurses and midwives</li> <li>• dentists, dental hygienists, dental prosthetists, and dental therapists</li> <li>• osteopaths</li> <li>• the following practitioners, provided they are registered under a law of a State or Territory: <ul style="list-style-type: none"> <li>– herbalists</li> <li>– homoeopathic practitioners</li> <li>– naturopaths</li> <li>– nutritionists</li> <li>– practitioners of traditional Chinese medicine</li> <li>– podiatrists</li> </ul> </li> <li>• a person who is a member of an Australian branch of one of the bodies prescribed in Schedule 1 of the <i>Therapeutic Goods Regulations 1990</i></li> </ul> | <p><i>Code</i></p> <p>Section 42AA of the Act</p> |
| Health warning           | <p>health warning, in relation to therapeutic goods, means a statement that is required on the label or instructions for use that warns that a person who takes or uses the goods may:</p> <p>(a) die; or</p> <p>(b) require hospitalisation or a longer period of hospitalisation than would be required if the person had not taken or used the goods; or</p> <p>(c) require a medical practitioner to treat or prevent any of the following as a consequence of taking or using the goods:</p> <ul style="list-style-type: none"> <li>(i) injury</li> <li>(ii) disability</li> <li>(iii) incapacity</li> <li>(iv) impairment of any bodily function, organ or structure</li> </ul>  | <p><i>Therapeutic Goods Advertising Code</i></p>  |
| Included in the Register | <p>(a) in relation to a biological—means included in the Register under Part 3-2A of the Act; and</p>  | <p>Subsection 3(1) of the</p>                     |

| Term             | Definition  | Source                                    |
|------------------|---|---|
|                  | (b) in relation to a medical device to which Chapter 4 applies—means included in the Register under Chapter 4 of the Act  | Act                                       |
| Indications      | in relation to therapeutic goods, means the specific therapeutic uses of the goods  | Subsection 3(1) of the Act                |
| Ingredients      | (a) active ingredients; and<br>(b) substances or groups of substances that are required to be on the label of the medicine under paragraph 8(1)(j) of the <i>Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines</i>   | <i>Therapeutic Goods Advertising Code</i> |
| Label            | in relation to therapeutic goods, means a display of printed information:<br>(a) on or attached to the goods; or<br>(b) on or attached to a container or primary pack in which the goods are supplied; or<br>(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                    |
| 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:<br>(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;<br>(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;<br>(iii) investigation, replacement or modification of the anatomy or of a physiological process;<br>(iv) control of conception;<br>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<br>(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or<br>(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<br>(b) an accessory to an instrument, apparatus, | Subsection 41BD(1) of the Act             |

| Term                         | Definition  | Source  |
|------------------------------|---|---|
|                              | appliance, material or other article covered by paragraph (a), (aa) or (ab)   |   |
| Medical Devices Regulation   | means the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>   | <i>Therapeutic Goods Advertising Code</i>   |
| Medicine                     | means:<br>(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<br>(b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of <b>therapeutic device</b> , not to be therapeutic devices   | Subsection 3(1) of the Act  |
| Other therapeutic goods      | therapeutic goods that are not medicines, biologicals or medical devices  | <i>Therapeutic Goods Advertising Code</i>   |
| Patient information leaflets | In relation to an implantable device, means:<br>(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<br>(2) The leaflet must include the following information:<br>(a) information identifying the device, or the kind of device<br>(b) the intended purpose of the device<br>(c) information explaining how to use the device safely<br>(d) other information about the device as specified in Clause 13A.3 that the manufacturer considers would be useful for patients<br>(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   | <i>Therapeutic Goods Advertising Code</i>   |
| 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   | Subsection 3(1) of the  |

| Term                                  | Definition  | Source                                    |
|---------------------------------------|---|---|
|                                       | goods and any advertising or other informational material associated with the goods   | Act                                       |
| Price information                     | information about:<br>(a) the total purchase price of medicines that is to be paid by consumers of those medicines; and<br>(b) in relation to medicines that are listed on the Pharmaceutical Benefits Scheme (or Repatriation Pharmaceutical Benefits Scheme), the price paid by the consumer when the prescription is dispensed   | <i>Therapeutic Goods Advertising Code</i> |
| 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)<br><br>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:<br>(a) having the same prominence as the most noticeable representations or statements in the advertisement; and<br>(b) in the case of a visual statement—standing out so as to be easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; and<br>(c) in the case of a spoken statement—able to be clearly heard and understood; and<br>(d) in the case of a visual advertisement not designed to be viewed all at once—repeated as often as is necessary to ensure that is likely to be seen by a viewer | <i>Therapeutic Goods Advertising Code</i> |
| Public health campaign                | a campaign about a public health matter that is conducted, approved or funded by:<br>(a) the Commonwealth; or<br>(b) a State or Territory; or<br>(c) a Commonwealth, State or Territory statutory authority   | <i>Therapeutic Goods Advertising Code</i> |
| 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 Register) who undertakes, as a business activity in its own right:<br>(a) the publishing of the advertisement in specified media other than broadcast media; or  | Section 42B of the Act                    |



| Term                      | Definition  | Source                                    |
|---------------------------|---|---|
|                           | (b) the placement of the advertisement for such publication   |   |
| 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<br><br>Also referred to as the 'ARTG'.  | Subsection 3(1) of the Act                |
| Regulations               | the <i>Therapeutic Goods Regulations 1990</i>   | <i>Therapeutic Goods Advertising Code</i> |
| 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:<br>(a) mainstream media; or<br>(b) broadcast media; or<br>(c) cinematograph films; or<br>(d) displays about goods, including posters:<br>(i) in shopping malls (except inside an individual shop); and<br>(ii) in or on public transport; and<br>(i) on billboards   | Section 42B of the Act                    |
| Sponsor                   | in relation to therapeutic goods, means:<br>(a) a person who exports, or arranges the exportation of, the goods from Australia; or<br>(b) a person who imports, or arranges the importation of, the goods into Australia; or<br>(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);<br>but does not include a person who:<br>(d) exports, imports or manufactures the goods; or<br>(e) arranges the exportation, importation or manufacture of the goods;<br>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  | Subsection                                |

| Term              | Definition  | Source                     |
|-------------------|---|----------------------------|
|                   | Territory   | 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            | <p>includes:</p> <ul style="list-style-type: none"> <li>(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and</li> <li>(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and</li> <li>(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and</li> <li>(d) supply by way of administration to, or application in the treatment of, a person</li> </ul>   | Subsection 3(1) of the Act |
| Therapeutic goods | <p>means goods:</p> <ul style="list-style-type: none"> <li>(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: <ul style="list-style-type: none"> <li>(i) for therapeutic use, or</li> <li>(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or</li> <li>(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or</li> </ul> </li> <li>(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: <ul style="list-style-type: none"> <li>(c) goods declared not to be therapeutic goods under an order in force under section 7; or</li> <li>(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</li> <li>(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 <i>Food Standards Australia New Zealand Act 1991</i>); or</li> <li>(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</li> </ul> </li> </ul> | Subsection 3(1) of the Act |

| Term                 | Definition  | Source                                    |
|----------------------|---|---|
|                      | <p>for humans in the form in which they are presented; or</p> <p>(g) goods covered by a determination under subsection 7AA(1) (excluded goods); or</p> <p>(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</p>   |   |
| Therapeutic use      | <p>means use in or in connection with:</p> <p>(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or</p> <p>(b) influencing, inhibiting or modifying a physiological process in persons; or</p> <p>(c) testing the susceptibility of persons to a disease or ailment; or</p> <p>(d) influencing, controlling or preventing conception in persons; or</p> <p>(e) testing for pregnancy in persons; or</p> <p>(f) the replacement or modification of parts of the anatomy in persons</p>                   | Subsection 3(1) of the Act                |
| Total purchase price | <p>in relation to therapeutic goods, means the total cost of the goods to a consumer, including:</p> <p>(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</p> <p>(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</p> | <i>Therapeutic Goods Advertising Code</i> |
| Traditional use      | <p>for a designated active ingredient, means use of the designated active ingredient that:</p> <p>(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</p> <p>(b) accords with well established procedures of preparation, application and dosage</p>   | <i>Therapeutic Goods Regulations 1990</i> |

# Attachment B – Other guidance on the application of the Code

## Prominence of mandatory information

### Prominently displayed or communicated

#### What needs to be ‘prominently displayed or communicated’

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

- warnings regarding persistence or worsening of symptoms and the need to consult a healthcare professional
- for advertising of goods that will not be available for physical examination before purchase for which health warnings exist, warnings alerting the viewer that the good may not be suitable for them
- statements required for the advertising of Schedule 3 medicines and analgesics
- the appropriate use of sunscreens



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

The ‘prominently displayed and communicated’ requirement has been restricted to a small number of provisions where this information is critical from a public health and safety perspective. All other statements need only be displayed or communicated so as not to dilute the impact of those statements which are required to be prominently displayed and communicated.

### Practical application

Advertisements often contain several ‘messages’ or claims and there is usually at least one claim that is the ‘major claim’ with other claims being ‘secondary claims’ which tend to be displayed or communicated less prominently than the major claim(s).

For information to satisfy the requirement of being ‘prominently displayed or communicated’ the information must have at least the same prominence as the major claim (i.e. the most prominent claim) to ensure the required information makes an impression in the mind of viewers that is at least equal to the impression made by the major claim.

How this is achieved may depend on the reasonable consumer to whom the advertisement is directed – for example, an advertisement directed to people with eyesight difficulties may require special consideration to ensure the message is received in its entirety.

To satisfy the requirement to be ‘prominently displayed or communicated’, visual statements, may need to be provided in a similar font (including colour, contrast, size etc.) to that used for the name of the therapeutic goods advertised.

To satisfy the requirement to be ‘prominently displayed or communicated’ in online advertising including social media, mobile phone apps and e-mails:

- the information needs to be available in the same locale as the advertising content (i.e. the viewer must be able to view it without having to scroll or click through to a separate tab or page)
- a pop-up may provide such information to consumers (provided that it cannot be disabled)

For spoken statements, this may require:

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

Ensuring that such information 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. Therefore, for a website and a printed brochure, in order to meet the ‘prominently displayed’ requirement, mandatory information would need to appear on each webpage and each printed page respectively.

Noting that not all advertisements for therapeutic goods require information to be prominently displayed or communicated, if the advertisement must display certain information in this way, advertisers should ensure that they choose advertising mediums that provide sufficient scope to meet the requirement to [prominently display or communicate](#) the required information for advertisements for therapeutic goods. (A fact sheet on ‘Prominently displayed or communicated’ is currently under development.)

## Reason for requirement

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

- identify where a particular therapeutic good may not be suitable for them and/or
- ensure they monitor symptoms and seek medical attention when needed
- be provided with the information to assist them in the safe and responsible use of the therapeutic goods advertised

The requirement for information to be “prominently displayed or communicated” (i.e. to be of equal or greater prominence than the most prominent statement, claim or representation in an advertisement) is to ensure important consumer health and safety information about the advertised therapeutic good is easily seen and captures the attention of the audience.

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

## Displayed or communicated

For statements made in an advertisement to satisfy the requirement to be 'displayed or communicated' they must reasonably be expected to be able to be read or heard:

- for visual statements a 'reasonable viewing distance' is the distance from which the consumer would be expected to be visualising the information. This distance would be very different for an advertisement in a magazine and an advertisement on a billboard on the side of a road
- for spoken statements the volume, accent and pace of the delivery of the message must be such that one could reasonably expect the consumer would hear the information

## Legible

Some mandatory information is only required to be legible within the advertisement. For example, the approval number.

## Promotion of goods for use by specific populations

Where you promote a good as being for use in specific populations (e.g. 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 or 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"

Further information about generic information is in section 42DN of the Act. Section 42DP of the Act requires generic information to comply with certain sections of the Code, as defined in Regulation 8<sup>9</sup>.

(Further information on the differences between advertising, generic information and other activities is currently under development.)

## Unbranded advertising

Branded advertising is where the company or brand associated with the therapeutic good being advertised is identifiable in the advertisement and is the most common type of therapeutic good advertising. Unbranded advertising, while it does not link the therapeutic goods (including therapeutic ingredients) being advertised with a specific company, it is considered advertising and is subject to the requirements of the Act and the Code. Care is needed to ensure unbranded advertising does not contravene the Code, including section 11, which requires a reference to the name of the therapeutic good. Unbranded advertising is not considered generic information as it is promotional.

Unbranded advertising, while it shares some characteristics of information properly classified as 'disease state awareness' (DSA) information (or disease education activities), which generally seeks to raise awareness about diseases and health issues, there is a key difference. In DSA disease awareness information, it is not possible for the consumer to identify, from the published or broadcast material, a therapeutic good (including a therapeutic ingredient) and is therefore not considered advertising. DSA campaigns focus on raising awareness about particular diseases with the aim of encouraging consumers to talk to their doctor.

## 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.

Some limited exceptions apply to this advertising prohibition, including an exception for those Schedule 3 substances listed in Appendix H to the current Poisons Standard, which 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. Therapeutic goods containing Pharmacist-Only substances that have been listed in Appendix H of the Poisons Standard can also be advertised to consumers, subject to the same exclusions and requirements.

---

<sup>9</sup> In the transition from the 2015 Code to the 2018 version, the numbering of the Code sections has changed. This will require a further change to Regulation 8.

Advertisements for complementary medicines or over-the-counter (OTC) medicines that are to appear in specified media ordinarily require pre-approval before broadcasting or publication. However, price advertising for these medicines that is to appear in specified media does not require pre-approval, provided that the advertisement contains no more than the following information:

- the brand name and/or picture of the medicine and which does not include any therapeutic claim
- the price of the medicine and/or
- the place and time(s) of sale

However, 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 (e.g. 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 Australian Register of Therapeutic Goods for that medicine (i.e. “off-label” use).

## Natural claims

### Therapeutic goods cannot be promoted as entirely natural

The words “natural”, “all natural”, “100% natural” and similar terms, when used in the advertising of a therapeutic good, would be interpreted by a reasonable consumer to mean that the entire good is ‘natural’ and does not contain any synthetic or man-made substances. At its core, the use of the term ‘natural’ implies that the good is taken from nature and has not been through any processing by humans.

All therapeutic goods undergo at least some form of processing, no matter how minimal, and therefore would not meet the above understanding of the term ‘natural’. Given this, a claim stating or implying that the good is natural in its entirety would be considered misleading and, therefore must not be used in the advertising of therapeutic goods.

The reasons for these requirements are:

- comparative issues – It is likely that a reasonable consumer may form a preference for a therapeutic good that claims it is ‘natural’ over a comparable good for which the same claim is not made. This has the potential to be misleading as the differences in the source of the ingredients in the two products are likely to be minimal
- implied claims about safety – A reasonable consumer would likely interpret a ‘natural’ product to be safer than a product that does not make this claim. There is a general (mis)perception by consumers that ‘natural’ equates to safe. All therapeutic products, whether they have natural or synthetic origins, can have side effects
- misleadingness – As stated above, use of the term ‘natural’ is likely to imply to a reasonable consumer that the entirety of the therapeutic good has been sourced naturally. This is highly unlikely to be the case, especially in the case of tableted or complex formulations



which generally include synthetic ingredients. Further, as also noted above, all therapeutic goods require at least minimal processing before being available to consumers

## Claims about natural and naturally derived ingredients

Claims that one or several ingredients in a therapeutic good are [“natural”](#) or [“naturally derived”](#) are permissible, as long as it is clear to which ingredient(s) the claim applies and the proportion of the product made up by that ingredient.

For example, a topical cream which contains 2% grapefruit seed extract with the rest of the ingredients being synthetic could be advertised as containing 2% naturally derived grapefruit seed extract. Note that both the percentage amount of the naturally sourced ingredient and the name of the ingredient is disclosed.

If you choose to advertise your therapeutic good as containing natural or naturally derived ingredients, you will need to hold appropriate evidence to substantiate the claim. This evidence will include sources of ingredients and information about manufacturing processes.

You should exercise caution if claiming that an excipient is ‘natural’ or ‘naturally derived’ as consumers may incorrectly assume that the ingredient has an active role in providing the therapeutic effect. In such cases, you should also identify the role of the ingredient e.g. “1% natural saffron for colouring”.

## Definitions - natural vs naturally derived

*Natural Ingredient:* A substance (ingredient) obtained from a natural source material and which is in a form found in nature. The ingredient must have only undergone very minimal processing, e.g. drying, grinding, powdering, chopping, encapsulating. Example: encapsulated powdered tumeric.

*Naturally derived Ingredient:* A substance (ingredient) which is found in nature and obtained via the extraction, isolation and/or processing of plant, algal, fungal, bacterial, or animal materials, or minerals. Processing of the ingredient may involve steps such as boiling and steaming. The ingredient is required to have the same chemical identity as that of the source material. Ingredients are considered synthetic, i.e., not from a natural source, if they undergo any form of chemical modification including being transformed into derivative or salt form of the initial substance.

[Health Canada](#) provides a useful example using the various forms of Vitamin E.

Many of the considerations above are also relevant to ‘organic’ claims.

## Organic claims

Claims about a therapeutic good, or one or more of its components, being organic are only permissible where organic certification is available for the good, or the component of the good that is claimed to be organic, from a body authorised by the Commonwealth Department of Agriculture and Water Resources<sup>10</sup>.

Advertising must clearly identify the component(s) that are certified and the proportion of the good made up by that ingredient. Like natural claims, it may also be necessary to identify the role of the organic ingredient/s to ensure the advertising does not mislead.

<sup>10</sup> See [Department of Agriculture Organic Approved Certifying Organisations](#) list

## Puffery

Puffery is defined by the Macquarie Dictionary as the “act of praising unduly” or “exaggerated commendation”. However, for the purposes of therapeutic goods advertising, this definition requires refining and the Australian Competition and Consumer Commission relevantly [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.

There are numerous cases in Australia and internationally that have grappled with puffery. Puffery is generally characterised by:

- a lack of specificity in the statement
- the use of subjective claims
- the absence of “...a definitive statement as to a characteristic or consequence of the claim...”
- an inability to prove the statement to be correct or incorrect

In order for a statement in advertising to be considered puffery, it would need to be extremely exaggerated. Marginally exaggerated claims would not be considered puffery, especially through the eyes of a reasonable consumer with health literacy issues and other vulnerabilities who may be more inclined to take such claims at face value.

Whether a part of an advertisement can be considered puffery needs to be considered through the eyes of the [reasonable person to whom the advertising is directed](#). The statement purported to be puffery also needs to be considered in the context of the entire advertisement as it may contain information that alters the viewer’s perception and interpretation of the statement.

In addition, consideration should be given to whether a statement can be proven or disproven. For example, a claim that a vitamin C chewable tablet is “the tastiest in the universe” clearly could not be proven or disproven. However, a claim that the same tablet was “rated number 1 as the tastiest chewable supplement in Australia by Readers’ Digest readers” could be. As such, the latter would not be considered puffery. It should also be considered whether puffery has a place in ethical and responsible advertising of therapeutic goods to consumers. If you are unsure whether a particular statement that you consider puffery will be seen in the same way by the public and that it might therefore mislead the public, you should remove the statement.

## Version history

| Version | Description of change   | Author                      | Effective date |
|---------|---|-----------------------------|----------------|
| V1.0    | Original publication – draft for consultation   | Advertising Compliance Unit | 29 March 2018  |
| V1.1    | Incorporates changes following public consultation<br><br>Some information has been relocated to the Australian Regulatory Guidelines for Advertising Therapeutic Goods | Advertising Compliance Unit | August 2018    |

Historical consultation document

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605  
<https://www.tga.gov.au>

Reference/Publication #D18-10839132