Australian Government
Department of Health
Therapeutic Goods Administration

Advertising guidance for providers of disease education activities

Complying with therapeutic goods advertising restrictions

Version 1.0, October 2019

TGA Health Safety Regulation

Contents

About this guidance

The Therapeutic Goods Administration (TGA) recognise that sponsors and other information providers may wish to provide information and increase public awareness about health conditions and their management (**disease education activities**). These activities can be a valuable source of information for Australian consumers as they raise awareness about diseases, aid recognition of symptoms and encourage consumers to seek appropriate advice if necessary.

This guidance is to assist providers of disease education activities (including sponsors, health professionals, pharmacies, peak organisations and community educators) to ensure that disease education activities do not inadvertently become advertisements for therapeutic goods.

We accept it can sometimes be difficult for information providers to distinguish between material that may have the effect of promoting therapeutic goods and material that is merely providing disease information. However, it is important to be able to identify when material is advertising therapeutic goods, as that material would then be subject to the regulatory requirements set out in Australia's therapeutic goods legislation, including the prohibitions around advertising certain therapeutic goods to the public.

Additionally, we understand that sponsors and other information providers may wish to provide disease education information in conjunction with promotional (advertising) material. Fundamentally, the collective material is advertising and therefore must comply with the legislation, specifically the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code (No.2) 2018 (the Code). This guidance highlights the key advertising requirements.

The TGA is authorised to pursue sanctions and penalties against those who do not comply with the advertising and other applicable regulatory requirements for therapeutic goods.

If you are a member of the public and are interested in how therapeutic goods advertising is regulated or would like to make a complaint about an advertisement, please see the Advertising hub.

Disease education activities

Disease education activities can comprise a broad range of education methods delivered across varied settings, such as:

- campaigns
- seminars and webinars
- workshops, courses and other face-to-face education
- audio-visual education material
- online education resources including downloadable materials
- community-level resources such as flyers, posters, booklets etc.

Disease education activities often involve diseases or conditions that require diagnosis, monitoring, treatment or management by a health professional.

While a disease education activity may make reference to a **range** of treatment options, if the information provided is likely to encourage consumers to seek to obtain a particular good, or seek a prescription for a particular medicine, then it will be considered an advertisement.

Special care is required for disease education activities where there are limited treatment options, as the information may draw attention to one specific therapeutic good, whether that good is named or not.

Definition of advertising

The Act (section 3) defines **advertise** in relation to therapeutic goods to include:

- 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:
  - is on the label of the goods; or
  - is on the package in which the goods are contained; or
  - is on any material included with the package in which the goods are contained.

The intention referred to above is gauged not by what the person responsible for the content intends, but rather what the reasonable consumer views as being intended by the content. This means that if members of the public or health professionals would reasonably consider that the information promotes the use or supply of the identified goods, then the TGA would be likely to consider it an advertisement (see Activities that represent advertising).

This definition applies to all forms of media, including:

· traditional media (such as television, radio, print media and posters/displays)

· electronic media (such as websites, emails, blogs, discussion forums and social media)

Additionally, material presented to the public through other means (e.g. workshops and education sessions) may meet the definition of advertise, depending on the content of the material.

For additional information see the Advertising Hub: Advertising code and guidance and Why and how the advertising of therapeutic goods is regulated.

See the TGA glossary for definitions relevant to the regulation of therapeutic goods in Australia.

Why there are advertising restrictions

Therapeutic goods are intended to have a therapeutic effect and influence the health status of the people that use, or are considering using, them. Many of these people will be vulnerable because of the disease or condition that they are facing or because of a general concern about their health. This may impact on their ability to critically evaluate advertising (including labels) to assess whether a particular good is appropriate for them.

Therefore, the advertising of therapeutic goods is subject to special advertising requirements in order to protect consumers.

We have the authority to use various enforcement tools if your advertising does not comply with requirements.

Roles and responsibilities

Advertisers

Advertisers have obligations under the Act and the Code to ensure advertising material is compliant.

Providers of disease education

When preparing disease education activities (whether directed to the public or health professionals), you must ensure that the material is not advertising. If it is advertising, as an advertiser, you must consider the applicable regulatory requirements relating to advertising therapeutic goods. Criminal and civil penalties may apply if you do not meet these legal requirements.

Additionally, you may have advertising obligations under the *Competition and Consumer Act 2010*, as well as relevant State and Territory health or fair trading/consumer protection legislation.

The Communications Council has a useful list of advertising codes and regulations that apply in Australia.

TGA

Advertising for therapeutic goods is subject to the requirements of the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code (No.2) 2018 (the Code). The TGA is responsible for administering the Act and the Code.

The Act:

- prohibits certain types of therapeutic goods from being advertised to the public,
- requires advertising to comply with the Code, and
- provides for a range of compliance and enforcement tools that the TGA may employ to address non-compliant advertising.

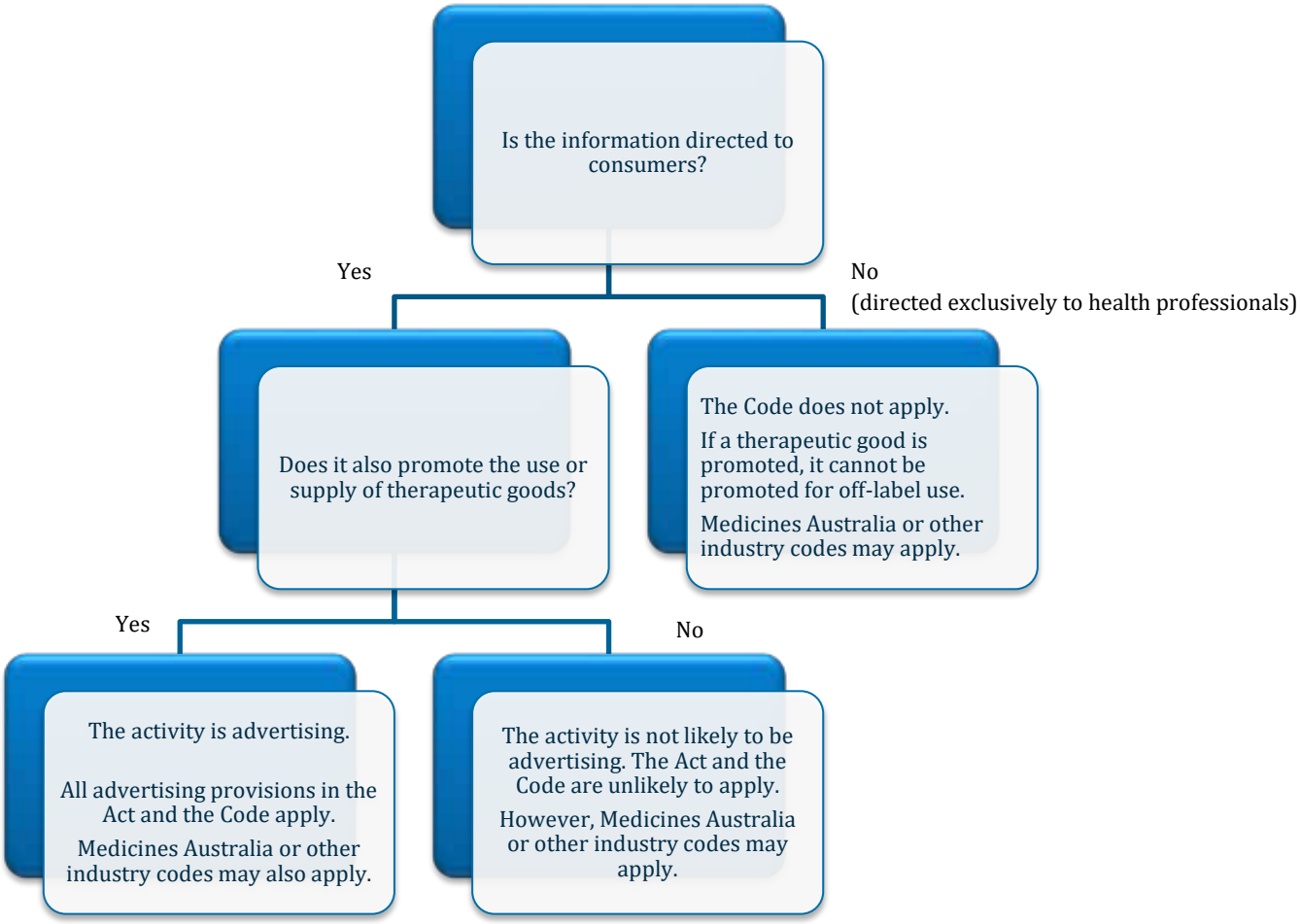
The Code ensures that the marketing and advertising of therapeutic goods is conducted in a responsible manner and promotes the quality use of therapeutic goods that does not mislead or deceive the public.

Medicines Australia Code of Conduct

When prescription medicines are registered in the Australian Register of Therapeutic Goods (ARTG), it is a condition of their registration that any promotional activities comply with the Medicines Australia (MA) Code of Conduct. The MA Code of Conduct includes requirements around the provision of disease education activities. Non-compliance with the MA Code of Conduct may have serious penalties under the Act.

Is it disease education or advertising?

The following diagram sets out key concepts to assist you to categorise information as either disease education or advertising, and identify if legislative or other requirements will apply. Note the legislative requirements for therapeutic goods advertising differ according to whether the advertising is directed to the general public or health professionals.



Activities that may constitute advertising

The following information is designed to assist you to understand what material may be considered advertising. If content is 'advertising', the advertising prohibitions and restrictions in the Act will apply.

Promotional activities and material are advertising

Factual statements about the treatments and therapies that do not promote the use or supply of therapeutic goods may not, depending on the context, amount to advertising.

However, if the information would draw a consumer's mind to a particular therapeutic good and encourage them to seek out that good, then it is likely the information would be considered promotional.

Particular attention is needed in this regard where there may be only one recognised treatment for the disease or condition concerned. You should also note that including testimonials that relate to a particular therapeutic good would make the information an advertisement.

The nature of the information provider

The nature and purpose of the organisation undertaking disease education activities may be a contributing factor to whether a reasonable consumer would consider the information provided to be advertising therapeutic goods.

Disease education activities of organisations with a commercial interest in the manufacture, sale or supply of therapeutic goods are more likely to be taken to be advertising therapeutic goods because of an actual or perceived inability of the organisation to provide unbiased, factual and non-promotional information. It is harder to decouple promotional intent from information when presented by a commercially motivated organisation.

Organisations with no commercial interest in therapeutic goods, but are established for the purpose of supporting disease awareness, such as peak bodies, may more easily be able to provide educational material as they do not derive a profit from therapeutic goods.

Testimonials and additional information

If material, which on face value appears to be disease education, provides links to additional resources or alternate information (including testimonials or endorsements) which would have the effect of promoting particular therapeutic goods, then the originating material would be considered to be advertising.

Patient support groups

The TGA encourages the provision of accurate and balanced information to support patients in the use of therapeutic goods. Patient support groups can be useful sources of information for their members.

Members of patient support groups are members of the public and the prohibitions on advertising certain therapeutic goods apply.

Disease education activities provided to patient support groups should **not** actively encourage people to seek a particular therapeutic good. For serious health conditions, the decision to use a particular therapeutic good is a decision that is most appropriately made in conjunction with a treating health professional.

Particular attention is needed to open platforms such as social media with easy, broad access and can be viewed by any member of the public. These online platforms are not immune from advertising requirements.

General requirements and prohibitions when advertising therapeutic goods

If you are providing disease education activities that also promote therapeutic goods, the TGA considers it to be an advertisement. In such cases, you need to consider the requirements that are applicable to all advertising of therapeutic goods.

The following information sets out some of the key advertising requirements and prohibitions. However, it is not an exhaustive list and the onus is on the advertiser to ensure full compliance with all applicable requirements.

You **cannot** advertise the following to the public:

- indications or uses that are not consistent with those indications or uses that have been accepted in relation to the product's inclusion in the ARTG (section 22, 32BJ and 41ML of the Act). (Note this requirement also applies to advertising to health professionals.)
- substances, or goods containing substances, in Schedules 3, 4 or 8 of the current Poisons Standard but not in in Appendix H of the current Poisons Standard (i.e. **restricted scheduled substances**)[1],
- biologicals[2], or
- therapeutic goods that are not in the ARTG and are not the subject of an exemption, approval or authority under the Act or the *Therapeutic Goods Regulations 1990*[3],
- medical devices and/or in-vitro diagnostic devices to the public that are in-house in-vitro diagnostics or contain restricted scheduled substances.

In addition, advertising must not:

- use a prohibited representation (unless permitted by the TGA). A prohibited representation is a representation in an advertisement about therapeutic goods that refers to abortifacient action or the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to:
  - neoplastic disease
  - sexually transmitted diseases
  - human immunodeficiency virus and acquired immune deficiency syndrome (HIV AIDS)
  - hepatitis C virus (HCV)
  - mental illness
- use Restricted representations (without prior approval or permission from the TGA). A restricted representation is a representation that refers to serious forms of diseases, conditions, ailments or defects (e.g. diabetes, asthma),
- advertise medicines (on television or in radio, newspapers, consumer magazines, billboards and cinema films) to the public without prior approval
  - see section 42C of the Act and Part 2 Division 2 of the Regulations.

[1] Subsection 42DL(10) of the Act.
[2] Subsection 42DL(11) of the Act.
[3] Subsection 42DL(12) of the Act.

In addition, to reduce the likelihood that advertising would breach the therapeutic goods legislation, advertisers should ensure that the material is:

- Ü accurate
- Ü truthful
- Ü balanced
- Ü reflective of current evidence
- Ü able to be substantiated
- Ü compliant with the Act and Code

Generally, it should not:

- Û contain misleading or unverifiable statements
- Û be likely to induce medically unjustifiable use of the therapeutic good
- Û be likely to give rise to undue risks

Please see the Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG) for more information.

Disease education activities that also promote services

Where an advertiser is seeking to promote a service to the public that involves one or more prescription medicines, the advertising should focus on the services provided without inadvertently promoting the use or supply of a therapeutic good, including restricted scheduled substances or a therapeutic good that contains such substances. Implied references, for example trade names of therapeutic goods containing a restricted scheduled substance or the ingredient name of a restricted scheduled substance (e.g. abbreviations, acronyms), are also unlawful in advertising.

For further guidance see:

- Advertising cosmetic services and injections
- Advertising vaccinations services

The ARGATG provides more information about advertising therapeutic goods with related services and the requirements for advertising different types of therapeutic goods.

Advertising to health professionals

Although appropriate controls on advertising are required to protect public health, health professionals require access to information about therapeutic goods to make informed decisions in the best interests of their patients.

Advertisements for therapeutic goods **directed exclusively to health professionals** (section 42AA of the Act) are not subject to the Code. For advertising to be considered as directed exclusively to health professionals, the content must not be available to the public at all.

Care should be taken to ensure that advertising claims for any particular therapeutic goods that are included in the ARTG aligns with the approved indications/intended use in the ARTG.

Promotion of off-label indications is **prohibited** for goods included in the ARTG, **even to health professionals.**

For more information, refer to advertising directly to health professionals and the ARGATG.

Advertising compliance and enforcement

The TGA undertakes compliance and enforcement activity where there is a breach of the advertising requirements set out in the Act and the Code.

Some of the factors that inform our assessment of the risk associated with a breach of the advertising requirements include:

- the nature of the alleged breach
- the risk posed to the public
- the advertiser's attitude towards compliance, including their history of non-compliance in relation to advertising or other requirements

We have the authority to use various enforcement tools if your advertising does not comply with requirements. We can apply these actions at any time, even if your advertisement was not brought to our attention by a complaint. These actions can have various consequences for you as the advertiser ranging from mild to very serious.

Our compliance toolkit has four tiers of activity:

Voluntary compliance through education and guidance

Most responsible entities want to comply with their obligations. The TGA provides education and guidance tools to aid advertisers with voluntarily complying with the advertising requirements.

Assisted compliance through education and guidance

Where advertisers may be unaware of, or fail to understand how to comply with the advertising requirements the TGA informs and/or warns them of the consequences of failing to comply.

An **obligations letter** may be used to inform an advertiser that their advertising may not be compliant and advises them of their obligations. The letter may also provide educational and guidance material to assist the advertiser with reviewing their advertising and ensuring compliance.

In some circumstances the TGA will send a **warning** to an advertiser to inform them that their advertising is non-compliant. The letter sets out the alleged non-compliance and requires the advertiser to respond to the TGA, including outlining the steps they will carry out and the timeframe required to achieve compliance. Failure to respond may result in further regulatory action.

Regulatory compliance and enforcement

Where the TGA uses the powers provided in the Act to ensure compliance.

Compliance assurance

The TGA undertakes a compliance assurance program to ensure that advertisers who come to our attention maintain their compliance.

Refer to Advertising: Sanctions and penalties for specific details and more information.

Further information

The examples in this document are for guidance only. Further information about the advertising requirements is available on the Advertising Hub.

If you require clarification on specific aspects of advertising then please contact TGA Advertising by calling 1800 020 653 (free call within Australia) or lodge your enquiry via our online form.

To make a complaint about advertising that you think may breach the advertising requirements, or find out the outcome of a complaint, see complaints and outcomes or see Complaints handling for the advertising of therapeutic goods.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Legal Services Branch (RLSB) Regulatory Education and Compliance Branch (RECB)	October 2019

Therapeutic Goods Administration

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