Australian Government
Department of Health
Therapeutic Goods Administration

Australian Regulatory Guidelines for Advertising Therapeutic Goods (ARGATG)

Guidance for advertisers

This guidance for advertisers applies to the current *Therapeutic Goods Advertising Code 2015* but incorporates amendments to the *Therapeutic Goods Act 1989* (the Act) that came into effect on 6 March 2018, and has been further updated to provide specific information on advertising biologicals and to also include more background information on advertising requirements.

The Therapeutic Goods Advertising Code (No.2) 2018 was made on 31 October 2018 to replace the 2018 Code which will come into effect on 1 January 2019. A summary of the changes is available. To assist advertisers with implementation, we have also published guidance material; Complying with the Therapeutic Goods Advertising Code (No. 2) 2018.

Version 2.1, November 2018

TGA Health Safety Regulation

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This guidance is effective from 1 July 2018, unless otherwise specified.

Sections of this guidance are still under development. We will be adding information to the ARGATG in stages.

This guidance informs advertisers (including sponsors, manufacturers, importers, pharmacists and health professionals) of their responsibilities when advertising therapeutic goods. All advertising of therapeutic goods is subject to the requirements of the *Therapeutic Goods Act 1989* (the Act). For those therapeutic goods that can be advertised to the public, advertising must comply with the requirements of the Act and the Therapeutic Goods Advertising Code (the Code).

The Therapeutic Goods Administration (TGA) is responsible for administering the Act and the Code. We have the authority to apply penalties with various consequences for advertisers who do not meet their advertising requirements.

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

This guidance provides information to advertisers about:

- the advertising regulatory framework
- advertising different types of therapeutic goods
- restricted representations
- pre-approvals for advertising
- sanctions and penalties for non-compliant advertising
- activities that represent advertising
- advertising therapeutic goods with related services
- advertising specific types of therapeutic goods
- advertising interface products
- handling of advertising complaints

For additional educational tools and fact sheets to help you understand your advertising requirements, see Advertising therapeutic goods on the TGA website.

This guidance has been developed by TGA and therefore the use of 'we' and 'us' throughout refers to TGA.

All examples provided in this guidance have been compiled to demonstrate the application of the legislation.

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

The advertising regulatory framework

Advertisements for therapeutic goods are subject to the requirements of the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods Regulations 1990*, the *Competition and Consumer Act 2010*, and other relevant laws. Advertisements for therapeutic goods directed to the public must also comply with the Therapeutic Goods Advertising Code (the Code).

Advertising and the Act

Section 3 of the Act 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 in the definition above is not what you, as the advertiser, intend by releasing the information but rather what the end viewer thinks you intended. If the public or health professional considers that the information promotes the use or supply of the identified goods, then we would consider it an advertisement (see Activities that represent advertising).

The Act:

- prohibits certain types of therapeutic goods from being advertised to the public
- contains a range of requirements that you must meet when advertising therapeutic goods. This includes the requirement for all therapeutic goods advertising to the public to comply with the Code.
- provides for a range of compliance and enforcement tools that the TGA may employ to address non-compliant advertising.

Advertising and the Code

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

On 1 January 2019, the current version of the Code (2015) will be replaced by the 2018 Code.

Replacing the 2015 Code with the 2018 Code

The 2018 Code contains a number of changes and improvements from the 2015 Code. The 2018 Code aims to:

- assist all advertisers in understanding the advertising requirements
- provide objective tests to determine breaches of the Code, which is needed to support the broadened sanctions and penalties (including infringement notices)
- address the inconsistencies between medicines and medical devices (where appropriate)

- incorporate changes to the Code that have been discussed with stakeholders in recent years but have been on hold while the advertising framework was under review.

A consultation on proposed improvements to the Code was held in August 2017.

The Therapeutic Goods Advertising Code 2018 is available on the TGA website, following public consultation on a draft of the 2018 Code.

There is more information on the transition arrangements for the 2018 Code on the TGA website.

Legal basis for the Code

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

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

Limitations on advertising to the public

When advertising therapeutic goods to the public, you **cannot** advertise:

- indications for products that are not consistent with those indications that have been accepted in relation to the product's inclusion in the Australian Register of Therapeutic Goods (ARTG) (section 22, 32BJ and 41ML of the Act). Note that this requirement also applies to advertising to health professionals
- products containing ingredients specified in Schedules 3, 4 or 8 of the current Poisons Standard unless, in the case of Schedule 3 medicines, the ingredients appear in Appendix H of the current Poisons Standard (section 42DL(10) of the Act)
- biologicals (section 42DL(11) of the Act)
- autologous human cell and tissue (HCT) products excluded from being subject to therapeutic goods legislation, because one of the criteria for exclusion is not being advertised directly to consumers
- therapeutic goods that are required to be entered but are not in the ARTG (illegal therapeutic goods) (section 42DL(12) of the Act).

You are required to seek:

- a permission or approval from TGA before using Restricted representations (representations which refer to serious diseases or conditions) in advertising therapeutic goods to the public
- pre-approval before publishing advertisements for medicines appearing on television or radio, newspapers, consumer magazines, billboards and cinema films (section 42C of the Act and Part 2 Division 2 of the Regulations).

Jurisdiction

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

a. activities by corporations; and

b. activities by natural persons:

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

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

   iii. in relation to the Commonwealth

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

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

Other requirements

When preparing to advertise therapeutic goods to the public, you will need to consider other legal requirements as well as those set out in the Act and the Code.

Other relevant laws include:

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

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

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

- Medical Technology Association of Australia Code of Practice; and
- IVD Australia Code of Conduct.

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

Quality use of medicines

The therapeutic goods advertising legislation is 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 use in the care of themselves or their family.

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

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

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

World Health Organization criteria

The advertising legislation, especially the Code, also draws on concepts used in the World Health Organisation: Ethical Criteria for Medicinal Drug Promotion 1988, namely:

a. Promotion refers to all informational activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products.

b. All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or give rise to undue risks.

c. Comparison of products should be factual, fair and capable of substantiation.

d. Advertisements to the general public should help people to make rational decisions on the use of drugs determined to be legally available without prescription. While they should take into account people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health, nor mislead the consumer into unwisely relying on medicines to solve physical, emotional or mood problems.

e. The provision of free samples to the general public for promotional purposes is difficult to justify from a health perspective.

f. Advertisements may claim that a drug can cure, prevent or relieve an ailment only if this can be substantiated.

g. Language which brings fear or distress should not be used.

h. Advertisements should not be allowed for certain serious conditions that can be treated only by qualified health practitioners.

Advertising and endorsements

You are not permitted to refer to TGA, use a government logo, or imply that any government body (including a foreign government agency) endorses a therapeutic good in any advertisement to the public.

Implying government approval

Do not make reference to government agencies (domestic or foreign), including TGA, in any advertising or promotional material as this potentially implies endorsement by that agency. This includes:

- û statements such as ‘TGA approved’ or ‘Government endorsed’
- û using the TGA logo or the Commonwealth Coat of Arms
- û statements that a therapeutic good is 'included in the ARTG by the TGA', 'registered by the TGA', 'TGA listed' or similar.

Advertising ARTG entry

The ARTG contains information about therapeutic goods that can be commercially supplied in Australia.

We encourage you, as the advertiser, to provide the public with a product's ARTG details.

However, you are not permitted to make a broad statement that a therapeutic good is listed, registered, or included in the ARTG, even where factually correct, unless it forms part of a statement of the ARTG number.

You may use terms such as:

- ü For devices: ‘Product X is entered in the ARTG, <ARTG number>
- ü For biologicals: ‘Product X is included in the ARTG, <ARTG number>
- ü For medicines and other therapeutic goods that are:
  - listed in the ARTG: ‘Product X is listed in the ARTG, AUST L <ARTG number>’
  - registered in the ARTG: ‘Product X is registered in the ARTG, AUST R <ARTG number>’

You should also be aware of the important differences between TGA classifications for products entered in the ARTG. We classify medicines as registered, assessed listed or listed. It would be inaccurate and misleading to identify a therapeutic good in advertising as a different classification.

Advertising different types of therapeutic goods

The regulation of advertising for different types of therapeutic goods can be quite different. It is important that you understand the specific requirements related to the type of good you are advertising.

Before advertising, restricted representation approval may be required and pre-approval for advertisements of medicines to appear in specified media may be required.

In this section:

- Restricted scheduled substances
- Medical devices
- Biologicals

Restricted scheduled substances

Restricted scheduled substances are therapeutic goods containing a pharmacist only medicine (schedule 3), prescription only medicine (schedule 4) or controlled drug (schedule 8) of the Poisons Standard. These substances need a health professional to assess whether the therapeutic good is appropriate and suitable for a patient before they are prescribed.

You cannot advertise restricted scheduled substances to the public. This is prohibited under subsection 42DL(10) of the Act and is not permitted.

There are some exceptions including:

- schedule 3 substances listed in Appendix H of the poisons standard
- prescription medicine price lists that comply with the Price Information Code of Practice (before 1 January 2019) or Schedule 4 of the 2018 Code (on or after 1 January 2019)

For information on the advertising requirements and restricted scheduled substances see:

- Advertising prescription medicines to health professionals
- Advertising cosmetic services and injections
- Advertising health services with Schedule 3, Schedule 4 or Schedule 8 medicines

Medical devices

For information on advertising medical devices see:

- Advertising health services with medical devices

Biologicals

Generally, you cannot advertise biologicals to the public (section 42DL(11) of the Act).

A few biologicals are entirely excluded from the therapeutic goods legislation, while others are only excluded on the condition that they are not advertised to the public. If such biologicals were advertised to the public, they would be subject to regulation under the biological framework and the advertising requirements (including offences) would apply.

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

Subject to any jurisdictional limitations, these requirements apply to advertising by any person, including health professionals, professional bodies, media outlets and commercial ventures. The requirements apply to advertising in 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)

As biologicals cannot be advertised to the public, the Therapeutic Goods Advertising Code will not generally be relevant.

Advertising of services is permitted

Services (that do not mention specific therapeutic goods) are permitted to be advertised, see advertising health services.

To advertise services and comply with the therapeutic goods legislation, the advertising should:

- ü focus on the services that your business provides without referencing the biological or excluded autologous human cell and tissue (HCT) product
- û not make any specific reference to biologicals or excluded autologous HCT products associated with the services
- û not provide information and/or advice, on medical or dental professional's (or clinics) websites, for patients to consider particular types of treatments involving biologicals or excluded autologous HCT products; however, such information can be provided to patients as part of a consultation with the professional
- û not reference trade names of biologicals or excluded autologous HCT products (e.g. abbreviations, acronyms) or colloquial names such as 'stem cells'

An advertisement for a health service that specifies the use of any biological or excluded autologous HCT product associated with that service is not permitted as it would promote the product also.

Testimonials that refer to biologicals or excluded autologous HCT products are likely to be considered advertising and are subject to the same requirements.

Restricted representations and advertising

You may only use a restricted representation (either expressly or by implication) in an advertisement for therapeutic goods directed to the public if TGA has permitted or approved the use of that representation. TGA has permitted the use of some key restricted representations for commonly advertised therapeutic goods. However, in many cases, you will need to apply to the TGA for prior approval from us for such use.

What is a restricted representation?

A representation in an advertisement about therapeutic goods that refers to a serious form of a disease, condition, ailment or defect, as specified in the Code, is a restricted representation.

The Code sets out the definition of serious for the purposes of determining which diseases, conditions, ailments and defects would constitute such a reference.

Any representation in an advertisement for a therapeutic good can be a restricted representation if the representation refers (whether overtly or impliedly) to a serious form of a disease, condition, ailment or defect. The representation does not have to be a therapeutic claim to be a restricted representation. For example, the representations: 'Do not use this product if you have diabetes' and 'We proudly support Osteoporosis Australia' and 'may help relieve pain associated with arthritis' are all considered to be restricted representations.

Permitted restricted representations

TGA has permitted the use of certain restricted representations by all advertisers of therapeutic goods meeting the characteristics and requirements specified by the TGA. The permitted restricted representations include:

- certain neural tube defect risk reduction in pregnancy representations when advertising medicines that deliver a minimum of 400 micrograms of folic acid in a daily dose
- representations about reducing the risk of osteoporosis when advertising medicines that deliver a minimum of 290mg of elemental calcium in a daily dose
- representations about sleep apnoea, Obstructive Sleep Apnoea (OSA) and Central Sleep Apnea/Apnoea (CSA) in relation to Continuous Positive Airway Pressure (CPAP) equipment

Details of permissions are available from the published notices of approved & permitted restricted representations.

Unless the permission has been granted to a specific person or business, all advertisers promoting therapeutic goods that are the subject of these permissions are exempted.

It is not necessary to apply for approval to use restricted representations that have already been permitted by the TGA, unless your claims or goods are not captured by the terms of the permission.

Applying for approval to use restricted representations

You are required to make an application to TGA before using a restricted representation in an advertisement for therapeutic goods which is directed to the public if there is no existing permission. This includes representations made on the product's labels and other advertising. You do not require such approval for advertising to healthcare professionals and in generic information.

Complete an Application for approval to use a restricted representation in advertising.

What to consider when seeking approval

We can only grant approval for the use of a restricted representation for therapeutic goods that are already entered in (or exempt from inclusion on) the ARTG.

Any proposed restricted representation must be consistent with:

- the product's accepted indications or intended purpose, as per its ARTG entry; and/or
- any mandatory warning or cautionary statements which are required to be included in the product packaging/labelling in order to satisfy other regulatory requirements.

Assessing an application to use a restricted representation

Factors we consider when assessing an application

When we assess an application to use a restricted representation, we consider whether the proposed representation is accurate, balanced and not misleading or likely to be misleading. In forming a view about these requirements, we consider various factors including:

- the context in which the proposed representation will be used
- the actual wording of the proposed representation
- substantiating evidence provided to justify the use of the proposed representation and to satisfy TGA that the use of the representation will be accurate
- any relevant information the decision maker may be aware of
- the public interest criteria specified in the Code.

You do not need to provide specific examples of advertising and it should be noted that advertisements in their entirety are not approved. However, you may wish to provide a specific example or examples with your application to provide support and context in relation to the proposed use of the restricted representation.

Public interest criteria

We take public interest criteria, as set out in the Code, into account when considering an application for approval to use a restricted representation in an advertisement. Include a statement in your application to explain to TGA how you see the public interest criteria applying to your proposed representation and advertising.

The public interest criteria consider whether the reference to a serious form of a disease in the advertisement is likely to:

- take advantage of the vulnerability of consumers
- result in consumers not seeking appropriate medical advice
- have a negative impact on public health.

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

Decision to approve or refuse an application

The decision to approve, or to refuse to approve, is made by the Secretary to the Department of Health (or his or her delegate at TGA). However, the Secretary (or delegate) may seek advice from the Advisory Committee on Non-Prescription Medicines (ACNPM), the Advisory Committee on Complementary Medicines (ACCM) or the Advisory Committee on Medical Devices (ACMD) about the application prior to making their decision.

The Secretary must take into consideration any recommendation made by the committees prescribed under Regulation 6AA, which include ACNPM or ACCM (section 42DF of the Act).

Applicants that are not satisfied with the decision in relation to an application can seek a review of that decision. Details on how to seek a review will be set out in the decision letter issued by TGA.

Pre-approvals for advertising

You must seek pre-approval under the Regulations for advertisements of medicines that are to appear in specified media. This requirement will continue until the pre-approval process is removed on 1 July 2020.

You should be aware that there a range of offences relating to the publication or broadcast of an advertisement for medicines in specified media.

You need to obtain approval for any restricted representations to appear in your advertisement before seeking pre-approval for your advertisement.

Extension of pre-approval process

The Review of Medicines and Medical Devices Regulation (the Review) recommended:

- replacement of the current pre-approval arrangement for advertisers with a more self-regulatory regime
- that requirements for advertising therapeutic goods to the public be made consistent for all medicines and medical devices.

Both of these recommendations could largely be achieved through removing the need for pre-approval. Consumer concerns were raised during consultation of the Bill and the Government has decided to extend the pre-approval process until 1 July 2020. We will work to support advertisers throughout the transition period by providing you with clear guidance and the required information to achieve compliant advertising.

You will continue to be required to obtain prior approval from us for use of restricted representations in advertisements for therapeutic goods when the pre-approval requirements are removed in 2020.

See Advertising therapeutic goods for more information about the removal of pre-approvals for advertising.

Approval number

You must include the approval number for approved advertisements that appear in mainstream media or are displays about goods.

The approval number must stand alone, be legible and be located in the bottom right hand corner of approved print advertisements. It usually begins with the letters 'ASMI' or 'CHC' followed by a 5-6 digit number and date code.

Approvals are valid for 2 years.

Specified media advertisements require approval

Specified media is defined under section 42B of the Act as:

- mainstream media (this includes any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions)
- broadcast media
- cinematograph films

- displays about goods, including posters:
  - in shopping malls (except inside an individual shop)
  - in or on public transport
  - on billboards

For the purposes of pre-approval, the concept of 'specified media' excludes those types of broadcast media specified in Regulation 5BA, including internet, pay television and digital radio.

Offences relating to advertising approvals

Offences relating to the publication or broadcast of an advertisement for medicines in specified media are specified under section 42C of the Act. These include publishing or broadcasting an advertisement:

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

Before you lodge an application for pre-approval, you will need to obtain approval from us for any restricted representations that appear in the proposed advertisement.

Application for advertising approval

You must complete an application for advertising approval to seek approval for advertising therapeutic goods in specified media, as described above.

Approval application types

You need to include your advertisement and application type in your application. There are four types of approval applications:

- New advertisement – a completely new advertisement
- Minor change to Approval number – typographical error, changed sponsor contact details or a change in the address/location from where the advertised goods are available
- Variation of Approval number – cut down of an existing advertisement. A variation does not allow for the addition of any new matter, including new claims
- Re-approval of Approval number – re-approval of an identical advertisement whose approval number has expired

Fees for advertising approval applications

You can find the prescribed fee for each application type under Advertising on the Fees and charges on the TGA website.

Where to send your application for advertising approval

Submit the completed form together with supporting documentation and the prescribed fee to the appropriate Advertising Services Manager. The Advertising Services Manager will then consider the application in accordance with the criteria for approval specified in Regulation 5G.

Type of advertisement and medicine	Submit application to
· Complementary medicines to appear in **specified media** (other than broadcast media)	The Office of Advertising Compliance Complementary Healthcare Council of Australia PO Box 820 MAWSON ACT 2607 Phone: 02 6260 4066 Fax: 02 6260 4122 Email: advertising@chc.org.au
· Complementary medicines in **broadcast media** · All other therapeutic goods (other than goods that are not designated therapeutic goods) to appear in specified media	Advertising Services Australian Self Medication Industry PO Box 764 NORTH SYDNEY NSW 2059 Phone: 02 9955 7205 Email: asmiadvertising@asmi.com.au

Minimum requirements for the submission of advertisements for approval

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

Applicants should note that:

- evidence to substantiate therapeutic claims needs to be provided to the Advertising Services Manager upon request
- substantiation, in line with levels of evidence required to be held by the sponsor at the time of listing or registration, may be required by the Advertising Services Manager
- notwithstanding the above, further substantiation may also be requested
- a claim / indication entered on the ARTG entry for the medicine will not automatically be approved as an advertising claim
- advertisements should not be booked for publication before advertising approval has been granted or before the medicine has been included in the ARTG.

Review of a decision to refuse to approve an advertisement

You can submit a request to review a decision in relation to advertising approval to the Minister for Health in writing (Regulation 5M of the Regulations). The Advertising Services Manager can provide you further instructions on how to request a review of a decision.

When to request review of a decision

You must make the request within **30 days** after notice of the decision is given to the applicant and must be accompanied by information to support the request.

A request for reconsideration given to the Minister outside the statutory 30 day reconsideration period cannot be accepted unless the information is provided in response to a request from the Minister (or the Minister's delegate).

Who reviews a decision

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation. The internal review officer can confirm the original decision to refuse to approve the advertisement or substitute a new decision if the decision under review is found to be defective on matters of law, the merits or administrative process.

The Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision (subregulation 5M(4) of the Regulations).

There is no time limit set out in the Regulations within which the Minister (or the Minister's delegate) must make a decision upon reconsideration under regulation 5M.

Further review of a decision

If you are dissatisfied with the internal review of the merits of the decision, you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision. The AAT can assess the merits of the decision being challenged and decide whether the decision was 'correct and preferable'.

The initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under regulation 5M of the Regulations OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Sanctions and penalties for non-compliant advertising

TGA's approach to compliance is described in the Regulatory Compliance Framework. This framework allows us to escalate actions to achieve compliance, depending on the severity of the non-compliance and your attitude towards compliance.

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.

We may take any of the following actions when advertising is found to be non-compliant:

- Educational letter or educational visits
- Referral
- Warning letter
- Substantiation notice NEW
- Direction from the secretary NEW and UPDATED
- Suspension or cancellation of therapeutic goods from the ARTG
- Public warning notice
- Infringement notice NEW
- Enforceable undertakings
- Criminal prosecution NEW and UPDATED
- Civil action NEW

*As of 1 July 2017, the value of a penalty unit is $210. The value of a penalty unit is listed in the *Crimes Act 1914*.

Educational letter or educational visits

We may send you a letter or visit you in person to educate you or your staff on advertising requirements for therapeutic goods. You may choose to engage with a regulatory affairs consultant or a lawyer to assist you in ensuring your advertisement complies with all relevant requirements. You should implement procedures to ensure that all future advertising meets relevant requirements to avoid further or more serious compliance action.

Referral

We may refer:

- any practice concerns to state or territory health departments and/or the Australian Health Practitioner Regulatory Agency (AHPRA)
- pricing issues to the Australian Competition and Consumer Commission (ACCC) or state or territory fair trading agencies
- issues about tastefulness, violence and competitor complaints about non-therapeutic related claims to the Advertising Standards Bureau

Warning letter

We may send you a warning letter requesting that you amend your advertisement to ensure compliance within a specified timeframe. We will then confirm with you whether the advertisement has been made compliant. If you fail to address the compliance issues identified in the warning letter, we may escalate the compliance action.

Substantiation notice

We may use substantiation notices to request information to establish the person responsible for an advertisement or to obtain information to substantiate claims made in an advertisement. If you receive a substantiation notice from us, you must provide the information we have requested.

If you fail to comply with a substantiation notice, we may publish a warning notice under section 42DY to alert the public to possible advertising issues or prosecute you under section 42DS of the Act. This carries a maximum penalty of 500 penalty units* (in 2017-18, $105,000).

Providing false or misleading information in response to a substantiation notice can also be prosecuted with a maximum penalty of 1000 penalty units* and/or 12 months imprisonment. We may also pursue civil action for the provision of false or misleading information (section 42DT of the Act).

Direction from the secretary

The Secretary of the Department of Health directs you to take steps to address non-compliant advertising and/or retract or correct your advertising.

If you fail to comply with a direction, it may result in criminal prosecution or civil proceedings.

We will publish directions on the TGA website.

You can request a review of a direction issued under section 42DV of the Act.

Suspension or cancellation of therapeutic goods from the ARTG

Under the Act, we can suspend or cancel your therapeutic good from the ARTG on the basis of advertising non-compliance. Suspension or cancellation is limited to cases where the sponsor of the therapeutic good is responsible for the non-compliant advertising.

Public warning notice

If we suspect that there has been a breach of the legislation in relation to the advertising of the therapeutic good, we can issue a written notice to the public containing a warning about the advertised goods, if it is satisfied that it is in the public interest to issue the notice.

We can also issue a public warning notice if you fail to comply with a substantiation notice and it is in the public interest to issue such a notice.

Infringement notice

Infringement notices will have a maximum 12 penalty units* for an individual or 60 penalty units* for an incorporated body for non-compliant advertising.

In 2017-18, this will result in fines of $2520 for an individual and $12,600 for an incorporated body.

We may issue multiple infringement notices, depending on the number of non-compliances identified. Even if the notice is paid, you will need to address the non-compliant advertising that resulted in the infringement notice in order to avoid future criminal or civil proceedings.

Enforceable undertakings

Under certain circumstances, and where it is clear that the advertiser wants to comply, we may accept the offer of an enforceable undertaking instead of pursuing court action when an offence or civil penalty provision in the legislation has been, or is likely to be, breached. If we accept the undertaking, you are bound by the terms agreed to in the undertaking. Terms may include mandatory training of your staff and taking the steps needed to ensure compliance of any future advertising.

A breach of the terms may result in the matter being referred to the Federal Court who can make orders under section 42YL(5) of the Act.

Criminal prosecution

If you are convicted by a court for advertising non-compliance (including failure to comply with a direction from the Secretary), penalties may be up to:

- imprisonment for 5 years or 4,000 penalty units*, or both, where the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person
- imprisonment for 12 months or 1,000 penalty units*, or both, for intentional non-compliance
- 100 penalty units* for strict liability offences (where intent does not need to be demonstrated)

Offences by corporations can also attract a 5x multiplier.

We may pursue multiple advertising offences. There is also provision for continuing offences (i.e. increased penalties for each day of non-compliance following notification of compliance issues).

Civil action

If a court finds that you have failed to comply with the relevant advertising requirements or directions, it can impose civil penalties up to a maximum of:

- 5,000 penalty units* for an individual; or
- 50,000 penalty units* for a body corporate

for each contravention.

Activities that represent advertising

Not all information released to the public about therapeutic goods is advertising. However, if information you release intends (from the end viewer's point of view) to directly or indirectly promote the use or supply of a therapeutic good then we would likely consider it to be advertising and it must meet legislative requirements as set out in Act and the Code (see Advertising and the Act).

Promotional activities and materials are considered advertising

We consider promotional material to be a form of advertising. Even if the material or the format of advertising can be said to promote the use or supply of relevant goods only in an indirect way, the material or format will still be an 'advertisement'.

Information that is purely factual and balanced and is disseminated for the appropriate use of the goods (for example, consumer medicine information, instructions for use) is unlikely to be considered promotional.

Characteristics of promotional material

Your information is more likely to be considered promotional if it contains:

- unsolicited information rather than solicited information
- unbalanced information (for example, it focuses on the positive qualities of a therapeutic good and omits or downplays the negative qualities such as possible side effects or limitations of use)
- the use of superlatives[1], for example, describing a therapeutic good as 'the best' or 'works fastest'
- the use of descriptive adjectives or statements that are emotive (for example, describing a therapeutic good as 'brilliant' or 'changed my life')
- information that is disseminated on multiple occasions with regular or semi-regular frequency (for example, three times a week during the evening news)
- any information that is disseminated by, or on behalf of, manufacturers, sponsors, retailers and any other party with a financial interest in the sale of the goods referenced.

Considerations when assessing communications

When deciding whether your information is an advertisement, we take into consideration the following factors:

- the context in which the information or activity occurs
- the audience the information is directed to, what their likely take-out message is and are they likely to consider it to be promotional
- the use of non-verbal and unwritten messages (such as pictorial elements). These may be just as important in assessing the communication and can alter the take-out message that viewers receive.

[1] The use of superlatives indicates a comparison (whether express or implied).

Forms an advertisement may take

Any promotional activity for a therapeutic good is likely to fall under the definition of an advertisement.

Advertisements may be targeted to the masses (for example, a newspaper advertisement for cold relief products), to a specific patient group (for example, an advertisement for blood glucose meters in a magazine for diabetics) or specific individual consumers (for example, a letter to individuals that have bought certain types of products from a retailer in the last 12 months).

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

Depending on the content and the context in which such material is provided to the public, some documents and content may be considered not to be advertisements.

For example:

- reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make therapeutic or promotional claims
- information relating to human health or diseases where there is no reference to therapeutic goods
- advertising for health services that does not refer, either directly or indirectly, to therapeutic goods
- correspondence, possibly accompanied by material of a non-promotional nature, to answer a specific unsolicited question about a therapeutic good.

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

The Act and the Code apply to digital communications channels such as social networking sites, blogs and discussion forums when these are used to promote therapeutic goods. Even when these dissemination tools are not used with the conscious intent to promote therapeutic goods, if this is the likely effect of the material on the reasonable consumer, then the material would be subject to the Act and the Code. Website and social media managers should:

- ensure that materials posted on the internet, including comments made by third parties, do not contravene the Act or the Code
- remove content that contravenes the Act or Code.

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

Advertising therapeutic goods with related services

Advertising health services

TGA does not regulate the advertising of health services. We do not consider advertisements **solely** for health services to be advertisements for therapeutic goods.

To ensure that your advertisement for a health service isn't also considered an advertisement for therapeutic goods, do not refer (either directly or indirectly) to any therapeutic goods used in the delivery of the service in the advertisement.

This may be difficult for services that inherently involve therapeutic goods, for example, imaging or vaccination services. Such advertisements will need to comply with the legislative requirements for advertising therapeutic goods as well as any requirements governing the advertising of services.

Requirements when advertising health services

You should be aware that there are requirements that apply when advertising health services, such as:

- Medical Board of Australia
- Pharmacy Board of Australia
- Australian Consumer Law
- Australian Health Practitioner Regulation Law (and applicable advertising guidelines)
- state and territory laws

Advertising extemporaneously compounded medicines

Advertisements for extemporaneously compounded medicines must comply with the Act and other relevant laws, including the Health Practitioner Regulation National Law (and applicable advertising and dispensing guidelines), the Australian Consumer Law, and State and Territory Laws. Extemporaneously compounded medicines, although exempt from some parts of the Act, are not exempt from the advertising provisions of the Act.

Generally, it is unlawful to publish or broadcast an advertisement to consumers for an extemporaneously compounded medicine, that:

- refers to a substance (any ingredient of a medicine) or a good containing a substance classified in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) as a pharmacist only medicine (Schedule 3), prescription only medicine (Schedule 4) or controlled drug (Schedule 8) (some exceptions apply); or
- has not been pre-approved by the Secretary of the Department of Health, if that advertisement is for a 'designated therapeutic good' published or broadcast in 'specified media'.

Applying advertising provisions to extemporaneously compounded medicines

Both a medicine and an ingredient used in the manufacture of a medicine is a therapeutic good.

The advertising requirements in Part 5-1 of the Act apply to advertisements that are:

- directed to the general public; and
- for therapeutic goods, even where an advertisement also promotes other goods or services that are not therapeutic goods.

The advertising provisions in Part 5-1 of the Act do not apply to advertisements:

- for services, for example an advertisement that only promotes the service of extemporaneously compounding medicines, that do not promote or impliedly promote any therapeutic goods
- that are directed exclusively to health professionals (however, not all health practitioners are included in this exemption).

Advertisements for extemporaneously compounded medicines must not refer to any medicine that contains a restricted scheduled substance, even where:

- the restricted scheduled substance is one of several ingredients, including substances that are not restricted scheduled substances; or
- the advertisement does not refer to the restricted scheduled substance by name.

There is an exception, to the offence of advertising a medicine that contains a restricted scheduled substance, for those Schedule 3 substances listed in Appendix H to the current Poisons Standard. Please note that there are certain exemptions from the scheduling requirements which may also apply.

Some advertisements for non-scheduled medicines require pre-approval

It is an offence to publish or broadcast in 'specified media' an advertisement about 'designated therapeutic goods' to the general public unless your advertisement has been pre-approved by the Secretary of the Department of Health (section 42C of the Act).

Generally, 'designated therapeutic goods' will include any extemporaneously compounded medicines that do not contain a restricted scheduled substance.

Advertising vaccination services

All vaccines for human use are classified as prescription-only medicines (Schedule 4) in the Poisons Standard. You **cannot** advertise prescription-only medicines to consumers (subsection 42DL(10) of the Act).

We do not regulate the advertising of health services but if your advertisement for a vaccination service also promotes the use of a therapeutic good it may then become an advertisement of a therapeutic good.

What to avoid when advertising vaccination services

When advertising vaccination services, avoid using:

- û information that might enable consumers to identify the particular vaccine or the manufacturer of the vaccine provided with the service
- û statements or representations that harmful effects will occur from not receiving the vaccine
- û references to any misleading therapeutic benefit of a vaccine (for example, a use that is not a TGA-approved indication for the vaccine)
- û an indication that the vaccine administered as part of the service is superior to other vaccines
- û portrayals of the vaccine or service in a way that trivialises or conflicts with public health policies, or misleads consumers in any other way
- û price comparisons
- û incentives to encourage the consumer to obtain the service or vaccine, or
- û any other claim that promotes the use or supply of the vaccine

Use of any of the above makes advertising of your service to be more likely considered advertising of the vaccine itself and subject to therapeutic goods legislation.

What to include when advertising vaccination services

We recommend that advertisements for seasonal influenza vaccination services should inform the public:

- ü of the vaccine type, for example, trivalent or quadrivalent
- ü that influenza vaccines are free to people from high risk groups identified in the National Immunisation Program Schedule
- ü that people from high risk groups should seek advice from their medical practitioner.

High risk groups eligible for free influenza vaccines

High risk groups that are eligible for free influenza vaccines include:

- Aboriginal and Torres Strait Islander people aged 0 to 5 years
- Aboriginal and Torres Strait Islander people who are aged 10 years and over
- pregnant women
- people aged six months and over with medical conditions such as severe asthma, lung or heart disease, low immunity or diabetes that can lead to complications from influenza
- people aged 65 years and over.

Advertising cosmetic services and injections

Advertising cosmetic services containing Schedule 4 substances

You **cannot** publish an advertisement to the public about therapeutic goods that contains a statement referring to goods, or substances or preparations containing goods, included in Schedules 3, 4 or 8 of the Poisons Standard (section 42DL(1)(f) of the Act).

The products listed below (and most cosmetic injections) contain substances that are in Schedule 4 of the current Poisons Standard and are therefore regulated as Prescription Only Medicines:

- Anti-wrinkle injections
- Dermal Fillers
- Improvement of the appearance of submental fat

Cosmetic injections are generally administered to temporarily remove/reduce wrinkles and lines on the face, around the eyes, forehead (anti-wrinkle injections and dermal fillers), lips and neck (dermal fillers only) or to improve the appearance of submental fat (deoxycholic acid).

We consider prescription medicines to be high risk products and the patient should be assessed by a medical professional before their use. Health professionals and cosmetic or beauty clinics are **not** permitted to advertise cosmetic injections (such as those above) to the public.

Some cosmetic injections may be compounded by a pharmacy for an individual patient rather than supplied by a manufacturer as a finished product. The advertising of compounded cosmetic injections that contain prescription-only substances to the public is also prohibited. For more information, see Advertising extemporaneously compounded medicines.

Advertising cosmetic injections compliantly

To continue legally promoting your cosmetic service to the public, there are some acceptable general terms that you can use to describe certain cosmetic injections in advertisements.

You **cannot** make any reference in your advertisement to:

- Û individual Schedule 4 substances or ingredients
- Û therapeutic goods containing Schedule 4 substances or ingredients (most injections for cosmetic use).

This includes abbreviations of either the ingredient or trade names.

Acceptable general terms

You may use the following acceptable general terms and phrases in your advertising (noting a therapeutic good must not be advertised for an indication or intended purpose that is not accepted in relation to the inclusion of the good on the ARTG):

- Ü cosmetic injections (anti-wrinkle injections, dermal fillers and submental fat)
- Ü anti-wrinkle injections/treatments (anti-wrinkle injections and dermal fillers)
- Ü wrinkle injections/treatments (anti-wrinkle injections and dermal fillers)
- Ü injections/treatments for lips (dermal fillers)

- Ü injections/treatments for fine lines/folds/age lines (anti-wrinkle injections and dermal fillers)
- Ü wrinkle and lip enhancement/fulfilment/augmentation (dermal fillers)
- Ü injections to enhance pouting of the lips (dermal fillers)
- Ü injections which reduce the depth of fine lines/wrinkles around the face/lips (dermal fillers)
- Ü injections to improve the appearance of chin/neck/jaw line (dermal fillers)
- Ü injections for improving the appearance of submental fat/fullness under the chin. (submental fat)

You may also use other words and phrases with similar meaning, provided that they do not refer to specific products or ingredient names. It is not acceptable to use acronyms, nicknames, abbreviations or hashtags of the medicine's name (or some part thereof), which may be taken by a consumer to be a 'reference' to a specific medicine or substance.

You may also have obligations under the Competition and Consumer Act 2010 and state and territory fair trading/consumer affairs legislation.

Advertising specific types of therapeutic goods

We are currently developing this guidance.

Advertising interface products

We recognise that there can be a regulatory 'interface', or potential overlap, between certain foods, medicines, devices, cosmetics and consumer goods. Products at this interface may seem very similar, but can be regulated differently.

We describe examples of three such interfaces below:

1. Food medicine interface
2. Cosmetic medicine interface
3. Consumer goods medicine interface

Food medicine interface

Sometimes it isn't clear whether a product for oral consumption is a therapeutic good or a food. The potential overlap between certain foods and medicines is referred to as the food-medicine interface.

Generally, if your product is covered by a food standard, or is traditionally used as a food in the form that it is presented, it is regulated as a food. If your product is not a food, it is likely to be considered a therapeutic good.

TGA has developed a Food-Medicine Interface Guidance Tool (FMIGT) in consultation with Food Standards Australia and New Zealand (FSANZ) and Australian state and territory agencies. This tool helps you determine how your product is regulated. Use this guidance and the FMIGT to determine whether your product is a food or a therapeutic good.

Making therapeutic claims, statements or indications for a product that you intend to market as a food, might lead a consumer to think the product is for therapeutic use. This could result in your product being regulated as a therapeutic good.

Probiotics and advertising

A probiotic is a product containing live bacteria that is taken orally to restore the body's beneficial bacteria. Probiotics are presented as ready-to-eat yoghurt or milk products, in powders for mixing in food and drink, or in gelatine capsules. Probiotics are often positioned at the food-medicine interface.

Probiotics that are regulated as foods

Probiotic products that are clearly covered by a food standard, or that are traditionally used as foods in Australia or New Zealand in the form they are presented in, are regulated as foods.

For example, yoghurt and yoghurt drinks are covered by Food Standard 2.5.3 for fermented milk products. Accompanying general level health claims for such products would be limited to lactose digestion covered by the nutrition, health and related claims set out in Food Standard 1.2.7. High level health claims need to be separately approved by FSANZ.

A probiotic that is not covered by a food standard or that is not traditionally used as a food in Australia or New Zealand, however, is not automatically considered a therapeutic good.

Probiotics that are regulated as therapeutic goods

If the product is accompanied by a therapeutic claim, statement or instructions for use, it may meet the definition of a therapeutic good because:

- by making such claims, you are representing it as a therapeutic good
- it is perceived by a consumer to be for therapeutic use, even if you intend to market the product as food.

For example, a sachet of probiotic powder might be marketed as a food but other factors such as claims about its health benefits, warning statements or a dosage regime may lead consumers to believe it is a therapeutic good.

If you decide to market your product as a therapeutic good, it will be regulated as one. If the product is manufactured overseas, we must approve your products manufacturing before it can be imported and released for supply in Australia.

These kinds of products are often regulated as complementary medicines and listed on the ARTG. If you have suitable supporting evidence, listed therapeutic goods can make low-level therapeutic claims on the product label and in your advertising, in line with the Code.

If you would like your probiotic product to be regulated as a food rather than a therapeutic good, consider how you market and present it to consumers.

Further information

Contact a regulatory affairs consultant or your state or territory food authority for further information, or see the following useful links:

- Food Standards Code
- Food and medicine regulation
- Food-Medicine Interface Guidance Tool
- Australian Food & Grocery Council
- Complementary Medicines Australia

Cosmetic medicine interface

Most cosmetic products are generally not considered therapeutic goods, as they tend not to be for a therapeutic use and we do not regulate them. However, a cosmetic may be a therapeutic good, depending on its ingredients, route of administration and if therapeutic claims are made on the product label or in advertising. Products for topical use (including for use on teeth or the oral mucosa) may be regulated as a cosmetic or a therapeutic good depending on the type of product and the claims made. Generally, a product for topical use that is covered by the Excluded Goods Order will be regulated as a cosmetic. Products not covered by the order may still be regulated as cosmetics, provided that you do not make therapeutic claims.

- Order that Goods are Therapeutic Goods No 2 of 1999 made under section 7 of the Act (see below) declares that products labelled or promoted for cosmetic purposes when promoted for oral consumption are, for the purposes of the Act, therapeutic goods
- Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 made under section 7 of the Act (see below) declares a number of products that are covered by the Cosmetics Standard 2007 made under the Industrial Chemicals (Notification and Assessment) Act 1989 not to be therapeutic goods.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulates cosmetic products under the Industrial Chemicals (Notification and Assessment) Act. That Act underpins the Cosmetics Standard 2007 and this Standard is supported by the NICNAS Cosmetic Guidelines 2007. Further information on the regulation of cosmetics is available from NICNAS.

Claims on cosmetic labels are regulated by the Australian Competition and Consumer Commission.

Consumer goods medicine interface

Note: We are currently developing this guidance.

Handling of advertising complaints

Effective handling of complaints enables advertisers of therapeutic goods to comply with legislative requirements, be socially responsible and assist in delivering good health outcomes. Complaints about advertising are currently considered by us or one of a number of industry associations depending on the advertiser, type of product and the medium in which the advertisement appeared.

We will become the single body responsible for handling complaints about the advertising of therapeutic goods to the public from 1 July 2018. The decision for us to consolidate all complaints about the advertising of therapeutic goods to the public will simplify and streamline the process and address many of the criticisms made about the current disjointed arrangements.

Complaints Resolution Panel

We have established transition arrangements with the Complaints Resolution Panel (the Panel) to minimise inconvenience to complainants. Until now, the Panel has been the primary body responsible for handling complaints about advertising to consumers. Where the Panel was unable to obtain compliance from the advertiser, it would refer the matter to us for follow up action. TGA's policy is to publish the outcomes of investigations into such complaints. We report outcomes based on whether:

- advertising compliance is achieved following TGA intervention or the complaint is closed due to other reasons
- a Regulation 9 order is issued

We will publish new arrangements for the publication of outcomes when we introduce the new complaints handling processes.

Lodging a complaint

Anyone may lodge a complaint about an advertisement for therapeutic goods. All complaints are treated in confidence unless the complainant consents to the release of their personal details. We also accept anonymous complaints.

To make a complaint, you can either:

- email TGA at tga.advertising@tga.gov.au
- send a written complaint to:

  Advertising Compliance
  Regulatory Practice, Education and Compliance Branch
  Therapeutic Goods Administration
  PO Box 100
  WODEN ACT 2606

When a complaint is lodged, the following details should be included where possible:

- the name of the advertiser
- a copy of the advertisement
- the name of the publication and the date published (if applicable)
- details of what it is about the advertisement that the complainant finds unacceptable

See commonly recorded breaches of the Act and the Code as a guide.

You can find more information about how we may use personal information received in a complaint on the Privacy page of the TGA website.

Education sessions

Please see our dedicated Advertising therapeutic goods section of the TGA website for details on upcoming webinars and roadshows to assist you in understanding your advertising responsibilities and being compliant with current legislation.

If you are new to therapeutic goods regulation and wish to advertise your product in Australia, you may also benefit from attending our training on advertising and making claims for therapeutic goods.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Advertising compliance section and Regulatory guidance team	4 June 2018
V2.0	Additional information about: · the advertising regulatory framework · advertising different types of therapeutic goods · restricted representations · activities that represent advertising Some minor editorial changes have also been made	Advertising compliance section and Regulatory guidance team	July 2018
V2.1	Minor editorial changes to reflect the making of the Therapeutic Goods Advertising Code (No.2) 2018 (the Code) and the inclusion of the Pricing Information Code of Practice at Schedule 4 of the Code from 1 January 2019.	Advertising Education and Assurance Section	November 2018

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