



Australian Government
Department of Health
Therapeutic Goods Administration

Advertising guidance for businesses involved with medicinal cannabis products

Complying with therapeutic goods advertising requirements

1 November 2019

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About this guidance

This guidance aims to assist providers of medicinal cannabis products and therapies (including sponsors, manufacturers, importers, pharmacists, health professionals and marketers) to comply with the therapeutic goods advertising restrictions. Criminal and civil penalties may apply if you do not comply with your legal requirements.

The focus of this guidance is to help you to understand how to promote your business and service without advertising medicinal cannabis products to the public, **which is prohibited**.

The guidance provides information about:

- the definition of advertising as it applies to therapeutic goods
- activities that may constitute advertising
- advertising compliance and enforcement

We will review and update this guidance in line with legislative changes and emerging technologies.

Failing to have regard to the general principles set out here may risk the statement or promotion being a contravention of the *Therapeutic Goods Act 1989* (the Act) and the Therapeutic Goods Advertising Code (No.2) 2018 (the Code).

For general information on advertising therapeutic goods, see the [Advertising Hub: Advertising code and guidance](https://www.tga.gov.au/advertising-advertising-code-and-guidance) ([//www.tga.gov.au/advertising-advertising-code-and-guidance](https://www.tga.gov.au/advertising-advertising-code-and-guidance)) and [Why and how the advertising of therapeutic goods is regulated](https://www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated) ([//www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated](https://www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated)).

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 see the [Advertising Hub](https://www.tga.gov.au/advertising-hub) ([//www.tga.gov.au/advertising-hub](https://www.tga.gov.au/advertising-hub)).

Medicinal cannabis products

The *Narcotic Drugs Act 1967* defines a 'medicinal cannabis product' as:

a product, including but not limited to, a substance, composition, preparation or mixture, that:

- a. includes, or is from, any part of the cannabis plant; and
- b. is for use for the purposes of curing, or alleviating the symptoms of, a disease, ailment or injury.

Cannabis plants are plants from the botanical genus *Cannabis*. There are different species and numerous strains of cannabis plants, all of which contain cannabinoid compounds with varying effects. The most common cannabinoid compounds are:

- (delta-9) tetrahydrocannabinol (THC)
- cannabidiol (CBD)
- cannabinal (CBN)

The term medicinal cannabis also covers a range of dosage forms such as capsules, and preparations such as oils and tinctures.

For more information about medicinal cannabis in general, refer to [guidance on medicinal cannabis](https://www.tga.gov.au/medicinal-cannabis-guidance-documents#guidance-docs) ([//www.tga.gov.au/medicinal-cannabis-guidance-documents#guidance-docs](https://www.tga.gov.au/medicinal-cannabis-guidance-documents#guidance-docs)) and the [Office of Drug Control's medicinal cannabis page](https://www.odc.gov.au/medicinal-cannabis) (<https://www.odc.gov.au/medicinal-cannabis>).

Advertising medicinal cannabis to the public is prohibited

Medicinal cannabis can be included in the [Australian Register of Therapeutic Goods \(ARTG\)](https://www.tga.gov.au/australian-register-therapeutic-goods) ([//www.tga.gov.au/australian-register-therapeutic-goods](https://www.tga.gov.au/australian-register-therapeutic-goods)) as a [prescription medicine](https://www.tga.gov.au/australian-regulation-prescription-medical-products) ([//www.tga.gov.au/australian-regulation-prescription-medical-products](https://www.tga.gov.au/australian-regulation-prescription-medical-products)). If a medicinal cannabis product is not in the ARTG, it is an [unapproved therapeutic good](https://www.tga.gov.au/guidance-tool-access-unapproved-therapeutic-goods) ([//www.tga.gov.au/guidance-tool-access-unapproved-therapeutic-goods](https://www.tga.gov.au/guidance-tool-access-unapproved-therapeutic-goods)) and is only available through [specific access pathways](https://www.tga.gov.au/access-medicinal-cannabis-products-1) ([//www.tga.gov.au/access-medicinal-cannabis-products-1](https://www.tga.gov.au/access-medicinal-cannabis-products-1)).

Prescription medicines:

are prohibited from being advertised to the public

- advertising medicinal cannabis regulated as prescription medicines to the public is **prohibited** under the Act (subsection 42DL(10)). This subsection prohibits references (whether express or implied) to prescription medicines in advertisements for therapeutic goods.

may be advertised exclusively to health professionals:

- provided the advertising complies with the *Therapeutic Goods Act 1989* (including the following requirement)

Unapproved therapeutic goods:

are prohibited from being advertised to the public

- advertising medicinal cannabis products to the public that are not included in the ARTG and are not otherwise the subject of an exemption, approval or authority is also **prohibited** under the Act (subsection 42DL(12)).

Information for health professionals on [accessing unapproved medicinal cannabis products](https://www.tga.gov.au/access-medicinal-cannabis-products-1) ([//www.tga.gov.au/access-medicinal-cannabis-products-1](https://www.tga.gov.au/access-medicinal-cannabis-products-1)) is on the TGA website.

Definition of advertising

The *Therapeutic Goods Act 1989* (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](https://www.tga.gov.au/book-page/activities-represent-advertising) ([//www.tga.gov.au/book-page/activities-represent-advertising](https://www.tga.gov.au/book-page/activities-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.



See the [TGA glossary](https://www.tga.gov.au/acronyms-glossary) ([//www.tga.gov.au/acronyms-glossary](https://www.tga.gov.au/acronyms-glossary)) for definitions relevant to the regulation of therapeutic goods in Australia. Definitions relevant to advertising

are also provided in the [Advertising to the public guidance \(//www.tga.gov.au/book-page/definitions\)](https://www.tga.gov.au/book-page/definitions).

Roles and responsibilities

The TGA

The TGA regulates medicinal cannabis in conjunction with the [Office of Drug Control](#). The TGA is responsible for administering the Act and the Code, which specify requirements relating to advertising therapeutic goods.

The Act:

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

Office of Drug Control

The Office of Drug Control (ODC) within the Department of Health regulates the licences and permits relating to certain aspects of the supply of medicinal cannabis products, including:

- medicinal cannabis licences and permits authorising cultivation or production or both
- cannabis research licences and permits authorising similar process for research purposes
- manufacturing licences and permits authorising the manufacture of a drug or product
- export and import of medicinal cannabis products

For further information, see [the regulatory role of ODC \(https://www.odc.gov.au/medicinal-cannabis\)](https://www.odc.gov.au/medicinal-cannabis).

Medicinal cannabis businesses and services

As well as complying with the Act, you may have obligations under:

- the [Narcotic Drugs Act 1967 \(https://www.legislation.gov.au/Series/C1967A00053\)](https://www.legislation.gov.au/Series/C1967A00053),
- the *Customs (Prohibited Exports) Regulations (1958)* and *Customs (Prohibited Imports) Regulations (1958)*
- the [Competition and Consumer Act 2010 \(https://www.legislation.gov.au/Details/C2019C00149\)](https://www.legislation.gov.au/Details/C2019C00149),
- relevant State and Territory health or fair trading/consumer protection legislation
- the [Health Practitioner Regulation National Law Act 2009 and corresponding state and territory laws \(https://www.ahpra.gov.au/About-AHPRA/What-We-](https://www.ahpra.gov.au/About-AHPRA/What-We-)

[Do/Legislation.aspx](#))

- local state and territory laws regarding medicinal cannabis

For general information on advertising therapeutic goods, see the [Advertising Hub: Advertising code and guidance](#) ([//www.tga.gov.au/advertising-advertising-code-and-guidance](https://www.tga.gov.au/advertising-advertising-code-and-guidance)) and [Why and how the advertising of therapeutic goods is regulated](#) ([//www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated](https://www.tga.gov.au/why-and-how-advertising-therapeutic-goods-regulated)).

Local states and territories

Your local state or territory will have their own laws around medicinal cannabis. You should contact your local state and territory health department to establish your local obligations.

[Contact details](#) ([//www.tga.gov.au/access-medicinal-cannabis-products-using-access-schemes](https://www.tga.gov.au/access-medicinal-cannabis-products-using-access-schemes)) are available on the TGA website.

Activities that may constitute advertising

Not all information provided to the public about therapeutic goods is advertising. However, if information you provide promotes (from the end viewer's point of view), 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 the Act and the Code (see [Advertising and the Act](#) ([//www.tga.gov.au/book-page/advertising-regulatory-framework](https://www.tga.gov.au/book-page/advertising-regulatory-framework))).

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. For further information, please see the [Australian Regulatory Guidelines for Advertising Therapeutic Goods \(ARGATG\)](#) ([//www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg](https://www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg)).

Promotional material

A statement, pictorial representation or design intended as promotion of either the use or supply of therapeutic goods will fall within the definition of 'advertise' and the advertising prohibitions and restrictions in the Act will apply (see [Definition of advertising](#)).

Factual and balanced statements about medicinal cannabis are those that do not promote the use or supply of medicinal cannabis and may, depending on the context, not be considered to be advertising.

Factual information may take many forms, including medical journal articles, or genuine news. Further information about whether material is information or advertising is provided in the [Australian Regulatory Guidelines for Advertising Therapeutic Goods, ARGATG](#) ([//www.tga.gov.au/book-page/activities-represent-advertising](https://www.tga.gov.au/book-page/activities-represent-advertising)).

Factual and balanced information about medicinal cannabis

A healthcare consumer advocacy group website publishes information about medicinal

cannabis.

The website outlines the endocannabinoid system and the effect cannabinoids might have in the human body. The information discusses research findings in relation to medicinal cannabis and explains that for most therapeutic purposes, more research needs to be done.

The website, while it generally discusses potential benefits of medicinal cannabis, also explains the contra-indications and potential side-effects in detail, as well as how medicinal cannabis is regulated and provides a link to the TGA website explaining how it may be accessed in Australia.

Omitting important information can make material promotional

A healthcare consumer advocacy group website publishes information about medicinal cannabis and describes its therapeutic purposes.

No information on side-effects or the paucity of clinical evidence in relation to therapeutic treatments is divulged. The information is persuasive on the merits of medicinal cannabis and provides contact details for clinics.

The website promotes the use of medicinal cannabis.

Promoting your health service or business

It is possible to promote health services involving medicinal cannabis. However, to ensure such promotion does not additionally illegally advertise a therapeutic good, you **must not** refer, either overtly or by implication, to medicinal cannabis. This includes making references through:

- company, business or trading names
- product names or trade names
- abbreviation or acronyms for the good
- colloquial names
- any other reference, including images, that are likely to draw the consumer's mind to medicinal cannabis

Compounding pharmacy services and medicinal cannabis

Compounded medications for a specific patient on a valid prescription are generally exempt from inclusion in the ARTG.^[1]

However, **advertising restrictions are still applicable**. Compounding pharmacies are a health service that **must** follow the same obligations as other health services or businesses providing medicinal cannabis products ([//www.tga.gov.au/activities-promoting](https://www.tga.gov.au/activities-promoting)).

An example of health service promotion advertising the supply of various dosage forms of medicinal cannabis that contravenes the Act

Jackson's Pharmacy website says they offer a compounding service featuring their own

highest quality medicinal cannabis products. This includes CBD oil capsules and CBD oral liquid in pre-loaded syringes for easy administration.

Note that compounded medicines, including medicinal cannabis, are ineligible for inclusion in prescription price lists as they are not entered in the ARTG^[2].

Company business or trading names

If you are a business that promotes treatment services, you need to take care to ensure that you are not, in addition to promoting your services, also promoting medicinal cannabis. If your business name includes a reference to medicinal cannabis, it is likely that a consumer viewing the promotion of the service would reasonably consider that the service includes the use of medicinal cannabis.

This includes references made to medicinal cannabis through:

- a trade name for a medicinal cannabis product
- an abbreviation or acronym for the good
- a colloquial name

or

- any other reference (including images) that would draw the consumer's mind to medicinal cannabis

An example of a business name where there is a risk of contravening the Act

A clinic that offers treatment of pain associated with musculoskeletal disease states in the promotion of the service the name of the clinic:

'Far East Med Can Clinic'

The consumer would reasonably interpret that the clinic is involved in arranging the prescription and/or supply of medicinal cannabis as an aspect of the treatment it offers.

An example of a business name that would not contravene the Act

A clinic that offers treatment of pain associated with musculoskeletal disease is called 'Far East Musculoskeletal Clinic'.

Provided the clinic is otherwise compliant (see [ARGATG \(//www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg) for more info) then the clinic's website would not convey to the reasonable consumer that the pain treatment could involve the prescription of medicinal cannabis.

Referencing additional information

Referencing additional information (such as external websites and testimonials) that is promotional or endorses medicinal cannabis, may be considered advertising.

Including additional information can render material an advertisement

A website for a pain management clinic might state that the clinic can tailor a treatment plan for osteoarthritis.

This material is not likely to be considered an advertisement for medicinal cannabis.

However, this (currently) compliant website links out to an overseas blog about how effective medicinal cannabis is for the treatment of pain associated with osteoarthritis.

This reference to the blog renders the original website as non-compliant advertising.

Additional information that would not make the primary material an advertisement

A website for a pain management clinic promotes its services as 'pain treatments'.

This material is not likely to be considered an advertisement for medicinal cannabis.

This (currently) compliant website links out to material from a patient advisory body with balanced information on the range of treatments for pain management.

This secondary material, while it may refer to medicinal cannabis products does so in the context of information about a range of treatments and does not promote the use of medicinal cannabis by emphasising its benefits over other treatments.

Patient support groups

The decision to use medicinal cannabis is a decision that **should be made in conjunction with a treating health professional**.

However, 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.

Material provided to patient support group members, either by businesses involved in medicinal cannabis or by a patient support group:

- **must not** promote medicinal cannabis
- **must not** encourage members to seek medicinal cannabis

An example of advertising to patient support group members that contravenes the Act

North West Child Epilepsy group members receive information from Jackson's Pharmacy advising that the pharmacy can compound various medicinal cannabis products to the formulation specified in a doctor's prescription.

The information is clearly targeted to parents of children with epilepsy and is therefore essentially promoting the use of medicinal cannabis for epilepsy.

An example of advertising to patient support group members that contravenes the Act

North West Child Epilepsy organisation provides its members with a list of compounding pharmacies that can compound various classes of medicines including medicinal cannabis. They advise that Jackson's Pharmacy can compound various medicinal cannabis products with a valid prescription.

An example of a patient support group providing information to its members that is unlikely to contravene the Act

Canberra Epilepsy Group has collated information about the use of medicinal cannabis in certain types of epilepsy. It disseminates the information to their members. The information is an accurate assessment of the full body of evidence relating to efficacy, possible benefits and possible drawbacks (including side effects) of the use of medicinal cannabis.

While the information could motivate a consumer to have a conversation with their health professional, it would be unlikely to result in a consumer being led to the view, in the absence of health professional advice, that medicinal cannabis would be of benefit to them.

Supply of medicinal cannabis

The definition of advertise relates to the promotion of the use and supply of therapeutic goods.



The **advertising** and **supply** of medicinal cannabis has the potential to pose a significant public health risk.

Unapproved therapeutic goods can only be accessed through [specific unapproved product access pathways \(//www.tga.gov.au/access-medicinal-cannabis-products-1\)](https://www.tga.gov.au/access-medicinal-cannabis-products-1). It is a criminal offence under section 19B of the Act for a person to supply in Australia an unapproved medicinal cannabis product for therapeutic use in humans outside of these access pathways.

Further information is available about the regulatory requirements that apply to [supplying therapeutic goods in Australia \(//www.tga.gov.au/overview-supplying-therapeutic-goods-australia\)](https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia).

There are criminal offences for advertising to the public unapproved therapeutic goods and therapeutic goods containing substances in Schedules 4 or 8 of the Poisons standard (i.e. prescription medicines).

A risk-based approach to enforcement

TGA's approach to compliance is described in the [Regulatory Compliance Framework \(//www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management\)](https://www.tga.gov.au/hubs/compliance-and-enforcement/compliance-management). This framework allows us to escalate actions to achieve compliance, depending on the severity of the non-

compliance and your attitude towards compliance.

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, and
- 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.

The TGA has a broad range of compliance and enforcement tools available to ensure compliance with advertising requirements for therapeutic goods. 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 \(//www.tga.gov.au/book-page/sanctions-and-penalties-non-compliant-advertising#civil\)](https://www.tga.gov.au/book-page/sanctions-and-penalties-non-compliant-advertising#civil) for specific details and more information.

Consequences of advertising breaches on licence holders

A breach of the advertising restrictions may be a breach of licencing conditions and result in cancellation of a medicinal cannabis licence.

Further information

If you require clarification on specific aspects of your statements and promotions then please contact TGA Advertising by calling 1800 020 653 (free call within Australia) or (02) 6289 4644 (direct) or lodge your enquiry via our [online form \(https://compliance.tga.gov.au/advertising-enquiry/\)](https://compliance.tga.gov.au/advertising-enquiry/).

Footnotes

- [1] Item 6, Schedule 5 of the Therapeutic Goods Regulations 1990 (Cth).
- [2] Prescription price lists are required to comply with the Code. Section 7 of the Code provides that price information can only be provided for registered 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

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