

Advertising guidance for businesses involved with medicinal cannabis products

Complying with therapeutic goods advertising requirements

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About this guidance

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Aged Care and regulates therapeutic goods in Australia, including medicinal cannabis products.

The advertising and supply of therapeutic goods must comply with the requirements set out in the:

- <u>Therapeutic Goods Act 1989</u> (the Act)
- Therapeutic Goods Regulations 1990 (the Regulations)
- <u>Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021</u> (the Advertising Code).

Medicinal cannabis products are generally regulated as prescription medicines. Under the Act, the advertising of prescription medicines, including medicinal cannabis, to the public is prohibited unless specifically authorised by the TGA in exceptional circumstances¹.

This guidance is intended to assist those who disseminate information about medicinal cannabis products, or advertise health services involving medicinal cannabis products, to ensure they do not unlawfully advertise medicinal cannabis to consumers, including through the promotion of their business or services.

This guidance provides information about:

- the <u>definition of advertising</u> as it applies to therapeutic goods
- activities that may constitute advertising of medicinal cannabis
- information about medicinal cannabis that is unlikely to be considered advertising
- activities that are exempt from the advertising restrictions
- advertising compliance and enforcement.

Significant fines, and criminal and civil penalties can be imposed in relation to contraventions of the Act, including in relation to advertising of prescription medicines to the public. The TGA will take action in relation to unlawful advertising of these products.

Offences may also apply under State and Territory legislation.

More information on sanctions and penalties can be found on the TGA website.

¹ An example is the advertising of registered COVID-19 vaccines, with conditions, in the context of the pandemic.

For an overview of the medicinal cannabis regulatory framework and the types of products that fall within the definition of medicinal cannabis see: <u>Medicinal cannabis: Information for sponsors and manufacturers</u>

Advertising medicinal cannabis to the public is prohibited

Medicinal cannabis can be included in the <u>Australian Register of Therapeutic Goods</u> (<u>ARTG</u>) as a <u>prescription medicine</u>. If a medicinal cannabis product is not included in the ARTG, it is an <u>unapproved therapeutic good</u> and is only available to patients through <u>specific</u> access pathways.

Neither prescription medicines nor unapproved medicines supplied under the special access scheme or an authorised prescriber authority can be lawfully advertised to the public.

This section outlines the key restrictions in the Act that apply to the advertising of therapeutic goods, including medicinal cannabis.

For more information on the restrictions on advertising therapeutic goods such as medicinal cannabis to the public see: The advertising regulatory framework.

Prescription medicines are prohibited from being advertised to the public

Medicinal cannabis products currently available for use and supply in Australia meet the criteria for Schedule 4 (prescription only medicines) or Schedule 8 (controlled drugs) in the <u>Poisons Standard</u> and are regulated as prescription medicines.

Advertising medicinal cannabis products that are regulated as prescription medicines to the public is prohibited under subsections 42DL(10) and 42DLB(7) of the Act.

Certain preparations of cannabidiol may be supplied as a Schedule 3 Pharmacist Only medicine. Schedule 3 cannabidiol cannot be advertised to the public. At the time of writing, there are no products on the ARTG that meet the requirements for this classification.

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, including those supplied through <u>specific access pathways</u>, is prohibited under subsections 42DL(12) and 42DLB(9) of the Act.



Prescription medicines and unapproved therapeutic goods, including medicinal cannabis, may be advertised exclusively to health professionals.

For more information see: <u>Advertising directed exclusively to health</u> professionals.

Other potential advertising offences

If you unlawfully advertise medicinal cannabis products you may also be contravening other criminal and civil provisions under the Act, as outlined below.

Non-compliance with the Advertising Code

Advertising of therapeutic goods to the public that does not comply with the Advertising Code is prohibited under sections 42DM and 42DMA of the Act. These provisions apply to advertising of all therapeutic goods, including medicinal cannabis products.

Therefore, the unlawful advertising of a prescription medicine that does not comply with the Advertising Code would attract an offence for unlawful advertising of a prescription medicine as well as non-compliance with the Advertising Code.

Restricted and prohibited representations

It is unlawful to use representations in advertisements for therapeutic goods that refer to serious forms of diseases, conditions, ailments or defects in advertisements to the public without prior authorisation from the TGA. These representations are:

- 'restricted representations' if they refer to serious forms of diseases, conditions, ailments, or defects which require diagnosis or treatment from a suitably qualified health professional. Examples of restricted representations include representations which refer to epilepsy, multiple sclerosis (MS) or chronic pain
- 'prohibited representations' if they are representations regarding the treatment, cure, prevention or detection of specific serious conditions, such as cancer, sexually transmitted diseases and mental illnesses.

The use of prohibited and restricted representations in advertising without prior permission or approval is prohibited under subsections 42DL(5) and 42DLB(2), and 42DLB(7) and 42DLB(4) of the Act respectively.

For more information see: Restricted and prohibited representations.

Government endorsements

It is unlawful to suggest or imply that a product has been recommended, approved or endorsed by a government agency, such as the TGA, without authorisation. This includes, for example:

- statements such as 'TGA approved', 'Government endorsed' 'U.S. Food & Drug Administration (FDA) approved', or similar
- using the TGA logo or the Commonwealth Coat of Arms
- statements to the effect that a therapeutic good is 'included in the ARTG by the TGA',
 'registered by the TGA', 'TGA listed' or similar.

The use of government endorsements without authorisation is prohibited under subsections 42DL(9) and 42DLB(6) of the Act.

For more information, including what can be included in an advertisement, see: <u>The claim</u> 'TGA approved' must not be used in advertising.

Definition of advertise

Under the Act, advertise in relation to therapeutic goods includes making:

any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

- (a) is on the label of the goods; or
- (b) is on the package in which the goods are contained; or
- (c) is on any material included with the package in which the goods are contained.

Whether information is intended to promote the use or supply of therapeutic goods is determined not by what the person responsible for the content intends, but by what a reasonable consumer would understand the intent of the content to be.

This means that if members of the public would reasonably consider that information has been intended to promote the use or supply of therapeutic goods, then the TGA would likely consider it to be an advertisement. For more information see Activities that represent advertising.

The definition of advertise applies to all forms of media, including:

- traditional media (such as television, radio and print media)
- electronic media (such as websites, mass communication via email or text messages, blogs, podcasts, discussion forums, social media and online business profiles)
- material presented to the public through other means (e.g. workshops and other face-toface sessions, expos, exhibitions, billboards, shopfronts, signage, leaflets and posters/displays).

Context in which the material is viewed

When considering whether information disseminated about therapeutic goods is advertising, it is important to consider the broader context in which the material is viewed. This includes all elements of the material that contribute to the message it conveys, including:

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

For example, if an advertisement for a health service, such as a pain treatment service, included references to medicinal cannabis (including in the <u>company, business or trading name</u>), the reasonable person viewing the material would be likely to think that the material had been created to promote the use of medicinal cannabis (for pain) as well as to promote the pain treatment service.



Including a disclaimer or caveat, for example a statement advising the reader to 'speak with a health professional about appropriate treatment

options', does not mean that the material will not amount to advertising of a therapeutic good.

Activities that may constitute advertising

If information that you provide promotes the use or supply of medicinal cannabis, then it is advertising. For more information on the characteristics of promotional material see: Activities that represent advertising.

When promoting businesses and health services, you must ensure that such promotion does not unlawfully advertise medicinal cannabis products. It is likely to be taken that you are advertising medicinal cannabis if you:

- refer to medicinal cannabis products in promotional material, either overtly or by implication
- refer to medicinal cannabis in company, business or trading names
- advertise health services that supply or prescribe medicinal cannabis
- list medical conditions that can be treated with medicinal cannabis
- · use testimonials or endorsements about medicinal cannabis
- reference additional (third party) information about medicinal cannabis.

If content is 'advertising', the advertising prohibitions and restrictions in the Act will apply. For more information see: Advertising medicinal cannabis to the public is prohibited.



We see a spectrum of potentially non-compliant behaviour in relation to medicinal cannabis products, businesses or health services. Common examples are provided below.

These examples are not exhaustive, and businesses involved with medicinal cannabis products must assess their individual materials carefully.

Referring to medicinal cannabis products

The prohibition on advertising medicinal cannabis to the public applies to *any statement*, *pictorial representation or design* that promotes the use OR supply of medicinal cannabis. This means that any representation that would be understood by a reasonable consumer to be intended to promote the use or supply of a therapeutic good is considered to be advertising and would be unlawful. This can include references to medicinal cannabis through:

- company, business or trading names
- product names or trade names or part thereof, e.g. referring to medicinal cannabis generally or a specific medicinal cannabis product
- abbreviation or acronyms for the goods or their active constituents (e.g. CBD, THC, Delta-9 etc.)

- · colloquial names or nicknames for cannabis
- other means, including hashtags or images that are likely to draw the consumer's mind to medicinal cannabis:
 - this includes photos, logos, or graphics of cannabis plants or leaves.

Referring to medicinal cannabis in company, business or trading names

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.

For more information about naming therapeutic goods see: <u>The Advertising Code and naming therapeutic goods</u>.

Example of a business name that may contravene the Act

A clinic that offers treatment of pain associated with musculoskeletal disease promotes its services under the name 'Far East Medicinal Cannabis Clinic'.

The consumer may reasonably interpret that the clinic is involved in arranging the prescription and/or supply of medicinal cannabis as an aspect of the treatment services they offer.

✓ Example of a business name that would not contravene the Act

A clinic that offers treatment of pain (including the potential prescribing of medicinal cannabis) associated with musculoskeletal disease promotes its services under the name 'Far East Musculoskeletal Pain Clinic'.

The name of this clinic would not convey to the reasonable consumer that the pain treatment could involve the prescription of medicinal cannabis.

Advertising health services that supply or prescribe medicinal cannabis

Where an advertisement for health service also promotes the use or supply of medicinal cannabis, the advertisement is prohibited under the Act. This means that it is unlawful for businesses (such as clinics) to indicate that they, or any other business, can supply medicinal cannabis, such as by stating that:

- they provide medicinal cannabis prescriptions or consultations
- they can fill prescriptions or dispense medicinal cannabis products.

The advertising of health services is not subject to the laws relating to the advertising of therapeutic goods so long as the advertising of the health service does not also promote a therapeutic product such as medicinal cannabis.

The distinction between the promotion of a health service and the therapeutic good used in the delivery of that health service can be subtle, so advertisers are urged to consider if a reasonable consumer would understand an advertisement to be promoting the use and supply of the therapeutic good.

For more information see advertising for health services.

Example of an advertisement for a health service that is likely to contravene the Act

A pain management clinic lists the following services on its website:

- Pain management
- Psychology
- Medicinal cannabis consultation and prescribing.

A reasonable consumer is likely to consider that the clinic is promoting the use of medicinal cannabis as a potential pain management treatment as well as promoting its supply through offering a prescription.

Listing medical conditions that can be treated with medicinal cannabis

A statement, pictorial representation or design that refers to medical conditions that may benefit from treatment with medicinal cannabis is likely to be an advertisement.

This includes, for example:

- listing the medical conditions that may benefit from therapy with medicinal cannabis
- listing medical conditions which medicinal cannabis has been approved to treat under the Special Access Scheme
- providing a form or other facility from which consumers can self-select from a list of medical conditions (e.g. from a drop-down box) to determine whether they may be a suitable candidate for treatment with medicinal cannabis.

Medicinal cannabis treatment should only be discussed with a patient during a consultation with a medical practitioner where the suitability of medicinal cannabis alone or in combination with other medications or therapies can then be explored.

When considering this guidance, please refer to information below on the types of information about medicinal cannabis that is unlikely to be considered advertising.

Using consumer testimonials or endorsements for medicinal cannabis

The use of testimonials and endorsements to promote the use and supply of medicinal cannabis products is likely to be considered advertising and is therefore unlawful. The use of testimonials and endorsements made by certain people is also prohibited by the Advertising Code and the Act.

An endorsement is a form of support, approval or sanction.

A testimonial is a statement about a therapeutic good made by a person who claims to have used that good or to have used it while caring for someone else.

For more information see Testimonials and endorsements in advertising.

Referencing additional (third party) information about medicinal cannabis

When considering whether information disseminated about medicinal cannabis is advertising, the <u>context</u> in which it is presented is a relevant factor. This includes additional or third-party materials that are associated with the information (such as external websites, articles or testimonials) that are likely to be seen by a person viewing the information.

Business owners are responsible for the content of any materials created or managed by them, including websites, social media channels, blog posts, hashtags, or discussion forums. This responsibility extends to user-generated content, such as third-party comments posted on those social media platforms that are controlled by the business.

For more information see social media advertising guide.

Including additional information that may render material an advertisement

A website for a pain management clinic states that the clinic can tailor a treatment plan for osteoarthritis. The website itself makes no express or implied reference to medicinal cannabis.

On this basis, the website would not be an advertisement for medicinal cannabis.

However, the website also links out to an overseas blog that promotes medicinal cannabis for the treatment of pain associated with osteoarthritis.

This reference to the blog may cause the original website to become non-compliant advertising of medicinal cannabis.

✓ Additional information that would not make the primary material an advertisement

A website for a pain management clinic promotes its services as 'pain treatments' without referring to any medicinal cannabis product.

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

The website also links to material from a patient advisory body with balanced information on the range of treatments for pain management, including medicinal cannabis.

While this secondary material refers to medicinal cannabis products, it does so in a balanced way in the context of information about a range of treatment options, and does not promote the use of medicinal cannabis by emphasising its benefits over other treatments.

Types of information about medicinal cannabis that are unlikely to be considered advertising

Not all information about therapeutic goods is considered advertising. However, when that information would be understood by a reasonable consumer to be intended to promote the

use or supply of a therapeutic good, it is advertising and the advertising provisions in the Act will apply. The context in which information is presented can be critical to whether it is understood to be promotional. See Context in which the material is viewed above.

The TGA understands that there are businesses that exist primarily to deliver educational information. These may be advocacy groups, tertiary education programs, or training aimed to educate health professionals. Factual and balanced information about medicinal cannabis is unlikely to be considered advertising, depending on the context in which the information is presented.

Examples of information that may not necessarily be promotional include:

- certain information disseminated by consumer advocacy groups
- <u>operational information about a company or business</u>, provided the information does not promote the use or supply of medicinal cannabis
- <u>genuine news</u>, reference material and scientific reports (e.g. text books, government publications, peer reviewed articles from reputable medical or scientific journals).

For more information on the characteristics of non-promotional material see: Activities that represent advertising.

Referencing or republishing non-promotional information can change information from being strictly information, to being advertising within the definition in the Act.



For example, if a medicinal cannabis manufacturer or health service refers to or republishes a scientific paper that describes the benefits of medicinal cannabis for a certain health condition on their website with introductory content such as "Dr Smith finds medicinal cannabis has significant benefits for the treatment of [condition]", this website may then be considered advertising.

For more information see: Referencing additional (third party) information above.

Information disseminated by consumer advocacy groups

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

Consumer advocacy and patient support groups can be useful sources of information for their members. Factual and balanced information about medicinal cannabis provided to support patients in relation to treatment options may not be considered to be advertising if it does not:

- actively encourage consumers to seek medicinal cannabis, for example by disseminating materials designed to persuade consumers as to:
 - the benefits of medicinal cannabis for certain medical conditions
 - the benefits or qualities of a specific medical cannabis product or manufacturer
- provide information about where to access medicinal cannabis prescriptions.

For more information see: <u>Advertising guidance for providers of disease education activities</u>.

✓ Example – information given to patient support group members which is unlikely to contravene the Act

An epilepsy patient support group provides its members with information about the use of medicinal cannabis in certain types of epilepsy. The information is an accurate assessment of the full body of evidence relating to efficacy, possible benefits and possible limitations (including potential side effects) of the use of medicinal cannabis.

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

Example – Information given to patient support group members that is likely to contravene the Act

A community organisation provides support for families dealing with child epilepsy.

They provide their members with a list of health services that can prescribe medicinal cannabis and local pharmacies who can dispense medicinal cannabis products to persons with a valid doctor's prescription.

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

Operational information about a company or business

Businesses involved in the medicinal cannabis sector may undertake a range of activities, including importation of finished product or starting materials, cultivation, harvesting and manufacture of finished products.

Businesses may publicly state what their operational activities involve but it is important that the information remains balanced and factual to ensure the material does not promote the use or supply of medicinal cannabis.

Examples of information that may not be promotional:

- information about the regulatory status of the entity, e.g. 'We are a licenced importer and supplier of medicinal cannabis products', provided that it does not:
 - refer to the quality of the products and the use of superlatives (consistent with our Activities that represent advertising guidance)
 - suggest or imply that a product has been approved or endorsed by a government agency, such as the TGA. For more information see: <u>Advertising prohibition on</u> <u>government endorsements</u>.
- information about company leadership, e.g. 'Our company directors are'
- financial details of the company
- information about current research projects.

Businesses should ensure that information contained in ASX announcements (and other company announcements) is not considered therapeutic goods advertising. For more information see: Therapeutic goods advertising and ASX announcements.

Activities that are exempt from the advertising restrictions

The advertising requirements do not apply in the activities described below.

Advertising directed exclusively to health professionals

The advertising of therapeutic goods directed exclusively to health professionals (and other persons mentioned in section 42AA of the Act) is permitted. The TGA recognises that the training and expertise of health professionals means they have the appropriate knowledge to critically evaluate information contained in advertisements.

Allowing persons other than health professionals to view advertising intended for health professionals will generally be considered unlawful advertising to the public. Such advertising may disrupt the doctor/patient relationship and create an inappropriate demand for a good or encourage inappropriate self-diagnosis.

Businesses must ensure that information provided for health professionals is not in the public domain or publicly accessible.

See <u>advertising to health professionals</u> for more information.

Information shared between a health practitioner and their patient

Information shared between a health practitioner and their patient during consultation or treatment is not subject to the advertising rules for therapeutic goods, including the prohibition on advertising prescription medicines such as medicinal cannabis.

Unsolicited mass communications (such as by email or text message) to customers containing information about a therapeutic good are unlikely to be exempt from the advertising rules because they are not advice or information given directly to a patient by a health practitioner in the course of treatment of that patient. These mass communications may amount to unlawful advertising.

Exemptions relating to news reports

There are some exceptions to the advertising rules for broadcasters, and publishers of magazines and newspapers, but they do not apply uniformly in all circumstances. It is important that broadcasters and publishers familiarise themselves with the precise scope of each exception.

The TGA is concerned about individuals and companies engaging publishers and broadcasters to promote medicinal cannabis in contravention of the Act. In these circumstances, broadcasters and publishers may be exempt from some civil penalty provisions where, as a result of steps taken by them, it is reasonable for them to assume that an advertisement does not breach those civil penalty provisions. This may be met where, for example, the broadcaster or publisher has:

- verified the identity of the advertiser
- received assurance from the advertiser, or advice from an independent legal adviser or regulatory affairs consultant, that the advertisement complies with the requirement of the Act, and

notified the advertiser that it is their responsibility to comply with the Act.

This exemption does not apply where the broadcaster or publisher is also the advertiser. , for example, where the advertisement is a news story or article.

To ensure that new stories and articles about medicinal cannabis do not constitute advertising it is important that the information presented is factual and balanced and does not, for example. emphasise the benefits over the risks and limitations or omit important information about medicinal cannabis. For more information see: Activities that represent advertising.

The Advertising Code does not apply to 'genuine news' that is published or broadcast in any medium by a broadcaster, datacaster, the SBS, the publisher of a print edition of a newspaper or magazine.

Advertising compliance and enforcement

The TGA uses a range of compliance and enforcement tools to ensure compliance with the therapeutic goods requirements. Sanctions and penalties can be imposed against those who do not comply with the advertising and other applicable regulatory requirements.

In deciding on a course of action to take in a particular case, the TGA takes into consideration a range of factors including:

- the seriousness of the alleged non-compliance and failure to follow the regulatory requirements
- the compliance history and behaviour of the responsible person or business.

See the TGA's compliance and enforcement hub for more information.

Further information

If you require clarification on specific aspects of your statements and promotions, you can:

- contact the TGA by calling 1800 020 653 (free call within Australia), or
- lodge your enquiry via our online form.

See also:

- Medicinal cannabis: Information for sponsors and manufacturers
- Unapproved therapeutic goods can only be accessed through <u>specific unapproved</u> <u>product access pathways</u>
- Further information about the regulatory requirements that apply to <u>supplying therapeutic</u> goods in Australia
- The Therapeutic Goods Act 1989
- The Therapeutic Goods Regulations 1990
- The Therapeutic Goods (<u>Therapeutic Goods Advertising Code</u>) Instrument 2021
- The Australian Register of Therapeutic Goods (ARTG)
- Information on the definition of 'therapeutic goods'

- Information on the use of <u>restricted representations or prohibited representations</u> in the advertising of therapeutic goods
- Guidance on advertising via social media
- Publishing of investigation outcomes occurs at <u>Advertising Compliance Investigations</u> <u>Outcome · Custom Portal (health.gov.au)</u>

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