

# Advertising guidance for businesses involved with medicinal cannabis

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.<sup>1</sup>

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

- Therapeutic Goods Act 1989 (the Act)
- <u>Therapeutic Goods Regulations 1990</u> (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, **advertising medicinal cannabis to the public is prohibited**.

This guidance is intended to assist those who disseminate information about medicinal cannabis, or advertise health services involving medicinal cannabis, 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
- the type of information about medicinal cannabis that is likely to be considered advertising
- the type of <u>information about medicinal cannabis that is unlikely to be considered</u> 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:

- the Narcotic Drugs Act 1967
- the <u>Competition and Consumer Act 2010</u>
- the <u>Health Practitioner Regulation National Law Act 2009</u> and corresponding state and territory laws
- State and Territory legislation.

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

<sup>&</sup>lt;sup>1</sup> Throughout this document references to medicinal cannabis should be taken to be a reference to medicinal cannabis as a substance and to finished medicinal cannabis products.

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</u>: <u>Information for sponsors and manufacturers</u>.



This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation. It provides the TGA's interpretation of requirements based on current knowledge of the subject matter. It is the responsibility of each sponsor, advertiser and supplier to understand and comply with the regulatory requirements contained in the Act and supporting legislation. You are encouraged to seek your own independent legal advice on how therapeutic goods legislation and other applicable laws apply to you.

## 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 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 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 publication, 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 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.

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 42DL(7) and 42DLB(4) of the Act respectively.

For more information see: Restricted and prohibited representations.

#### **Government endorsements**

It is unlawful to use representations in advertisements for therapeutic goods that suggest or imply that a therapeutic good 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: The claim '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 <a href="Activities that represent advertising">Activities that represent advertising</a>.

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, webinars, podcasts, expos, exhibitions, billboards, shopfronts, signage, leaflets and posters/displays).

## Whether material is advertising depends on the context in which it 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 discharge the obligation to comply with legislation.

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

If information that you provide promotes the use or supply of medicinal cannabis, or would be understood by the audience to have been designed with that intent, then it is advertising and the advertising prohibitions and restrictions in the Act will apply. For more information see: Advertising medicinal cannabis to the public is prohibited.

The TGA encounters a spectrum of potentially non-compliant behaviour in relation to medicinal cannabis, businesses or health services. These guidelines set out examples of activities and materials the TGA considers to be unlawful advertising.

These examples are not exhaustive and have been provided to help businesses understand the legislative requirements. They are not the only activities that would be considered unlawful advertising. Businesses involved with medicinal cannabis must assess their individual materials carefully.

For more information on the characteristics of promotional material see: <u>Activities that</u> represent advertising.

### Referring to medicinal cannabis in promotional materials

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 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.

Whether material is considered advertising does not depend on there being a single promotional element. Advertising can be formed from the combination of separate statements, pictorial representations, or designs that, taken together, promote the use or supply of therapeutic goods. Therefore, a reference to 'plant-based medicine', although not expressly referring to medicinal cannabis is likely to be considered promotional if, based on the surrounding context, it draws the viewers' mind to medicinal cannabis.

## Referring to medicinal cannabis in 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 cannabis
- a colloquial name for cannabis.

#### **x** Example of a business name that may contravene the Act

A clinic that offers treatment of pain associated with musculoskeletal disease includes 'Medicinal Cannabis Clinic' in its business name.

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 includes 'Musculoskeletal Pain Clinic' in its business name.

The name of this clinic would unlikely 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

Almost all references to a prescription-only medicine in the context of an advertisement for a health service would risk the advertisement becoming an advertisement in relation to a therapeutic good.

Health services where the only available treatment option involves the use of a specific prescription medicine, as is often the case with medicinal cannabis clinics, should only promote the type of consultations the service offers, not the product. For example: 'our clinic offers consultations related to pain management'.

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.

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 good, 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.

To legally promote your business or service to the public, focus your advertising on the health services you provide and do not refer to medicinal cannabis.

For more information see TGA guidance on advertising for health services.

The advertising of health services may also be subject to requirements in the laws governing Australian Consumer Law and the Health Practitioner Regulation National Law. For more information see also Ahpra Guidelines for advertising a regulated health service (ahpra.gov.au).

Ahpra and National Boards developed guidance to inform registered health practitioners and the community, their expectations of practitioners who have telehealth consultations with patients, particularly those that can prescribe medicinal cannabis such as medical practitioners and nurse practitioners. These are <u>Guidelines – Telehealth consultations with patients (Medical Board of Australia)</u> and <u>Telehealth guidance for practitioners (Ahpra and National Board)</u>.

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:

- Massage and movement therapy
- Cognitive Behaviour Therapy
- · 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. The clinic is likely to be seen as promoting the clinic as a means to obtain a prescription for medicinal cannabis.

## 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, eligibility checklist or questionnaire) 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. For more information see:

Information shared between a health practitioner and their patient below.

## Using consumer testimonials or endorsements for medicinal cannabis

The use of testimonials and endorsements about medicinal cannabis is likely to be considered advertising and is therefore unlawful.

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 <u>Testimonials and endorsements in advertising.</u>

The use of testimonials in advertising for a health service is not permitted under the <u>Health Practitioner Regulation National Law</u>. Ahpra <u>guidelines</u> explain the prohibition of using a testimonial to advertise a regulated health service, including the meaning of testimonial used for the purposes of the National Law. This applies to all registered health professionals.

## Referencing additional (third party) information about medicinal cannabis

When considering whether information disseminated about medicinal cannabis is advertising, the context in which it is presented is a relevant factor.

Businesses are reminded to carefully consider whether additional or third-party materials that are associated with information they disseminate (such as links to external websites, articles or testimonials) draw the viewers' mind to medicinal cannabis and are likely to be considered promotional. Such links, when provided in material provided by the business (such as a website), will make the business' website an advertisement for medicinal cannabis, even where it would otherwise not have been.

Additionally, 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 is likely to result in the original website being deemed an unlawful advertisement for 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 medicinal cannabis.

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, it does so in a balanced way in the context of information about a range of treatment options and is unlikely to promote the use of medicinal cannabis by emphasising its benefits over other treatments.

## Activities that are exempt from the advertising restrictions

The advertising requirements do not apply to the types of advertisements 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 advertising to health professionals 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, even where such information is promotional of medicinal cannabis, is not subject to the advertising rules for therapeutic goods.

Mass communications, such as by email or text message, or at public events such as webinars, to prospective 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 during treatment of that patient. These mass communications may amount to unlawful advertising.

### 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>
- <u>Australian Health Practitioner Regulation Agency Guidelines for advertising a regulated health service (ahpra.gov.au)</u>
- Guidelines Telehealth consultations with patients (Medical Board of Australia)
- Telehealth guidance for practitioners (Ahpra and National Board).

### **Version history**

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V1.0	Original publication	Regulatory Legal Services Branch Regulatory Education and Compliance Branch	October 2019
V2.0	Complete update and substantial rewrite	Advertising and Compliance Education and Policy Section Regulatory Compliance Branch	December 2023

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