

### Advertising a health service

Guidance on advertising services that involve therapeutic goods.

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### **Purpose**

The TGA regulates the advertising, manufacture, import, export and supply of therapeutic goods, in line with the <u>Therapeutic Goods Act</u> <u>1989</u> (the Act).

By contrast, the regulation of the promotion of health services is not within the TGA's jurisdiction.

However, if advertisements for these services also advertise therapeutic goods such as prescription-only medicines, the advertiser must comply with the requirements of the Act.

This guidance helps you to understand the advertising requirements for therapeutic goods. To ensure that your advertisement for a health service is not also considered an advertisement for therapeutic goods, it is best not to refer to any therapeutic goods used in the delivery of the service in the advertisement.

Advertising services that unavoidably involve therapeutic goods generally need to comply with the legislative requirements for advertising therapeutic goods as well as any requirements governing the advertising of services.

### Legislation

**Therapeutic Goods Act 1989** 

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

The Poisons Standard

### What is advertising?

Under the Act, advertising in relation to therapeutic goods is defined as 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.

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

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

References to both therapeutic goods and an ingredient or component used in their manufacture are taken to be references to a therapeutic good.

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; or

- that are directed exclusively to health professionals (however, not all health practitioners are included in this exemption).
  - Allowing persons other than health professionals to view advertising intended for health professionals will generally be considered unlawful advertising to the public. Businesses must ensure that information provided for health professionals is not in the public domain or publicly accessible.

For more information, please see Activities that represent advertising.

### Treatments involving prescription-only medicines

Advertising therapeutic goods to the public that contain substances included in Schedule 4 (prescription-only medicines) or Schedule 8 (controlled drugs) to the <u>Poisons Standard</u> is prohibited under sections 42DL and 42DLB of the Act. The promotion of a health service (including telehealth) as a means to obtain a prescription-only medicine is likely to amount to advertising prescription-only medicines. Decisions about treatments that involve the use of prescription-only medicines are made by a health professional in consultation with each individual patient.

When advertising health services, please have regard to the following:

- Do not directly or indirectly promote prescription-only medicines.
- Almost all references to a prescription-only medicine in the context of an advertisement for a
  health service will risk the advertisement becoming an advertisement in relation to a
  therapeutic good.
  - This applies to terms that act as a substitute for direct references to prescription-only medicines such as 'plant-based medicine', 'wrinkle reducing injections' or 'weight loss

injections'.

• The TGA considers price information for a prescription-only medicine to be an advertisement for that medicine.

When advertising health services where the available treatment(s) involve the use of prescription-only medicines or goods containing such substances, including clinics specifically established for the prescribing of nicotine vaping products, or dermal fillers, advertisers should only refer to the type of consultations the service offers. For example: 'our clinic offers consultations related to smoking cessation'; or, 'our clinic can provide consultations about reducing wrinkles'.

# Referring to prescription-only medicines in company, business or trading names

If you are a business that promotes treatment services, take care to ensure that you are not, in addition to promoting your services, also promoting prescription-only medicines.

If your business name includes a reference to a prescription-only medicine, such as 'medicinal cannabis' or 'injectables', it is likely that a consumer viewing the promotion of the service would reasonably consider that the service includes the use of these prescription-only medicines.

This includes references made directly or indirectly to prescription-only medicines through references such as:

- a trade name
- an abbreviation or acronym
- a colloquial name.

### **Cosmetic injection services**

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).

Most cosmetic injectables contain substances that are in Schedule 4 to the <u>Poisons Standard</u> and cannot be advertised to the public.

Either directly or indirectly, you cannot make any reference in your advertisement for cosmetic injection services to prescription-only substances or to product trade names of such products. This includes acronyms, nicknames, abbreviations and hashtags, which may be taken by a consumer as a reference to a specific prescription-only medicine or substance.

#### This includes:

- anti-wrinkle injections
- dermal fillers
- injectable products used for improvement of the appearance of submental fat.

This does not apply to cosmetic injectables that do not contain any prescription-only substances.

Prescription-only medicines are high risk products and patients should be assessed by a health professional before their use. Health professionals and cosmetic or beauty clinics are not permitted to advertise cosmetic injections that contain prescription-only medicines to the public.

It should be clear that the customer is being offered a health-practitioner-led consultation and that, depending on the outcome of the

consultation, this may or may not lead to the provision of a prescription.

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 <u>Compounding pharmacies</u> (below).

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

### **Medicinal cannabis prescribers**

In Australia, medicinal cannabis is currently only available on prescription from a medical practitioner. If the product is not on the <u>Australian Register of Therapeutic Goods</u> (ARTG), it must be requested by the medical practitioner for the patient through special pathways for accessing unapproved medicines.

Prescription-only medicines and unapproved medicines cannot be advertised to the public.

Advertising a health service with references to medicinal cannabis would likely have the effect of advertising medicinal cannabis.

For more information, see <u>Advertising guidance for businesses involved with medicinal cannabis products</u>.

### **Compounding pharmacies**

Extemporaneously compounded medicines are those prepared by community and hospital pharmacies for patients with requirements that cannot be met with existing commercially produced medicines.

Extemporaneously compounded medicines, although exempt from some parts of the Act, are not exempt from the advertising provisions of the Act.

### Advertising compounding services compliantly

To legally promote your service to the public, focus your advertising on the services you provide and do not refer to prescription-only substances or products containing these substances.

Take care to avoid referring to serious forms of diseases, conditions, ailments or defects without prior authorisation from the TGA. These references are prohibited or restricted representations. For more information, see Restricted and prohibited representations.

Advertisements for extemporaneously compounded medicines must not refer to any medicine that contains a substance included in Schedule 3 (pharmacist only medicines), Schedule 4 (prescription-only medicines) or Schedule 8 (controlled drugs) to the Poisons Standard, except where that substance is in Appendix H of the Poisons Standard.

#### This includes where:

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

Please note that there are certain exemptions from the scheduling requirements which may also apply.

### **Vaccine providers**

All vaccines for human use are prescription-only medicines and cannot be advertised to the public using brand names or ingredients.

Vaccine service providers cannot make any reference in advertising their health services to vaccine brands, product names or ingredients. It is also recommended that you avoid using:

- references to potentially harmful effects from not receiving the vaccine
- comparisons between vaccine types or pricing
- incentives to encourage vaccine usage
- information that conflicts with public health policies or campaigns.

### Advertising vaccination services compliantly

To legally promote your service to the public, focus your advertising on the services you provide and do not refer to prescription-only substances or products containing these substances. The only exception to this prohibition is advertising that has been authorised or required by a government or government authority within Australia. Vaccine service providers can use Australian government public health campaign advertising if displayed in full and unaltered. Advertisers who display such an advertisement must ensure that:

• the advertisement has been genuinely issued by either the Australian Government or a government of an Australian state or territory

- the advertisement itself has not been altered in any way, unless expressly provided for in the advertisement (e.g. where a space has been included for the express purpose of allowing clinics to add dates and times for vaccine availability)
- the take-out message of the advertisement is not altered in any way, including through the use of additional promotional messages near the advertisement

#### A compliant example:

A health provider displays in their clinic an Australian Government health campaign poster about the influenza vaccine. No additional promotional messages or information was included near the poster and the poster itself is unaltered. While the poster is advertising prescription-only medicines, the advertisement itself is not in contravention of the Act.

#### A non-compliant example:

• A health provider displays in their clinic an Australian Government health campaign poster about the influenza vaccine but added a note below the poster stating 'we only use [brand x] vaccines'. This additional information is promotional and would be interpreted in the context of the poster above it. The poster and additional information would be in contravention of the Act.

Public health campaigns relating to vaccination, in addition to referring to prescription-only vaccines, invariably use representations which refer to serious forms of diseases (i.e. vaccine preventable diseases). Such representations are 'restricted representations' which must not be used in advertisements for therapeutic goods without approval or permission from the TGA. The TGA has given permission for advertisements that are government public health campaigns, to contain 'restricted representations'.

Specific information on advertising COVID-19 vaccines is also available.

#### What to avoid when advertising vaccination services

When advertising vaccination services, avoid using:

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

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

### Services involving biologicals

Human Cell and Tissue (HCT) products comprise, contain, or are derived from human cells and/or tissues.

Under the therapeutic goods legislation, most HCT products are regulated as biologicals, which cannot be advertised to the public.

You cannot refer to these products when advertising your services, including brand names, abbreviations, specific references to cell types or any colloquial terms like 'stem cells'.

### Advertising services using HCT products compliantly

To legally promote your service to the public, focus your advertising on the services you provide and do not refer to HCT products or therapy procedures using these products.

Find out more about how to promote your business and service without advertising biologicals to the public.

### **Disease education**

Disease education activities can be a valuable source of information for Australian consumers as they raise awareness about diseases, aid recognition of symptoms and encourage consumers to seek appropriate advice if necessary.

These activities often involve providing information about diseases or conditions that require management by a health professional and

include references to a range of treatment options.

If the information provided is likely to encourage consumers to seek to obtain a particular good, or seek a prescription for a particular medicine, then it will be considered an advertisement.

### Providing disease education services compliantly

Educators must take care that the information they provide does not inadvertently become advertisements for therapeutic goods.

Factual, educational statements relating to treatments or therapies that a reasonable consumer would not consider to be promoting the use or supply of therapeutic goods will not amount to advertising. Whether factual, educational statements would be understood by a reasonable consumer as promoting the use or supply of therapeutic goods depends on the specific context and circumstances in which they are made.

However, if it is advertising, you must consider the applicable regulatory requirements relating to advertising therapeutic goods.

Find out more about how to promote your business and service without advertising therapeutic goods to the public.

### Additional 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.

#### **Related links**

Restricted and prohibited representations

**Topics:** 

Advertising Regulatory compliance Therapeutic goods regulation

### **Page history**

#### **18 December 2023**

Content amended to clarify how the application of the *Therapeutic Goods Act 1989* and related legislation applies to the advertising of medicinal cannabis.

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### **Related guidance**

## Advertising to health professionals so that consumer rules do not apply Updated

17 October 2024

Guidance about how to advertise therapeutic goods exclusively to health professionals.