



Australian Government
Department of Health
Therapeutic Goods Administration

Advertising guidance for businesses involved with stem cells and other human cell or tissue (HCT) products

Complying with therapeutic goods advertising restrictions

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TGA Health Safety
Regulation

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About this guidance

This guidance is to assist providers of stem cells and other human cell and tissue (HCT) products regulated as biologicals (including sponsors, manufacturers, importers, pharmacists, health professionals and marketers) in complying with the therapeutic goods advertising restrictions. Criminal and civil penalties may apply if you do not comply with your legal requirements.

The TGA has become aware that colloquial terms such as 'stem cells' are being used in advertising HCT products. Stem cells are a type of HCT product that are regulated as biologicals and cannot be advertised to the public.

This guidance is to assist your understanding about how to promote your business and service without advertising biologicals 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
- compliance and enforcement as it applies to non-compliant advertising

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

For general information on advertising therapeutic goods, see the [Advertising Hub: Advertising code and guidance](#) and [Why and how the advertising of therapeutic goods is regulated](#).

If you are a member of the public and are interested in how the advertising of therapeutic goods is regulated or would like to make a complaint about an advertisement see the [Advertising Hub](#).

Why there are advertising restrictions

Therapeutic goods are intended to have a therapeutic effect and influence the health status of the people that use, or are considering using, them. Many of these people will be vulnerable because of the disease or condition that they are facing or because of a general concern about their health. Additionally, if consumers have not found relief from the symptoms of a health condition through conventional means, they may be especially vulnerable to claims made about emerging, 'experimental' treatments. These factors may impact on their ability to critically evaluate advertising to assess whether a particular good is appropriate for them.

Therefore, the advertising of therapeutic goods is subject to special advertising requirements in order to protect consumers.

Failing to have regard to the general principles set out here may risk breaching the [Therapeutic Goods Act 1989](#) (the Act) and the [Therapeutic Goods Advertising Code \(No.2\) 2018](#) (the Code).



The decision to use HCT products is a decision that should be made in conjunction with a treating health professional.

Advertising most HCT products to the public is prohibited

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

[Autologous HCT products](#) are those that are removed from, and applied to, the same person. Autologous HCT therapies are often promoted as 'stem cell' therapies.

Under the therapeutic goods legislation, most HCT products are [regulated as biologicals](#).

HCT products regulated as biologicals

To understand if your HCT product is regulated as a biological, please visit our [What is regulated as a biological](#) page.

HCT products that are [regulated as biologicals](#):

- **are prohibited from being advertised to the public**
 - under the *Therapeutic Goods Act 1989* (subsection 42DL(11))

[Information for health professionals on accessing unapproved biologicals](#) is on the TGA website.

If you are unsure how your product is regulated please contact the TGA biologicals team on 1800 020 653 (free call within Australia) or via the [Request for advice - Biologicals](#) form.

HCT products that are not regulated as biologicals

HCTs are used in a [range of different types of therapeutic goods](#). How your HCT product is regulated will inform you of the restrictions and any prohibitions around advertising.

Even though your HCT product may meet the definition of a biological, it may not be regulated as a biological.

Refer to [Australian Regulatory Guidelines for Biologicals \(ARGB\)](#) to check if your biological is:

- excluded from TGA regulation
- regulated as a different therapeutic good, but not as a biological
- regulated as a biological

If you are unsure how your product is regulated please contact the TGA biologicals team on 1800 020 653 (free call within Australia) or via the [Request for advice - Biologicals](#) form.

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 not only what the person responsible for the material intends, but also what the reasonable consumer views as being intended by the material. If the reasonable consumer considers that the material promotes the use or supply of therapeutic goods, then the material is considered an advertisement according to the Act (see [Activities that 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, depending on the content of the material.



See the [TGA 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.

Roles and responsibilities

The TGA

The TGA regulates HCT products and is responsible for administering the Act and the Code, which specify requirements and prohibitions relating to the advertising of therapeutic goods.

The Act:

- prohibits biologicals 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.

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

The TGA may pursue [sanctions and penalties](#) against those who do not comply with the advertising and other applicable regulatory requirements.

HCT business and services

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

- the [Competition and Consumer Act 2010](#),
- 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](#)

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 therefore must meet the legislative requirements as set out in the Act and the Code (see [Advertising and the Act](#)).

Further information about the types of activities that can be considered advertising is provided in the [Australian Regulatory Guidelines for Advertising Therapeutic Goods \(ARGATG\)](#). However, the following additional considerations may also be relevant.

Is it information or promotion

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 HCT products are those that do not promote the use or supply of HCT products 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 [ARGATG](#).

Promoting your health service or business

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

- [company, business or trading names](#)
- product names or trade names
- abbreviation or acronyms for the good
- colloquial names (e.g. stem cells)
- any other reference, including images, that are likely to draw the consumer's mind to HCT products

An example of promotion of HCT products to the public that contravenes the Act

A clinic offering surgery that uses the patient's own cells promotes this service with statements such as:

"City West Beauty Clinic offers surgery that uses your own scientifically modified mesenchymal cells to stimulate collagen production, promote cell regeneration and enhance youthful skin behaviour".

This would promote the use and supply of HCT products, as it is directly referencing the use of an **individual's mesenchymal** cells.

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 HCT products. If your business name includes a reference to HCT products, it is likely that a consumer viewing the service promotion would reasonably consider that the service includes the use of HCT products.

This includes references made to HCT products through:

- a trade name for an HCT therapeutic good
- an abbreviation or acronym for the good
- a colloquial name (e.g. stem cells)

or

- any other reference (including images) that would draw the consumer's mind to an HCT product

An example of a business name that contravenes 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 Stem Cell Clinic”

The consumer would reasonably interpret that the clinic utilises an HCT product, ('stem cells') in the treatment it offers.

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

“Far East Musculoskeletal Clinic”

Provided the clinic is otherwise compliant (see [ARGATG](#) for more info) then the clinic's website would not reasonably convey to the consumer that the pain treatment would involve the use of HCT products.

Referencing additional information

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

Including additional information can render material an advertisement

Ü A website for a pain management clinic promotes its services as 'pain treatments' and includes a link 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 HCT products, does so in the context of information about a range of treatments and does not promote the use of HCT products by emphasising their benefits over other treatments.

Ü However, the material may be considered an advertisement for HCT products, if it was to include a link to an overseas blog about how effective stem cells are for the treatment of osteoarthritis. This would be assessed in context.

Patient support groups

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 HCT products or by a patient support group:

- must not promote HCT products
- must not encourage members to seek HCT products

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

An example of advertising to patient support group members that is likely to contravene the Act

Canberra Chronic Arthritis Group members receive material informing them that 'City West Clinic' offers the latest stem cell therapies which are beneficial in managing joint pain. The material states:

"We make these therapies from your own stem cells to produce MSC injections. City West Clinic supports and offers a discount for Canberra Chronic Arthritis Group members".

This information actively encourages Canberra Chronic Arthritis Group members to seek particular HCT products from the clinic and is therefore an illegal advertisement.

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

Canberra Chronic Arthritis Group has collated information about the use of stem cell treatments in managing joint pain. 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 HCT products.

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 HCT therapy would be of benefit to them.

Supply of biologicals

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



Supply of biological therapeutic goods has the potential to pose a significant public health risk.

It is a criminal offence under section 32BD of the *Therapeutic Goods Act 1989* for a person to supply in Australia an unapproved biological product for therapeutic use in humans. This includes HCT products regulated as biologicals.

The TGA undertakes compliance and enforcement activity where there is a breach of legislative requirements relating to the supply of therapeutic goods.

Further information is available about the regulatory requirements that apply to [supplying therapeutic goods in Australia](#).

A risk-based approach to enforcement

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

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 the advertiser ranging from mild to very serious.

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](#) for specific details and more information.

Further information

If you require clarification on specific aspects of advertising, 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](#).

Version history

Version	Description of change	Author	Effective date
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Therapeutic Goods Administration

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