

# Stem cell products cannot be advertised to consumers

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Before an autologous HCT product can be administered to a patient, a medical or dental professional needs to assess whether the therapeutic good is appropriate and suitable for that patient.

Advertising that encourages consumers to seek out such treatments prior to such an assessment may undermine the 'medical or dental practitioner-patient' relationship and is prohibited under the *Therapeutic Goods Act 1989* (the Act).

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 TGA may pursue sanctions and penalties against those who do not comply with the advertising and other applicable regulatory requirements.

Human cell and tissue (HCT) products are those that comprise, contain or are derived from human cells and tissues.

## Autologous human cell and tissue products

Autologous human cell and tissue (HCT) products are those that are removed from, and applied to, the same person, i.e. the donor and the recipient are the same. These include some products commonly referred to as 'stem cell treatments'.

## Examples of autologous human cell and tissue products

Examples of autologous HCT products that this guidance applies to include...

- blood and blood components (red cells, plasma, serum, platelets, and platelet-rich plasma (PrP))
- skin grafts for treatment of burns
- bone grafts
- bone marrow transplants
- conditioned serum
- genetically-altered lymphocytes to target cancers
- bone marrow-derived stem cells for non-haematological indications
- adipose-derived cell extracts (including stromal vascular fraction (SVF))

Most of these HCT products would be regulated as biologicals under the biological regulatory framework, except blood components.

Advertising of services is permitted

Services (*that do not mention specific products*) are permitted to be advertised. However, the advertisement must comply with...

- The Act and associated subordinate legislation,
- Health Practitioner Regulation National Law (and applicable advertising guidelines),
- Australian Consumer Law, and
- State and Territory Laws.

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, an advertiser *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.

## Compliance with the therapeutic goods legislation

### Advertising should...

- Focus on the services that the business provides *without referencing the autologous HCT product*.
- Not make any specific reference to autologous cell and tissue products associated with the services.
- Not provide information and/or advice, on medical or dental professional's websites, for patients to consider particular types of treatments involving autologous cells and tissue products.
- Not reference trade names of autologous HCT products (e.g. abbreviations, acronyms) or colloquial names such as 'stem cells'.
- Testimonials that refer to autologous HCT products are also likely to be considered advertising and are subject to the same requirements.

*An advertisement for a health service that specifies the use of any autologous HCT product associated with that service is not permitted as it would promote the product also.*

These requirements apply to health professionals and professional bodies.

*The requirements apply to all forms of media, including traditional media (such as television, radio, print media and posters/displays) and electronic media (such as websites, emails, blogs, discussion forums and social media).*

## Penalties for non-compliance

In the first instance, the TGA seeks to inform, educate and assist advertisers to comply with the rules relating to advertising. However, if this approach fails, we may take further action to achieve compliance.

The Act provides for financial penalties for advertising breaches. Fines for such offences can be up to \$840,000 for individuals and up to \$4,200,000 for corporations.

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