



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

# Advertising personalised medical devices in Australia

Guidance to understand the rules for advertising therapeutic goods to consumers.

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# Purpose

Sponsors of medical devices must follow the rules for advertising therapeutic goods to consumers. There are legal requirements you must meet under:

- the *Therapeutic Goods Act 1989* (the Act)
- the Therapeutic Goods Advertising Code (the Code)
- other relevant laws including the *Competition and Consumer Act 2010*.

The TGA administers the Act and the Code. In the event of inappropriate advertising for medical devices, we'll take required action. If necessary, we can issue infringement notices or take court action.

## Legislation

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Therapeutic Goods Act 1989

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Competition and Consumer Act 2010

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## Advertisements

Advertising is any statement, image, or design aimed to promote the use or supply of a therapeutic good. Examples include:

- statements, images, and designs promoting a device

- device information (label and packaging)
- electronic material posted on the internet (websites, social media)
- articles and advertorials published in magazines and newspapers (digital or hard copy)
- displays on posters and notices
- photographs, film, broadcast material and video recordings.

## What you can advertise

You can generally advertise to consumers if your medical device is:

- included in the Australian Register of Therapeutic Goods (ARTG) or
- exempt from ARTG inclusion because it is custom-made or
- a patient-matched medical device that is not included in the ARTG, providing you have submitted a transition notification.

## What you can't advertise

There are things you can't say in advertising.

'Prohibited representations' include language that refers to preventing, curing, treating, or diagnosing serious conditions. Examples include cancers, HIV, sexually transmitted infections (STI's) and mental illness.

You can only refer to other serious conditions and diseases including diabetes, asthma, and cataracts if you have our approval first.

This kind of wording is a 'restricted representation'.

You can apply for approval to use restricted representations in your advertisement. We will consider whether what you've said is accurate, balanced and not misleading.

# Examples

## Compliant advertising example



The image shows a Facebook post from the page 'BeanzAligners', which is marked as 'Sponsored'. The post features a list of two points and a large image of a smiling woman with curly hair.

**BeanzAligners** Sponsored

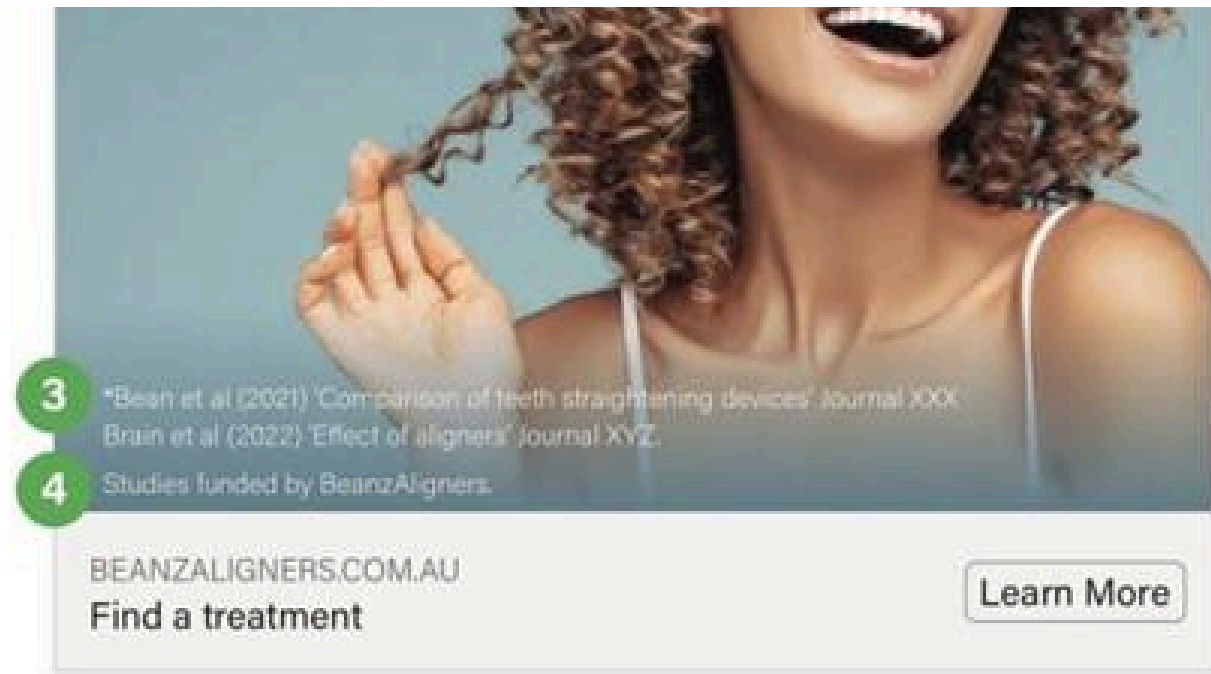
Shine through your smile with removable aligners:

- 1 • This treatment is a series of orthodontic aligners that gently move your teeth over time.
- 2 • Studies show our aligners will straighten your smile.

2 • ALWAYS FOLLOW THE DIRECTIONS FOR USE

**Studies show our aligners will straighten your smile.**

Ask your dentist if aligners are right for you.



1. Advertisements can provide balanced, factual, and substantiated information.
2. Must contain and prominently display either of the following mandatory statements:
  - Always follow the directions for use
  - Always read the label and follow the directions for use
3. Consumers must be able to locate or request details about clinical studies mentioned.
4. Scientific or clinical research references must identify the financial sponsor (if known).

Show description of image

The image shows a sponsored advertisement for BeanzAligners, a company offering removable dental aligners. The ad has several key components:

1. A logo featuring a tooth icon at the top.
2. Text outlining the benefits and instructions for their aligners:
  - "Shine through your smile with removable aligners"
  - "This treatment is a series of orthodontic aligners that gently move your teeth over time."
  - "Studies show our aligners will straighten your smile."
  - "ALWAYS FOLLOW THE DIRECTIONS FOR USE"
3. A central image featuring a woman with curly hair smiling broadly. She appears to have straight, white teeth.
4. A text overlay on the image stating: "Studies show our aligners will straighten your smile.\*" and "Ask your dentist if aligners are right for you."
5. Small print at the bottom referencing studies, likely as citations for their claims.
6. A "Learn More" button at the bottom right.
7. The company's website address: BEANZALIGNERS.COM.AU

The ad is designed to promote the effectiveness of their aligners for straightening teeth, emphasising the scientific backing of their claims and encouraging potential customers to consult with their dentists.



## Non-compliant advertising example



 **BeanzInsoles**   
Sponsored 

Our therapeutic insoles are designed for your foot and will provide:

- 1 • Optimal arch support guaranteed to reduce pain for life
- 2 • Relief from pain associated with arthritis
- 3 • Effective pain relief, unlike other devices that may cause harm





This advertisement is non-compliant because:

1. It states or implies that the advertised good is effective in all cases, or a guaranteed cure.
2. Ads referring to serious conditions and diseases can only be included with our approval.
3. It states or implies that another device is ineffective or harmful
4. Health professionals or medical researchers may not endorse products in advertisements
5. Advertisements cannot include phrases like 'TGA approved' or similar.
6. This advertisement does not contain the mandatory statements:
  - Always follow the directions for use
  - Always read the label and follow the directions for use.

Show description of image

This image is an advertisement for therapeutic insoles by a company called BeanzInsoles. The ad is presented as a sponsored social media post. Here's a detailed description of its contents:

1. The top of the image shows the company logo (a blue circle with a foot icon) and name "BeanzInsoles".
2. The main text introduces their product: "Our therapeutic insoles are designed for your foot and will provide:"
3. Three bullet points are listed, each numbered:
  - a. "Optimal arch support guaranteed to reduce pain for life"
  - b. "Relief from pain associated with arthritis"
  - c. "Effective pain relief, unlike other devices that may cause harm"
4. The central part of the image shows a bare foot hovering above a blue and yellow insole. The insole appears to have multiple layers and a contoured shape.
5. Below the image, two additional selling points are listed: 4. "Designed by podiatrists" 5. "TGA approved"
6. At the bottom, there's a website URL: "BEANZINSOLES.COM.AU" and a "Learn More" button.
7. The overall design uses a mix of blue and white colours, with red numbering for the bullet points.

This advertisement emphasises the medical benefits and professional design of their insoles, targeting individuals with foot pain or arthritis.

## Related links

[The Therapeutic Goods Advertising Code](#)

[Advertising](#)

[Regulatory affairs consultants](#)

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**Topics:**      [Advertising](#) [Medical devices safety](#)

## Page history

### 30 January 2024

Changed title from 'General requirements for advertising personalised medical devices to consumers' to 'Advertising personalised medical devices'.

Added introductory paragraph.

Renamed first subheading from 'What the TGA means by advertisements' to just 'Advertisements'. Rewrote first paragraph. Slight refinement of list.

Addition of subheading 'Examples'.

Renamed subheading from 'This is a compliant advertisement' to 'Compliant'. Updated list content.

Renamed subheading from 'This is a non-compliant advertisement' to 'Non-compliant'. Updated list content.

Renamed final section from 'Additional resources and information' to 'More information'. Distilled the content to just the links.

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## **9 May 2023**

Original publication.



