



# General requirements for advertising personalised medical devices to consumers

Does your product<sup>1</sup> meet the definition of a medical device? If so, you will need to make sure you understand the rules for advertising therapeutic goods to consumers. There are legal requirements you must meet under:

- the *Therapeutic Goods Act 1989*<sup>2</sup> (the Act)
- the Therapeutic Goods Advertising Code<sup>3</sup> (the Code)
- other relevant laws including the *Competition and Consumer Act 2010*

The Therapeutic Goods Administration (TGA) is responsible for ensuring that any advertising for medical devices adheres to legal requirements. We have powers to issue directions to advertisers, impose fines or pursue court action if needed.

For further information, please refer to the Links section at the end of the document.

## What the TGA means by 'advertisements'

A wide range of material can be advertising. Any statement, image or design that is intended, whether directly or indirectly, to promote the use or supply of a therapeutic good is advertising. Examples include:

- Statements, images and designs promoting a device
- Information you provide with the device, that might induce someone to use or supply the product (including, the label and packaging)
- Articles and advertorials published in magazines and newspapers (digital or hard copy)
- Displays on posters and notices
- Photographs, film, broadcast material and video recordings
- Electronic transmissions and material posted on the internet, including websites and in social media (Including

any comments, reviews or tags in social media posts that promote the use or supply of the device)

## What can you advertise?

You can generally advertise to consumers as long as your medical device is:

- Included<sup>4</sup> in the Australian Register of Therapeutic Goods (ARTG)<sup>5</sup>; or
- Exempt from ARTG inclusion because it is custom-made<sup>6</sup>; or
- A patient-matched medical device that is not included in the ARTG, providing you have submitted a transition notification<sup>7</sup>.

There are legal requirements around what you can say in advertisements and you must ensure you comply with them at all times. This includes ensuring your advertisements support the safe and proper use of the medical device, and contain information that is accurate, substantiated and not misleading<sup>8</sup>.

## What can't you advertise?

There are some specific things you can't say in advertising. "Prohibited representations"<sup>9</sup> include wording that refers to preventing, curing, treating or diagnosing certain serious conditions (including cancers, HIV, STI's and mental illness).

You can only include wording referring to other serious conditions and diseases including diabetes, asthma and cataracts if you have our approval first. This kind of wording is known as a "restricted representation"<sup>10</sup>. You can apply for approval<sup>11</sup> to use restricted representations in your advertisement. We will consider whether what you've said is accurate, balanced and not misleading.

## This is a compliant advertisement

1 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

2 Studies show our aligners will straighten your smile.

3 Ask your dentist if aligners are right for you.

3 \*Sean et al (2021) 'Comparison of teeth straightening devices' Journal XXX  
Brain et al (2022) 'Effect of aligners' Journal XYZ  
Studies funded by BeanzAligners.

4 BEANZALIGNERS.COM.AU  
Find a treatment [Learn More](#)

- 1 Advertisements can provide balanced, factual and substantiated information.
- 2 Advertisements for medical devices 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 Advertisements for medical devices must contain sufficient information for consumers to locate or request details about any scientific or clinical studies referenced.
- 4 Advertisements for medical devices that refer to scientific or clinical research must identify the financial sponsor of the research where the advisor knows or ought reasonably to have known that information.

## This is a non-compliant advertisement

1 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

4 Our insoles are: ✓ Designed by podiatrists ✓ TGA approved

6 BEANZINSOLES.COM.AU  
Get a quote today [Learn More](#)

- 1 Advertisements must not state or imply that the advertised good is effective in all cases, or a guaranteed cure.
- 2 Wording referring to serious conditions and diseases is only allowed to be included in your advertisement if we have approved you to do so.
- 3 Advertisements must not state or imply that another device is ineffective or harmful.
- 4 Advertisements cannot contain either explicit or implied endorsement of the product by health professionals or medical researchers.
- 5 Advertisements cannot include phrases like "TGA approved" or similar.
- 6 Advertisements for medical devices 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

## Additional resources and information

Check our answers to frequently asked questions<sup>12</sup> on advertising personalised medical devices.

Use our checklist<sup>13</sup> to help you assess your compliance with legal requirements for advertising to consumers.

The TGA advertising hub<sup>14</sup> contains guidance and learning resources for advertisers. It also contains updates and information about the regulation of therapeutic goods advertising.

You can seek advice from a regulatory affairs consultant<sup>15</sup> or obtain independent legal advice.

## Links

- [1] [www.tga.gov.au/sme-assist/my-product-therapeutic-good](http://www.tga.gov.au/sme-assist/my-product-therapeutic-good)
- [2] [www.legislation.gov.au/Series/C2004A03952](http://www.legislation.gov.au/Series/C2004A03952)
- [3] [www.tga.gov.au/publication/therapeutic-goods-advertising-code](http://www.tga.gov.au/publication/therapeutic-goods-advertising-code)
- [4] [www.tga.gov.au/publication/medical-device-inclusion-process](http://www.tga.gov.au/publication/medical-device-inclusion-process)
- [5] [www.tga.gov.au/australian-register-therapeutic-goods](http://www.tga.gov.au/australian-register-therapeutic-goods)
- [6] [www.tga.gov.au/custom-made-medical-devices](http://www.tga.gov.au/custom-made-medical-devices)
- [7] [www.tga.gov.au/medical-devices-reforms-personalised-medical-devices](http://www.tga.gov.au/medical-devices-reforms-personalised-medical-devices)
- [8] [www.tga.gov.au/guidance-applying-advertising-code-rules](http://www.tga.gov.au/guidance-applying-advertising-code-rules)
- [9] [www.tga.gov.au/restricted-and-prohibited-representations](http://www.tga.gov.au/restricted-and-prohibited-representations)
- [10] [www.tga.gov.au/restricted-representations](http://www.tga.gov.au/restricted-representations)
- [11] [www.tga.gov.au/form/application-approval-use-restricted-representation-advertising](http://www.tga.gov.au/form/application-approval-use-restricted-representation-advertising)
- [12] [www.tga.gov.au/regulatory-framework-personalised-medical-devices-frequently-asked-questions](http://www.tga.gov.au/regulatory-framework-personalised-medical-devices-frequently-asked-questions)
- [13] [www.tga.gov.au/resource/advertising-compliance-checklist-consumer-advertising](http://www.tga.gov.au/resource/advertising-compliance-checklist-consumer-advertising)
- [14] [www.tga.gov.au/hubs/advertising-therapeutic-goods](http://www.tga.gov.au/hubs/advertising-therapeutic-goods)
- [15] [www.tga.gov.au/regulatory-affairs-consultants](http://www.tga.gov.au/regulatory-affairs-consultants)