Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising software-based devices to consumers

This fact sheet includes guidance for industry about advertising software-based medical devices to consumers.

Different rules apply to advertising to health professionals. If you intend to advertise to health professionals, please refer to our fact sheet on: Advertising software-based devices to health professionals[1].

If you have a software-based product that meets the definition of a medical device, you will need to make sure you understand the rules for advertising devices before you advertise or provide promotional information about your product. There are legal requirements that must be met under:

- the *Therapeutic Goods Act 1989* (the Act)[2]
- the *Therapeutic Goods Advertising Code* (the Code)[3]
- other relevant laws including the *Competition and Consumer Act 2010*[4]

The Code is intended to ensure that the marketing and advertising of therapeutic goods is responsible, promotes safe and proper use of therapeutic goods, does not lead to delayed necessary medical attention, and does not mislead or deceive.

How advertising statements can make your product a medical device

If you make statements that your product can be used to diagnose, predict, prevent, treat or monitor a disease or medical condition, your product is likely to meet the definition of a medical device under the Act.

Some software designed solely for use by consumers does not need to be regulated by the TGA. More detail about excluded products can be found in the *Therapeutic Goods (Excluded Goods) Determination 2018*[5]. If your product is excluded, you do not need to comply with the advertising rules but consumer and competition laws[6] will continue to apply.

Further information on the definition of a medical device[7] and examples that illustrate the difference between regulated and unregulated software[8] is available on the TGA website.

Medical device

A smartphone app designed to detect or monitor sleep apnea (a medical condition) will meet the definition of a medical device and will need to comply with the advertising rules.

Not a medical device

A smartphone app solely designed to measure sleep quality does not meet the definition of a medical device and does not need to comply with the advertising rules for therapeutic goods.

What is advertising material?

Information that is intended, directly or indirectly, to promote the use or supply of your (therapeutic) product is advertising. Indirect intent refers to what the reasonable person viewing the material would consider the intent of the material is. Advertising can be provided in different locations, such as:

- displayed in an app or on a website
- in downloads or on app stores
- on your product's label and packaging
- provided with the product
- on your website and/or social media
- via training materials, such as slideshows and videos.

Advertisements are often published in the form of statements, images, and designs intended to promote a product on the internet, in magazines and newspapers, on posters and notices, via photographs and film, in broadcast media, video recordings, webinars and electronic transmissions (text, chat messages, etc.)

Advertisements are also often included in point-of-sale materials, catalogues and inserts, leaflets, booklets, and other promotional materials that include specific statements about your product.

Advertising that is made accessible to consumers

The claims that you can make in your advertising material will depend on whether you are advertising directly to consumers or limiting your advertising to health professionals only. If you do not take steps to ensure your material can only be accessed by a health professional, you must comply with the consumer advertising requirements.

You may be subject to civil and criminal penalties if your advertising is accessible to consumers and it does not comply with the legal requirements for advertising therapeutic goods to consumers. This is the case even if your intention is to advertise your medical device to health professionals only.

What you can't say when advertising to consumers

There are some words and phrases that you are not allowed to include when advertising medical devices:

- you **are not allowed** to say "TGA approved"
- you **are not allowed** to make unsubstantiated claims about the performance of your products
- you **are not allowed** to have endorsements or testimonials for your device from a health professional or medical researcher

Prohibited representations

You are usually **not allowed** to use any wording or images that refer to preventing, curing, monitoring, treating or diagnosing certain serious conditions (eg. all cancers, HIV, sexually transmitted diseases, hepatitis C and mental illness).

Where there is a public health benefit, the TGA can permit such references. See prohibited representations for further information[9].

Restricted representations

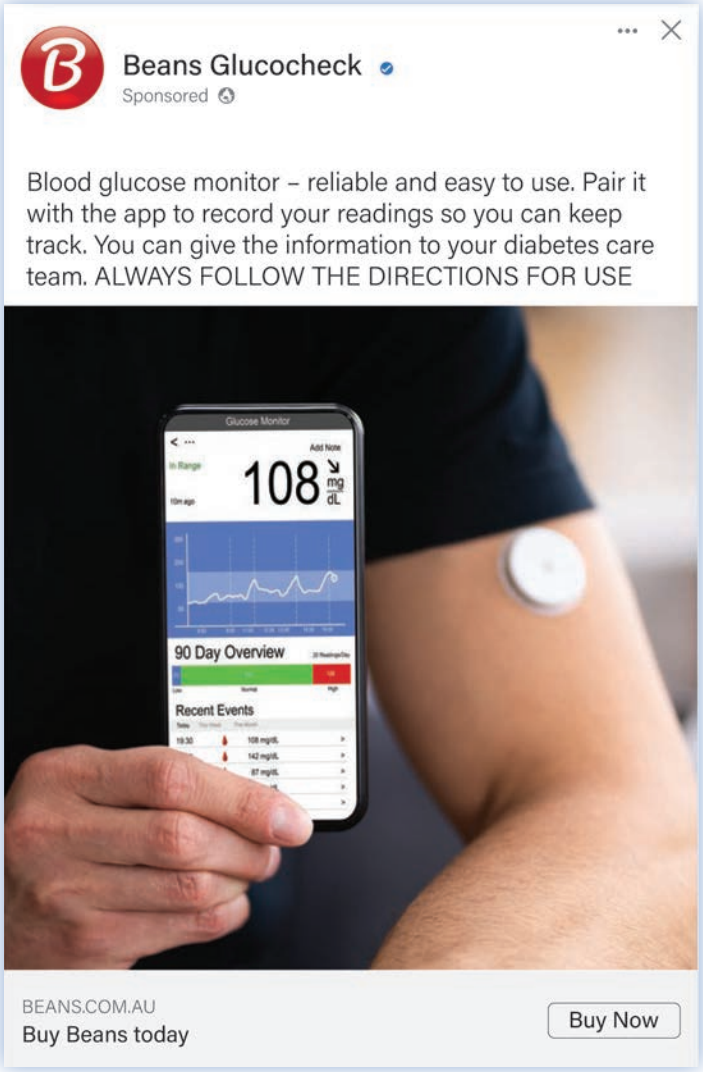
Representations that refer to other serious conditions and diseases (such as heart conditions, diabetes, and asthma) are 'restricted representations' and are only allowed to be used in your advertisement if the TGA has approved you to do so.

You can apply[10] to the TGA for approval to include wording in your advertisement that refers to a serious condition. What you propose must be accurate, balanced, and must not be misleading. Please refer to the list of already permitted restricted representations[11] for more information.

What you must say

Your advertisement must contain:

- your accurate description of the device
- your trade name of the device
- your intended purpose(s) of the device
- mandatory statements and health warnings as required[12]



You cannot refer to 'diabetes' – which is a 'restricted representation' – without prior approval from the TGA.

This applies event if the representation is made about an excluded app, because the representations is being made in an advertisement for a regulated medical device.

Links

1. tga.gov.au/sites/default/files/2023-04/factsheet-advertising-software-based-medical-devices-health-professionals.pdf
2. legislation.gov.au/Series/C2004A03952
3. legislation.gov.au/Series/F2021L01661
4. legislation.gov.au/Series/C2004A00109
5. legislation.gov.au/Series/F2018L01350
6. accc.gov.au/consumers/buying-products-and-services
7. tga.gov.au/how-we-regulate/manufacturing/medical-devices/manufacturer-guidance-specific-types-medical-devices/regulation-software-based-medical-devices
8. tga.gov.au/resources/resource/guidance/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices
9. tga.gov.au/how-we-regulate/advertising/how-advertise/restricted-and-prohibited-representations-advertising/restricted-and-prohibited-representations
10. tga.gov.au/resources/resource/forms/application-approval-use-restricted-representation-advertising
11. tga.gov.au/resources/advertising-permissions
12. tga.gov.au/complying-advertising-requirements
13. accc.gov.au

Further information

Visit the TGA's advertising hub: tga.gov.au/how-we-regulate/advertising

Advertisements must also comply with the *Competition and Consumer Act 2010*, which is administered by the Australian Competition and Consumer Commission (ACCC)[13], as well as state and territory government requirements.