Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Advertising software-based medical devices in Australia

Guidance about the requirements for advertising software-based medical devices to consumers or health professionals.

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Contents

Purpose

This guidance helps developers, and advertisers understand their legal obligations when promoting software based medical devices to the public. It outlines, key rules for advertising and how claims affect a product's regulatory status.

Legislation

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

Therapeutic Goods Act 1989

Introduction

Therapeutic goods can affect a person's health and the rules for advertising them are stricter than those for everyday consumer products. These additional rules exist to protect consumers, who may be particularly vulnerable when making decisions about their health. The rules also ensure consumers of therapeutic goods are properly informed about the goods they are choosing.

Most advertising rules do *not* apply when your advertising is directed *only* to health professionals. However, if your advertising targets consumers, the full set of rules applies. These requirements apply to all therapeutic goods, including software-based medical devices.

If your software is a medical device under section 41BD of the *Therapeutic Goods Act 1989* (the Act), it will be regulated by us. In that case, you are responsible for complying with the relevant legislation when you advertise your product.

Some software-based products that may seem to meet the definition of a medical device are excluded from regulation by us. If your product is excluded, you do not need to meet the advertising requirements under the Act providing you do not make any therapeutic claims which would void the exclusion. However, you must still comply with consumer and competition laws. For more information, refer to the Therapeutic Goods (Excluded Goods) Determination 2018 or our guidance on the exclusions.

If your product is a medical device, in addition to the Act, you must comply with the following legal requirements when advertising to consumers or health professionals:

- the *Therapeutic Goods Advertising Code* (the Code)
- other relevant laws including the *Competition and Consumer Act 2010* administered by the Australian Competition and Consumer Commission (ACCC)

The Code ensures that advertisements for therapeutic goods are responsible and supports safe and appropriate use.

Example 1: Software that is a medical device

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

Example 2: Software that is not a medical device

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

Advertising material

Advertising material includes any information that directly or indirectly promotes the use or supply of your therapeutic product. Indirect promotion includes material that a reasonable person would interpret as having a promotional purpose.

Advertisements can appear in many forms and locations. They often include statements, images or designs that promote a product. These may be published:

- online (including websites, apps, downloads and app stores)
- in print (such as magazines, newspapers, posters and notices)
- through media (including social media. photographs, films, video recordings, webinars and broadcasts)
- via electronic communication (such as text messages and chat platforms).

Advertisements may also appear in:

- point-of-sale materials
- catalogues and inserts
- leaflets, booklets and other promotional content that includes specific claims about your product.

Advertising claims can define your product’s regulatory status

The claims you make in advertising can impact whether your software will be regulated as a medical device. If you state that your product can diagnose, predict, prevent, treat or monitor a disease or medical condition, this may establish its intended purpose is therapeutic. In doing so, your product is likely to meet the definition of a medical device under the Act.

This means your product must comply with the relevant regulatory and advertising requirements. For more information on how software is classified and the distinction between regulated and unregulated products, see Understanding how we regulate software-based medical devices.

Advertising that is accessible to consumers

If your advertising is accessible to the public, it must

- comply with the Code, which sets standards for advertising therapeutic goods to the public. For more information see Applying the Advertising Code.
- not include prohibited or restricted representations unless you have our prior approval.

Even if your intention is to advertise only to health professionals, you may still be in breach of the law if the material is accessible to consumers.

Factual and balanced information – such as scientific or medical information intended for health professionals – does not need to be secured, providing it is not promotional. For example, product information indexed only by product name is generally acceptable. See also below Advertising to health professionals.

You may face civil or criminal penalties if your advertising is accessible to consumers and does not meet the legal requirements for consumer advertising. This is the case even if your intention is to advertise your medical device to health professionals only.

What you must include in consumer advertising

Your advertisement must contain:

- an accurate description of the device
- the trade name of the device
- the intended purpose(s) of the device
- any mandatory statements and, where relevant, health warnings.

What you must not include in consumer advertising

For example, you must **not**:

- claim your product is “TGA approved”
- make unsubstantiated claims about the product’s performance
- include endorsements or testimonials from health professionals or medical researchers.

Prohibited representations

You are generally **not allowed** to refer to preventing, curing, monitoring, treating or diagnosing serious conditions such as cancer, HIV, sexually transmitted infections, hepatitis C or mental illness.

In some cases, we may permit such references if there is a clear public health benefit. For more information, see our guidance on Restricted and prohibited representations in advertising.

Restricted representations

You may use representations in your advertisements that refer to other serious conditions (such as heart disease, diabetes or asthma) only if you have received TGA approval. Approval to use a ‘restricted representation’ will only be given where the representation is accurate, balanced and not misleading. See the Advertising permissions page for a list of approved restricted representations.

See the Restricted and prohibited representations in advertising page for information on how to apply for TGA

approval of a restricted representation.

Advertising to health professionals

If your advertising is accessible **only** to health professionals, it is exempt from almost all the requirements that apply to consumer advertising. However, if you do not take appropriate steps to restrict access, your material must comply with the rules for advertising to consumers.

Who is considered a health professional?

Section 42AA of the Act defines a health professional in the context of advertising. The definition includes:

- medical practitioners
- dentists and dental hygienists
- pharmacists
- optometrists
- physiotherapists
- nurses
- naturopaths
- nutritionists
- traditional Chinese medicine practitioners.

Section 42AA also mentions:

- persons involved in the **wholesale supply** of therapeutic goods
- **purchasing officers** for hospitals, government bodies, or registered charities
- **practice managers** working for any of the above health professionals (excluding those in retail pharmacy).

If your advertising is accessible to anyone **not** listed in section 42AA, it must comply with the requirements for consumer advertising.

How to restrict advertising to health professionals

To be exempt from the advertising requirements, you must ensure your advertising is secured and accessible only by verified health professionals. You can do this by:

- using secure authentication methods (e.g. encryption)
- implementing an authorisation process such as:
    - matching Australian Health Practitioner Regulation Agency (Ahpra) registration details (e.g. provider number)
    - requiring a declaration of health professional status, supported by identity checks (e.g. a hospital or clinic email domain)
    - in-person verification by a sales representative.
- limiting access to:
    - platforms restricted to health professionals (e.g. hospital IP ranges or approved apps)
    - professional-only publications (e.g. Australian Journal of Pharmacy; Australian Doctor).

For more information, see our guidance Advertising to health professionals so that consumer rules do not apply.

Requirements for advertising to health professionals

Advertisements directed exclusively to health professionals must comply with:

- the Australian Consumer Law
- the Act, which prohibits promoting a medical device for any purpose not included in its entry on the Australian Register of Therapeutic Goods (ARTG).

Penalties and compliance

Penalties for non-compliance with the advertising requirements can range from infringement notices to imprisonment.

More information

For more information, visit our advertising hub.

Page history

30 March 2026

Republication of previous information (fact sheets) as guidance content.