Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising software-based devices to health professionals

This fact sheet includes guidance on advertising software-based medical devices to health professionals. Different rules apply to advertising to consumers. If you intend to advertise to consumers, please refer to our fact sheet on: Advertising software-based devices to consumers[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 device 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.

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.

Some software 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 boundaries between regulated and unregulated software[8] is available on the TGA website.

Advertising that is accessible by consumers

The claims you can make in your advertising material depends on whether you are advertising directly to consumers or limiting your advertising to health professionals only. If you are able to ensure your advertising is only visible to health professionals, you may be exempt from the requirements that are usually placed on advertising a medical device to consumers.

Who is a health professional?

Section 42AA of the Act lists a number of practitioners captured as 'health professionals'. A range of mainstream and natural health practitioners are

included, such as medical practitioners, dentists, dental hygienists, pharmacists, optometrists, physiotherapists, nurses, naturopaths, nutritionists, traditional Chinese medicine practitioners and podiatrists. It also includes persons who are engaged in the wholesaling of therapeutic goods or purchasing officers in hospitals.

Advertising that is accessible to people not listed in section 42AA of the Act must comply with the consumer advertising requirements. Further information about how you can direct advertisements exclusively to 'health professionals' is available on the TGA website[9].

Ensuring that advertising is directed exclusively to health professionals

To be exempt from the advertising requirements, your advertising must be secured and accessible only by confirmed health professionals. You can restrict access in a number of ways including:

- using a suitable authentication method (encryption)
- establishing an authorisation process (manual or automatic) to ensure the material can only be accessed by a health professional. Examples of an authorisation process include:
  - matching a current Australian Health Practitioner Regulation Agency[10] (Ahpra) registration and confirmatory details (such as a provider number) with Ahpra's practitioner information exchange
  - a declaration that the user is a health professional, in combination with other identity confirmation protections (such as an email address with a domain for a hospital, clinic or established health service)
  - in-person confirmation of health professional status by visiting sales representatives
- limiting access to platforms that are only accessible by health professionals (such as a specific range of IP addresses used by a hospital or applications configured to run on approved hospital platforms only)
- advertising in publications available only to specific health professional groups, such as the Australian Journal of Pharmacy or Australian Doctor.

Guidance on cyber security for devices provides information on securing systems, and suitable access-control mechanisms can be found on the TGA website[11].

Requirements for ads directed to health professionals

Advertisements directed exclusively to health professionals are required to comply with the Australian Consumer Law.

Additionally, under the Act, these advertisements must not include promotion of a medical device for a purpose other than a purpose accepted in relation to the device's Australian Register of Therapeutic Goods entry.

What product information can be made available to the public?

Factual and balanced information, such as scientific/medical information intended for health professionals, does not need to be secured, providing it is not (directly or indirectly) promotional. Examples include providing product information indexed by product name only.

Indexing product information or factual information about the device by medical condition, or allowing the information to be accessible when searching online for a medical condition, is likely to be considered an advertisement to the public.

Penalties and compliance

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

Further information on how the TGA manages advertising compliance is available on the TGA website[12].

Links

1. tga.gov.au/sites/default/files/2023-04/factsheet-advertising-software-based-medical-devices-consumers.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/resources/resource/guidance/advertising-health-professionals
10. www.ahpra.gov.au
11. tga.gov.au/resources/publication/publications/medical-device-cyber-security-information-users
12. tga.gov.au/how-we-regulate/advertising/legal-framework/how-we-manage-advertising-compliance
13. www.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.