Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Understanding regulation of off-label use of medical devices

Guidance on the use of a medical device in a way that is not included in the intended purpose in the Australian Register of Therapeutic Goods (ARTG), and rules for advertising off-label uses.

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# Purpose

The purpose of this content is to explain the concept of 'off-label use' of medical devices in Australia, clarify the regulatory framework surrounding it, and outline the responsibilities and limitations for clinicians, sponsors, and advertisers regarding off-label use.

## Legislation

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**Therapeutic Goods Act 1989**

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# About off-label use

'Off-label use' is using a product for a reason not listed as one of the indications for use in the Australian Register of Therapeutic Goods (ARTG).

The ARTG includes therapeutic goods with specific indications or intended uses. The use outside of this is considered off label.

The *Therapeutic Goods Act 1989* (the Act) does not regulate clinical practice. 'Off-label use' is a clinical decision, made at the discretion of the treating clinician. This clinician is responsible for obtaining informed consent from their patient (which includes telling them if the use is off-label) and ensuring that the device selected is the most appropriate treatment option.

# Special Access Scheme Category B (SAS B)

SAS B approval is not required, nor does the TGA have authority to grant approval, for a sponsor to supply a medical device included in the ARTG. This includes circumstances where the device is for 'off-label use'.

You might need SAS approval to use a medicine or biological off-label. This is because there are different laws and legislation for medicines and biologicals.

# Advertising device 'off-label use'

Sponsors must make sure advertising material matches the device's intended use. This use is what the sponsor certified in their ARTG application (subsection 41FN (5) of the Act). As such, sponsors cannot advertise uses that are not approved and included in the ARTG entry.

There are also criminal and civil penalty provisions for advertising a medical device for a purpose that isn't approved in the ARTG. See sections 41ML and 41MLB of the Act.

Sponsors should be aware that the definition of 'advertise' in the Act.

This includes any:

- statement;
- pictorial representation; or
- design.

Sponsors should also be aware of the condition of inclusion in:

- subsection 41FN (5) of the Act, and
- the offence and civil penalty provisions in sections 41ML and 41MLB of the Act.

These rules apply to advertising targeted only at health professionals.

Sponsors can provide non-promotional information without risking penalties.

Sponsors can give non-promotional product information, like information on off-label usage, but only at the request of a treating clinician.

Information provided unsolicited about 'off-label uses' may be considered promotion. We'd consider this an advertisement.

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**Topics:** Advertising Australian Register of Therapeutic Goods (ARTG) Labelling and packaging

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