Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Off-label use of medical devices: Frequently asked questions

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What is 'off-label use' of a medical device?

'off-label use' generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in its Australian Register of Therapeutic Goods (ARTG) entry. Therapeutic goods are included in the ARTG with either specific indication(s) or intended purpose(s).

The *Therapeutic Goods Act 1989* does not regulate clinical practice. 'off-label use' is a clinical decision made at the discretion of the treating clinician who is responsible for obtaining informed consent from their patient and ensuring that the medical device is the appropriate treatment option and carries a positive benefit–risk profile.

Is Special Access Scheme Category B (SAS B) approval required for a sponsor to supply a medical device for 'off-label use'?

No. SAS B approval is not required for a sponsor to supply a medical device included in the ARTG including in circumstances where the device is to be used for 'off-label use'.

(Note: SAS approval may be required for 'off-label use' of a **medicine or biological**, because the legislative provisions relating to medicines and biologicals differ from those that apply to medical devices.)

Can SAS B approval be given for 'off-label use' of a medical device if the clinician or sponsor wishes to obtain approval?

No. The TGA does not have the authority to grant SAS B approval for a medical device that is already included in the ARTG.

Can a sponsor advertise their device for 'off-label use'?

No. It is a condition of inclusion in the ARTG that advertising material relating to a medical device is consistent with its intended purpose as certified by the sponsor in the application for inclusion of the device in the ARTG (subsection 41FN(5) of the Act).

Offence and civil penalty provisions also apply to the advertising of a medical device as being for a purpose that is not a purpose accepted in relation to its inclusion in the ARTG (sections 41ML and 41MLB of the Act).

Sponsors should be aware that the definition of 'advertise' in the Act includes any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of goods.

Sponsors should also be aware that the condition of inclusion in subsection 41FN(5) of the Act and the offence and civil penalty provisions in sections 41ML and 41MLB apply to advertising that is directed exclusively to health professionals (unlike the provisions in Part 5-1 of the Act that do *not* apply to advertisements directed exclusively to specified health professionals).

These penalty provisions do not preclude the provision of non-promotional information by sponsors. In the interests of patient safety, sponsors may, at the request of a treating clinician, provide technical product information of a non-promotional nature, including information to support safe 'off-label use'. This can only be done at the request of a treating clinician. The provision of unsolicited information in circumstances where 'off-label use' has not been proposed by a clinician is likely to be regarded as 'promotional' and therefore amount to an 'advertisement'.

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)