



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Regulation of therapeutic goods advertising in Australia

General information

The advertising of therapeutic goods to consumers and health professionals is administered via a co-regulatory system which is representative of all key stakeholder groups, namely consumers, health professionals, the regulated industry sectors, , the media, advertisers and government.

Advertisements for therapeutic goods are subject to the requirements of the *Therapeutic Goods Act 1989* (the Act) and Regulations, the *Competition and Consumer Act 2010* and other relevant laws. Additionally, advertisements for therapeutic goods directed to consumers must comply with the [Therapeutic Goods Advertising Code](#) (the Code).

The object of the Code is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive the consumer.

The Therapeutic Goods Advertising Code Council is responsible for the currency of the Code while Therapeutic Goods Administration administers the Code.

The Therapeutic Goods Advertising Code Council ([TGACC](#)), comprises of representatives from all key stakeholder groups and is established under the Regulations. Specifically, the role of the TGACC includes considering the advertising requirements for therapeutic goods, considering amendments to the Code and making recommendations to the Australian Government Minister for Health and Ageing.

An advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods (Refer to Section 3 of the Act)).

Advertising can be presented in several forms, including:

- consumer magazines, or newspapers
- television, radio or cinema
- the Internet
- Billboards or public transport
- leaflets, flyers, brochures, catalogues, letterbox drops; and
- medical journals,.

Section 22(5) of the Act specifies that advertising of a therapeutic good can only refer to the indications which are included in the Australian Register of Therapeutic Goods (the Register) for that specific good.

Prescription-only medicines

- Advertising direct to consumers is not permitted (prohibited by the Act).
- Advertising to health professionals is permitted and is regulated by a self-regulatory scheme operated by Medicines Australia.
- The requirements in relation to prior approval of advertisements set out in Part 2 of the Therapeutic Goods Regulations 1990 is not applicable.
- However, advertisements for prescription medicines must also meet the requirements of the *Competition and Consumer Act 2010*, section 22(5) of the Act (which establishes an offence where therapeutic goods are advertised with indications other than for which they have been accepted in the Register) and any other conditions which may be assigned to the marketing approval of the product.
- It is a condition of registration of therapeutic goods that the promotion of all prescription products (whether member or non-member) to comply with the requirements of the [Medicines Australia](#) Code of Conduct
- Complaints about advertisements for prescription medicines directed to health professionals are handled by Medicines Australia – see Attachment 1 below.
- If a complaint is made about the advertising activities of a non-member, the complaint is forwarded to the non-member with an invitation to have the complaint adjudicated by the Medicines Australia Code of Conduct Committee. If the non-member declines the invitation for adjudication, Medicines Australia may forward the complaint to the Therapeutic Goods Administration (TGA) or the Australian Competition and Consumer Commission.
- Where it has been determined that a breach of the Code has occurred, the Committee may impose a range of fines, depending on the nature of the breach. The Committee may also recommend to the Medicines Australia Board that a member be suspended or expelled.

Non-prescription medicines

- Non-prescription medicines are over-the-counter (OTC) medicines and non-prescription complementary medicines.
- Generally, advertisements for non-prescription medicines may be directed both to consumers and to health professionals. However, the Regulations prohibit the advertising to consumers of certain medicines included in Schedule 3 of the current Poisons Standard (pharmacist-only medicines).
- Advertisements for non-prescription medicines are regulated by both co-regulatory and self-regulatory arrangements operated by the TGA under the Act and Regulations, the Therapeutic Goods Advertising Code Council (TGACC), the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).
- Certain types of advertisements directed at consumers require prior approval by a Delegate of the Secretary of the Department of Health and Ageing.

Approval processes for direct-to-consumer advertising of non-prescription medicines

- Prior approval is required for certain types of advertisements and generic information advertised directly to consumers, specifically:
 - Broadcast media - TV and radio
 - Print media - newspapers & magazines (including inserts)
 - Outdoors - including billboards, bus shelters, sides & interiors of buses, taxi displays
 - Cinema films
- The Secretary of the Department of Health and Ageing or his/her delegate is responsible for approving advertisements. Under co-regulatory arrangements, this responsibility has been delegated to industry associations:
 - ASMI: all advertisements to be broadcast in broadcast media and advertisements for OTC medicines appearing outdoors or in print media (newspapers & magazines) (see Attachment 2); and
 - CHC: advertisements for complementary medicines appearing outdoors or in print media (newspapers & magazines) (see Attachment 3).

These industry associations represent sponsors and manufacturers of non-prescription (over-the-counter *and* complementary) medicines.

Complaints handling processes for advertising of non-prescription medicines

- Complaints about direct-to-consumer advertising in specified media such as television or radio, newspapers, consumer magazines, billboards and cinema films or the Internet are considered by the Complaints Resolution Panel, a body established in the Therapeutic Goods Regulations (see Attachment 4).
- The TGA reserves the right to intervene or investigate in matters where the breaches in advertising are of a serious nature, especially where consumer safety is a concern.
- Complaints about direct-to-consumer advertising that appear in other media such as leaflets, flyers, brochures, catalogues or letterbox drops or advertising to health professionals are handled by the relevant industry association under their codes of practice:
 - ASMI Code of Practice; and
 - CHC Code of Practice for the Marketing of Complementary Healthcare Products

These complaints follow a similar process to that for complaints about advertising of prescription medicines to health professionals.

Medical devices

- Medical devices may be advertised directly to consumers and the regulatory requirements are similar to those applying to direct-to-consumer advertising of non-prescription medicines. However there is no requirement for prior approval of these advertisements.
- The Complaints Resolution Panel considers complaints about advertisements for medical devices and therapeutic devices appearing in broadcast and mainstream print media, billboards, cinema films, the Internet etc.

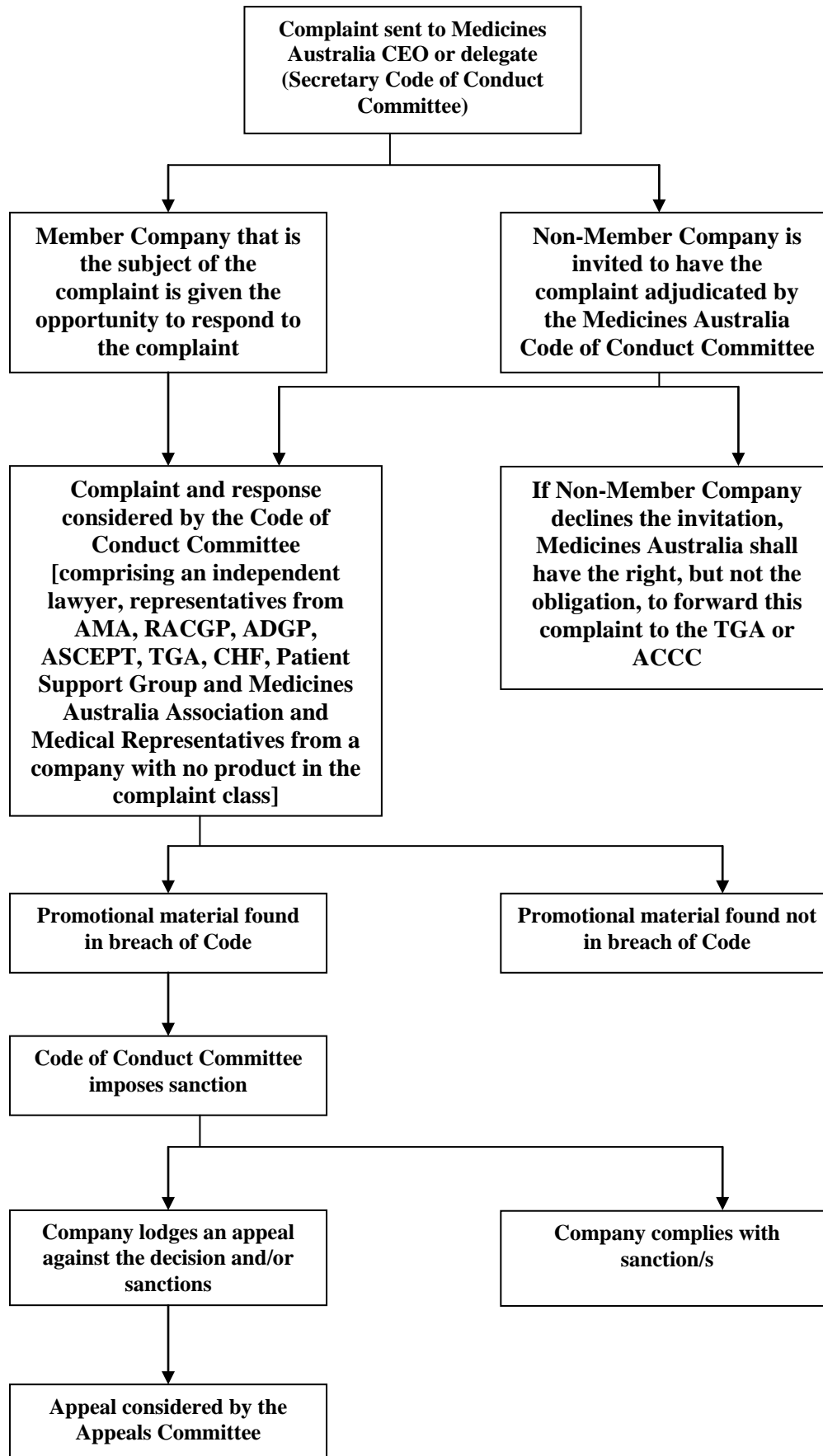
Summary of the regulation of advertising of therapeutic goods in Australia

	PRESCRIPTION MEDICINES		NON-PRESCRIPTION MEDICINES		MEDICAL DEVICES	
	Advertising direct to consumers	Advertising to healthcare professionals	Advertising direct to consumers	Advertising to healthcare professionals	Advertising direct to consumers	Advertising to healthcare professionals
Permitted?	Û	Ü	Ü except for certain pharmacist only goods	Ü	Ü	Ü
Regulated by?	TG Regs Medicines Australia Code of Conduct	TG Act TG Regs Medicines Australia Code of Conduct	TG Act TG Regs TGAC ASMI Code of Practice CHC Code of Practice Trade Practices Act	TG Act TG Regs ASMI Code of Practice CHC Code of Practice	TG Act TG Regs TGAC Trade Practices Act	TG Act TG Regs
Prior approval required?	n/a	Û	Ü Broadcast media (TV, radio); cinema; mainstream print media (newspapers & magazines; displayed outdoors (eg billboards) Û Other advertisements (eg indoor posters, leaflets, letterbox drops, brochures, catalogues, internet, etc.)	Û	Û	Û

	PRESCRIPTION MEDICINES		NON-PRESCRIPTION MEDICINES		MEDICAL DEVICES	
	Advertising direct to consumers	Advertising to healthcare professionals	Advertising direct to consumers	Advertising to healthcare professionals	Advertising direct to consumers	Advertising to healthcare professionals
Complaint handling process	TGA	Medicines Australia Code of Conduct Committee Complaints about non-members may be referred to TGA	Complaints Resolution Panel (for advertisements where prior approval is required); Industry associations (for other advertisements) TGA if advertiser is a non-member, a retailer or a distributors	Industry associations TGA if advertiser is a non-member, a retail outlet, a distributor or a practitioner	Complaints Resolution Panel (for broadcast media, mainstream print media, billboards, cinema films) TGA	TGA

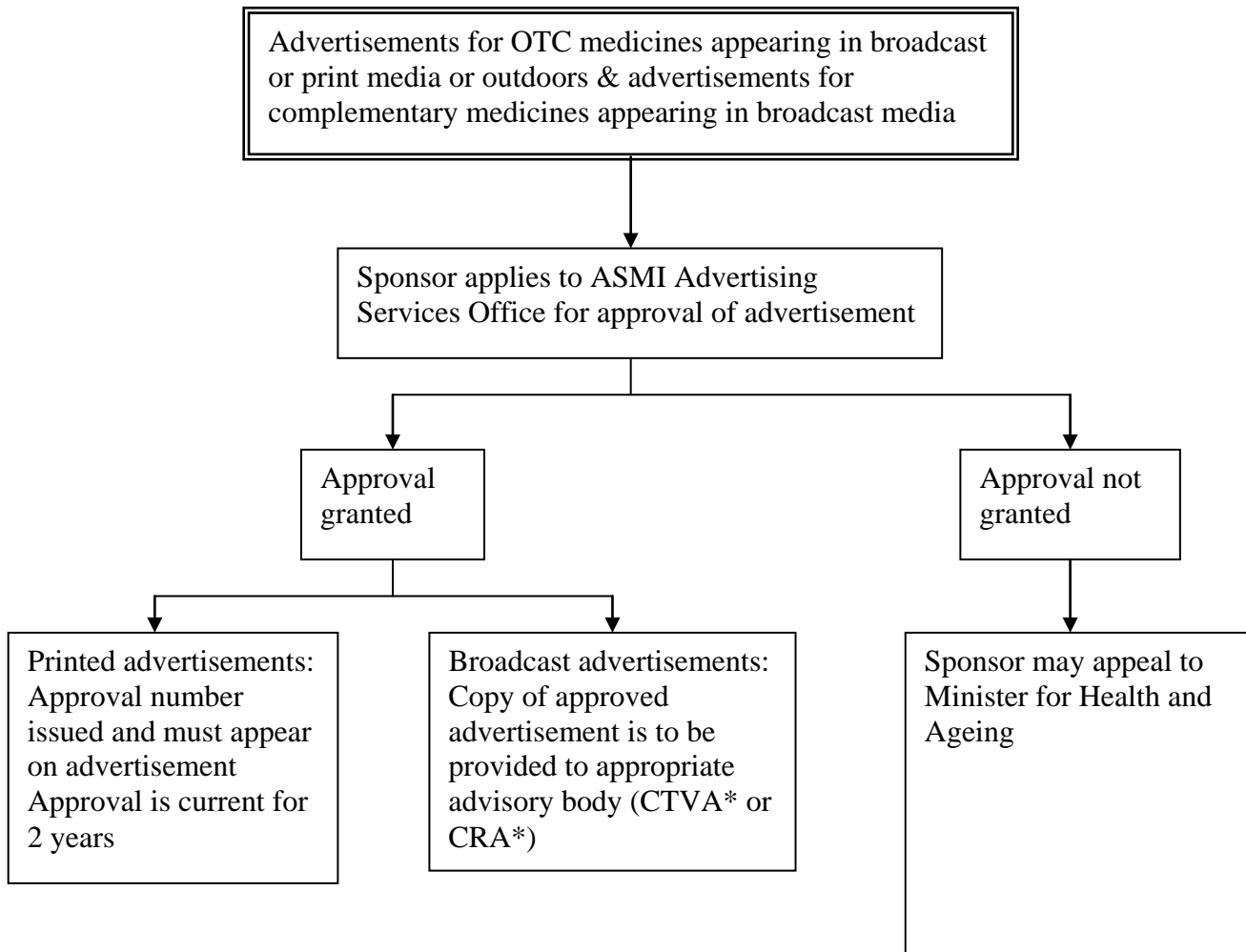
Attachment 1

Medicines Australia promotion of prescription medicines to health professionals complaints handling process



Attachment 2

ASMI approval process for direct-to-consumer advertising of non-prescription medicines (all broadcast advertisements AND advertisements for OTC medicines appearing outdoors or in print media (newspapers & magazines) or cinema films).

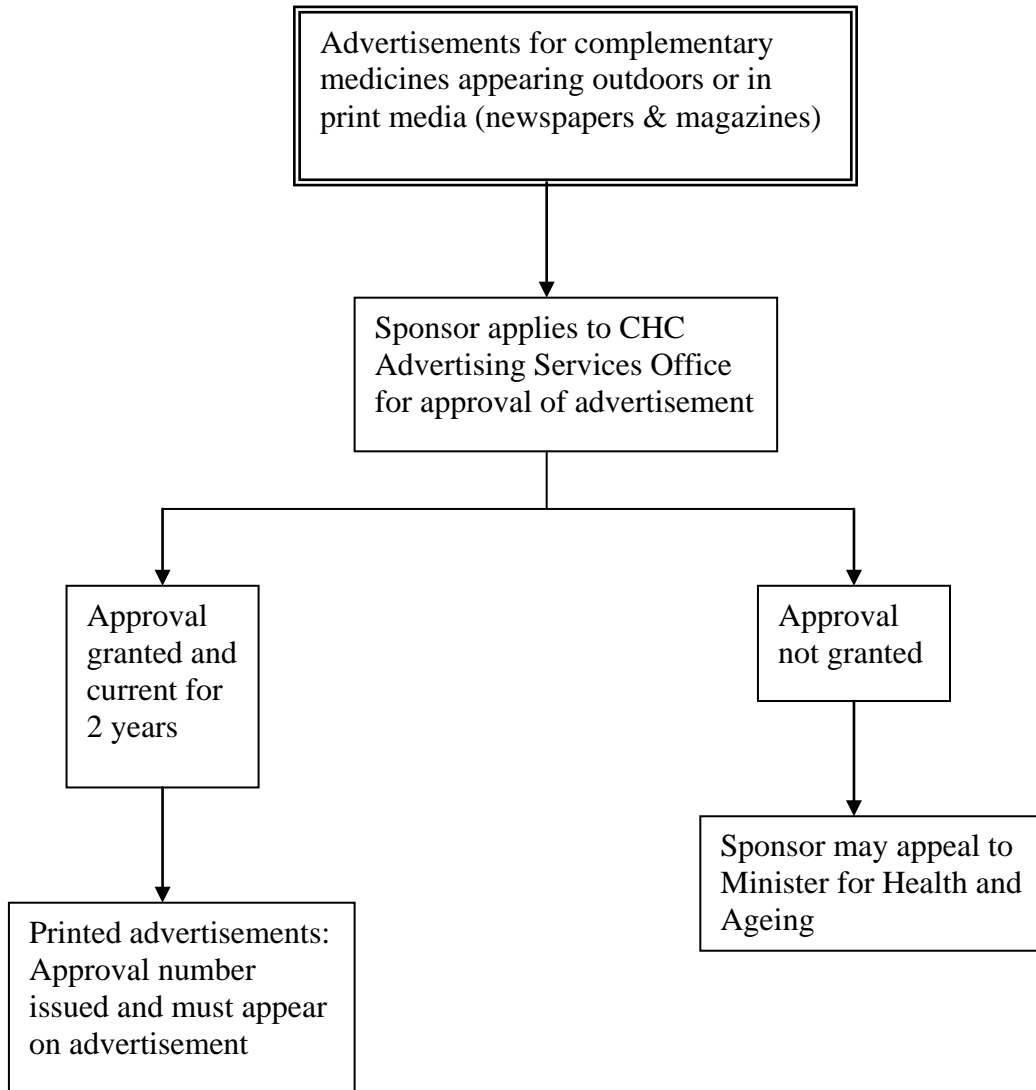


*CTVA : Commercial Television Australia

*CRA: Commercial Radio Australia Limited

Attachment 3

CHC approval process for direct-to-consumer advertising of non-prescription medicines (advertisements for complementary medicines appearing outdoors or in print media (newspapers & magazines) or cinema films).



Attachment 4

Complaints handling process for direct-to-consumer advertisements requiring prior approval

