

Advertising Approval Process for Medicines

Brief overview of regulatory requirements

All advertising of therapeutic goods directed to consumers must by law comply with the requirements and standards of the *Therapeutic Goods Advertising Code*, the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. To ensure that the standards developed for the public benefit over the last 30 years are met in all specified media advertising of medicines, a system of approval is applied before broadcast or publication.

Background

Therapeutic Goods Regulations 1990 which was gazetted on 18 December 1997, formalised the prior approval of advertisements intended for publication in mainstream print media. In April 2000 the requirement for formal approval of advertisements was extended to include cinematographic film and outdoor media advertising. The *Broadcasting Services Act 1992* required that advertisements relating to medicines be approved by the Secretary of the Department of Health and Ageing, or a nominated delegate, prior to broadcast. This requirement applied to all radio and television media. The Act was amended in December 1990, delegating the authority to approve advertisements in broadcast media to the Proprietary Medicines Association of Australia now called the Australian Self-Medication Industry (ASMI). The requirements in the *Broadcasting Services Act* were transferred to the *Therapeutic Goods Act* in December 2003.

Which advertisements require formal approval?

Specified media advertisements: television, radio, print, cinema and outdoor

The authority to approve or not approve an advertisement rests with the Secretary of the Department of Health and Ageing. In the event of a non-approval, the Secretary must give reasons for the refusal and inform the applicant of his/her right to have the Secretary's decision reviewed by the Minister. The Minister must take into account any recommendation by the Therapeutic Goods Advertising Code Council. The Minister's decision in turn may be reviewed on application to the Administrative Appeals Tribunal.

The regulations make provision for the Minister to delegate the approval function as follows:

- all broadcast advertising to the Australian Self-Medication Industry.
- mainstream print, cinema and outdoor advertising of all **over-the-counter** (OTC) non-prescription medicines to the Australian Self-Medication Industry.
- mainstream print, cinema and outdoor advertising of **complementary** healthcare products to the Complementary Healthcare Council of Australia.

The aims of the approval process are:

- to ensure compliance with the Act, Regulations and Code;
- to ensure consistency of allowed claims for similar products and for different advertisements of the same product over time;
- to ensure decisions are consistent and objective; *and*
- to ensure that claims are factual.

Approval is only required for advertising of medicines, not medical devices.

Submitting advertisements for approval

To have an advertisement approved, it must be submitted to the appropriate Advertising Services Office, as listed below. If it is the first proposed advertisement submitted for a particular product, or if the product has been changed (e.g. label alterations, modifications to approved indications) the following documentation should be provided in the application, either by mail, fax or e-mail:

1. Print: typed copy - black on white background.
2. Print: layout – clear description of the layout with copies of all visuals/graphics/packshots.
3. TVC: copy of script with storyboard.
4. Radio: copy of script with sound-effect descriptions.
5. Copy of supporting documentation:
 - A – certificate of listing/registration
 - B – label (legible copy)
 - C – approved indications for use as entered on the ARTG, where applicable.
 - D – research/surveys/data referenced in advertisement[†].
 - E – authenticated and authorised professional recommendations and testimonials
 - F – [completed application form](#)

[†] Substantiation of claims is to be provided on request. Substantiation, in line with levels of evidence required to be held by the sponsor at the time of listing/registration, may be required by the advertising services manager. Further substantiation may also be requested to show that *all* claims have already been verified by the advertiser. Listing or registration of a claim does not automatically mean that the claim may be advertised.

TV/Radio advertisements for all medicines should be submitted to:

ASMI Advertising Services Office
Australian Self Medication Industry Inc.
PO Box 764, North Sydney NSW 2059
Fax: (02) 9957 6204
Email: ASMIadvertising@asmi.com.au
www.asmi.com.au/industry/Advertising-Services.aspx

Print advertisements for non-prescription medicines other than complementary:

ASMI Advertising Services Office
Details as above

Print advertisements for complementary medicines should be submitted to:

Advertising Services
Complementary Healthcare Council of Australia (CHC)
PO Box 820
MAWSON, ACT, 2607.
Tricia Campbell: 02 9542 5860
Ruben Jones: 07 3314 0641
Fax: 02 6260 4122
Email: advertising@chc.org.au

Fees

All advertisements submitted for approval are subject to an application fee. Refer to the [attached schedule](#). Fees are set by Therapeutic Goods Administration and must be paid even if approval is not gained. All fees must be paid before approval can be released.

How do I pay?

Credit Card: Credit Card details should be supplied on the application form. Please note there is a processing fee (incl. GST): Visa/Mastercard 2.3%, Diners 3.32%, Amex 4.28%. Payment by Diners or Amex will add additional processing time.

EFT: Any advertiser not wishing to pay by credit card should email ASMI at accounts@asmi.com.au However, payment by EFT will add to approval times.

Approval process

The proposed advertisement will be reviewed and the advertiser notified of any changes or claim substantiation that may be required before the advertisement can be approved.

A distinguishing approval number is allocated for each approved advertisement and this number must be displayed in print advertisements. Publishing or inserting in mainstream print media an advertisement without its approval number is a breach of the *Therapeutic Goods Act* and liable to a fine.

Approvals are valid for a period of two years, subject to the provisions in the Act and Regulations. Particular note should be taken of Regulations 5K (variation of conditions of approval) and 5L (withdrawal of approval). Once an approval has expired, the advertisement must be submitted for re-approval.

How long does the approval process take?

The Regulations allow for a period of 60 days. However in practice every effort is made to process advertisements within 10 working days at ASMI, provided all the relevant material is received in the first instance.

What happens if an advertisement is not approved?

Should a particular proposed advertisement not be approved in spite of all reasonable attempts to ensure compliance with the Act, the Regulations and the Code, the advertiser has a right to have the decision reviewed by the Minister. A request for the review must be sent, within 30 days of the notice of non-approval of the advertisement, to:

The Assistant Minister for Health
c/o Parliament House
CANBERRA, ACT 2600 *and*

The Secretariat
The Therapeutic Goods Advertising Code Council
Level 13 Macquarie House
167 Macquarie Street
Sydney NSW 2000
Tel: (02) 8667 3026 or (02) 8667 3025
Email jbrimer@tgacc.com.au

REVIEW OF A DECISION OF THE SECRETARY TO APPROVE OR REFUSE TO APPROVE AN ADVERTISEMENT

In accordance with Part 2, Division 2 of the Therapeutic Goods Regulations

An applicant or approval holder (as defined in the Therapeutic Goods Regulations), who is dissatisfied with a decision of the Secretary to approve, disapprove, vary the conditions of approval or withdraw approval may, within 30 days of notification of the Secretary's decision, request, in writing, the Minister for Health and Aged Care to review the decision.

Requests should be headed "REVIEW UNDER REGULATION 5M OF THE THERAPEUTIC GOODS REGULATIONS" and sent to the following address:

Attn: The Assistant Minister for Health
c/o Parliament House
CANBERRA, ACT 2600

At the same time as writing to the Parliamentary Secretary, a copy of the request must be forwarded to the Therapeutic Goods Advertising Code Council (TGACC), addressed to:

Attn: The Secretariat
Therapeutic Goods Advertising Code Council
Level 13 Macquarie House
167 Macquarie Street
Sydney, NSW 2000

The Executive Officer must notify the complainant, the respective Advertising Services Manager and the Secretary of receipt of the request and the date of the meeting of the TGACC at which the matter will be considered.

The TGACC, at the conclusion of its deliberations, may recommend to the Parliamentary Secretary, that the Secretary's decision be:

- (a) confirmed; or
- (b) revoked and substituted with another decision [including a decision to impose conditions].

The TGACC will advise the Parliamentary Secretary, in writing, of the recommendation within 5 working days following its deliberation.

As soon as practicable after receiving the TGACC recommendation the Parliamentary Secretary must take into account this recommendation and then make his or her decision to confirm, revoke or substitute the Secretary's decision. The Parliamentary Secretary will then notify, in writing, the applicant or approval holder and the TGACC, outlining the decision and rationale for that decision and any conditions that apply and if the Parliamentary Secretary does not accept a recommendation of the TGACC, the Parliamentary Secretary must notify the applicant or approval holder of the fact.

Until the Minister makes a decision, the decision of the Secretary is not affected.

The Parliamentary Secretary either may deal with the review personally or send it to be dealt with by one of the Minister's delegates within the Commonwealth Department of Health and Aged Care. If the applicant or approval holder is dissatisfied with the result of the review then, subject to the *Administrative Appeals Tribunal Act 1975*, the applicant or approval holder may appeal to the Administrative Appeals Tribunal (AAT) for review of the Parliamentary Secretary's / delegate's decision.