

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, formalized 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. Until recently, 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 TGACC. 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 – authenticating and authorising professional recommendations and testimonials.
 - F – completed application form (see <http://www.tga.gov.au/docs/pdf/forms/advapp.pdf>)

[†] 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
PO Box 764, North Sydney NSW 2059
Fax: (02) 9957 6204
e-mail: ASMIadvertising@asmi.com.au
<http://www.asmi.com.au/advertising.htm>

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:

CHC Advertising Services Office
Complementary Healthcare Council of Australia
PO Box 104, Deakin West ACT 2600
Fax: 02 6460 4122
e-mail: tricia.campbell@chc-advertising.com.au
www.chc.org.au

Fees

All advertisements submitted for approval are subject to an application fee, based on a fee-for-service principle and calculated to cover costs. Refer to the attached schedule of fees.

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 2 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 and 10 working days at CHC, 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 Minister for Health & Ageing
Parliament House
Canberra ACT 2600

and The Secretariat
Therapeutic Goods Advertising Code Council
PO Box 764, North Sydney 2059

SCHEDULE FOR ADVERTISING APPROVAL APPLICATION FEES
Effective 11 August 2006

Source: Therapeutic Goods Regulations 1990, schedule 9, part 2, sections 17 & 17A

MEDIA	FEES GST exempt unless specified.
Television or cinema commercial Up to and including 150 second commercials. Up to 3 variations of the one concept for the one product.	\$840
TV commercial – regional retail outlets only Applicable to commercials produced for retail outlet (e.g. pharmacy or health food shop) advertising on one local REGIONAL station within their own regional location. Retail outlets will not receive this discount if the commercial will be aired on metropolitan stations or in more than one regional station.	\$430
Television advertorial Any television spots greater than 150 seconds in length. Fee is per script.	\$630 for first minute plus \$170 for every minute after that
Radio commercial Up to 6 variants of the one concept, for the same product.	\$310
Radio commercial – regional Up to 6 variants of the one concept for the same product	\$210
Print & still cinema media <p align="right">Classifieds Not more than 100 words Between 100 and 300 words Over 300 words</p> This category includes outdoor media, catalogues and all other forms of above-the-line promotional material. Fee levied per advertisement.	\$90 \$160 \$200 \$330
Revisions / re-approvals / cut-downs <ul style="list-style-type: none"> Minor amendments to an advertisement previously approved require re-approval of the revised advertisement. <u>Minor</u> amendments to a script within <u>3 months</u> after the date of approval will not attract a fee. Changes of retailer/outlet tags on a previously approved advertisement do not require re-approval, providing the approval is still current. Approvals normally have a 2-year life span. When approval expires, re-approval must be sought. Any cut down of a previously approved advertisement. This includes 5 & 10 second television billboards based on an existing approved television advertising campaign. 	Minor changes to print advertisements: \$90 All other advertisements: 50% of scheduled fee

The above fee schedule accounts for the 1st hour of approval time per ad. In the vast majority of cases this allocation should result in an ad ready for approval. The process includes invoicing and receipting, initial screening of ads, requesting and assessing substantiating data and supporting information, meetings with advertisers, advice at concept stage, recommendations for amendments, feedback via fax or phone and final approval.

Any extra time will attract an additional consultation fee levied at **\$140** per hour or any part thereof.

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 Minister of Health and Aged Care
c/o Parliamentary Secretary to the Minister for Health and Aged Care
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
c/o PO Box 764
North Sydney NSW 2059

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.