



Complementary Healthcare Council of Australia

Office of Advertising Compliance

**Final Decision Additional Time Policy
September, 2015**

Conditional Approvals

Purpose

The purpose of this Policy is to clarify the process for CHC Advertising Services Managers with respect to invoicing and payment of additional time that becomes necessary for a final decision on an application for advertising approval.

Scope

This Policy is applicable to all CHC ASM's and all final decisions that require advertising applicant be invoiced and pay for additional time.

Responsibility

The ASMs have responsibility for maintaining this Policy, ensuring it is up to date, and that any changes are incorporated and assimilated as soon as possible.

Background

THERAPEUTIC GOODS REGULATIONS 1990 - REG 5G

Approval of advertisements

(1) If an application for approval of an advertisement is made and the prescribed fee is paid, the Secretary must approve the advertisement if the Secretary is satisfied that it:

- (a) complies with the Therapeutic Goods Advertising Code; and
- (b) does not contain a prohibited representation (whether in express terms or by necessary implication) about the goods; and
- (c) contains a required representation about the goods; and
- (d) does not contain an unacceptable presentation of the goods within the meaning of [regulation 3A](#); and
- (e) does not contain a restricted representation about the goods the use of which has not been approved under section 42DF of the Act or permitted under subsection 42DK(1) of the Act.



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(3) Otherwise, the Secretary must refuse to approve the advertisement.

Therapeutic Goods Regulation 1990, Section 5G, states that an advertisement can be approved if the prescribed fee has been paid and certain stated conditions are met, otherwise approval must be refused.

Policy

CHC ASMs who find that they have run out of paid time in the midst of making a final decision on an application will themselves forward to the applicant a copy of a newly raised invoice for the necessary additional time and track the payment terms.

The process is:

The CHC ASM urgently requests that an invoice be raised for the necessary additional time they envisage will be necessary to make and document their final decision on an application for advertising approval.

The raised invoice will be forwarded to the CHC ASM, not direct to the applicant.

The CHC ASM will forward the invoice to the applicant along with an email advising that

- additional time is now necessary,
- payment terms are 7 days, and
- non-payment is grounds to refuse approval.

Until such time as this invoice is paid, it is CHC policy that the ASM cannot undertake any further work on the application.

Once the invoice is paid, work can recommence.

Should the invoice not be paid within the payment terms, the CHC ASM must refuse approval on the grounds that the advertisement cannot be approved unless the prescribed fee has been paid.

Relevant Legislation



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Therapeutic Goods Regulations 1990 – Regulation 5G

History of the Matter

Document History

Version 1: Issued June 2014

Version 2: Issued June 2015

Approved By

Carl Gibson, Chief Executive Officer

APPENDIX A



Complementary Healthcare Council of Australia *Office of Advertising Compliance*

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This message was sent with High importance.

From: Carl Gibson <carl.gibson@chc.org.au> Sent: Mon 10/05/2014 3:29 PM
To: Ruben Jones; Tricia Campbell
Cc: Emma Barthell
Subject: TGA: Follow up on Friday Meeting: Natural Justice in Advertising Approvals Process

From: David Poulton@tga.gov.au [mailto:David.Poulton@tga.gov.au]
Sent: Monday, 19 May 2014 3:23 PM
To: Carl Gibson
Cc: meck.s'conner@tga.gov.au
Subject: Follow up on Friday Meeting: Natural Justice in Advertising Approvals Process [SEC=UNCLASSIFIED]
Importance: High

Carl

I am following up in regards to our meeting on Friday regarding issuing an advertising approval with conditions.

Attached is the ASML "decision" that I believe we were discussing on Friday. As we have said previously, this varies the advertisement as a condition of approval even if the TGA might wish the wording was more explicit.

What I have noticed is that we have not been provided with prior emails. While I am sure that there would be some advice to the applicant by ASML prior to the final e-mail, I felt I should make this explicit to avoid any confusion.

There would still need to be at least one opportunity for the applicant to vary the advertisement or provide additional information prior to conditions being placed on the advertisement. Perhaps an analogy may assist - cant imagine anyone being happy with a driver's licence being approved but including a driving condition "only during daylight" without prior consultation. I believe the same would apply here. Even though the applicant is getting the approval it wasn't what was actually applied for. Therefore natural justice may require giving them the usual preliminary email setting out any problems and providing the opportunity to respond.

Your two strikes on variations still applies as well but you will recall the question of natural justice was discussed and applies there too. I recall from our conversation that you said the CHC templates (presumably including the first response) include this policy. So you are dealing with all the issues in one bite.

I hope this clarifies our discussion on Friday. Happy to discuss further if needed.

Dave

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Therapeutic Goods Administration
Department of Health