



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods Advertising Code: Amendments

I, NGAIRE BRYAN, Acting National Manager, Therapeutic Goods Administration and delegate of the Minister for Health and Ageing for the purposes of the definition of ‘Therapeutic Goods Advertising Code’ (the Code) under subsection 3(1) of the *Therapeutic Goods Act 1989* (the Act), HEREBY PUBLISH the following changes to the Code, being changes necessary as a result of amendments effected by the *Therapeutic Goods Amendment Act (No 1) 2003*.

Clause 2.3

- Delete the existing Clause 2.3 and replace with:

2.3 “Specified media,” in relation to an advertisement or generic information, means:

- (a) mainstream media, within the meaning of s.42B of the Act; or
- (b) broadcast media, within the meaning of s.42B of the Act; or
- (c) cinematograph films; or
- (d) displays about goods, including posters:
 - (i) in shopping malls (except inside individual shops);
 - (ii) in or on public transport; and
 - (iii) on billboards.

Clause 2.5

- After Clause 2.4, insert a new Clause 2.5 as follows:

2.5 “Broadcast media”, in relation to an advertisement or generic information, means any means (other than a means declared in the Therapeutic Goods Regulations to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms.

Clauses 2.5 to 2.8

- Renumber existing Clauses 2.5, 2.6, 2.7 and 2.8 as Clauses 2.6, 2.7, 2.8 and 2.9, respectively.

Clause 2.6 (formerly Clause 2.5)

- Delete the existing Clause 2.5 and replace with:

2.6 “Healthcare professional” includes a person that meets the description of a healthcare professional in subsection 42AA(1), (2), (3) of the *Therapeutic Goods Act 1989* (see Appendix 2) and any other person represented directly or indirectly to be a healthcare professional.

Clause 5.2

- Delete the word “Regulations” and replace with “Act 1989”.

Appendix 2

- Delete reference to “(clause 2.4)” and replace with a reference to “(clause 2.6)”.
- Delete the main heading and replace with “Section 42AA of the *Therapeutic Goods Act 1989*”
- Delete the words, “**4 This Part not to apply to advertisements directed at health professionals etc**”; and

Replace with, “**42AA This Part not to apply to advertisements directed at health professionals etc**”

- Delete the paragraph (1)(c), “herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine or osteopaths registered under a law of a State or Territory.”; and

Replace with a new paragraph (1)(c), “herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths registered under a law of a State or Territory.”

- Delete the following words, “(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies referred to in Schedule 1”; and

Replace with, “(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies prescribed for the purposes of this subsection”.

- In paragraph (3), delete the words “subregulation (2)” and replace with “subsection (2)”
- Insert, after 42AA(3), the following:

“(4) This Part does not apply to advice or information given directly to a patient by a person referred to in paragraph (1)(a) or (c) or paragraph (2) above in the course of treatment of that patient.”.

- Delete the words “Regulation 4(2)” from the last paragraph and replace with “subsection 42AA(2)”.

Appendix 3:

- In the first paragraph under Appendix 3, delete the reference to “specified media” and replace with “specified media, other than broadcast media and cinematograph films”.
- Also in the first paragraph, delete the e-mail address, “ tricia.campbell@optusnet.com.au ”; and

Replace with, “ tricia.campbell@chc-advertising.com.au ”

- Delete the paragraph:

Advertisements for all other therapeutic goods (other than devices) in mainstream print media and all therapeutic goods (other than devices) in broadcast media are required under the *Therapeutic Goods Act 1989* and Regulations, and the *Broadcasting Services Act*, to be submitted to:

Advertising Services
 Australian Self-Medication Industry
 Level 4, 140 Arthur Street
 NORTH SYDNEY NSW 2060
 Ph: (02) 9955 7205
 Fax: (02) 9957 6204
 Email: sonia@asmi.com.au ; and

Replace with:

Advertisements for complementary healthcare products advertised in broadcast media or cinematograph films, and all other therapeutic goods (other than devices) advertised in specified media, are required under the *Therapeutic Goods Act 1989* and Regulations to be submitted to:

Advertising Services
 Australian Self-Medication Industry
 PO Box 764
 NORTH SYDNEY NSW 2059

(Suite 2202
 Level 22, 141 Walker Street)
 NORTH SYDNEY NSW 2060

Ph: (02) 9955 7205
 Fax: (02) 9957 6204
 Email: cath@asmi.com.au

- Delete the paragraph:

All mainstream media print media for therapeutic goods must display the current approval number allocated to that advertisement as required under s 42C(5) of the *Therapeutic Goods Act 1989*; and

Replace with:

All specified media advertisements, other than broadcast media advertisements, for therapeutic goods must display the current approval number allocated to that advertisement as required under s 42C(4)(b) of the *Therapeutic Goods Act 1989*.

Appendix 4

- Delete the first paragraph; and

Replace with:

In the event of an advertisement not gaining approval, a request to review the decision must be submitted to the Minister for Health and Ageing (refer Regulation 5M).

- In the fourth paragraph delete “Division 5”; and

Replace with “Part 6, Division 3”.

- In the penultimate paragraph, delete the words “Therapeutic Goods Regulations” and replace with “*Therapeutic Goods Act 1989* or Regulations”.

Dated this 20th day of January 2005

Ngaire Bryan
Acting National Manager
Therapeutic Goods Administration
Department of Health and Ageing
(Delegate of the Minister for Health and Ageing)