



Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

# The Therapeutic Good Advertising Code Explained

September 2009

Susan Anido  
Head – Advertising Unit  
Advertising and Export Section  
Non-Prescription Medicines Branch





## WHAT IS AN ADVERTISEMENT?

Advertisement -

“...any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods”.





## WHAT IS AN ADVERTISEMENT cont?

Advertisements in print media – newspapers, magazines;

In broadcast media – TV, radio, cinema;

“Advertorials”;

Inserts - leaflets, flyers, etc;

Point of sale material, “shelf talkers / wobblers”;

Material distributed via letterbox drop;

Verbal representations; labels - separate requirements;

Press Releases; Letters to the Editor.

- virtually anything which satisfies the legal definition



# WHAT IS AN ADVERTISEMENT cont?

## Internet sites

All material on websites that is accessible to consumers **MUST** comply with the advertising provisions of the therapeutic goods legislation.

Promotional material provided on the internet to healthcare professionals must be accessible only via a secure system that is designed to prevent access by members of the general public.



# ADVERTISING REQUIREMENTS OF THE THERAPEUTIC GOODS LEGISLATION

- Specific advertising requirements are outlined in the Therapeutic Goods Act...
- Therapeutic Goods Advertising Code (TGAC) 2007;





# ADVERTISING REQUIREMENTS OF THE THERAPEUTIC GOODS LEGISLATION

- Subsection 41ML; and
  - A person is guilty of an offence if a kind of medical device is included in the Register in respect of a person; and the person, by any means, advertises the goods as being for a purpose other than that accepted in relation to that inclusion.
- Chapter 5.





## THERAPEUTIC GOODS ADVERTISING CODE 2007

- TGAC 2007 – registered in the Federal Register of Legislative Instruments (FRLI)
- Date of Effect: *8 March 2007*
- Includes amendments recommended to the Minister by the Therapeutic Goods Advertising Code Council
- Download from-
  - [www.tga.gov.au](http://www.tga.gov.au)
  - "A – Z guide"....."Advertising Therapeutic Goods"





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.1: Object of the Code
  - 'adverts must ... promote quality use of therapeutic goods, be socially responsible and must not mislead or deceive consumers.....'
- s.2: Definitions
  - as per statutory definitions in legislation
- s.3: Compliance with, and application of, the Code
  - Note 3(2) - "... impact upon the reasonable person"







## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.4: General Principles – Advertisements for tg's:
  - 4(1)(a): must comply with law
  - 4(1)(b): must contain correct and balanced statements and claims which sponsor has already verified
  - 4(2)(a): must not arouse unwarranted / unrealistic expectations of product effectiveness
  - 4(2)(c): must not mislead or be likely to mislead





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.4: General Principles – Advertisements for tg’s:
  - 4(2)(e): must not imply harmful outcome if not used
  - 4(2)(f): must not encourage or be likely to encourage inappropriate or excessive use
  - 4(2)(g): must not claim .... infallible, unfailing, magical, miraculous or guaranteed / sure cures, etc
  - 4(2)(i): must not claim “safe”, “no side effects”, etc





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.4: General Principles – Advertisements for tg's:
  - 4(3): must not offer incentives to retail assistants to recommend or supply products
  - 4(4): scientific info must be accurate, appropriate, readily understood by target audience & publication of research results must identify researcher & financial sponsor
  - 4(5): comparative advertising must be balanced, must not mislead, must not imply other goods are harmful or ineffective





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.4: General Principles – Advertisements for tg's:
  - 4(6)(a): may include reference to sponsorship of any government agency, hospital, healthcare facility. Sponsorship must be explicitly acknowledged & must not imply endorsement by that agency
  - 4(6)(b): must NOT contain government agency or healthcare professional endorsement, including endorsements by hospitals and other healthcare facilities
  - {**Exception** – healthcare professionals may advertise price and availability of therapeutic goods from their retail businesses}





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.4: General Principles – Advertisements for tg’s:
  - 4(7): may include testimonials, BUT testimonial must not breach TGAC, be documented, genuine, not misleading & illustrate typical cases only
  - 4(8): must not contain an offer of a sample (other than for devices and sunscreens)





## THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

- s.5: Prohibitions – Advertisements for tg’s:
  - 5(1): must not contain expressly or by implication a “prohibited representation”
  - 5(2): must not contain expressly or by implication a “restricted representation” without prior approval having been granted

Read in conjunction with Appendix 6 & note definition of “serious”.





# THERAPEUTIC GOODS ADVERTISING CODE 2007 cont.

## s.6: Minimum Requirements – Advertisements for tg's:

- 6(3): must include the trade name, reference to accepted indications, ingredients & range of other warning / cautionary statements depending upon type of advertisement and / or product.

## s.7: Specific Categories

- Analgesics, Vitamins, Weight Management

Appendices





# FURTHER INFORMATION

- TGA Website  
[www.tga.gov.au](http://www.tga.gov.au)
- Advertising and Export Section, TGA  
Tel: 02 6232 8757 Fax: 02 6232 8659  
E-mail: [tga.advertising@tga.gov.au](mailto:tga.advertising@tga.gov.au)
- Legislation - available from 'Comlaw' website  
[www.comlaw.gov.au](http://www.comlaw.gov.au)







Australian Government  
Department of Health and Ageing  
Therapeutic Goods Administration

# QUESTIONS?

