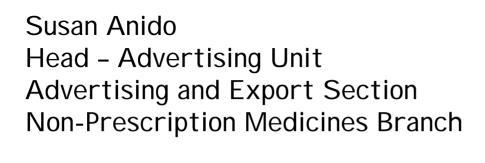


The Therapeutic Good Advertising Code Explained

September 2009







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
 - "A Z guide"......"Advertising Therapeutic Goods"



- 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"



- 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





- 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



- 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



- 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}





- 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)





- 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".





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 <u>www.tga.gov.au</u>

Advertising and Export Section, TGA

Tel: 02 6232 8757 Fax: 02 6232 8659

E-mail: tga.advertising@tga.gov.au

Legislation - available from 'Comlaw' website www.comlaw.gov.au



QUESTIONS?







