

**Australia New Zealand**

**Therapeutic Products Advertising Code**

**4th draft August 2003**

**Version 4**

**Part I**

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## **PART 1**

### **1. OBJECT OF THE CODE**

The object of the Code is to safeguard public health and safety, protect the public interest, support the quality use of therapeutic products and informed healthcare choices.

The Code sets the standard for the advertising of therapeutic products and services in Australia and New Zealand. The standard is to ensure the advertising of therapeutic products is socially responsible, promotes the appropriate, judicious, effective and safe use of therapeutic products<sup>1</sup> and does not mislead or deceive.

### **2. INTERPRETATION**

The Code is to be read and applied in accordance with the Therapeutic Products Advertising Guidelines (the Advertising Guidelines), as amended by the Advertising Board from time to time.

The Code is the standard applied to all advertisements and in the consideration of complaints and appeals (refer Guideline 4). In interpreting the Code, the total presentation and context of the advertisement will be considered in terms of the content, as well as the spirit and intent, of the Code. The conformity of an advertisement with the Code will be assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed.

The Advertising Guidelines specify public interest criteria to be applied in decisions relating to application of the Code.

### **3. LEGISLATIVE FRAMEWORK**

The legal basis for the Code is to be found in the Therapeutic Products Act and Rules.

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<sup>1</sup> Refer National Medicines Policy and National Strategy for Quality Use of Medicines at <http://www.health.gov.au>.

## 4. DEFINITIONS

**Advertisement** means any words, whether written, printed or spoken, and any pictorial representation or design, used or appearing to be used, to promote the use, sale or supply of therapeutic products, or services embracing the use, sale or supply of therapeutic products, or which imparts information or seeks to educate with a view to promoting the use, sale or supply of therapeutic products.[refer Guideline 1.1(b)]

**Label** A definition is being developed under the Joint Agency work program

**Healthcare Practitioner** means

- (I) for the purposes of determining whether an advertisement is directed to healthcare practitioners, a person who is described in a Schedule (to be developed jointly by Australia and New Zealand) to the Rules and,
- (II) for the purposes of representations made in advertisements, a person represented to be a healthcare practitioner.

**Sponsorship advertisement** means a representation that the advertiser is sponsoring a person, competition, activity, program or event and no therapeutic claim is made.

***[Note that the term advertiser includes the advertiser's product]***

**Therapeutic product** These definitions are being developed under the Joint Agency

**Therapeutic use** work program. The latest version can be found at Attachment A.

**Generic information** means information about substances that may be used as an ingredient or component in the manufacture of therapeutic products but which does not identify those particular therapeutic products.

#### **4. APPLICATION OF THE CODE**

The Code applies to advertisements for the use, sale or supply of therapeutic products, and services embracing the use, sale or supply of therapeutic products, in all forms of media in Australia and New Zealand (refer Guideline 1).

Guidelines to this Code, as determined by the Advertising Board, must be observed.

The Code applies to advertisements directed to healthcare practitioners. The oversight of the application of this Code to advertisements directed to healthcare practitioners, will reside with the Advertising Board, with the administration primarily delegated to the relevant industry bodies in Australia and to the ASA in New Zealand.

The Code does not apply to bona fide news, bona fide editorials and bona fide public interest programs

***NOTE: The equity of treatment for advertisements for foods or cosmetics that make therapeutic claims is an outstanding issue for further discussion by the Interim Council.***

## **5. PRINCIPLES**

### **KEY PRINCIPLES**

The object of the following Key Principles is to safeguard public health and safety, protect the public interest, support the quality use of therapeutic products and informed healthcare choices.

#### **Principle 1**

Advertisements must comply with the Therapeutic Products Act(s) and Rules and the Therapeutic Products Advertising Code. [refer Guidelines 1 – 4]

#### **Principle 2**

Advertisements must be truthful and not misleading

Claims must be valid and substantiated

#### **Principle 3**

Advertisements must observe a high standard of social responsibility

**The following Advertising Rules must be observed:**

1. Advertisements must comply with the statute and common law of the country(ies) in which the advertisement is published or broadcast.
2. Advertisements must not encourage inappropriate or excessive use. [refer Guideline 2.5].
3. Advertisements must contain required information to ensure responsible use .[refer Guideline 2.1].
4. Advertisements must contain correct and balanced representations and claims that have already been substantiated and:
  - a) for medicines – must be consistent with the indications included on the database of therapeutic products maintained by the trans Tasman Therapeutic products Agency [refer Guideline 3.1];
  - b) for medical devices – must be consistent with the manufacturer’s intended purposes, included on the database for therapeutic products maintained by the trans Tasman Therapeutic products Agency [refer Guideline 3.1]; and
  - c) for exempt therapeutic products – must be compliant with the Code
5. Advertisements must not by implication, omission, ambiguity or comparison:
  - (a) mislead or deceive, or be likely to mislead or deceive, or
  - (b) abuse trust, or exploit lack of knowledge (refer Guideline 2.8), or
  - (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress (refer Guideline 3).
6. Advertisements must not unduly glamorise products or services, or prey on the vulnerability of particular audiences, including minors. (refer Guideline 2.4)
7. Advertisement containing or implying endorsement by any government agency [refer Guideline 2.7], hospital or other facility providing healthcare services, or healthcare professionals in their professional capacity, must have prior consent, name the entity giving the endorsement, be authenticated and acknowledge any valuable consideration.
8. Testimonials, in advertisements where not prohibited by law, must comply with the Code, be authenticated, genuine, current, typical and acknowledge any valuable consideration,.
9. Advertisements to consumers must not refer directly or by implication to serious diseases, conditions, ailments or defects without approval of any claim, taking into account the Code, by the JTPA [refer Guideline 4.2]. [*Some kinds of devices are exempted from this requirement [refer Guideline (to be developed by MDARG)].*]

## 6. PROHIBITIONS

1. In Australia, it is prohibited to advertise directly to consumers, prescription medicines i.e. Schedule 4 substances and non-prescription Schedule 3 substances that do not appear in Appendix H to the Standard for Uniform Scheduling of Drugs and Poisons. The prohibition does not apply where the Australian Commonwealth, States and Territory governments include information about specific products in public health education initiatives such as vaccination campaigns. (Comment: reworded for clarity)
2. In New Zealand, advertisements for Class A and Class B controlled drugs, as defined in the *Misuse of Drugs Act 1975*, must be directed only at healthcare practitioners and in appropriate media.

## Attachment A

### A therapeutic product is a product

- (a) that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken to be or intended to be:
- (i) for therapeutic use; or
  - (ii) for use as an ingredient or component in the manufacture of therapeutic products; or
  - (iii) for use as a container or part of a container for products of the kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of products the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes medical devices and products declared to be therapeutic products under an Order made by the Managing Director, but does not include:
- (c) products declared not to be therapeutic products under an Order made by the Managing Director; or
- (d) products in respect of which an Order made by the Managing Director is in force, being an Order that declares the products not to be therapeutic products when used, advertised, or presented for supply in the way specified in the Order where the products are used, advertised, or presented for supply in that way; or
- (e) products (other than products declared to be therapeutic products under an Order made by the Managing Director) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or
- (f) products which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

*(Comment – NZ consultation raised need to review whether services should be included for purposes of the advertising Code. Note if health services are included caution may be required in applying to certain sectors of industry eg optometrists and the line between therapeutic product regulation and “professional practice” regulation)*

### Therapeutic use

- means use in or in connection with:
- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
  - (b) influencing, inhibiting or modifying a physiological process in persons; or

- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling or preventing conception in persons; or
- (e) testing for pregnancy in persons; or
- (f) the replacement or modification of parts of the anatomy in persons.