

## PROPOSED Medsafe Guidelines for Advertising Non-prescription (Over-the-Counter) Medicines Direct to the Consumer

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### PREFACE

The Principles and Requirements of these Guidelines are modelled on the Australia New Zealand Therapeutic Products Advertising Code developed in anticipation of and for use under ANZTPA.

In particular, the current restrictions that prevent complementary medicines making therapeutic claims apply.

**PRINCIPLE 1:**        **Advertisements must comply with the laws of New Zealand as interpreted by this Guideline.**

**PRINCIPLE 2:**        **Advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated.**

**PRINCIPLE 3:**        **Advertisements must observe a high standard of social responsibility.**

### ADVERTISING NON-PRESCRIPTION (OTC) MEDICINES TO CONSUMERS

The advertising of all medicines, other than controlled drugs, directly to consumers is legal in New Zealand. The advertising of medicines is regulated under Part IV of the Medicines Act 1981 and Part III of the Medicines Regulations 1984. In addition, member companies of the New Zealand Self-Medication Industry Association (SMI) adhere to the SMI Code of Practice, whereby all advertisements must comply with the Advertising Standards Authority (ASA) codes, particularly the Code for Therapeutic Advertising.

**Requirement 1:**        **Advertisements must not encourage, or be likely to encourage, inappropriate or excessive use.**

**Requirement 2:**        **Advertisements must contain the mandatory information to encourage responsible use.**

Advertisements for therapeutic products are exempt from this requirement where:

- the advertisement does not contain a therapeutic claim and displays only the:
  - brand/name/picture of the therapeutic products; or
  - the name of the sponsor and/or the price and/or simple point of sale; or
- the advertisement is an unbranded, or a reminder, or a sponsorship advertisement.

### MANDATORY STATEMENTS

All required statements must be prominently displayed or communicated, i.e. standing out so as to be easily read from a normal viewing distance, and/or be heard and understood. (Uppercase or bold font is not a requirement but is used in these guidelines to highlight the required mandatories.)

**Comment [RB1]:** Accepted by Medsafe

For all required statements, other than 'Always read the label', words conveying the same meaning may be used.

Advertisements to consumers for OTC medicines must contain:

- the **trade name** and labelled **indications** consistent with those included in the database of therapeutic products maintained by Medsafe; **and**
- the following mandatory statement:

**Comment [RB2]:** No comment by Medsafe, assume this will be deleted?

#### **ALWAYS READ THE LABEL**

**and** the following statement or words with the same meaning:

#### **USE ONLY AS DIRECTED**

**and** the following statement, or words with the same meaning, where relevant

#### **IF SYMPTOMS PERSIST SEE YOUR HEALTHCARE PROFESSIONAL**

**Comment [RB3]:** Accepted by Medsafe

If the product, when used according to the directions:

- has known serious adverse effects (in terms of severity and clinical importance);
  - or**
  - is contraindicated for a known group of people because it could cause serious adverse effects and this is reflected in the regulatory requirements on the label or in the Consumer Medicine Information (CMI),
- an appropriate warning of those effects must be given.

**Comment [NT4]:** This is inconsistent with TGAC which does not have this requirement

Categories of OTC medicines which would be likely to meet the above criteria include analgesics, sedating anti-histamines, pseudoephedrine and non-steroidal anti-inflammatory drugs (NSAIDs).

**Comment [RB5]:** Not discussed in Meds Regs consultation, need clarification from Medsafe if this is still required or is covered by "Always read the label."

#### **Oral Analgesics**

In addition to the requirements specified above, oral analgesics (excluding preparations for internal use in self-limiting conditions and which contain an analgesic in combination with one or more other active ingredients such as cough mixtures and cold tablets) require the following statement:

#### **INCORRECT USE COULD BE HARMFUL**

An advertisement for analgesics must not represent that:

- (a) analgesic consumption is safe; and/or
- (b) analgesics will relax, relieve tension, sedate or stimulate.

#### **NSAIDs (internal use only)**

#### **DO NOT USE IF YOU HAVE STOMACH ULCERS**

#### **Sedating Antihistamines**

#### **MAY CAUSE DROWSINESS (AVOID ALCOHOL AND DRIVING)**

#### **Pseudoephedrine**

#### **MAY CAUSE INCREASED HEART RATE**

The above statements are regarded to be the **minimum** requirement, particularly for electronic media.

**Comment [RB6]:** Not discussed in Meds Regs consultation, need clarification from Medsafe if this is still required or is covered by "Always read the label."

### **Classification**

If it is a restricted/pharmacist only medicine, the following words are required:

**YOUR PHARMACIST'S ADVICE IS REQUIRED;  
Or  
AVAILABLE ONLY FROM YOUR PHARMACIST**

### **Direct or Internet Marketing**

Where an advertisement is for the sale or supply of therapeutic products by mail order, direct mail, or the internet, the advertisement must contain, in addition to the above:

**Comment [RB7]:** Seem to have agreement on this, clarification needed from Medsafe

- a full list of the active ingredients.  
Where the product name is also the single active ingredient, the pack shot displaying the product name will be sufficient to meet this requirement.
- the mandatory warning statements prominently displayed on each page of the catalogue or internet that features therapeutic goods;
- if the product, when used according to the directions:
  - has known serious adverse effects (in terms of severity and clinical importance); **or**
  - is contraindicated for a known group of people because it could cause serious adverse effects and this is reflected in the regulatory requirements on the label or in the CMI;an appropriate warning of those effects must be given.

### **Radio Commercials 15 seconds or less**

Require the following verbal statement;

**USE ONLY AS DIRECTED.**

**Comment [RB8]:** Not discussed in Meds Regs consultation, need clarification from Medsafe on whether this will be applicable.

### **Vitamins**

An advertisement for vitamins must not represent that vitamin supplements:

- are a substitute for good nutrition or a balanced diet; and/or
- are superior to, or more beneficial than, dietary nutrients or that normal health may be affected by not taking vitamin supplements.

**Comment [RB9]:** Not discussed in Meds Regs consultation, need clarification from Medsafe on whether this will be applicable.

### **Weight Management**

Advertisements for therapeutic products containing claims for weight management, meaning weight loss, measurement reduction, clothing size loss and weight control/maintenance, must have an appropriate balance between those claims and references to healthy energy-controlled diet and physical activity.

**Comment [RB10]:** Not discussed in Meds Regs consultation, need clarification from Medsafe on whether this will be applicable.

**Requirement 3:** Claims must be consistent with the indications approved by Medsafe and included on the product labelling.

**Requirement 4:** Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison:

**Comment [RB11]:** Medsafe to confirm that these Requirements (including sub headings) will still be included in the revised advertising guideline

- (a) mislead or deceive, or be likely to mislead or deceive; or
- (b) abuse trust, or exploit lack of knowledge; or
- (c) exploit the superstitious or, without justifiable reason, play on fear or cause distress.

**An advertisement must not:**

- i) contain any claim, statement or implication that the product is safe or that its use cannot cause harm or that it has no side effects or risks associated with its use;
- ii) contain any claim, statement or implication that the product is effective in all cases of a condition;
- iii) contain any claim, statement or implication that the product is infallible, unfailling, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- iv) contain any matter which is likely to lead persons to believe that;
  - they are suffering from a serious ailment, or
  - harmful consequences may result from the therapeutic product not being used.

**Comparative advertising**

Comparative advertising must be balanced and must not be misleading, or likely to be misleading, either about the product advertised or any therapeutic products, or classes of therapeutic products, with which comparison is made.

Comparative advertisements must not be disparaging but must be factual, fair and already substantiated, referenced to the source and reflective of the body of available evidence.

In comparing products, advertisements must not discourage consumers from taking therapeutic products prescribed by a healthcare practitioner.

**Scientific information**

Scientific information within an advertisement must be presented in an accurate manner. Scientific terminology must be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed.

An advertisement using research results should cite the journal reference if applicable.

**Requirement 5:** Advertisements must not unduly glamorise products or services, or prey on the vulnerability of particular audiences.

**Requirement 6:** Advertisements may include reference to sponsorship of any government agency, hospital or other facility providing healthcare services, provided that sponsorship is explicitly acknowledged and cannot be misconstrued as an endorsement of a product.

Advertisements may contain or imply an endorsement by individual, or individual groups of, healthcare practitioners in their professional capacity, bodies or associations representing the interests of the health of consumers, conducting or funding medical research or representing health practitioners, provided that the endorsement does not in any way imply endorsement by any government agency, hospital or other facility providing healthcare services. However, such endorsements must have prior consent from the endorser, be authenticated and the advertisement must contain, prominently displayed, the

**Comment [RB12]:** Not discussed in Meds Regs consultation, need clarification from Medsafe on whether this will be possible.

**name of the endorser and acknowledgement of any valuable consideration.**

**Requirement 7:**

**Testimonials must not breach the Code. They must be documented, genuine, not misleading and illustrate typical cases only.**

**Comment [NT13]:** It is not clear whether this is consistent with Australia or not. Can we rather use the exact same wording as the TGAC so there is no room for inconsistent interpretation

**Comment [RB14]:** Not discussed in Meds Regs consultation, need clarification from Medsafe on whether this will be possible.

**Other requirements**

**Length of time on screen (TV, cinema)**

Required information must be clearly legible and displayed on screen long enough to be read by the ordinary viewer with clarity being paramount. Suitable colour contrast, font size, separation of mandatory statements and time on screen should be used.

**Advertisement should not imply endorsement by any Government agency.**

Cannot claim 'approval' by Medsafe / Ministry of Health.