

THERAPEUTIC AND HEALTH ADVERTISING CODE

Purpose of the Code

The purpose of this Code is to ensure that advertisers maintain rigorous standards in therapeutic and health advertising.

All advertising shall adhere to the laws of New Zealand and the Principles and Rules set out in this Code. The ASA Advertising Standards Code should also be consulted. Many sectors in this category have their own codes with specific advertising requirements and these should also be taken into account by advertisers.

Definition of Advertisement

“Advertising and Advertisement(s)” means any message, the content of which is controlled directly or indirectly by the advertiser, expressed in any language and communicated in any medium with the intent to influence the choice, opinion or behaviour of those to whom it is addressed.

Application of the Code

This Code covers all words and visual depictions in all advertising for therapeutic products (medicines and medical devices), natural health products and dietary supplements, health services and methods of treatment. This Code may also apply when therapeutic or health claims are made in advertisements for other products or services not defined in this code. This Code does not apply to labels or packaging. However, when a label or packaging appears in an advertisement it forms part of the advertisement and therefore any visible aspects are covered by this Code.

Interpreting the Code

Social responsibility in advertising is embodied in the Principles and Rules of the Code. In interpreting the Code, emphasis must be placed on compliance with both the spirit and intention of the Code. It is possible for advertising to be in breach of one or more of the Principles in the Code without being in breach of a specific Rule.

In determining whether a Principle has been breached, the Complaints Board will have regard to all relevant matters, including;

- generally prevailing community standards;
- previous decisions;
- the consumer takeout from the advertisement;
- the context, medium and intended audience; and
- the product or service being advertised.

For the avoidance of doubt, where legislation relevant to this Code has been updated and/or if a conflict occurs in relation to legislative and code requirements, legislative requirements will prevail.

The Therapeutic Advertising Pre-Vetting Service (TAPS) is a user-pays service available to all advertisers making therapeutic and health claims to help minimise the risk of breaching the ASA Codes of Practice as well as other industry codes and relevant legislation. Information about TAPS is available at <http://www.anza.co.nz>.

Definitions for the purposes of this Code:

‘Medicine’ – Medicines are any substance or article or active ingredient that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose (see definition below for therapeutic purpose). A medicine achieves, or is likely to achieve, the principal intended action in or on the human body by pharmacological, immunological, or metabolic means.

Only medicines that have been evaluated by Medsafe and have consent to distribute may be advertised in New Zealand. The medicine(s) advertised may be available on prescription or may be purchased ‘over-the-counter’.

A product can be a medicine in three ways.

1. It is, or contains, a scheduled ingredient
2. A therapeutic claim is made on the label or in advertisements
3. It is a product with consent to distribute

Advertisers should not rely on the medicines classification schedule to determine whether or not a product is a ‘medicine with consent to distribute’ and is therefore able to be advertised.

Section 3 of the Medicines Act 1981 (Meaning of Medicine) is available here www.legislation.govt.nz.

‘Medical Device’ – Medical Devices are devices that have a therapeutic purpose (see definition below for therapeutic purpose).

A product can appear to be a Medical Device by virtue of the way it works or the claims that are made on the label or in advertisements.

Section 3 (A) of the Medicines Act 1981 (Meaning of Medical Device) is available here www.legislation.govt.nz.

‘Therapeutic Purpose’ – The Medicines Act provides the following definition:

- (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
- (b) influencing, inhibiting, or modifying a physiological process; or
- (c) testing the susceptibility of persons to a disease or ailment; or
- (d) influencing, controlling, or preventing conception; or
- (e) testing for pregnancy; or
- (f) investigating, replacing, or modifying parts of the human anatomy.

Only medicines with consent to distribute in New Zealand and medical devices can claim to have a therapeutic purpose in advertisements.

A ‘therapeutic purpose claim’ in an advertisement will likely refer to a medicine(s) or medical device that has a therapeutic effect on an actual or implied medical condition / disease or physiological process (see definition below for disease). A ‘therapeutic purpose claim’ may be accompanied by words such as enhance, improve, prevent, interfere with, terminate, reduce, increase, accelerate, inhibit, boost, treat, relieve and stimulate. For medicines, the therapeutic claims(s) must be consistent with the indication(s) that have been approved for the product.

‘Disease’ – The Medicines Act provides the following definition;

Disease includes any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind.

‘Natural Health Products and Dietary Supplements’ – Products for the primary purpose of bringing about a health benefit (see definition below for health benefit) to the person who uses the product. May include Natural Health Products, Dietary Supplements, Herbal Preparations and Traditional Medicines.

‘Health Benefit’ – Means any one of the following benefits:

- (a) the maintenance or promotion of health or wellness
- (b) nutritional support
- (c) vitamin or mineral supplementation
- (d) maintaining the normal structure or function of the body

Health Benefit claims in advertisements for a Natural Health Product and Dietary Supplement must be supported by scientific or traditional substantiation. Only products that meet the definition in this Code of a Natural Health Product or Dietary Supplement may claim a health benefit in advertisements.

‘Health Services’ – Services that offer a method of treatment (see definition below for method of treatment) for a range of medical conditions OR services that offer support for normal healthy body functions. Providers may or may not be registered health professionals (as defined in the NZ Medicines Act). May include (but not limited to), services for Medicine, Surgery, Physiotherapy, Nursing, Rehabilitation, Diagnostics, Psychotherapy, Counselling, Fertility, Sterilisation, Relaxation Massage, Homeopathy, Naturopathy, Chiropractic, Acupuncture, Traditional Chinese medicine and Ayurvedic medicine.

‘Method of Treatment’ – The Medicines Act provides the following definition;

Any method of treatment for reward undertaken, or represented to be undertaken, for a **therapeutic purpose**.

‘Healthcare Professional’ – The Medicines Act provides the following definition;

A health practitioner who is, or is deemed to be, registered with an authority established or continued by the Health Practitioners Competence Assurance Act 2003 as a practitioner of a particular health profession.

When advertising is directed to Healthcare Professionals or Healthcare Professionals appear in advertisements, this definition also includes those who are studying or undertaking research in relation to any of the registered health professions and employees of healthcare professionals.

Note: The Medicines Act does not permit healthcare professionals endorsing a medicine or a medical device in advertisements to **consumers**.

Guidelines

Advertisers should take care in using the term ‘healthcare professional’ in advertisements. People in advertisements, or who are referred to in advertisements, should only be labelled as a Healthcare Professional (or are studying, undertaking research or are employees of healthcare professionals) if they fit the legal definition otherwise the advertisement may be misleading.

Weight Loss / Weight Management Programme’ – A programme that may include the sale of e.g. food, meals, meal replacement or gym equipment, and may include advice on diet, exercise, and lifestyle changes. Weight is lost or managed through reduced energy intake and / or increased energy is expended. Where there is suitable substantiation, claims for weight loss may be made in advertisements for weight programmes.

Advertisements for weight programmes are NOT subject to the Medicines Act unless there is a medicine or medical device advertised with the programme. Advertisements for weight programmes that include a Medicine, Medical Device, Natural Health Product or Dietary Supplement or Health Service are subject to the advertising requirements of this Code for these products.

Guidelines

Advertisements for Weight Programmes that include a medicine, medical device or health service may only claim ‘weight loss’ if this claim can also be made about the product / device / service. A weight loss claim in an advertisement for weight programmes such as these will infer a weight loss claim on the product / device / service.

This could be misleading if the product / device / service is not able to make a weight loss claim when advertised alone (without the weight programme).

Natural Health Products and Dietary Supplements when advertised alone may not make weight loss claims in advertisements. When included in an advertisement for a weight management programme weight loss claims cannot be made about the product or the programme.

PLEASE NOTE: There are further detailed guidance notes on the Advertising of Weight Management Programmes at the end of this code. These guidance notes assist advertisers to produce advertisements in a socially-responsible manner and so consumers are not deceived or misled.

PRINCIPLE 1: SOCIAL RESPONSIBILITY

Therapeutic and Health advertisements shall observe a high standard of social responsibility particularly as consumers often rely on such products, devices and services for their health and wellbeing.

Rule 1 (a) Mandatory information	Guidelines
<p>Advertisements shall contain the following mandatory information to encourage responsible prescribing, recommendation, sale and use.</p> <p>This information shall be set out in a way (legible / audible) that ensures it can be readily understood by the audience to whom it is directed.</p> <p>Medicines</p> <p>Mandatory information as required by the most recent edition of the Medicines Act, Medicines Regulations, Medsafe Guideline on Advertising therapeutic products, Medicines NZ Code of Practice and the Self-Medication Industry Code of Practice.</p> <p>Medical Devices</p> <p>Mandatory information as required by the most recent edition of the Medicines Act, Medicines Regulations and any other applicable legislation, Medsafe Guideline on Advertising therapeutic products and the MTANZ Code of Practice and where appropriate;</p> <p>The following statement (or words to this effect);</p> <ul style="list-style-type: none"> • <i>Always read the label and follow the instructions.</i> <p>The following statement (or words to this effect) where a device requires the administration,</p>	<ul style="list-style-type: none"> • Name and Address of the Advertiser <p>Including the name and address of the advertiser in advertisements for therapeutic and health products, devices and services allows consumers to determine who is responsible for the advertisement. They are then able to make contact with the advertiser to, for example, ask questions or request more information. Including the name and address of the advertiser is a legislated requirement for advertisements for medicines and medical devices.</p> <p>The advertiser’s address may be limited to the City name providing the advertiser can be easily located via an online search or in the White / Yellow Pages. Advertisers may also include their company website address.</p>

application or implant by a healthcare professional;

- *This Medical Device must be administered / applied / implanted by a healthcare professional.*

Natural Health Products and Dietary Supplements

Any mandatory information as required by the applicable legislation and the following statements;

- Name and address of the advertiser
- *Always read the label and use as directed.*

For products that contain vitamins and / or minerals, the following additional statement (or words to this effect).

- *Vitamins and minerals are supplementary to and not a replacement for a balanced diet.*

For products that may be used for a short time, after which the consumer should seek medical advice, the following additional statement (or words to this effect).

- *If symptoms persist, see your healthcare professional.*

Health Services

- Name and address of the advertiser.

Weight management programme where 'Weight Loss' is claimed

The following statements (or words to the effect).

- *Weight loss takes time and effort to be successful. People should seek professional advice on diet, exercise and lifestyle changes.*

- *Individual results may vary.*

- Name and address of the advertiser.

Where food, meals or low calorie meal replacement products are sold in addition to any programme membership fees it shall be clear to the consumer that the cost of these items is additional to any cost for membership. For example, where meals or food are sold, these statements shall appear;

‘Food additional’ or ‘Plus the cost of food’.

Any other mandatory information relevant to products, devices or services advertised with the programme.

Weight management programme where ‘Support for Weight Management’ is claimed

The following statement (or words to the effect).

- *Weight management takes time and effort to be successful. People should seek professional advice on diet, exercise and lifestyle changes.*

- *Individual results may vary.*

- Name and address of the advertiser.

Any other mandatory information relevant to products, devices or services advertised with the programme.

<p>Rule 1 (b) Safety and effectiveness</p>	
<p>Advertisements shall not contain any claim, statement or implication that the products, devices or services advertised:</p> <ul style="list-style-type: none"> • are safe or that their use cannot cause harm or that they have no side effects or risks. • are effective in all cases • are infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure • are likely to lead persons to believe that; <ul style="list-style-type: none"> ○ they are suffering from a serious ailment, or ○ harmful consequences may result from the therapeutic or health product, device or service not being used. 	
<p>Rule 1 (c) Vulnerable audiences</p>	
<p>Advertisements should not portray unrealistic outcomes or prey on or misrepresent vulnerable audiences (e.g. sick, elderly, pregnant women, overweight people).</p>	
<p>Rule 1 (d) Scientific language</p>	
<p>The use of scientific language in advertisements is acceptable providing that it is appropriate to, and readily understood by, the audience to whom it is directed.</p>	

PRINCIPLE 2: TRUTHFUL PRESENTATION

Advertisements shall be truthful, balanced and not misleading. Advertisements shall not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole.

Rule 2 (a) Truthful presentation

Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated. Substantiation should exist prior to a claim being made. For medicines and medical devices, therapeutic claims must be consistent with the approved indication(s) (for medicines) or the listed intended purpose (for medical devices).

Guidelines

In addition to the ASA Guidance Note on Responding to a Complaint about Misleading Claims, the following guidance is specific to advertising therapeutic products, natural health products and dietary supplements and health services. Substantiation varies for claims made in advertisements depending on what is being advertised.

For example;

- i. Therapeutic claims for Medicines shall be those approved by Medsafe and thus would be consistent with the product Data Sheet, Consumer Medicine Information and / or the approved Label.
- ii. Therapeutic claims for Medical Devices should be consistent with the 'Intended Purpose' noted on the WAND listing and the claims must be able to be supported by appropriate substantiation.

Medical Devices must be listed on WAND within 30 working days after the device is first imported, exported or manufactured (Note: There are some exceptions to this WAND listing requirement).

There is no independent evaluation in New Zealand of the substantiation for claims made about a medical device. The onus to have substantiation on-hand and provide it when necessary, lies with the advertiser.

Please note: The WAND database is not accessible to members of the public or any other party except Medsafe and the New Zealand sponsor.

Note: It is an offence under the Fair Trading Act to make a claim in an advertisement that cannot be substantiated. Advertisers must be able to back up a claim before the claim is made in an advertisement. This Commerce Commission Fact Sheet provides an overview of the substantiation provisions of the Fair Trading Act.

<p>Rule 2 (b) Inappropriate or excessive use</p>	
<p>Advertisements shall not encourage, or be likely to encourage, inappropriate or excessive purchase or use. Advertisements for prescription medicines shall not encourage, or be likely to encourage, inappropriate or excessive prescriptions or requests for a prescription.</p>	
<p>Rule 2 (c) Comparative advertising</p>	
<p>Comparative advertising shall be balanced and shall not be misleading, or likely to be misleading, either about the product, device or service advertised or classes of products, devices or services, with which the comparison is made.</p> <p>i. Comparative advertisements shall not be disparaging and shall be factual, fair and able to be substantiated, referenced to the source and reflective of the body of available evidence.</p> <p>ii. Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner.</p> <p>iii. Comparative advertisements shall compare ‘like with like’.</p> <p>Advertisements for Natural Health Products and Dietary Supplements shall not include comparisons with medicines or medical devices either specifically or generally.</p>	

<p>Rule 2 (d) Sponsorship</p>	
<p>Advertisements may include reference to the advertiser’s 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 the product, device or service being advertised.</p>	
<p>Rule 2 (e) Endorsements</p>	
<p>Advertisements shall not claim or imply endorsement of the product, device or service by any government agency, professional body or independent agency unless there is prior consent, the endorsement is current, verifiable and the agency or body is named.</p>	
<p>Rule 2 (f) Testimonials and healthcare professional endorsements</p>	<p>Guidelines</p>
<p>Patient testimonials and healthcare professional endorsements in advertisements, where not prohibited by law, shall comply with the Code, be authenticated, genuine, current, and typical and acknowledge any valuable consideration. Exceptional cases shall be represented as such.</p>	<p>The Medicines Act Section 58 (1) (c) (iii) prevents the use of patient testimonials in advertisements to consumers for medicines or medical devices or methods of treatment where a therapeutic benefit is obtained (Note: Section 60 of the Medicines Act exempts advertisements that are circulated solely or principally to healthcare professionals). This means that an advertisement to consumers cannot include (or imply) a patient (or group of patients / class of people) with a medical condition or disease, taking a medicine or using a medical device or have accessed a method of treatment and showing in some way that they have benefited from it.</p> <p>Testimonials for natural health products and dietary supplements, and health services to support a normal bodily function are permitted. However, these testimonials should not include any information that implies the product is a medicine or medical device or that the service has a therapeutic benefit. This is likely to breach the Medicines Act. The content of testimonials must be consistent with the claims allowed in the advertisement for these products and services.</p>

Healthcare Professional Endorsements

The Medicines Act Section 58 (1) (c) (ii) prevents the use of healthcare professional endorsement in advertisements **to consumers** for medicines or medical devices or methods of treatment where a therapeutic benefit is obtained (Note: Section 60 of the Medicines Act exempts advertisements that are circulated solely or principally to healthcare professionals). This means that an advertisement to consumers cannot include a registered healthcare professional (real or fictitious) recommending (or implying to recommend) a medicine or medical device or a method or treatment for a therapeutic benefit to members of the public.

Healthcare Professional endorsements for natural health products and dietary supplements are not permitted.

Healthcare Professional endorsements for health services to support a normal bodily function are permitted. However, the endorsement should not include any information that implies that the service has a therapeutic benefit. This is likely to breach the Medicines Act. The content of a healthcare professional endorsement must be consistent with the claims allowed in the advertisement for these services.

Endorsements by people who are not Healthcare Professionals and endorsements by organisations

Other individuals or organisations may endorse a medicine, medical device, therapeutic service, natural health product and dietary supplement or health service in advertisements. The endorsement should be consistent with the claims allowable for what is being advertised. These endorsements should not include or imply a testimonial (i.e. have used themselves and benefited) unless the testimonial is consistent with the statements above in the testimonial section of these Guidelines. To be consistent with the legislation, advertisements for medicines or medical devices that include endorsement by a Government Agency must not state or imply that the Government Agency has approved the content of the advertisement.

Testimonials and Endorsements in advertisements should not breach the Therapeutic and Health Advertising Code, Principle 2, Rule 2 (b) Advertisements shall not encourage, or be likely to encourage, inappropriate or excessive purchase or use.

Further Guidance on Advertising Weight Management Programmes

The advertising for Weight Management Programmes should be conducted in a socially responsible manner and should not deceive or mislead consumers. These guidelines recognise the social and health issues arising from obesity and its impact on society. It is generally accepted that losing weight and maintaining the weight loss is difficult in many circumstances. Consumers targeted by advertisements for weight loss may be unduly influenced by claims for quick or easy weight loss or ‘magic bullet’ solutions. Advertisers should avoid these kinds of claims.

So that advertisements for Weight Management Products and Programmes observe a high standard of social responsibility, the following guidance is provided.

a) Advertisements should acknowledge nutrition and exercise as major elements in individual weight management.

To help comply with the requirement for a high standard of social responsibility, Advertisers shall include reference to the need for a balanced, healthy diet and regular exercise as key elements of individual weight management. See the Therapeutic and Health Advertising Code for suitable statements.

b) Advertisements should not suggest or imply that consumers follow a diet which is not nutritionally well-balanced or include a plan or process that has, or is likely to have, an energy intake less than that recommended by an authoritative dietary expert and specified from time-to-time in the Guidance Notes.

Advertisers shall not promote a diet plan with less than 3500 kilojoules (800 calories) per day on average over the course of one week.

Also see:

<https://www.health.govt.nz/publication/clinical-guidelines-weight-management-new-zealand-adults>

<https://www.health.govt.nz/publication/clinical-guidelines-weight-management-new-zealand-children-and-young-people>

c) Advertisements should not imply that the product or service is a substitute for a balanced diet.

d) Claims for specific weight loss or reduction in body measurement should be realistic and supportable.

e) Advertisements should not promote unrealistic, rapid, or unsafe outcomes.

f) Advertisements should not be directed nor have strong appeal, to people under the age of 18.

g) Advertisements should not suggest or recommend weight loss during pregnancy.

h) Advertisements should not suggest that it is socially or culturally desirable to be underweight.

i) Statements or implications to the effect that consumers of an advertised product or service can “...eat as much as you like...” or “...eat, eat and get slim...” cannot be used.

Please Note: The ASA Complaints Board has regularly upheld complaints about weight loss or management products and services which make claims similar to those above. It is deemed socially irresponsible to encourage those who are trying to lose weight to eat an unlimited amount of food, regardless of the effects of the product or service being promoted.

j) Advertisements for intensive physical activity programmes, products and services should encourage users to check with a doctor or professional adviser before commencing.

Use of models / actors in weight management advertisements

Advertisers should take care that models or actors, and any person providing testimonials, should not be underweight and have a generally-accepted weight to height ratio and body-mass index.

In addition, when using permitted testimonials, images should not be manipulated to misrepresent actual results.

Product or Service Guarantees in weight management advertisements

Guarantees in weight management advertising must be used with great care. In particular, if a guarantee offered is for your money back, as opposed to in support of the efficacy of the product, this must be clear.