



ADVERTISING STANDARDS AUTHORITY

DRAFT GUIDANCE NOTES

FOR THE CODE FOR THERAPEUTIC AND HEALTH ADVERTISING

July 2015

These Guidance Notes are to be read in conjunction with the Code for Therapeutic and Health Advertising. They are intended to provide interpretation assistance to the industry and consumers on the Principles and Guidelines of the Code.

SECTION A

Definition – Therapeutic Purpose vs Health Purpose

The advertising of therapeutic and health products, devices and services are governed by New Zealand legislation including the NZ Medicines Act (“the Act”). The definitions in the Act of ‘**Therapeutic Purpose**’, ‘**Disease**’, ‘**Medicine**’ and ‘**Medical Device**’ mean that only registered medicines and listed medical devices can make actual or implied therapeutic purpose claims in advertisements. A ‘therapeutic purpose claim’ in an advertisement will refer to or imply a medical condition / disease or physiological process (as defined in the Act) and may be accompanied by words to affect the disease or condition such as enhance, improve, prevent, interfere with, terminate, reduce, increase, accelerate, inhibit, boost, treat, relieve and stimulate. Where there is scientific evidence to support a therapeutic claim for a product, this evidence must first be evaluated by Medsafe and consent for distribution as a medicine must be granted by the Minister of Health before any advertising of the therapeutic claim can occur. A device that has scientific evidence to support a therapeutic claim must first be listed on the WAND (Web Assisted Notification Database) before any advertising of the therapeutic claim can occur.

This means that all health products and health devices (Natural Health Products, Dietary Supplements, Herbal Remedies, Traditional Remedies, Homeopathic Remedies and Sunscreens may only claim (or imply) in advertisements to support an aspect of health or support overall good health. Advertisements for these products and devices must not refer to a disease / medical condition or to affecting a physiological process in the body. A ‘health purpose claim’ is likely to refer to a specific part of the body or system or the overall body and may be accompanied by words such as support, normal, natural, soothe, calm, regular and nourish

Definition – Weight Management vs Weight Loss

Weight Loss programmes generally include advice on diet, exercise and lifestyle changes. The programme may or may not also sell food as meals or meal replacements and apparatus such as gym equipment or kitchen appliances. These programmes are not subject to the Medicines Act and are able to claim to affect ‘weight loss’ in advertisements due to the inclusion in the programme of a reduction of energy intake and / or increase in energy

expended. There must be no claim or implication that any of the food, appliances or equipment can have a direct effect on the weight of the human body. The claims that can be made for these weight loss programmes should be limited to the effect of energy intake reduction, energy increase expended and lifestyle management of these changes to help with weight loss.

If a weight programme also sells a product to be ingested or a device to be used that both directly affect the weight of the human body, then the product must be a registered medicine and the device must be a listed medical device. This is because to claim (or imply) that a product or device can directly affect weight loss by being ingested or used on the body is a therapeutic purpose claim.

When a health product or health device is sold in conjunction with a weight programme, the advertisements for the weight programme may only claim to 'support weight management' (or other words to this effect). The advertisements may not claim 'weight loss' as this would infer a weight loss claim on the health product or device that is being sold with the programme.

Please see the end of this document for additional guidance on the advertising of weight loss programmes.

SECTION B

PRINCIPLE 1

Name and Address of the Advertiser

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.

The advertiser's address may be limited to the City providing that the advertiser can be easily located via an online search or in the White / Yellow Pages.

SECTION C

PRINCIPLE 2, Guideline 2 (A)

Claim Substantiation

In addition to the ASA Guidance Note on Responding to a Complaint about Misleading Claims, the following guidance is specific to advertising therapeutic and health products, devices and services. The type of substantiation varies for claims made in advertisements depending on what is being advertised. For example;

- i. Therapeutic claims for Medicines should be consistent with the product Data Sheet, Consumer Medicine Information or the registered Label.

The substantiation for claims made about a medicine should be supported by the medicine data sheet, consumer medicine information and registered label. This substantiation has been independently evaluated by Medsafe and the medicine has been registered for sale and advertising in New Zealand.

- ii. Therapeutic claims for Medical Devices should be consistent with the 'Intended Purpose' noted on the WAND listing. Medical Devices should be listed on WAND prior to any advertising.

There is no independent evaluation in New Zealand of the substantiation for claims made about a medical device. The onus to have and provide substantiation 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 advertiser.

- iii. Health claims for Dietary Supplements should comply with section (11) of the Dietary Supplements Regulations 1985.

There is no independent evaluation in New Zealand of the substantiation for claims made about a Dietary Supplement. The onus to have and provide substantiation when necessary lies with the advertiser.

The onus to have and provide substantiation when necessary for other Natural Health Products lies with the advertiser.

- iv. The onus to have and provide substantiation when necessary for claims for Health Devices and Therapeutic & Health Services lies with the advertiser.

SECTION D

PRINCIPLE 2, Guideline 2 (F)

Testimonials

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) with a medical condition or disease, taking a medicine or using a device or have accessed a method or treatment and showing in some way that they have benefited from it.

Testimonials for health products, health devices and health services are permitted. However, these testimonials should not include any information that implies that the advertised product, device or service has had a therapeutic effect. 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, devices and services.

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 health products, health devices or health services are permitted. However, the endorsement should not include any information that states or implies that

the advertised product, device or service has a therapeutic effect. 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 products, devices and 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, health product, and health device or health service in advertisements. The endorsement should be consistent with the claims allowable for what has been 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 this Guidance Note.

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

SECTION E

Weight Loss Programmes

It is generally accepted that losing weight and maintaining weight loss is difficult in most circumstances. Consumers targeted by advertisements for weight loss programmes may be unduly influenced by claims that a programme may provide quick or easy weight loss or that it is a 'magic bullet' solution. Advertisers should avoid these kinds of claims.

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

1. Advertisements should not suggest or imply that consumers should have a diet which is not nutritionally well-balanced nor advertise a diet plan with less than 3500 kilojoules (800 calories) per day.
2. Advertisements should not promise unrealistic or unsafe rapid weight reduction.
3. Advertisements should neither be directed at, nor have strong or evident appeal to people under the age of 18 in particular.
4. Advertisements should not suggest that it is desirable to be underweight or use underweight models. Models of generally accepted height/weight ratios should be used.
5. Advertisements for intensive exercise programmes should encourage users to check with a doctor or professional advisor before commencing.
6. Advertisements should not imply that the advertised product is a substitute for a balanced diet.

So that advertisements for Weight Loss Programmes do not by implication, omission, ambiguity or exaggerated claim, mislead or deceive or be likely to mislead or deceive consumers, abuse the trust of or exploit the lack of knowledge of consumers, exploit the superstitious or without justifiable reason play on fear, the following guidance is provided.

1. Claims for specific weight loss or reduction in body measurement should be typical, realistic, factual and able to be proved.
2. Advertisements should not have depictions which unduly glamorise the product or portray unrealistic outcomes.
3. Claims such as "Eat as much as you like", "Eat, eat, eat" or "Eat and get slim" are unacceptable.

Advertisements for Weight Loss Programmes should only include testimonials that are real (not actors), valid, current, documented and exceptional cases should be represented as such, not as typical. The claims in testimonials should be verifiable. Testimonials in advertisements should be accompanied by the statement '*Individual Results May Vary*'.

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