



MEDSAFE

NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY

A BUSINESS UNIT OF
THE MINISTRY OF HEALTH

Guideline on the Regulation of Therapeutic Products in New Zealand

Part 7:

Advertising of therapeutic products

Edition 1.0

October 2011



Section 1: Legislation

Section summary

This section outlines the provisions relating to advertising that are found in Part 4 of the Medicines Act 1981, Schedule 1 to the Act, and Part 3 of the Medicines Regulations 1984.

1.1 Introduction

The Medicines Act 1981 (the Act), the Medicines Regulations 1984 (the Regulations) and the Misuse of Drugs Regulations 1977 contain specific provisions relating to advertisements for products (medicines, medical devices, related products, and controlled drugs used as medicines) and methods of treatment. The provisions are set out in:

- ☞ [Part 4 of the Medicines Act 1981](#) (in sections 56 to 61)
- ☞ [Part 7 of the Medicines Act 1981](#) (in section 96(3))
- ☞ [Schedule 1](#) to the Act
- ☞ [Part 3 of the Medicines Regulations 1984](#) (in regulations 7 to 11)
- ☞ [Part 7 of the Misuse of Drugs Regulations 1977](#) (in regulation 50)

This guideline is intended to assist with the interpretation of the legislation.

Advertisers should also make themselves familiar with provisions in the Fair Trading Act 1986 and the Consumer Guarantees Act 1993 that can impact on advertising copy.

While this guideline describes the minimum requirements set in legislation, companies are encouraged to include additional information that promotes the safe and efficacious use of the product and is socially responsible.

1.1.1. Definitions relating to advertising

The terms *advertisement*, *medical advertisement*, *method of treatment* and *publish* have the special meanings given to them in [Section 56](#) of the Act.

In simple terms, a *Medical Advertisement* is an advertisement relating to a medicine, medical device, or related product (or an ingredient or component of them), or a method of treatment.

1.1.2. Restrictions on, and requirements for, advertisements

[Sections 57 and 58](#) of the Act set out a number of restrictions applying to medical advertisements. In summary, an advertisement must not:

- ☞ contain any statement that contradicts or conflicts with information that is required by regulations to be on or attached to the product or its container or package

- ⊞ fail to include any wording relating to the name or description of the product that is required by regulations to be on or attached to the product or its container or package
- ⊞ contain information that is prohibited by regulations from being on or attached to the product or its container or package
- ⊞ fail to include any statement required by regulations to be in an advertisement
- ⊞ include any statement prohibited in regulations from being in an advertisement
- ⊞ contain false or misleading information
- ⊞ state or imply that products of the kind being advertised cannot harm a person or class of persons or are not habit-forming
- ⊞ state or imply that a product or method of treatment will prevent, alleviate or cure any disease, or prevent, reduce or terminate any physiological condition, specified in Part 1 of [Schedule 1](#) to the Act ¹
- ⊞ state or imply that a product or method of treatment will prevent or cure any disease, or prevent or terminate any physiological condition, specified in Part 2 of Schedule 1 to the Act ¹
- ⊞ state or suggest that the product or method of treatment being advertised
 - is a panacea or is infallible
 - has been used or recommended by a registered health professional such as a doctor, nurse, or pharmacist
 - has had a beneficial effect on the health of a particular person or class of persons, whether real or fictitious (often referred to as a testimonial)
- ⊞ invite people to send correspondence, photographs or bodily specimens for the purpose of diagnosis or treatment of any disease or physiological condition.

[Section 59](#) of the Act details the requirements for publication of the name and address of the advertiser.

[Section 60](#) of the Act exempts advertisements intended for health professionals from certain requirements.

[Section 61](#) of the Act details prohibitions in relation to misleading branding of products or their labels or containers.

[Section 96\(3\)](#) applies Part 4 of the Act to related products as if they were medicines.

[Part 3 of the Regulations](#) (regulations 7 to 11) covers the following aspects of advertising:

- ⊞ [Regulation 7](#) prohibits the inclusion of any statements indicating that the Medicines Assessment Advisory Committee or the Medicines Adverse

¹ Note, however, that it is a defence in any prosecution if the defendant can prove that the matter claimed, indicated or suggested in the advertisement is true.

Reactions Committee, or a member of either committee, or an officer of the government has approved or refrained from disapproving the advertisement

- ☞ [Regulation 8](#) specifies the mandatory information that advertisements for medicines (other than those covered by regulation 11) must include. Regulation 8 also specifies the types of advertisements (such as a label, price list, or a point of sale material) to which reduced requirements apply
- ☞ [Regulation 9](#) specifies the mandatory information that must be included in an advertisement for a related product
- ☞ [Regulation 10](#) specifies the mandatory information that must be included in an advertisement for a medical device.
- ☞ [Regulation 11](#) specifies the requirements for advertisements that are directed at registered health professionals. In the case of medicines, the requirements in regulation 11 apply instead of the requirements in regulation 8. In the case of related products and medical devices, the requirements in regulation 11 apply in addition to the requirements in regulations 9 and 10.

[Regulation 50](#) of the Misuse of Drugs Regulations 1977 prohibits advertising of controlled drugs other than:

- ☞ advertisements for exempted or partially exempted drugs
- ☞ advertisements to doctors, dentists and pharmacists.

An advertisement for a controlled drug must state the name and address of the advertiser and must clearly identify that the product is a controlled drug. If the advertisement is a price list or similar publication, the abbreviation “CD” is used to identify the controlled drug.

In addition to meeting these requirements, advertisements for controlled drugs used as medicines must also meet the requirements relating to advertising set out in the Medicines Act and Regulations.

Section 2: Advertisements for medicines

Section summary

This section provides information on the mandatory requirements for the content of advertisements for medicines. It describes the different requirements that apply to advertisements directed at the public, advertisements intended for health professionals, and specified kinds of advertisements such as point of sale material.

2.1 Introduction

It is lawful in New Zealand to advertise prescription and non-prescription medicines to the public.

Advertisements directed at the public must include specified mandatory information. This information varies according to the classification of the medicine. Additional requirements apply to internet, mail order and direct marketing advertisements. The requirements for advertisements directed at the public are explained in section 2.2 of this guideline.

The requirements for advertisements intended for registered health professionals vary depending on whether the purpose of the advertisement is to influence a prescribing decision, or only to provide some new information about a specific aspect such as the indications for the medicine or its listing on the Pharmaceutical Schedule. The mandatory requirements for advertisements intended for health professionals are set out in section 2.3 of this guideline.

The regulations also recognise that some advertisements, such as point-of-sale material, are intended only to convey a limited message. Reduced requirements for these types of advertisements are explained in section 2.2.7 of this guideline.

2.2 Advertisements directed at the public

2.2.1. Prescription medicines

Advertisements for **prescription medicines** must include:

- € the words “Prescription Medicine” or words of similar meaning
- € the name and quantitative particulars of each active ingredient
- € a statement of the purpose for which the medicine is intended to be used
- € a statement that the medicine has risks and benefits
- € a statement about how to find further information on the risks and benefits of the medicine. It is recommended that consumers are directed to the Consumer Medicine Information (CMI) for the medicine (if this is not provided as part of the advertisement) to obtain more detailed information. Suitable approaches for referencing access to the CMI in an advertisement include instructions for consumers to refer to the Medsafe or advertiser’s website or another published source for the CMI, or to contact the company

by using the contact details provided (for example 0800 number, phone or postal contact details)

- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.2.2. Restricted medicines

Advertisements for **restricted medicines** must include:

- ☞ the statement “Available only from your Pharmacist” or “Your Pharmacist’s advice is required”, or words of similar meaning
- ☞ the statement “If symptoms persist see your Doctor/Healthcare professional” or words of similar meaning
- ☞ the statement “Use only as directed” or words of similar meaning
- ☞ the name of each active ingredient or the statement “Always read the label” or words of similar meaning
- ☞ a statement of the purpose for which the medicine is intended to be used
- ☞ any warning statement that may be required by guidelines issued from time to time by the Ministry of Health. The required warning statements for advertisements are listed in section 2.2.4 of this guideline
- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.2.3. Pharmacy-Only and General Sale medicines

Advertisements for **pharmacy-only medicines** and **general sale medicines** must include:

- ☞ the statement “If symptoms persist see your Doctor/Healthcare professional” or words of similar meaning
- ☞ the statement “Use only as directed” or words of similar meaning
- ☞ the name of each active ingredient or the statement “Always read the label” or words of similar meaning
- ☞ a statement of the purpose for which the medicine is intended to be used
- ☞ any warning statement that may be required by guidelines issued from time to time by the Ministry of Health. The required warning statements for advertisements are listed in section 2.2.4 of this guideline
- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.2.4. Mandatory warning statements in advertisements for non-prescription medicines

The following table lists the mandatory warning statements that must be included in advertisements for non-prescription medicines that are directed at the public.

Type of medicine	Required statement (Words of similar meaning may be used)
<p>Analgesics for internal use</p> <ul style="list-style-type: none"> • salicylic acid and its salts, and derivatives of salicylic acid (including aspirin) and their salts • non-steroidal anti-inflammatory drugs (NSAIDs) • codeine • paracetamol <p><u>except</u> when in combination products used to treat minor self-limiting conditions (for example cough mixtures or tablets to treat the symptoms of a cold)</p>	<p>Incorrect use may be harmful</p>

2.2.5. Recommended warning statements in advertisements for non-prescription medicines

In addition to the mandatory warning statements set out in section 2.2.4 above, companies are recommended to include the following warnings in advertisements where appropriate.

Type of medicine	Recommended statement (Words of similar meaning may be used)
<p>All OTC medicines where the dose range/safety profile is considered to be critical</p>	<p>Incorrect use may be harmful</p>
<p>Sedating antihistamines</p>	<p>May cause drowsiness (avoid alcohol and driving)</p>
<p>Non-steroidal anti-inflammatory medicines (NSAIDs) for internal use</p>	<p>Do not use if you have stomach ulcers</p>

2.2.6. Internet, mail order, and direct marketing advertisements

Any internet, mail order or direct marketing advertisement must, in addition to the content requirements described in sections 2.2.1 to 2.2.3, include the following.

- ⑤ The name and quantitative particulars of each active ingredient.

- ☞ The name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.2.7. Point of sale material, labels, and price lists

Only one of the requirements described in sections 2.2.1 to 2.2.3 applies to point of sale material that is positioned immediately above, below, or next to the product (for example, shelf talkers), or to labels or price lists. This is the requirement to include:

- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.2.8. Advertisements that do not refer to a therapeutic purpose

Only one of the requirements described in sections 2.2.1 to 2.2.3 applies to an advertisement that does not refer to a therapeutic purpose. This is the requirement to include:

- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

2.3 Advertisements intended for health professionals

Advertisements directed at registered health professionals are required to include the following information.

- ☞ The statement “Prescription Medicine” or “Restricted Medicine” or “Pharmacy-Only Medicine.”
- ☞ A statement of the name and quantities of each active ingredient in the medicine.
- ☞ A statement of the purpose for which the medicine is intended to be used.
- ☞ A statement of the appropriate precautions to be taken in the use of the medicine.
- ☞ A statement of any contra-indications to the use of the medicine.
- ☞ A statement of the known or likely poisonous effects of, or adverse reactions to, the medicine.
- ☞ A statement of any restriction imposed on distribution.
- ☞ The dosage regimen and mode of administration, or method of use, of the medicine
- ☞ Information on the effectiveness and limitations of the medicine.
- ☞ Information on the likely potentiating effects and interactions with other substances, medicines, or environmental influences.

- Ⓔ The name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

Reduced requirements apply to an advertisement that does not enable the health professional to reach a prescribing decision and is intended only to provide information about a major therapeutic indication, a new or changed strength, or a listing in the Pharmaceutical Schedule. Such advertisements must include the following information.

- Ⓔ The statement “Prescription Medicine” or “Restricted Medicine” or “Pharmacy-Only Medicine”.
- Ⓔ The name of each active ingredient in the medicine.
- Ⓔ A statement of the purpose for which the medicine is intended to be used.
- Ⓔ A statement of the appropriate precautions to be taken in the use of the medicine.
- Ⓔ The name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

Section 3: Advertisements for medical devices

Section summary

This section provides information on the mandatory content of advertisements for medical devices. It describes the different requirements that apply to advertisements directed at the public and advertisements intended for health professionals.

3.1 Advertisements directed at the public

All advertisements for medical devices (including labels and price lists) that are directed at the public must include:

- the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

Advertisements other than labels and price lists must also include the following, where appropriate.

- An accurate description of the medical device.
- A statement of the uses of the medical device.
- A statement of the appropriate precautions to be taken in the use of the device.
- A statement of any contra-indications to the use of the medical device.

3.2 Advertisements intended for health professionals

An advertisement for a medical device that is directed to registered health professionals must include:

- a statement of any restriction imposed on distribution
- the method of use of the medical device
- information on the effectiveness and limitations of the medical device.

Where appropriate, it must also include:

- an accurate description of the medical device
- a statement of the uses of the medical device
- a statement of the appropriate precautions to be taken in the use of the device
- a statement of any contra-indications to the use of the medical device.

Section 4: Advertisements for related products

Section summary

This section provides information on the mandatory content of advertisements for related products. It describes the different requirements that apply to advertisements directed at the public and advertisements intended for health professionals.

4.1 Advertisements directed at the public

All advertisements for related products (including labels and price lists) that are directed at the public must include:

- ☞ the appropriate designation of any active ingredient that is referred to in the advertisement
- ☞ the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office.

Advertisements other than labels and price lists must also include:

- ☞ a statement of the uses of the related product.

4.2 Advertisements intended for health professionals

An advertisement for a related product that is directed to registered health professionals must include:

- ☞ a statement of the uses of the related product
- ☞ the appropriate designation of any active ingredient that is referred to in the advertisement
- ☞ the dosage regimen and mode of administration of the related product
- ☞ information on the effectiveness and limitations of the related product
- ☞ a statement of any restriction imposed on distribution.

Section 5: Self-regulatory aspects of advertising

Section summary

This section provides information on the advertising codes of practice of the industry organisations and the Advertising Standards Authority, and the pre-vetting system for advertisements.

5.1 Introduction

Best practice advertising adheres to the following principles.

- ☞ Advertisements must comply with the laws of New Zealand.
- ☞ Advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated.
- ☞ Advertisements must observe a high standard of social responsibility.

These principles are set out in the *Therapeutic Products Advertising Code* published by the Advertising Standards Authority (see section 5.3 below) and are also endorsed by the peak industry bodies representing manufacturers and sponsors of therapeutic products in New Zealand.

5.2 Industry Codes of Practice

The New Zealand Self Medication Industry Association (SMI), Medicines New Zealand (MNZ), and the Medical Technology Association of New Zealand (MTANZ) have each developed Codes of Practice to underpin self-regulation of their members. They can be downloaded from:

<http://www.medicinesnz.co.nz/assets/2010-09-28-RMI-COP-Edition-15-Final.pdf>

<http://www.nzsmi.org.nz/documents/code-of-practice.pdf>

<http://mtanz.org.nz/Professional-Development/Code-of-Practice-6440.htm>

Compliance with the MNZ, SMI and MTANZ codes is a condition of membership for each organisation. Non-members of these organisations are also recommended to make themselves familiar with, and to follow, these codes because they provide helpful guidance on responsible advertising practice.

5.3 Advertising Standards Authority Code of Practice

The prime function of the Advertising Standards Authority (ASA) is to self-regulate advertising in New Zealand. The ASA, in collaboration with Medsafe and other stakeholders, has developed and published the *Therapeutic Products Advertising Code* and the *Therapeutic Services Advertising Code*. These codes are designed to ensure that advertising for therapeutic products or services will be conducted in a manner which is socially responsible and does not mislead or deceive the consumer. The codes can be downloaded from:

http://www.asa.co.nz/code_therapeutic_products.php

http://www.asa.co.nz/code_therapeutic_services.php

All therapeutic product and therapeutic services advertisements, in all media, are expected to comply with these codes.

5.4 Pre-vetting service for therapeutic product advertisements

The Association of New Zealand Advertisers (ANZA) runs a pre-vetting system for advertisements for medicines, medical devices and related products – the Therapeutic Advertising Pre-vetting Service (TAPS).

In addition to assessing and approving advertisements, TAPS also issues ‘delegated authorities’ allowing individuals who work for pharmaceutical or media companies to pre-vet certain advertisements placed or published by the company for which they work. Further information on delegated authorities can be obtained from http://www.anza.co.nz/category?Action=View&Category_id=258

Those wishing to advertise through mainstream media will require a TAPS approval number (issued by a TAPS adjudicator or a delegated authority) before their advertisement will be accepted for publication. All advertisers are strongly encouraged to use this service as a means of identifying any problems with their advertisements and obtaining advice on how those problems can be overcome.

Advertisers should be aware, however, that use of the pre-vetting service does not remove the liability of a company for the content of its advertisements. The pre-vetting service is able to provide guidance, but does not guarantee compliance with the various advertising codes and the legislation.

To access the Therapeutic Advertising Pre-vetting Service (TAPS), organisations must first register with:

ANZA
P O Box 9348
Newmarket
Auckland 1149

Phone: +64 9 300 5932

Further details are available at http://www.anza.co.nz/category?Action=View&Category_id=258

5.5 Complaints about advertisements

Complaints about advertisements for therapeutic products or services can be made to the Advertising Standards Authority. Information on the complaints process and how to make a complaint can be found at:

http://www.asa.co.nz/how_to_make_a_complaint.php

Each of the industry associations referred to in section 5.2 also operates a complaints mechanism to hear, and adjudicate on, alleged breaches of their codes of practice.