taps | therapeutic advertising pre-vetting service

GUIDELINE 4A **Medicines**	**Checklist for Advertising Prescription Medicines to Healthcare Practitioners – Where the advertisement contains therapeutic and / or promotional claims (MNZ 'Full Ad')**
Last Updated	August 2016
What kind of product is this guideline for?	Prescription Only Medicines.
What is the purpose of this guideline?	To provide guidance on the minimum information requirements for these advertisements and key content checks.

BACKGROUND

The minimum information requirements for advertisements for prescription medicines intended for healthcare practitioners is governed by the Medicines Act 1981, the Medicines Regulations 1984 (updated August 2011), the Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand, the Advertising Standards Authority Therapeutic and Health Advertising Code (ASA THAC) and the Medicines New Zealand Code of Practice (MNZCOP). The following guideline lists relevant requirements from each of these pieces of legislation or codes. Where a requirement is listed in more than one area, the primary place it occurs has been listed (e.g. legislative requirements are listed first and additional requirements beyond the legislation are listed after this). These requirements must appear in the body of the advertisement and if spoken in an advertisement they do not need repeating in the text. Also included in this checklist are some key content checks for these advertisements.

CHECKLIST for Advertising Prescription Medicines to Healthcare Practitioners	
Requirement	**Source**
1. Trade Name	MNZCOP 4.1.2.2
2. The following are legislative requirements; a. Medicine classification i.e. *'Prescription Medicine'.* b. Name and quantity of each active ingredient. c. Purpose for which the medicine is intended to be used (indication(s) relevant to the advertisement). d. Appropriate precautions to be taken when using the medicine. e. Information on the effectiveness and limitations of the medicine. f. Any restrictions imposed on distribution. g. Dosage regime and mode of administration, or method of use, of the medicine. h. Contraindications to the use of the medicine. i. Likely potentiating effects and interactions with other substances, medicines or environmental influences. j. Known or likely poisonous effects or adverse reactions. State 'very common', 'common' and rare or serious where the outcome could be critical.	Medicines Regulations 1984 11 (2) (a) (i) (a) (ii) & (iii) (a) (iv) (a) (v) (a) (vi) (a) (vii) (a) (viii) (a) (ix) (a) (x) (a) (xi)
3. In addition to the legislative requirements, the following additional statements are required for compliance with the Medicines New Zealand Code of Practice(MNZCOP); a. Name and address of the person or business that is responsible for the publication of the advertisement (may be shortened to name and city if able to be found in the telephone directory). b. A clear statement regarding the funding status of the medicine or any restrictions to the schedule listing e.g. i. *X is an unfunded medicine, a prescription charge will apply* ii. *X is a partially funded medicine, a prescription charge will apply* iii. *X is a funded medicine, restrictions apply.*	MNZCOP 4.1.2.2 (d) MNZCOP 4.1.2.2 (j)

iv. *X is a funded medicine, special authority criteria apply.* c. A clear statement directing the prescriber to review the data sheet before prescribing the medicine. d. Reference to where the data sheet is immediately accessible e.g. Medsafe website or similar.	 MNZCOP 4.1.2.2 (k) MNZCOP 4.1.2.2 (l)
4. Advertisements must not include; a. Efficacy and safety statements that omit relevant information so that the statement has a different meaning to that intended in the report. b. Unsubstantiated comparisons c. Statements from previously valid reports made obsolete or false by more recent findings. d. Statements that are outside of the consented indication and dosage (off-label).	 Medicines Regulations 1984 11 (2) (b) (i) (b) (ii) (b) (iii) (b) (iv)
5. Required information must be present in a large enough font size, with sufficient clarity and must be present long enough (e.g. on screen or radio) for the audience to be able to comfortably read and understand. See Guideline 3 in the 'General' section of the TAPS Guidelines for detailed recommendations for television advertisements.	Medicines Act, Section 57 (2)
6. Font size on printed material must be not less than 1.5mm as measured by the lower case 'e' and must be on a clear background.	MNZCOP 3.2.6
7. Where personal information is being collected an appropriate privacy statement must be included in order to comply with the Privacy Act.	Privacy Act
8. The content of a website must be compliant with the legislation and codes if the website address is to be included in an advertisement for a medicine.	Medicines Act
9. 'Advertorials' need to be clearly identified as such.	MNZCOP 3.11
10. Market research must be clearly identified and not confused with promotion or advertising.	MNZCOP 7.5.7
11. The content of speaker material and conference reports that are distributed by a company is the responsibility of the company and must comply with NZ legislation and codes.	MNZCOP 4.3
12. Competitions / draws are permitted. See MNZCOP 4.9 for guidance.	

ASA THERAPEUTIC AND HEALTH ADVERTISING CODE

The following requirements (see below) are the two principles and accompanying guidelines from the ASA Therapeutic and Health Advertising Code. Where a guideline or part of a guideline is not relevant to the advertising of prescription medicines to HCPs, it has not been included here.

Please Note: The ASA Therapeutic and Health Advertising Code and accompanying Guidance Notes should be read in full to prior to the development of any advertisement for a prescription medicine.

Advertisers should also be aware of the compliance requirements in the following ASA Codes:

Advertising Standards Code

Code for Comparative Advertising

Code for People in Advertising

ASA Therapeutic and Health Advertising Code (sections relevant to Prescription Medicine Advertisements to HCPs)

PRINCIPLE 1

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.

Guidelines

1(a) Advertisements shall contain the following mandatory information to encourage responsible prescribing, recommendation, sale and use. 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.

See 'Guidance Notes for the Therapeutic and Health Advertising Code' for further information on the inclusion of the **name and address of the advertiser** in advertisements.

Medicines

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.

1(b) Advertisements shall not contain any claim, statement or implication that the products, devices or services advertised;

- 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;
    - they are suffering from a serious ailment, or
    - harmful consequences may result from the therapeutic or health product, device or service not being used

1(c) Advertisements should not portray unrealistic outcomes or prey on or misrepresent vulnerable audiences (e.g. sick, elderly, pregnant women, overweight people).

1(d) 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.

PRINCIPLE 2

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.

Guidelines

2(a) 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).

See 'Guidance Notes for the Therapeutic and Health Advertising Code' for further information on substantiation and "Guidance note on responding to a complaint about misleading claims".

2(b) 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.

2(c) 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.

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.

II. Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner.

III. Comparative advertisements shall compare 'like with like'. Advertisements for Natural Health Products and Dietary Supplements shall not include comparisons with medicines or medical devices either specifically or generally.

2(d) 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.

2(e) 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.

2(f) 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.

See ‘Guidance Notes for the Therapeutic and Health Advertising Code’ for further information.