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GUIDELINE 4B **Medicines**	**Checklist for Advertising Prescription Medicines to Healthcare Practitioners – Where the advertisement does not contain therapeutic and / or promotional claims (MNZ 'Short 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 and key content checks for advertisements for Prescription Medicines that are directed to healthcare professionals and that do not contain any promotional or therapeutic claims.

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 Therapeutics and Health Advertising Code (ASA THAC) and the Medicines New Zealand Code of Practice, Edition 16 (MNZCOP). The following guideline lists relevant requirements from each of these pieces of legislation or codes. These minimum information requirements must appear either in the body of the advertisement, in the voice-over (if radio or TV) or in a set of written statements that appear in addition to the body of the advertisement. Also included in this checklist are some key content checks for this kind of advertisement.

DEFINITIONS:

The Medicines Regulations 1984 define an advertisement with no claims as follows;

Section 11 (3)

(a) is intended to provide a practitioner with details of—
(i) a major therapeutic indication of a medicine; or
(ii) the listing of a medicine in the pharmaceutical schedule (within the meaning of section 6(1) of the New Zealand Public Health and Disability Act 2000); or
(iii) a new or changed strength of a medicine; ***and***

(b) does not enable the practitioner to reach a prescribing decision.

The Medicines New Zealand Code of Practice define an advertisement with no claims as follows;

Section 4.1.3.1

A short advertisement is designed to remind a prescriber of a product's existence but must not contain therapeutic or promotional claims.

It is important to note that TAPS views the intent of both these definitions to mean that these are simple advertisements where a medicine brand name and indication is noted along with other non-promotional and specified pieces of information. These advertisements should not try to include promotional or therapeutic claims by way of wording, images or graphics that could be interpreted as a claim.

CHECKLIST for the Mandatory Information Requirements When Advertising Prescription Medicines to Healthcare Practitioners and the advertisement does not contain any claims

Requirement	**Source**
1. Trade Name	MNZCOP 4.1.3.2 (e)
2. The following are legislative requirements;	
a. Medicine classification i.e. *'Prescription Medicine'.*	Medicines Regulations 1984 11 (3) ((2) (a) (i)) and MNZCOP 4.1.3.2 (a)
b. Name of each active ingredient.	Medicines Regulations 1984 11 (3) ((2) (a) (ii)) and MNZCOP 4.1.3.2 (f)
c. A statement of the purpose for which the medicine is intended to be used (indication(s) relevant to the advertisement).	Medicines Regulations 1984 11 (3) ((2) (a) (iv)) and MNZCOP 4.1.3.2 (b)

d. A statement of the appropriate precautions to be taken when using the medicine. *(Please see the next section of this guideline for further information on how to effectively meet this requirement.)*	Medicines Regulations 1984 11 (3) ((2) (a) (v)) and MNZCOP 4.1.3.2 (c)
3. In addition to the legislative requirements, the following additional statements are required for compliance with the Medicines New Zealand Code of Practice (MNZCOP, Edition 16); 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 directing the prescriber to review the data sheet before prescribing the medicine. c. Reference to where the data sheet is immediately accessible e.g. Medsafe website or similar. *(Please see the next section of this guideline for further information on how to effectively meet these two requirements and the requirement for a statement of the appropriate precautions to be taken in the use of the medicine.)*	MNZCOP 4.1.3.2 (g) MNZCOP 4.1.3.2 (h) MNZCOP 4.1.3.2 (i)
4. The Medicines NZ Code of Practice also provides <u>optional</u> information inclusions for these advertisements; a. A statement of available dosage forms. b. Graphics of a non-promotional nature. c. Details of the reimbursement status of a medicine. d. A statement that further information is available from the company. e. The company URL.	MNZCOP 4.1.3.2 (j) – (n)

FURTHER COMMENT AND RECOMMENDATION on how to effectively meet the Medicines Regulations requirement to include;

A statement of the appropriate precautions to be taken when using the medicine.
Medicines Regulations 1984 11 (3) ((2) (a) (v)) and MNZCOP 4.1.3.2 (c)

The issue of how to address the requirement for a 'statement of the appropriate precautions to be taken in the use of the medicine' for advertisements such as the ones defined in this guideline has been carefully considered by TAPS and Medsafe. Our interpretation is not necessarily the final word on the matter and interpretations are ultimately tested when matters are referred to the Courts.

The question centres on the interpretation of regulation 11(2)(a)(v) when 11(3) applies. That is, it applies to advertisements for the health professionals and where the advertisement is only intended to provide certain basic information and is not intended to provide a prescriber with

enough information to make a prescribing decision (also referred to as a 'short ad' in the MNZCOP).

The TAPS and Medsafe interpretation is based on the following:

- The intent of the legislation is to protect public / patient / consumer safety
- This situation is limited to advertisements for health care professionals who are accorded considerable responsibility in ensuring their decisions are supportable
- The intent has been to streamline and simplify advertisements whilst retaining checks and balances
- The interpretation has stood for some time without any known issues
- The internet now provides a very ready source of good information and health care professionals are used to using this resource. Referral to the data sheets on the Medsafe website ensures a reputable source is referred to which has regulatory endorsement. This resource is well known and accessible to health care professionals.

In determining how best to address this requirement TAPS and Medsafe had the following comments:

1. For some, if not many medicines, there would be difficulties for companies, TAPS and Medsafe in determining what the 'appropriate precautions' should be. Further, it seemed unrealistic to provide these in a 'short' advertisement. Trying to comply and list these may well result in a message that was misleading.
2. TAPS and Medsafe agreed that, in the circumstances, it was acceptable to refer to another document. Referral to the data sheet appeared, on balance, to be the best way to ensure the relevant information was available to health care professionals.
3. TAPS and Medsafe agreed on examples of statements that would be appropriate. Words that signalled to the prescriber that there were certain important areas to consider when prescribing would be appropriate.

The following examples (or words of similar meaning) for inclusion in these advertisements are considered appropriate to address the Medicines Regulations requirement 11(3) ((2) (a) (v)) and the MNZCOP requirements 4.1.3.2 (c), (h) & (i).

Before prescribing [Medicine] please refer to the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is on the Medsafe website.

Before prescribing [Medicine] read the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects.

Review the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects.

In addition to the Mandatory Information Requirements noted above for this type of advertisement, the following checks should also be made.	
1. 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.	Medicines Act, Section 57 (2)
2. 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 3.2.5
3. Advertisements must observe a high standard of social responsibility (higher than the code of ethics which requires a 'due standard').	ASA THAC, Principle 1
4. The content of a website, when the website address is included in the advertisement, must be compliant with the legislation and codes.	Medicines Act