the voice of New Zealand advertisers

anza association of New Zealand advertisers

taps | therapeutic advertising pre-vetting service

GUIDELINE 2A **Medicines**	**Checklist for Advertising OTC Medicines to Healthcare Practitioners where the advertisement contains promotional or therapeutic claims.**
Last Updated	July 2016
What kind of product is this guideline for?	**Over the Counter Medicines advertised to HCPs where the advertisement contains a promotional or therapeutic claim.**
What does this guideline **NOT** apply to?	Advertisements for OTC medicines that are intended for healthcare professionals where there is no therapeutic or promotional claims and the advertisement only provides the practitioner details of; (a) A major therapeutic indication; or (b) The listing of the medicine on the pharmaceutical schedule; or (c) A new or changed strength of a medicine **and**; Does not enable the practitioner to reach a prescribing or dispensing decision.
What is the purpose of this guideline?	To provide guidance on the mandatory information requirements for these advertisements and key content checks.

BACKGROUND

The mandatory information requirements for advertisements for OTC medicines intended for healthcare practitioners are governed by the;

- Medicines Act 1981
- Medicines Regulations 1984 (updated August 2011)
- Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand
- Advertising Standards Authority Therapeutic and Health Advertising Code (ASA THAC)
- Self-Medication Industry Code of Practice

Healthcare practitioners include medical, dental, pharmaceutical and related professions and any staff that work under supervision of these registered practitioners. This includes Pharmacists and Pharmacy Assistants.

The Medicines Act definition of a healthcare professional is;

Registered health professional means 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

The Advertising Standards Complaints Board (ASCB) has reinforced this definition of healthcare practitioner in its decisions (to include pharmacists and pharmacy assistants).

The following guideline lists relevant information requirements from each of the relevant 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 somewhere 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.

This checklist only applies where the advertisement to the healthcare professional is solely or principally intended for this audience (Medicines Act section 60). For example, the *Pharmacy Today* publication and training material developed for pharmacy assistants.

Please Note: This guideline does not cover every aspect of every code. Advertisers should be familiar with the codes that are relevant to their products and their customers.

Section 1. CHECKLIST for Advertising Over the Counter Medicines to Healthcare Practitioners	
Mandatory Information Requirements	**Source**
1. Trade Name	
2. The following are legislative requirements from the Medicines Regulations 1984 Section 11 (2); a. Medicine classification i.e. *Restricted Medicine, Pharmacy-Only Medicine, General Sale 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.	 (a) (i) (a) (ii) & (iii) (a) (iv) (a) (v) (a) (vi) (a) (vii)
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.	(a) (viii) (a) (ix) (a) (x) (a) (xi)
3. The Medicines Act Section 59 requires the 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).	Medicines Act Section 59
4. The Medicines Regulations 1984 Section 11 (2) state that 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.	 (b) (i) (a) (ii) (b) (iii)

d. Statements that are outside of the consented indication and dosage (off-label).	(b) (iv)
5. When multiple OTC products appear in the same advertisement and these advertisements contain promotional or therapeutic claims, the required information must still be present. Common information (such as the advertisers name and address or the medicine classification) may appear once at the bottom of the page for the advertisement. Specific information relating to each product should appear with or near to that product advertisement.	
6. Where a pack shot is shown in an advertisement and that image includes some of the required information, this required information does not need to be repeated anywhere else in the advertisement ***providing that the information is legible and can be easily read by the majority of the target audience.***	
7. 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 6 for detailed recommendations for television advertisements.	Medicines Act, Section 57 (2)

Section 2. CHECKLIST for Advertising Over the Counter Medicines to Healthcare Practitioners	
Key Content Check	**Source**
1. Healthcare professional endorsement in advertising to healthcare professionals is permitted. Endorsement must have prior consent, be authenticated and transparent (include name of endorser and any financial considerations).	Medicines Act Section 60 ASA THAC, Principle 2, Guideline 2 (f)
2. Patient testimonials are permitted (i.e. a person or class of persons benefitting from taking the medicine). They must be authenticated, genuine, current, typical (not exceptional) and must acknowledge any valuable consideration.	Medicines Act Section 60 ASA THAC, Principle 2, Guideline 2 (f)
3. 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
4. **Advertisements for OTC Medicines should observe a high standard of social responsibility particularly as consumers often rely on such products, devices and services for their health and wellbeing.**	**ASA Therapeutic and Health Advertising Code, Principle 1.**
5. Advertisements not to contain any claim, statement or implication that the product advertised; • Is safe or that use cannot cause harm or that there are no side effects or risks. • is effective in all cases • is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure • is likely to lead persons to believe that; o they are suffering from a serious ailment, or o harmful consequences may result from the therapeutic or health product, device or service not being used	ASA Therapeutic and Health Advertising Code, Principle 1, Guideline 1(b)
6. Advertisements should not portray unrealistic outcomes or prey on or misrepresent vulnerable audiences (e.g. sick, elderly, pregnant women, overweight people).	ASA Therapeutic and Health Advertising Code, Principle 1, Guideline 1(c)
7. 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.	ASA Therapeutic and Health Advertising Code, Principle 1, Guideline 1(d)
8. **Advertisements shall be truthful, balanced and not misleading. Advertisements should not or should not be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear.**	**ASA Therapeutic and Health Advertising Code, Principle 2.**

This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole.	
9. Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated. Claims must be consistent with the approved indication(s) (for medicines).	ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (a)
10. Advertisements shall not encourage, or be likely to encourage, inappropriate or excessive purchase or use.	ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (b)
11. Comparative advertising shall be balanced and shall not be misleading, or likely to be misleading, either about the product advertised or classes of products 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'.	ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (c)
12. 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 being advertised.	ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (d)
13. Advertisements shall not claim or imply endorsement of the product 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.	ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (d)
14. The following are requirements from the Self-Medication Code of Practice Section A5 that are considered additional to the requirements of the legislation and the ASA Code for advertising therapeutics; a. Advertisements must be pre-vetted for compliance with requirements of the Therapeutic Advertising Pre-vetting System (TAPS) and where appropriate or required bear the approval number issued b. Use of the term 'new' for one calendar year following the national launch. c. Any research results included in an advertisement must include a citation of the report.	 5.1.1.3 5.1.2.13 5.2.3.1

d. Competitions or inducements should not be offered to HCPs if it would interfere with their independence or professionalism or if they would encourage consumers to purchase inappropriate or excessive quantities of the medicine.	5.5.2.2
15. Where personal information (not available in the public domain) is being collected an appropriate privacy statement must be included in order to comply with the Privacy Act.	Privacy Act