

**TAPS** | therapeutic advertising  
pre-vetting service

<b>GUIDELINE 2B Medicines</b>	<b>Checklist for Advertising OTC Medicines to Healthcare Practitioners where the advertisement <u>does not contain promotional or therapeutic claims.</u></b>
Last Updated	July 2016
What kind of product is this guideline for?	<b>Brief advertisements for OTC Medicines advertised to HCPs</b>
What does this guideline <b>NOT</b> apply to?	Advertisements for OTC medicines that are intended for healthcare professionals where there are therapeutic or promotional claims within the advertisement.
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

Advertisements for OTC medicines that are intended for healthcare professionals where there is no therapeutic or promotional claims may only provide the practitioner details of;

- (a) The brand name
- (b) A major therapeutic indication; or
- (c) The listing of the medicine on the pharmaceutical schedule; or
- (d) A new or changed strength of a medicine **and**;

And does not enable the practitioner to reach a prescribing or dispensing decision.

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.

**Section1. CHECKLIST for Advertising Over the Counter Medicines to Healthcare Practitioners where the advertisement does not contain promotional or therapeutic claims.**

Mandatory Information Requirements	Source
1. Trade Name	
<p>2. The following are legislative requirements from <b>the Medicines Regulations 1984 Section 11 (3)</b>;</p> <ul style="list-style-type: none"> <li>a. Medicine classification i.e. <i>Restricted Medicine, Pharmacy-Only Medicine, General Sale Medicine.</i></li> <li>b. Name of each active ingredient.</li> <li>c. Purpose for which the medicine is intended to be used (indication(s) relevant to the advertisement).</li> <li>d. Appropriate precautions to be taken when using the medicine. <i>These can be noted and / or include the following statement;</i></li> </ul> <p style="text-align: center;"><i>Before dispensing please read the data sheet (available at <a href="http://www.medsafe.govt">www.medsafe.govt</a>) or the label for information on dosage, contraindications, precautions, adverse effects and interactions.</i></p>	<ul style="list-style-type: none"> <li>(a) (i)</li> <li>(a) (ii)</li> <li>(a) (iv)</li> <li>(a) (v)</li> </ul>
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. <b>When multiple OTC products appear in the same advertisement, the mandatory 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.</b>	
5. <b>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 <u>providing that the information is legible and can be easily read by the majority of the target audience.</u></b>	
6. 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 where the advertisement does not contain promotional or therapeutic claims.**

Key Content Check	Source
1. 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
2. <b>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.</b>	ASA Therapeutic and Health Advertising Code, Principle 1.
3. 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)
7. 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; <ul style="list-style-type: none"> <li>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</li> <li>b. Use of the term 'new' for one calendar year following the national launch.</li> </ul>	<p>5.1.1.3</p> <p>5.1.2.13</p>