

# TAPS | therapeutic advertising pre-vetting service

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| <b>GUIDELINE 1</b><br><b>Medicines</b>      | <b>Checklist for Advertising OTC Medicines Directly to the Consumer</b>                                  |
| Last Updated                                | July 2016  |
| What kind of product is this guideline for? | <b>Restricted (Pharmacist-Only) Medicines, Pharmacy-Only Medicines and General Sale Medicines</b>        |
| What is the purpose of this guideline?      | To provide guidance on the mandatory information requirements for advertisements and key content checks. |

## BACKGROUND

The mandatory information requirements for advertisements for these medicines are governed by the Medicines Act 1981, the Medicines Regulations 1984 (updated August 2011), Medsafe's Guideline on the Regulation of Therapeutic Products in New Zealand and the Advertising Standards Authority (ASA) Therapeutic and Health Advertising Code.

There are three sections in this Guideline.

1. Mandatory Information Requirements for all OTC medicine advertisements **except**:
  - a. Point of Sales Material, Labels and Price Lists or;
  - b. Advertisements that do not refer to a therapeutic purpose
2. Mandatory Information Requirements for OTC medicine Point of Sales Material, Labels, Price Lists or Advertisement that do not refer to a therapeutic purpose.
3. A checklist on other key advertising compliance requirements.

**Section 1. CHECKLIST for Mandatory Information Requirements in Advertisements for OTC Medicines (Restricted (Pharmacist-Only), Pharmacy-Only & General Sale) Directly to the Consumer EXCEPT;**

- a. Point of Sales Material, Labels and Price Lists and;
- b. Advertisements that do not refer to a therapeutic purpose

| Requirement  | Source   |
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| 1. Trade Name  |  |
| <p>2. The following statements or statements with a similar meaning;</p> <ul style="list-style-type: none"> <li>a. <i>'Available only from your Pharmacist' or 'Your Pharmacist's advice is required'</i>. <b>THIS IS ONLY REQUIRED FOR ADVERTISEMENTS FOR <u>RESTRICTED MEDICINES</u>.</b></li> <li>b. <i>'If symptoms persist see your Doctor or health professional'</i>.</li> <li>c. <i>'Use only as directed'</i>.</li> <li>d. The name of each active ingredient <b>or</b> <i>'Always read the label'</i>.</li> <li>e. A statement of the purpose for which the medicine is intended to be used (this can appear in the body of the advertisement).</li> <li>f. Mandatory warning statements for the following ingredients as required by the Ministry of Health (as of February 2012). <ul style="list-style-type: none"> <li>i. ANALGESICS FOR INTERNAL USE</li> <li><i>'Incorrect use may be harmful'</i> or words of a similar meaning for; <ul style="list-style-type: none"> <li>1. Salicylic acid and its salts, and derivatives of salicylic acid (including aspirin) and their salts.</li> <li>2. Non-steroidal anti-inflammatory drugs (NSAIDS).</li> <li>3. Codeine</li> <li>4. Paracetamol (<u>except</u> when in combination products used to treat minor self-limiting conditions e.g. cough mixtures or tablets to treat the symptoms of a cold.</li> </ul> </li> </ul> </li> </ul> | <p>Medicines Regulations 1984 8 (2)</p> <p>Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand.</p> |

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| <p>g. Recommended warning statements for the following ingredients as recommended by the Ministry of Health (as of February 2012).</p> <ul style="list-style-type: none"> <li>i. <i>'Incorrect use may be harmful'</i> or words of a similar meaning for; <ul style="list-style-type: none"> <li>1. All OTC medicines where the dose range/safety profile is considered to be critical.</li> </ul> </li> <li>ii. <i>'May cause drowsiness (avoid alcohol and driving)'</i> or words of a similar meaning for; <ul style="list-style-type: none"> <li>1. Sedating antihistamines</li> </ul> </li> <li>iii. <i>'Do not use if you have stomach ulcers'</i> or words of a similar meaning for; <ul style="list-style-type: none"> <li>1. Non-steroidal anti-inflammatory medicines (NSAIDs) for internal use.</li> </ul> </li> </ul> <p>h. 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).</p> | <p>Medsafe Guideline on the Regulation of Therapeutic Products in New Zealand.</p> <p>Medicines Act , Section 59</p> |
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**Section 2. CHECKLIST for Mandatory Information Requirements for OTC Medicines Point of Sales Material, Labels, Price Lists or Advertisement that do not refer to a therapeutic purpose.**

In the case of Point of Sale Materials (shelf talkers, shelf strips, boxes that contain the product packs etc) less information is required than for other types of advertisements. The key information that is usually required is available on the product packaging and therefore consumers can access it here when the advertisement is placed near to the product or the product packaging.

Therapeutic and promotional claims are allowed on these Point of Sale items. Other product information can be included in these advertisements and this is at the discretion of the advertiser.

TAPS reviews such advertisements in good faith based on what the item is called at the time it is reviewed. Advertisers cannot entirely control what the pharmacists do with such items so they provide these in good faith that they are used appropriately i.e. positioned immediately above, below or next to the product.

| Requirement  | Source                     |
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| 1. Trade Name  |                            |
| 2. 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 |

### **Section 3. CHECKLIST of other key advertising compliance requirements**

| <b>Requirement</b>   | <b>Source</b>   |
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| 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 consumers to be able to comfortably read and understand. See Guideline 6 for detailed recommendations for television advertisements.  | Medicines Act, Section 57 (2)   |
| 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>   | <b>ASA Therapeutic and Health Advertising Code, Principle 1.</b>          |
| 3. Advertisements not to contain any claim, statement or implication that the product advertised; <ul style="list-style-type: none"><li>• Is safe or that use cannot cause harm or that there are no side effects or risks.</li><li>• is effective in all cases</li><li>• is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure</li><li>• is likely to lead persons to believe that;<ul style="list-style-type: none"><li>○ they are suffering from a serious ailment, or</li><li>○ harmful consequences may result from the therapeutic or health product, device or service not being used</li></ul></li></ul> | ASA Therapeutic and Health Advertising Code, Principle 1, Guideline 1(b)  |
| 4. 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)  |
| 5. 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)  |
| 6. <b>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. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole.</b>   | <b>ASA Therapeutic and Health Advertising Code, Principle 2.</b>          |
| 7. 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) |

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| <p>8. Advertisements shall not encourage, or be likely to encourage, inappropriate or excessive purchase or use.</p>   | <p>ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (b)</p> |
| <p>9. 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.</p> <p>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.</p> <p>ii. Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner.</p> <p>iii. Comparative advertisements shall compare 'like with like'.</p> | <p>ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (c)</p> |
| <p>10. 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.</p>   | <p>ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (d)</p> |
| <p>11. 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.</p>   | <p>ASA Therapeutic and Health Advertising Code, Principle 2, Guideline 2 (d)</p> |
| <p>12. <b>NO healthcare professional endorsement.</b> Avoid any implication that e.g. a pharmacist or doctor recommends a product. Check copy and visuals for actual or implied endorsements.</p>  | <p>Medicines Act, Section 58 (1) (c) (ii)</p>                                    |
| <p>13. <b>NO testimonials</b> that claim the medicine has beneficially affected a person or a group / class of people. Check copy and visuals for actual or implied testimonials.</p>  | <p>Medicines Act, Section 58 (1) (c) (iii)</p>                                   |
| <p>14. Where personal information is being collected an appropriate privacy statement must be included in order to comply with the Privacy Act.</p>  | <p>Privacy Act</p>   |
| <p>15. 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.</p>  | <p>Medicines Act</p>   |