GUIDELINE 3 **Medicines**	**Checklist for Advertising Prescription Medicines Directly to the Consumer**
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 mandatory information requirements for advertising prescription medicines to consumers and to provide a checklist of important content checks to help ensure compliance with NZ legislation and relevant advertising codes.

BACKGROUND

The minimum mandatory information requirements for advertisements for prescription medicines intended for consumers 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 (ASA) Therapeutic and Health Advertising Code (THAC) and the Medicines New Zealand Code of Practice. The following guideline lists relevant mandatory information requirements from each of these pieces of legislation or codes. Where a requirement is listed in more than one of the above governing documents, the primary place it is listed has been noted (e.g. legislative requirements are listed first and additional requirements beyond the legislation are listed after this).

This guideline also provides a checklist for a number of aspects of compliance with the NZ Legislation, ASA THAC and Medicines NZ that go beyond the minimum mandatory information requirements.

CHECKLIST for Advertising Prescription Medicines Directly to the Consumer – Mandatory Information Requirements	
Requirement	**Primary Source Of Requirement**
1. Trade Name	Medicines NZ Code Of Practice Edition 16 5.11.10 (b)
2. The following statements are legislated mandatory information requirements;	
a. *'Prescription Medicine'* or words of a similar meaning.	Medicines Regulations 1984 8 (1) (a)
b. The name and quantity of each active ingredient.	Medicines Regulations 1984 8 (1) (b) & (c)
c. A statement of the purpose for which the medicine is intended to be used (relevant indication).	Medicines Regulations 1984 8 (1) (d)
d. A statement that the Medicine has risks and benefits. *Note: This statement needs to be clear and obvious to the consumer, especially when no other information is included about specific risks.*	Medicines Regulations 1984 8 (1) (e)
e. A statement about how to find further information on the risks and benefits of the medicine. It is recommended that consumers are directed to the Consumer Medicine Information (CMI) available at the Medsafe website, the company website, another published source or by contacting the company (0800 number, phone number or postal contact). *Note: This statement needs to be clear and obvious to the consumer so that they can easily access further information about the medicine being advertised. If your medicine is particularly relevant to low socio-economic consumers then a 'free' option to access more information should be provided. For example a 0800 number where details can be collected and information posted free of charge to the consumer.*	Medicines Regulations 1984 8 (1) (f)
f. The name and address of the person or business that is responsible for the publication of the advertisement.	Medicines Act Section 59

3. In addition to the legislated mandatory information requirements in section 2, the following additional statements (or similar wording) are required for compliance with the Medicines NZ Code of Practice Edition 16;	
a. *'Ask your Doctor if (Product Name) is right for you'*	Medicines NZ Code Of Practice Edition 16 5.11.11 (a)
b. *'Use strictly as directed'.*	Medicines NZ Code Of Practice Edition 16 5.11.11 (b)
c. *'If symptoms continue or you have side effects, see your doctor, pharmacist or healthcare professional'*	Medicines NZ Code Of Practice Edition 16 5.11.11 (c)
d. A clear statement regarding the funding status of the product that can be understood by members of the public. Examples include; i. *X is an unfunded medicine – a pharmacy charge will apply.* ii. *X is a partially funded medicine – a pharmacy charge will apply.*	Medicines NZ Code Of Practice Edition 16 5.11.11 (d)
e. A statement that normal doctor's charges apply	Medicines NZ Code Of Practice Edition 16 5.11.11 (e)
f. The TAPS approval number and / or TAPS DA number (required for but does not need to be displayed on television or in radio commercials)	Medicines NZ Code Of Practice Edition 16 5.11.11 (f)
g. Written promotional material should include the most important information on the common and serious adverse events associated with the use of the product being promoted.	Medicines NZ Code Of Practice Edition 16 5.11.11
4. Electronic Media Promotion to Consumers The Medicines NZ Code of Practice Edition 16 3.14.6 states that the mandatory information requirements from section 1 and 2 of the above checklist must appear on the first screen / first view a consumer has of the advertisement. The mandatory information requirements from section 3 of the above checklist must be available through a link from the first screen / first view of the advertisement if they are not present on the first screen / first view. There must be a statement on the first screen / first view that alerts the consumer to this additional information.	

Product claims can appear on the first screen / first view. A 'first view' may be a set of revolving tiles in the case of a banner advertisement.	
TAPS TIPS • When part or all of the mandatory information appears in the body of the advertisement, it does not have to also appear in a set of statements that are often seen at the bottom or the end of an advertisement. This can help reduce clutter and manage the mandatory content required when space is an issue. • The name and address of the advertiser can be shortened to name and city when the advertiser can be located in the online New Zealand telephone directory. • Where there is space and where information has been included on the benefits of a medicine, it is recommended that this information is balanced with the inclusion of important and relevant information on contraindications, precautions and side effects. This ensures consumers receive a fair disclosure of information. It also ensures that the advertisement meets other code compliance requirements such as 'balance' and the 'high standard of social responsibility'. • Where space is restricted in the on-line environment, the mandatory information can be split between revolving tiles or part of the information can be available via a 'hover' screen. • It is recommended that two sets of 'mandatory information' are developed for the product being advertised. One set should contain the minimum requirements and can be used when the advertisement is simple and / or space is an issue. The second set should contain more information including appropriate information on contraindications, precautions and side effects that would be relevant to the consumer. This set of statements can be used when the advertisement is more detailed e.g. product website, patient information brochure and where space allows.	

The following requirements cover many of the key compliance requirements (beyond the mandatory information requirements) when advertising a prescription medicine to consumers. Not all aspects of compliance are covered in this list. The NZ Medicines Legislation, ASA Therapeutic and Health Advertising Code and the Medicines NZ Code of Practice Edition 16 should be reviewed to obtain information on all compliance requirements.	
1. Advertisements should observe a high standard of social responsibility (higher than the code of ethics which requires a 'due standard') particularly as consumers often rely on such products for their health and well-being. **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. **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. *Note: Use of phrases such as 'well tolerated', 'known safety profile' and 'tolerability profile' are recommended* • 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; 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 1(c) Advertisements should not portray unrealistic outcomes or prey on or misrepresent vulnerable audiences (e.g. sick, elderly, pregnant women, overweight people).	ASA THAC, Principle 1 and Guidelines 1 (a) – 1 (d)

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.	
2. 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. **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). 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. 1. 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. 2. Comparative advertisements shall not discourage consumers from following the advice of their healthcare practitioner. 3. 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	ASA THAC, Principle 2. Medicines Act

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. *Not permitted in advertisements for prescription medicines when directed to consumers.* ***Note: The Medicines NZ Code of Practice 3.10.6 also prohibits endorsement from a celebrity.***	
3. DTCA must not by implication, omission, ambiguity or exaggeration; claim, mislead or deceive or be likely to mislead or deceive consumers or HCPs; abuse the trust of or exploit the lack of knowledge of consumers or HCPs; exploit the superstitious, or without justifiable reason play on fear.	Medicines NZ Code Of Practice Edition 16 5.11.4
4. DTCA must provide balanced information on the benefits and risks of the product. Specifically, risks and safety information in DTCA must be presented in clear, understandable language, without distraction from the content, and in a manner that supports responsible dialogue between patients and HCPs.	Medicines NZ Code Of Practice Edition 16 5.11.6
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 consumers to be able to comfortably read and understand. See TAPS Guideline 6 for detailed recommendations for television advertisements. *Note: The Medicines NZ Code of Practice Edition 16 3.2.5 states that the type-size on printed material should not be less than 1.5mm as measured by the height of the font's lower case 'e'.*	Medicines Act, Section 57 (2)
6. Information in advertisements must be accurate, balanced, not misleading and must show due consideration to the role of the healthcare professional and the importance of the prescriber-patient relationship.	Medicines NZ Code Of Practice Edition 16 5.11.1
7. Direct product comparisons should not be used in DTCA where the aim is to encourage consumers to choose between two different medicines and where the Dr / Patient relationship may be undermined.	Medicines NZ Code Of Practice Edition 16 3.4.4. and 5.11.8
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. Television and Radio advertisements must be no less than 30 seconds in duration.	Medicines NZ Code Of Practice Edition 16 5.11.13

10. Direct mail programmes must allow the consumer to opt out.	Medicines NZ Code Of Practice Edition 16 5.11.14
11. Promotional competitions for consumers are prohibited.	Medicines NZ Code Of Practice Edition 16 5.11.15
12. Images used must be consistent with the approved medicine data sheet and must also comply with the legislated and code requirements. For example; a. Where there is an age restriction for use, images of the people in the advertisement should be consistent with this age range. b. Images must not offend e.g. minority groups, race etc	
13. Where other company product brands are quoted, respect for the trademark should be noted. For example; *Product X is the registered trademark of Company Y*	
14. Where other medicines not marketed by the advertiser are mentioned in the advertisement, advice should be provided to the consumer about where to find information on these products. For example; *For more information on Product X please read the Consumer Medicine Information available at www.medsafe.govt.nz .*	
15. Advertisements for prescription medicines must not claim official approval. This means that the advertisement content should not state or imply that the advertisement has been approved by Medsafe or any other advisory or technical committee established under section 8 of the NZ Medicines Act. *Note: For example, it is recommended that the statement 'now registered for use for …..' or 'has consent to distribute' (or words to this effect) are used rather than 'approved by Medsafe for ……'.*	Medicines Regulations, Part 3, Section 7
16. Pre-campaign notification must be given to doctors and pharmacists at least seven days before the commencement of any DTCA campaign.	Medicines NZ Code Of Practice Edition 16 5.11.9
17. Where personal information is being collected an appropriate privacy statement must be included in order to comply with the Privacy Act.	Privacy Act