taps therapeutic advertising pre-vetting service

GUIDELINE 1 **Medical Devices**	**Checklist for Advertising Medical Devices to Consumers and to Healthcare Professionals**
Last Updated	August 2016
What kind of product is this guideline for?	Medical Devices
What is the purpose of this guideline?	To provide guidance on the development of advertisements for Medical Devices and a checklist of important content checks to help ensure compliance with NZ legislation and relevant advertising codes.

BACKGROUND

The Medicines Act 1981 provides the following relevant definitions.

3A Meaning of medical device
In this Act, unless the context otherwise requires, **medical device**—
(a) means any device, instrument, apparatus, appliance, or other article that—
(i) is intended to be used in, on, or for human beings for a therapeutic purpose; and
(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and
(b) includes a material that—
(i) is intended to be used in or on human beings for a therapeutic purpose; and
(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and
(c) also includes—
(i) anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and
(ii) any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of this Act; but
(d) does not include a device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations not to be a medical device for the purposes of this Act.

4 Meaning of therapeutic purpose
In this Act, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
(b) influencing, inhibiting, or modifying a physiological process; or
(c) testing the susceptibility of persons to a disease or ailment; or
(d) influencing, controlling, or preventing conception; or
(e) testing for pregnancy; or
(f) investigating, replacing, or modifying parts of the human anatomy.

disease includes any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind

The ASA Therapeutic and Health Advertising Code has this definition for a Medical Device;

'Medical Device' – Medical Devices are devices that have a therapeutic purpose (see definition below for therapeutic purpose *This is the definition from the Medicines Act 1981 - above*).
A product can appear to be a Medical Device by virtue of the way it works or the claims that are made on the label or in advertisements.

Listing on the Medsafe WAND database

Most Medical Devices need to be listed on the Medsafe WAND database in order to advertise in New Zealand. See the Medsafe website for details. There are some exceptions to this requirement.

The WAND database cannot be accessed by members of the public or by the TAPS Adjudicators. Advertisers should forward their WAND information to the TAPS Adjudicators when they send advertisements for review and approval.

If you are unsure as to whether or not your device meets the legal definition it is strongly recommended that you seek advice from Medsafe prior to listing on WAND and prior to advertising. *Please note: From time to time, the TAPS Adjudicators will ask the advertiser to seek clarification from Medsafe regarding the classification of the product they are seeking TAPS advice on. This is so that the Adjudicator is certain they are reviewing advertising for a Medical Device rather than another therapeutic product (e.g. a medicine). Medsafe will consider a range of information including data on the product and the claims the advertiser is expecting to make in advertisements. Medsafe has the right to refuse a WAND notification on review if the product is deemed to not be a Medical Device.*

TAPS Review and Approval for advertisements for Medical Devices

TAPS undertakes a review for an advertisement for a medical device based on the following;

(a) The device is listed on the WAND database.

(b) A check is made that the claims in the advertisement are consistent with the 'Intended Purpose' as per the WAND application and the advertisement complies with the ASA Therapeutic and Health Advertising Code.
Please note: It is the responsibility of the supplier to hold current and robust evidence that the device can actually do what it claims in the 'Intended Purpose'. The 'Intended Purpose' is usually defined on the 'Manufacturer's Evidence of Conformity Assessment Certificate' (along with the risk class of the device, site of manufacture and GMDN code).

The Commerce Commission requires that substantiation exists prior to claims being made and will require this should a complaint be made.
Medsafe may review this substantiation after notification on the WAND database as part of a review to determine the product classification and / or the Intended Purpose / Claims Made.

(c) A check that the mandatory information required as per the ASA Therapeutic and Health Advertising Code and Medsafe Guideline are present. *See below for these requirements*

(d) TAPS does not undertake a review of the 'Evidence of Conformity Assessment' the manufacturer is required to have to support the safety and efficacy of the device. *A TAPS Adjudicator cannot perform this task as it would make them somewhat of a 'regulator' and this is not the role of a TAPS Adjudicator.*

CHECKLIST for Advertising Medical Devices to Consumers and Healthcare Professionals

The following Medsafe Guideline outlines the 'mandatory' / legislated information requirements for inclusion in an advertisement for a Medical Device to Consumers (3.1) and to Healthcare Professionals (3.2). Comments are in *purple italics.*

Guideline on the Regulation of Therapeutic Products in New Zealand

Part 7.

Advertising of therapeutic products

Section 3: Advertisements for medical devices

3.1 Advertisements directed at the public

All advertisements for medical devices (including labels and price lists) that are directed at the public must include:

- the name and address of the person or business on whose behalf the advertisement is published. In the case of a body corporate, the address can be provided as the name of the place where the company has its registered office. *TAPS is able to check for this when reviewing and approving an advertisement. The address may be shortened to the city if the advertiser can be found in the online telephone directories (White or Yellow Pages)*

Advertisements other than labels and price lists must also include the following, where appropriate.

- An accurate description of the medical device. *TAPS is able to check for this when reviewing and approving an advertisement.*
- A statement of the uses of the medical device. *TAPS is able to check for this when reviewing and approving an advertisement.*
- A statement of the appropriate precautions to be taken in the use of the device. *TAPS is not able to check on the appropriateness of precautions included in your*

advertisement. It is the responsibility of the advertiser to determine what, if any, precautionary information is included.

- A statement of any contra-indications to the use of the medical device. *TAPS is not able to check on the appropriateness of contraindications included in your advertisement. It is the responsibility of the advertiser to determine what, if any, contraindications are included.*

3.2 Advertisements intended for health professionals

An advertisement for a medical device that is directed to registered health professionals must include:

- a statement of any restriction imposed on distribution *This information can only be determined by the advertiser.*
- the method of use of the medical device *This information can only be determined by the advertiser.*
- information on the effectiveness and limitations of the medical device. *This information can only be determined by the advertiser.*

Where appropriate, it must also include:

- an accurate description of the medical device *TAPS is able to check for this when reviewing and approving an advertisement.*
- a statement of the uses of the medical device *TAPS is able to check for this when reviewing and approving an advertisement.*
- a statement of the appropriate precautions to be taken in the use of the device *TAPS is not able to check on the appropriateness of precautions included in your advertisement. It is the responsibility of the advertiser to determine what, if any, precautionary information is included.*
- a statement of any contra-indications to the use of the medical device. *TAPS is not able to check on the appropriateness of contraindications included in your advertisement. It is the responsibility of the advertiser to determine what, if any, contraindications are included.*

Full guideline here

The following ‘mandatory’ information requirements are from the ASA Therapeutic and Health Advertising Code and are in addition to above legislated requirements.

PRINCIPLE 1

Therapeutic and Health advertisements shall observe a high standard of social responsibility particularly as consumers often rely on such products, devices and services for their health and wellbeing.

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.

Medical Devices

Mandatory information as required by the most recent edition of the Medicines Act, Medicines Regulations and any other applicable legislation, Medsafe Guideline on Advertising therapeutic products and the MTANZ Code of Practice and where appropriate;

 The following statement (or words to this effect);

Always read the label and follow the instructions.

 The following statement (or words to this effect) where a device requires the administration, application or implant by a healthcare professional;

This Medical Device must be administered / applied / implanted by a healthcare professional.

Please Note: In order to meet the ‘high standard’ required for therapeutic and health advertisements, advertisers and the TAPS Adjudicator should discuss and include appropriate precautions and contraindications. If in doubt, err of the side of caution and include this information in the 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.

- Where there is space and where information has been included on the benefits of a medical device, it is recommended that this information is balanced with the inclusion of important and relevant information on contraindications and precautions. 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.

The following requirements cover many of the key compliance requirements (beyond the mandatory information requirements above) when advertising a Medical Device. Not all aspects of compliance are covered in this list. The NZ Medicines Legislation and the ASA Therapeutic and Health Advertising Code 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. *Note: Requirements for a Medical Device are already noted in the above sections.* 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). 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. *Please Note: Advertisers should keep the product claims within the 'Intended Purpose' for the Medical Device. This is important in reaching the 'high standard' required for such advertisements.*	ASA THAC, Principle 1 and Guidelines 1 (a) – 1 (d)

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 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. ***Please Note: Testimonials and HCP endorsements are NOT PERMITTED in advertisements for medical devices when the advertisement is directed to***	ASA THAC, Principle 2. Medicines Act

consumers. *This would be a breach of the Medicines Act 1981 Section 58 (1) (c) (ii) and (iii)*	
3. 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.	Medicines Act, Section 57 (2)
4. 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. Knowingly referring customers to non-compliant website advertising is a breach of the legislation and advertising codes. There is a precedent case where an advertiser suffered a hefty fine as a result of doing this.	Medicines Act
5. Images used must be consistent with the WAND listed Intended Purpose 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	
6. 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*	
7. Advertisements for medical devices must not claim official approval. This means that the advertisement content should not state or imply that the content in the advertisement has been approved by Medsafe or any other advisory or technical committee established under section 8 of the NZ Medicines Act.	Medicines Regulations, Part 3, Section 7
8. Where personal information is being collected an appropriate privacy statement must be included in order to comply with the Privacy Act.	Privacy Act