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taps therapeutic advertising pre-vetting service

GUIDELINE 1 **NHPaDS**	**Therapeutic Purpose Claims on labels and in advertising**
Last Updated	July 2016
What kind of product is this guideline for?	This guideline is intended for advertisers who are advertising a product that is taken internally in a measured dose form for a health benefit and the product is NOT a medicine.
What is the purpose of this guideline?	This guideline explains the legislated definition of a therapeutic purpose and how this piece of the legislation is applied to products that are NOT medicines.

BACKGROUND

Therapeutic Purpose Claim. As the issue of "therapeutic purpose claims" is central to many Natural Health Products and Dietary Supplements in the review of advertising it is useful to highlight the benchmarks used in relation to the ASA Advertising Codes and the Medicines Act 1981. The ASA Therapeutic and Health Advertising Code ("The Code") is the main benchmark against which these advertisements are referenced. This Code has clear definitions, 2 principles and a number of guidelines. The Code also states that all advertising shall adhere to the laws of New Zealand, of which the primary relevant legislation is the Medicines Act 1981, the Medicines Regulations 1984 and the Dietary Supplements Regulations 1985. The ASA Therapeutic and Health Advertising Code covers Natural Health Products and Dietary Supplements as well as medicines, medical devices, health services and weight management.

Whilst Natural Health Products and Dietary Supplements are not classified as medicines they would be deemed to be medicines (as per the Medicines Act) for three reasons that might not be obvious..

A product can be a medicine in three ways;

1. It is, or contains, a scheduled ingredient (medicine)
2. **A therapeutic claim is made on the label or in advertisements**
3. It is a product with consent to distribute (a medicine able to be advertised)

The ingredients in a product being sold or advertised are classified as a medicine under the Classification of Medicines (c.f. Medsafe website www.medsafe.govt.nz for the full classification list). If you are unsure about the classification of ingredients in your product it would be worth checking with Medsafe to avoid any later expensive revision of the labels or the advertising.

Part 2, Section 20 of the Medicines Act defines certain restrictions on sale or supply or new medicines

(2) No person shall

(a) sell; or

(b) distribute by way of gift or loan or sample or in any other way; or

(c) advertise the availability of—

any medicine before the consent or provisional consent of the Minister to the distribution of the medicine has been notified in the *Gazette*.

This means that if your product contains a medicine (point 1 above) or the product label or advertisement contains a therapeutic claim (point 2 above), then it is a breach of this section of the Medicine Act unless it is a medicine with consent to distribute (point 3 above). The product / advertisement would be seen as a 'new medicine' that has yet to be reviewed by Medsafe and is yet to receive consent to distribute as notified in the Gazette.

MEANING OF THERAPEUTIC PURPOSE

The definition of "therapeutic purpose" is quite comprehensive in the Medicines Act and covers some key aspects of therapeutic products and their use.

Medicines Act, Section 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.

It can be seen from the above definition that it is quite comprehensive and therefore quite limiting on the claims that can be made about a product that is not a medicine. As a guideline terms like "relief from or reduction of a medical condition or disease" are indicative of a therapeutic claim and would therefore be prohibited by the Medicines Act for these products. Mention of the disease in the historical or other context such as testimonial in an advertisement for a product is also likely to be a problem as this generally implies a therapeutic claim indirectly for the product being advertised i.e. advertising a therapeutic claim by association.

ADDITITIONAL INFORMATION

Section 58 of the Medicines Act also expressly refers to a therapeutic purpose regarding the advertising of any medicine, medical device or method of treatment that "will prevent, alleviate, or cure any disease or prevent, reduce or terminate any physiological condition specified or belonging to a class of disease in the First Schedule of the Act". This schedule covers about 60 of the common diseases for which treatments are generally produced. The effect of this section 58 is to prohibit making therapeutic claims for these lists of medical conditions/diseases.

There is the option for a company to apply for evaluation of a product by Medsafe so that consent by the Minister of Health can be obtained for a product with a "therapeutic claim" under section 21 or 23 of the Medicines Act. The product will have an approved claim for a therapeutic purpose and be deemed to be a medicine. There will be a fee involved and a length of time for proper evaluation by Medsafe, details of which can be given be Medsafe. Generally, however, consent will not be obtained without completion of some robust double-blind controlled clinical trials. Ministerial consent is for a specific approved therapeutic purpose(s) only and advertising is permitted in law only for the approved purpose(s). This evaluation option may be beyond the pocket of small and medium sized businesses and may not be worth it commercially, taking into account the compilation of a registration dossier. In addition if a product is classified as a medicine then it must comply with some mandatory statements in its advertising. Account should also be taken that testimonials and healthcare professional endorsement are prohibited under section 58 of the Medicines Act for those products classified as medicines (& medical devices).

Otherwise a company may still advertise a product without getting consent providing the advertisement is without a "therapeutic purpose claim". Essentially there is leeway for certain health or nutritional claims or statements relating to the normal physiological or biochemical function. This is covered generally by such statements as "supports the normal physiological function". Even terms like "enhancement" "fortify" and "improvement" would need to be used with care and would generally be a problem, as they imply an improvement or acceleration to the normal function. Often it is a simply a question of wording. For example, a statement such as "provides nutritional support for a healthy immune system" escapes therapeutic specificity whereas, "prevents, treats or cures flus or viruses" attracts liability and would be prohibited under the Medicines Act.

This is a brief explanation of the guidelines used in assessing the issue of "therapeutic purpose claim". It does not claim to be comprehensive. There are more detailed comments for certain products such as those in the memory, concentration and brain area.

Section 58a of the Medicines Regulations notes that certain substances are not medicines though restricted therapeutic purpose claims may be made in advertisements:-

1. Dentifrice products that prevent decay and improving oral hygiene
2. Anti-Dandruff hair products
3. Anti-acne skincare products provided claim is for prevention of acne and not treatment
4. Barrier Cream products provided claim is only for preventing nappy rash.
5. Anti-bacterial skin products provided it is not claimed to be for use in relation to any therapeutic purpose except preventing the spread of bacteria (but not a named bacterium);

Care is needed to ensure that these products do not contain a medicine.

This is a summary only and the detailed information should be obtained from the Medicines Regulations 1984 Part 12 58(a).