

# TAPS | therapeutic advertising pre-vetting service

<b>GUIDELINE 5</b> <b>NHPaDS</b>	<b>Use of Clinical Trials in advertisements for Natural Health Products and Dietary Supplements</b>
Last Updated	August 2016
What kind of product is this guideline for?	Natural Health Products and Dietary Supplements
What is the purpose of this guideline?	To provide background and guidance on the use of Clinical Trials in advertisements for Natural Health Products and Dietary Supplements.

## BACKGROUND

The practice of quoting Clinical Trials and the claim 'Clinically Proven' for Natural Health Products and Dietary Supplements is an issue in New Zealand for these products. The Medicines Act 1981 prevents advertisements for these products from making a therapeutic purpose claim or representing itself as having a therapeutic purpose. Using the words 'Clinically Proven' is likely to imply a therapeutic claim.

**'Therapeutic Purpose'** – The Medicines Act provides the following definition;

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

Only medicines with consent to distribute in New Zealand and medical devices can claim to have a therapeutic purpose in advertisements.

A 'therapeutic purpose claim' in an advertisement will likely refer to a medicine(s) or medical device that has a therapeutic effect on an actual or implied medical condition / disease or physiological process (see definition below for disease). A 'therapeutic purpose claim' may be accompanied by words such as enhance, improve, prevent, interfere with, terminate, reduce, increase, accelerate, inhibit, boost, treat, relieve and stimulate. For medicines, the therapeutic claims(s) must be consistent with the indication(s) that have been approved for the product.

**'Disease'** – The Medicines Act provides the following definition;

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

**'Medicine'** – Medicines are any substance or article or active ingredient that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose (see definition below for therapeutic purpose). A medicine achieves, or is likely to achieve, the principal intended action in or on the human body by pharmacological, immunological, or metabolic means.

Only medicines that have been evaluated by Medsafe and have consent to distribute may be advertised in New Zealand. The medicine(s) advertised may be available on prescription or may be purchased 'over-the-counter'.

A product can be a medicine in three ways;

1. It is, or contains, a scheduled ingredient
2. A therapeutic claim is made on the label or in advertisements
3. It is a product with consent to distribute

Advertisers should not rely on the medicines classification schedule to determine whether or not a product is a 'medicine with consent to distribute' and is therefore able to be advertised.

Section 3 of the Medicines Act 1981: [Meaning of Medicine](#).

There are further restrictions for advertising under Section 58 of the Medicines Act, which don't allow claims to be made directly or by implication or by suggestion to prevent, alleviate or cure a disease, or prevent, reduce or terminate any physiological condition specified in the schedules to the act, unless the product referred to has Ministerial Consent to be distributed as a medicine. Part of that consent application will be extensive clinical trials to prove the efficacy of the medicine to treat the diseases and conditions claimed.

A Clinical Trial has the following meaning;

*Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and / or other pharmacodynamics effects of an investigational product(s), and / or to identify any adverse reactions to an investigational product(s), and / or to study absorption, distribution, metabolism, and excretions of an investigational product(s) with the object of ascertaining its safety and / or efficacy.*

In New Zealand evidence from clinical trials for Natural Health Products and Dietary Supplements may equate to claims that the product is a medicine and it should therefore be registered as one. Having the clinical trial information and claiming the results of clinical trials (particularly with regard to efficacy) is not possible unless the product has gone through the registration process and the results of those trials have been rigorously evaluated by Medsafe.

If the product is to remain as a Natural Health Product or Dietary Supplement and not go through the medicine registration process in NZ then there cannot be therapeutic claims either directly or by implication, and this means that Clinical Trials cannot be used to advance the case, as this would then be claiming a therapeutic purpose.

This rules out the mention of Clinical Trials at all for a Natural Health Product or Dietary Supplement as the implication of a Clinical Trial whether stated or not, is that it has been trialled by Clinicians in a clinical setting and would have a therapeutic intent or purpose.

Use of the term "clinically proven" is also ruled out as this would imply "proven or established beyond doubt by clinical trials (generally a number) that the product works and is effective as a medicine i.e. this is why Ministerial Consent is required re clinical trials which help to prove that the product works as a medicine for therapeutic treatment.

#### **GUIDANCE**

Words that would be acceptable, provided no therapeutic claim is attached to them would be:

*Scientific studies*

*Scientific research*

*Scientific study shows*

*Scientifically shown*