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TAPS therapeutic advertising pre-vetting service

GUIDELINE 2 **NHPaDS**	**Definition of "Disease" as per the Medicines Act 1981**
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 'Disease' and how this piece of the legislation is applied to labels and advertisements for products that are NOT medicines.

BACKGROUND

In addition to the "TAPS Guideline 01. NATURAL HEALTH PRODUCTS AND DIETARY SUPPLEMENTS Therapeutic Purpose Claims on Labels and in Advertising", it is important to cover the issue of "Disease" as defined in the Medicines Act 1981. A "Disease" or "Medical Disorder" is defined under section 2 "Interpretation" of the Medicines Act. These two guidelines are interrelated and it is useful to read the two prior to any advertising of a product without Ministerial Consent for a therapeutic claim as a medicine.

The definition is as follows:-

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

Like the Medicines Act definition for "therapeutic purpose" this is a comprehensive definition of "disease" and embraces essentially any "abnormal functioning" or "abnormal physiological function" or "any disorder of both the body and the mind". Both physical and mental disorders are therefore covered as well as any situation where there is infection of bacterial, viral, parasitical or protozoan type. It covers even the simple things like "sore throats" and more generalised non-specific conditions like "pain".

It is therefore important in advertising Natural Health Products and Dietary Supplements that mention of a disease or any abnormal body or mind function is likely to be interpreted as a therapeutic purpose claim.

Advertisements for these products should only make only "health benefit claims" i.e.

(a) the maintenance or promotion of health or wellness

(b) nutritional support

(c) vitamin or mineral supplementation

(d) maintaining the normal structure or function of the body

Claims that meet the descriptions above rather than claims for **prevention, relief**, **alleviation**, **treatment or cure** of a "disease" or "medical disorder" do not require Ministerial consent to market and are permitted in advertisements.

While this rule clearly limits the scope of claims that can be made for Natural Health Products and Dietary Supplements, the law has been drafted to permit consumers access to the product while preventing manufacturers from marketing products with misleading claims and claims that do not have the adequate burden of scientific support/evidence.

In order not to breach the Medicines Act it will be necessary to confine "health benefit claims" to the help and support of the normal physiological function.

Note that nearly 60 specified "disease states" or "medical conditions" are outlined in the First Schedule Parts 1 & 2 of the Medicines Act. Unless Ministerial Consent has been granted then any claim in advertisements made to "prevent, alleviate, or cure any disease, or prevent, reduce, or terminate any physiological condition specified (in the First Schedule) would be a breach of section 58 of the Medicines Act. It is important to note that in Part 2 both the "common cold" and "influenza" are specifically mentioned. Essentially these are all the common disease states or medical conditions.

Making a Therapeutic Purpose Claim

It should be noted that the appropriate gold standard required for applications to market a medicine making therapeutic purpose claims such as preventing or treating a disease or a medical condition is double blind randomised controlled trials in human subjects with the relevant disease state.

"In vitro" or "laboratory tests" and "trials in animals" are not sufficient to establish a claim for a "therapeutic purpose". Evidence derived from this type of approach is subject to many confounding factors and these are unreliable models of the human physiological response to a substance. At best "in vitro" or animal models can only generate a hypothesis that the product may have some effect in humans. Adequately conducted clinical trials in appropriate patient numbers are required to confirm or test the hypothesis.