Natural Health Products Bill 2011 (2012 No 324-2)

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**Purpose**

The aim of this Bill is to establish a system for the regulation of low-risk natural health products in New Zealand.

*The Bill as introduced is described in Bills Digest No 1927.*

**Main changes**

**Title**

The Bill’s title is changed to “Natural Health and Supplementary Products Bill” and the words “and supplementary” are added to every reference to natural health products throughout the Bill so that they are always described as “natural health and supplementary products” *(Clause 1).*

**Scientific or traditional evidence**

In relation to the description of the basic principles, the bar-2 Bill provides that either scientific or traditional evidence should support health benefit claims made for natural health or supplementary products. Definitions of the terms are provided:

- **scientific evidence** means evidence derived from either or both of the following sources: empirical studies; repeatable experiments;
• **traditional evidence** means evidence of traditional use of a substance based on knowledge, beliefs, or practices passed down from generation to generation (Part 1, Clause 4 (“Principles”); Clause 5, inserting new definitions, those of “scientific evidence” and “traditional evidence”).

**Comment**
The Select Committee noted that concern was expressed by submitters “that the Bill would ‘allow untrue claims and prevent true claims’. This was because some low-risk natural products with associated health claims for named conditions, for which there was scientific evidence, would be required to be registered as medicines. It would however be permissible to make a health claim for products based on traditional evidence, but without scientific evidence”.1

**Other definitions**
The bar-2 Bill includes other new or amended definitions, including the following:

• **dietary supplement** is new and means a product that is:
  - sold in controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet); and
  - intended to be ingested orally; and
  - intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food;

• **health benefit** has been amended and means any 1 of the following benefits:
  - the maintenance or promotion of health or wellness;
  - nutritional support;
  - vitamin or mineral supplementation;
  - affecting or maintaining the structure of the body;
  - relief of symptoms;

• **manufacture** is new and means: in relation to a product, to make up, prepare, produce, or process the product for the purposes of sale, and includes the packaging of the product in a container for the purposes of sale (Part 1, Clause 4 (“Principles”); Clause 5, inserting new definitions).

**Natural health and supplementary product**
The bar -2 Bill has redefined the term “natural health and supplementary product” in a completely different manner (for a description of the original definition see [Bills Digest No 1927](#)).

Essentially, a “natural health and supplementary product has the following characteristics:

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1 Natural Health Products Bill, 2012 No 324-2, As reported from the Health Committee, Commentary p. 3.
it is a product for human use;

it is for the primary purpose of bringing about a health benefit to the user;

it contains only permitted ingredients
  o unless it is an ingredient in respect of which the Natural Health and Supplementary Products Regulatory Authority either has not raised any concern or has not commenced a safety audit and 90 days have elapsed since the “product notifier” applied to the Authority under Clause 22(2)(b)(i) or
  o the product is a dietary supplement;

it is not, or is not presented as, food (which is “anything that is ordinarily used or represented for use as food or drink for human beings).

The bar-2 Bill provides that a “natural health and supplementary product” does not include:

a medicine, related product or medical device (all under certain provisions of the Medicines Act or certain regulations under that Act) (Part 1, Clause 6(1)-(3), definitions of “natural health and supplementary product” and “food”).