Technical Alert

Proposed amendments to the NZ Natural Health Products Bill- Consultation

Dear member,

The final version of the NHSP Bill Supplementary Order Paper, which is to go to Cabinet for final approval in early September, is currently open for consultation. Comments on the Bill may be sent to Naturalhealthproducts@moh.govt.nz by **Thursday 27 August 2015.**
Our colleagues over at Natural Product NZ are pleased with the consultation draft and would like it to proceed as soon as possible.

This Supplementary Order Paper amends the NZ Natural Health Products Bill.
The effect of these changes is that dietary supplements in NZ will be regulated as natural health products. See more detail below.
Note: a new term, permitted natural health product, is proposed in place of natural health and supplementary product.

Requirements for evidence (traditional & scientific)

The evidence must be able to be replicated and the method of administration used in the evidence must be the same as the recommended administration of the product.

Providing a summary of evidence

The Bill requires the product notifier to provide, for each health benefit claim made for the product, a summary of evidence relied on to support the claim.

> Section 20(4) - Product Notification.
> Before completing the product notification, the product notifier must make available on an Internet site, in respect of each health benefit claim made for the product, a summary of the evidence that the product notifier relies on to support the claim.

Given the extremely tight timeframe for this consultation, members are asked to identify specific concerns with regard to this requirement and provide this feedback directly to the Ministry (copying CMA).

The evidence must be:

- relevant to the target population
- directly measure the health benefit
- reasonably applicable to NZ self-care
- representative of a wider body of evidence.

Evidence of traditional use:

- Claim is “traditionally used for X”
- Evidence from approved pharmacopeia
- Evidence from other traditional sources

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Scientific evidence:
Claim is: “does X”

- Systematic reviews
- Critically appraised topics
- Critically appraised individual articles
- Randomised controlled trials
- Cohort studies
- Case-controlled studies, case series, time series
- Background information, expert opinion

Manufacturing of Natural Health Products

Legislative requirements:

- A manufacturer will need to be compliant with the Code of Manufacturing Practice within 3 years of commencement of the Act
- Manufacturing facilities will need to be registered and licenced. Licences last 5 years
- Overseas facilities must meet equivalent standards

Elements of Code

- Risk-based tiered system - requirements proportionate to risk
- Likely that Authority will recognise some other Codes
- Audit requirements depending on risk level

The most significant change proposed to provisions relating to the manufacture of natural health products (*clauses 8 to 15*) is that the obligation to obtain a licence to manufacture now extends to manufacturers of natural health products (instead of the narrower range of natural health and supplementary products).

Fees

- Cost recovery
- Third-party audit
- General costs recovered via notification fee
- Very sensitive to number of products

Resources:

NHSP Bill Supplementary Order Paper – Consultation Draft
Draft list of NZ permitted ingredients (as of 20 July 2015)
Ministry of Health Natural Health Products – workshop on regulatory detail June/July 2015

ENDS

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