Towards Natural Health Products Regulation in New Zealand

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Policy and strategic advice on the development of the traditional, complementary and alternative medicine professions in New Zealand and their integration with mainstream health care

Natural Health Products Regulation in NZ

- New regulatory scheme for natural health products is being introduced
- Separate from regulation of pharmaceutical products and foods
- Joint National-Greens initiative

Natural Health Products Bill

- First Reading in Parliament on 15 Sept 2011
- Referred to Health Committee
- Submissions closed on 24 Feb 2012
  - 900 submissions received
- Health Committee must report back to Parliament by 30 May 2012
- Bill to be enacted by the end of 2012.
- Date of commencement of the Act?
  - Depends on availability of Regulations and online database

"Safe, true to claim, true to label"

- Natural health products must be fit for human consumption or use
- Their regulation must be proportionate to the risks associated with their use
  - Low risk = light touch, low cost regulation
- The products must be accompanied by information that is accurate and tells consumers about the risks and benefits of using the product

What is a Natural Health Product?*

- Herbal remedies, traditional treatments, homeopathic remedies, dietary supplements, extracted natural ingredients, synthetic equivalents.
- Intended to bring about a health benefit
- Contains only "natural health product ingredients" and no "prohibited ingredients"
- Not a food
- Not a prescription medicine, pharmacy-only medicine or controlled drug
- Cannot be administered by injection or parenteral infusion; or to the eye or in the ear

** Health Committee wants further work on the definition*

Health Benefit Claims

- Maintenance or promotion of health or wellness
- Nutritional support
- Vitamin or mineral supplementation
- Affecting or maintaining the structure or function of the body
- Relief of symptoms of any condition that is not a serious condition
  - Serious condition = disease, disorder, condition, ailment or defect that is not suitable for self-diagnosis and/or self-management.

Regulatory Authority

- Director-General of Health is the "Natural Health Products Regulatory Authority"
- New unit within the Ministry of Health
- Supported by a technical advisory committee
  - Interim committee already established, to help develop regulations
- Authority is able to recognise the decisions of other regulators

Regulatory Scheme

- Online database for product notification prior to product distribution
- Self certification against scheme requirements
  - Contains only natural health product ingredients *already listed* on database
  - Does not contain listed prohibited ingredients
  - Manufacturer complies with code of manufacturing practice
  - Product meets labelling requirements
  - Evidence is held to support health benefit claims
    - Traditional evidence vs scientific evidence
    - Levels of evidence within each category
- All documentation to be kept for random audits

Regulatory Scheme (cont..)

- Exemptions from product notifications
  - Health practitioners making and supplying products directly to patients
  - Specific categories of products
- New ingredient notification at least 90 days ahead of product notification
  - Regulator's decision can be: (a) Approval or (b) Safety assessment required
- All manufacturers require a license
  - Audit of compliance against Code of Manufacturing Practice
- Export certification
- Fees

Implementation

- Require a suite of Regulations under the Act
  - Work has already commenced on the Regulations
  - Developed by the Regulator, with support of Interim Technical Expert Advisory Committee and Industry Reference Panel
  - Public consultation document
    - Cabinet approval prior to public consultation
  - Regulations drafted in light of consultation
  - Approved by Minister of Health
  - Reviewed by Regulations Review Committee
  - Adopted by Order in Council
- Transitional provisions for products already in the market
  - Notification – 1 year after commencement of Act
  - Labelling – 2 years after commencement
  - Manufacturing standards – 3 years after commencement

Thank You

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