



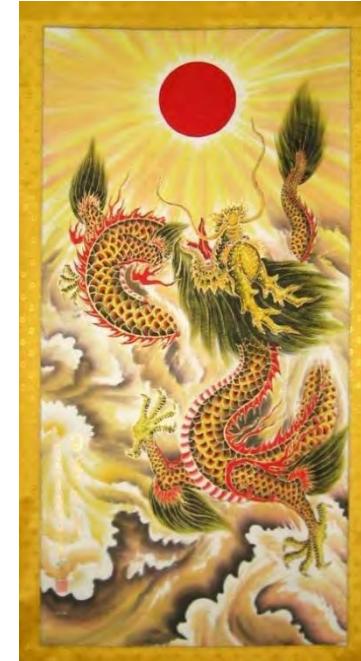
Towards Natural Health Products Regulation in New Zealand





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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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