Developments in regulations for complementary medicines (including traditional medicines and other natural health products)

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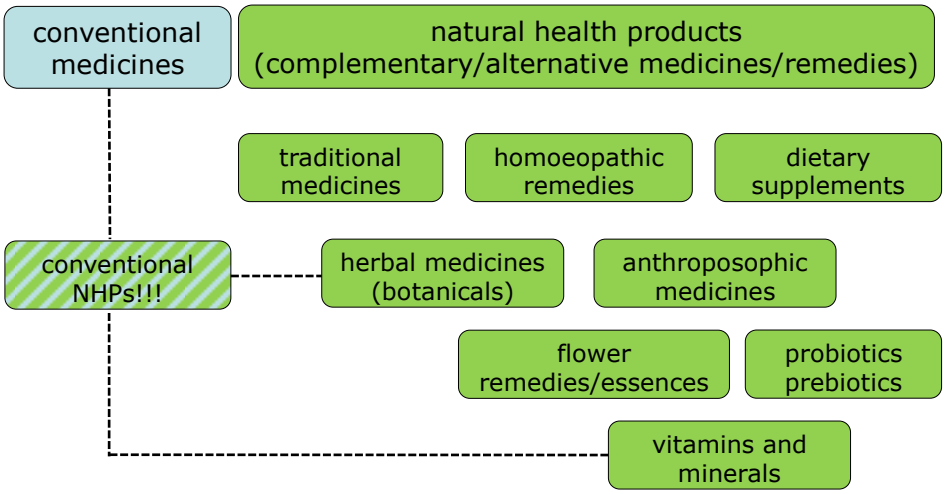
21 June 2018

Outline

- What are complementary medicines (CMs), including traditional medicines (TMs) and other 'natural health' products (NHPs) in the NZ context
- Current regulation of TMs and NHPs in NZ
- Proposed regulations for TMs and NHPs in NZ
- Regulation of complementary medicines in Australia
- Impact of regulatory change

Types of natural health products



NHPs in NZ

- formulated manufactured products containing single or multiple 'natural health' ingredients; typically purchased from health-food stores, pharmacies, supermarkets, and on-line suppliers
- NZ natural health products (NHPs) industry is said to exceed NZ$1 billion in revenue

Natural Products New Zealand. Available at: http://www.naturalproductsnz.org/cms/wp-content/uploads/2012/03/Natural-Products-industry-recognises-top-performers-22-3-12.pdf

- preparations of crude herbs, herbal tinctures, and topical herbal preparations supplied following a consultation with a natural health practitioner (e.g. herbalist, naturopath, traditional Chinese medicine practitioner, traditional healer)

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Natural health products are available in a range of dose forms

(n.b. Use of image does not imply product endorsement by J. Barnes, School of Pharmacy or University of Auckland)

Image from European Herbal Practitioners Association website

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Traditional medicine in NZ

- Te Rongoā - Māori traditional system of healing involving use of traditional plant medicines (rongoā rakau), massage (mirimiri) and prayer (karakia)
- System of healthcare is based on a holistic model that incorporates physical, emotional, family and spiritual aspects of health; each aspect is important to ensure full recovery of the patient
- Tohunga (Māori traditional healers) still have a significant role in the practice of rongoā Māori, although their practices and use of medicinal plants varies between practitioners

Te Ara (Encyclopaedia of New Zealand)
http://www.teara.govt.nz/en/rongoa-medicinal-use-of-plants

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Regulation of CMs in NZ

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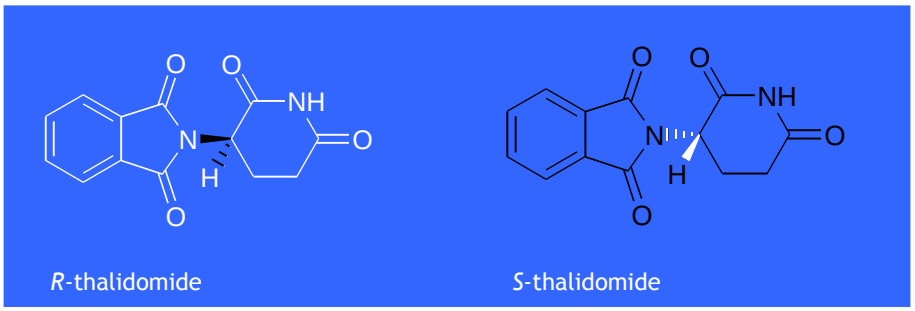
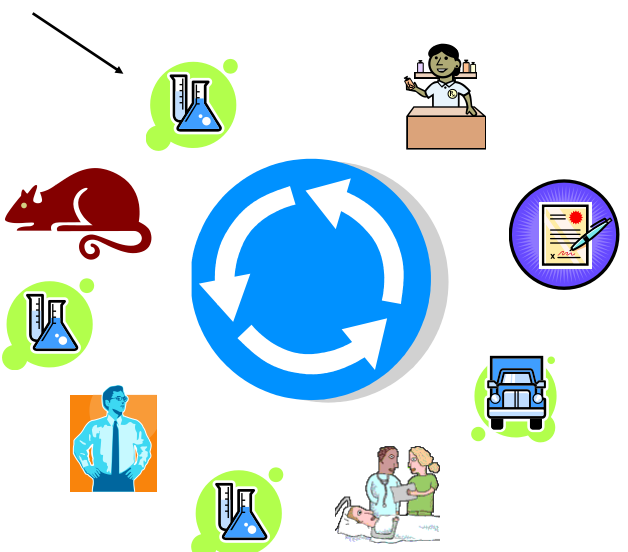
Thalidomide tragedy



Medicines Act (UK 1968); NZ 1981



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Pre-approval process for new medicines

- Sponsor (manufacturer) applies to competent authority (Medsafe) and provides evidence that medicine meets NZ and/or international standards for quality, efficacy, safety; fees apply
- Medsafe may request more information from manufacturer; if satisfied, Medsafe makes recommendation to Minister
- Competent authority considers chances of benefits and risks of harms

benefits > harms

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Chance of benefit-risk of harm balance

benefits > harms

? Quality
? Efficacy
? Safety

harms > benefits

Regulation of NHPs supplied by 'natural health' practitioners

- Exemption in Medicines Act ('herbalists' exemption') allows 'natural health and other practitioners' to make herbal remedies and other individualised natural health treatments for individual patients in response to one-to-one consultations
- N.B. no statutory regulation of 'natural health' practitioners in NZ
- Medicines Act and its Regs will be replaced with new Therapeutic Products Bill; consultation on an exposure draft expected in 2018?

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Also see Medsafe:

http://www.medsafe.govt.nz/profs/NaturalHealth.asp

Regulation of NHPs

- Medicines Act 1981 defines herbal (plant material subjected to simple processing) & homoeopathic preparations (active ingredient <20ppm), but provides **exemptions from licensing requirements** (pre-market approval with respect to quality, safety, efficacy) provided these preparations are sold without any recommendation as to its use.
- Some herbal substances are restricted/scheduled as POM or pharmacist only
- (N.B. Medicines Act to be replaced with Therapeutic Products Bill)
- 'Complementary medicines'/NHPs, sold as 'dietary supplements', regulated under Dietary Supplement Regulations (DSR) 1985, under the Food Act 1981; some restrictions on ingredients; no therapeutic claims allowed.
- Long recognised that current legislation doesn't adequately regulate NHPs: do not protect public health; unlevel playing field; affects exports

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Developments in regulation of NHPs

- 2006: Therapeutic Goods Administration, Australia and Medsafe, NZ to form a joint Trans-Tasman Agency – ANZTPA (Australia New Zealand Therapeutic Products Authority)
- Would regulate medicines, including CMs, as well as medical devices, blood products etc
- Likely that provisions for CMs would have been similar to those already existing in Australia for CMs
- But, in 2007, was postponed indefinitely after failed to achieve support in NZ parliament.

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Developments in regulation of NHPs

- March 2010: amendment to DSR narrowed definition of DS to therapeutic-type products only, transferred responsibility to Medsafe
- March 2010: Consultation paper on Development of a Natural Health Products Bill to regulate products on NZ market; including product approvals, quality standards, lists of permitted ingredients, permitted health claims etc.
- 'Herbalists' exemption' unaffected by these proposed regulations.
- Developed under a Memorandum of Understanding (MoU) between National and Green parties.
- Also, development of ANZTPA re-activated in 2011; would not regulate CMs initially. ANZTPA ceased permanently in 2014.

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Developments in regulation of NHPs

- Became the Natural Health and Supplementary Products Bill
- November 2015: Consultation documents released on draft proposals for Natural Health & Supplementary Products Bill (closed 3 March 2016; ingredients, conditions - ended 5/2016)
- Legislation was to be introduced 20[illegible];2014;2015;2016;2017;2018? Would be phased in over 3 years.
- Was waiting for its third (and final) reading in Parliament before becoming an Act. Once the Act was passed by Parliament, Government would have the power to refine the detail of the Regulations. The Regulations must always stay within the framework allowed by the Act.

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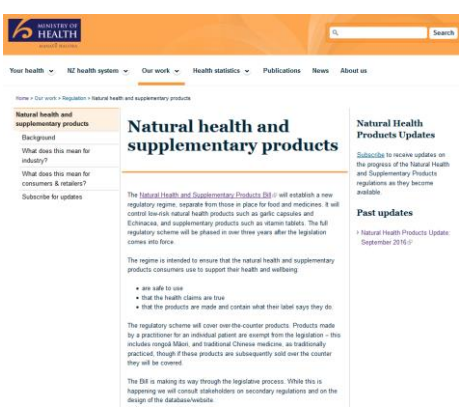
Natural Health & Supplementary Products Bill



http://www.health.govt.nz/our-work/regulation-health-and-disability-system/natural-health-and-supplementary-products

http://www.parliament.nz/en-nz/pb/legislation/bills/00DBHOH_BILL11034_1/natural-health-and-supplementary-products-bill

Proposed regulations

Regulatory system for 'low-risk' NHPs.

Safety

- Permitted ingredients list; contains a dients, including some traditional Māori me
- active ingredients at <20 eduled medicines)
- Permitted health ir-limiting conditions suitable for self
- Products minimum labelling requirements
- Obligations f nufacturers to report serious adverse events
- Web-based online notification system for manufacturers to submit information on their NHPs prior to marketing; notification number

Proposed regulations

Quality

- Products, including imported products, n ufactured in facilities that meet the requirements of facturing Practice (The Code), based on princ acturing Practice; manufacturers have 3

Covers:

- manufacturing pr personnel, premises and equipment used sures in place, production and supporting d
- manage and recalls
- contract n nd analysis
- collection ar rification of starting materials of herbal and animal origin
- testing requirements for specifications for dosage forms.
- site audits, depending on level of risk.

Proposed regulations

Evidence

- Health claims must be supported by evid… …cientific studies (e.g. clinical trials) or traditional… …as 75 years' use of same preparation for same ind…

- Scientific evidence needs t… …n humans. Evidence from SRs/MAs, R… …etc. Preclinical studies can be used as suppor… …e insufficient alone to support claims of e… …ns.

- Manufac… …idence summaries available to public via website

- Legislation w… …tablish an NHPs Authority at Ministry of Health

Ministry of Health. The Regulation of Natural Health Products: Consultation document. Wellington: Ministry of Health, 2015.Available at: http://www.health.govt.nz/publication/regulation-natural-health-products-consultation

Impact of regulatory changes … possibly

- Access to appropriate quality, safe, effective NHPs, suitable for use in self-treatment of minor, self-limiting conditions, and with evidence to support health claims available to consumers
- Better informed choice for consumers
- Gives health professionals more assurances re product quality
- Safety: low risk ≠ no risk; AE reporting + monitoring
- Better alignment of NZ with other developed countries with respect to regulation of NHPs; benefits for NZ manufacturers exporting NHPs; SMEs will be most challenged
- Monitoring of compliance; audit and enforcement critical
- Actual impact on different stakeholders needs to be explored

CMs regulation in Australia

- The Australian National Medicines Policy (1999) explicitly includes CMs; principles within the national policy equally apply to the quality, safety and efficacy and the quality use of all CMs in the Australian health system.
- Australia began with two-tiered regulatory framework; most CMs are identified as lower-risk medicines and categorised as 'Listed' products ('AUST L'); >12,000 CMs listed on the Australian Register of Therapeutic Goods (ARTG) & 200 'registered'.
- Post-market regulatory activities include: audit of manufacturers and products; controls on advertising, labelling; reporting of AEs;
- Review of CMs regulation in 2015; several changes introduced in 2018.

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CMs regulation in Australia

- List of permissible indications (previously 'freetext' field)
- New application categories for substances to be included on permissible ingredients list
- New category 'assessed listed medicines' introduced; medicines listed through this pathway will be included in the ARTG following self-certification of the safety and quality of the product, and **TGA pre-market assessment of efficacy evidence (based on finished product) supporting the proposed indications**
- allows higher level claims
- encourages industry to improve standard of evidence
- bridges gap between listed and registered categories

https://www.tga.gov.au/assessed-listed-medicines

Further reading

Barnes J, McLachlan AJ, Sherwin CT, Enioutina EY. Herbal medicines: challenges in the modern world. Part 1: Australia and New Zealand. *Expert Rev Clinical Pharmacol* 2016;9(7):905-15

Ministry of Health
http://www.health.govt.nz/our-work/regulation-health-and-disability-system/natural-health-and-supplementary-products
https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime

Medsafe
http://www.medsafe.govt.nz/regulatory/DietarySupplements/Regulation.asp
http://www.medsafe.govt.nz/profs/NaturalHealth.asp

TGA https://www.tga.gov.au/complementary-medicines

Medical Council of New Zealand
https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Complementary-and-alternative-medicine.pdf

Summary

- In NZ, currently, CMs/NHPs are subject only to very weak regulations
- There is no pre-market approval of quality, efficacy, or safety
- Proposed regulations for CMs/NHPs were dropped in 2017; these would have introduced a 'light-touch' regulatory framework based around providing assurances on product quality, safety, and effectiveness in the context of minor, self-limiting health claims
- Australia now has a 3-tiered system of regulation for CMs/NHPs
- There is no statutory regulation of 'natural health' practitioners in NZ; a Medicines Act Exemption ('herbalists' exemption') allows 'natural health and other practitioners' to make herbal remedies and other individualised natural health treatments for individual patients in response to one-to-one consultations
- Medicines Act to be replaced by new Therapeutic Products Bill