



MEDSAFE

**New Zealand Medicines and Medical
Devices Safety Authority**

A business unit of the Ministry of Health

National Health Committee

A regulators perspective on the integration of complementary medicines into the management of chronic diseases.

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The Case For Regulation

Evidence based practice requires evidence of:

- Safety –
- Quality
- Efficacy

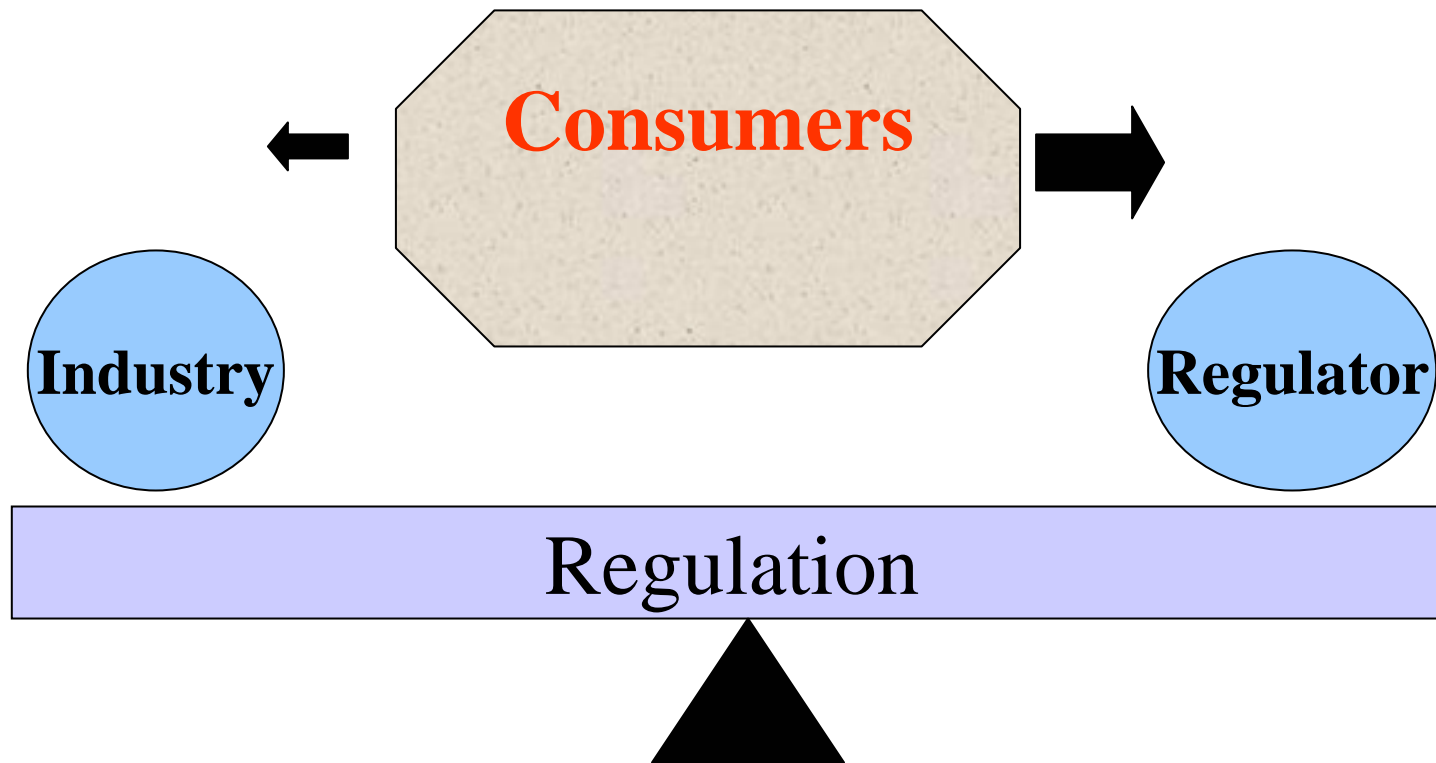
Medicines are not items of ordinary commerce

- Oversight by an expert authority is necessary.

Current Regulatory Controls

Activities	Assessed by Regulator	
	Medicines	Dietary Supplements
Safety of ingredients	Yes	No
Quality in manufacture	Yes	No
Effectiveness/claims	Yes	No (not permitted)
Ministerial approval	Yes	No
Dose	Yes	No
Labelling	Yes	Yes
Additives	Yes	Yes

Balancing Expectations



Shared Expectations

Products:

- Safe
- High Quality
- Effective
- Predictable
- Accessible

Regulation:

- Simple
- Risk based
- Cost efficient
- Transparent
- Equitable

International Requirements

- WHO - support registration and quality controls for complementary medicines
- USA - DSHEA limits claims, introducing quality controls, proposing to introduce active regulation.
- Europe – increasing regulatory controls on complementary medicines, herbal and traditional medicines and adverse reactions monitoring.
- Australia – pre-market approval, standards, quality (GMP), claims limited by evidence, controls over advertising, adverse reactions monitoring
- Canada – new legislation, registration, quality (GMP), controls over claims, adverse reactions monitoring

Risk Assessment

Risk identification:

- Intrinsic – risk arising from the ingredients themselves e.g. aristolochia.
- Extrinsic – risk arising from the way goods are manufactured e.g. spiking with sildenafil.
- Inappropriate use - risk arising from misuse, abuse e.g. 1,4 butandiol, misinformed use, and inappropriate claims e.g. lyprinol.

Risk Management Strategy

- Legislation introducing:
 - Minimum quality standards
 - Ingredient safety requirements
 - Adverse reactions monitoring
 - Appropriate therapeutic claims

Scope and Coverage of the Regulatory Scheme

- Manufacture, import, supply, promotion and export of therapeutic products in New Zealand and Australia
- Prescription medicines, non-prescription medicines, complementary medicines, medical devices and other therapeutic products

Key Elements of the Regulatory Framework for Medicines

- Compliance with standards
- Licensing of manufacturers
- Product licensing
- Post-market monitoring and surveillance

Risk Classification for Medicines

Class I

- Contain only ingredients from permitted list; no scheduled medicines
- Product not for prevention or treatment of a serious disease
- Excludes products required to be sterile (e.g. injections, eye drops)

All other medicines are **Class II** medicines

Licensing of Manufacturers

- Agency will license New Zealand and Australian manufacturers
- Manufacturers audited for compliance with manufacturing principles
- Licence issued subject to conditions
- Annual fee and declarations to maintain licence
- Certain medicines or persons exempt

Product Licensing

For **Class I** complementary medicines

- Simple, internet based application system
- Relies on sponsor self-assessing product against a set of requirements
- No pre-market evaluation by agency
- No delay to market entry

• For **Class II** complementary medicines

- Sponsor submits application for evaluation by agency
- Data requirements depend on characteristics of product

Product Licensing (continued)

- Export-only PL available (internet-based application)
- Each PL has a unique identifier
- Product licence document sets out particulars of product and conditions subject to which licence is issued

Product Licensing (continued)

- PL may be varied
- PL may be revoked or suspended
- Certain medicines exempt from PL requirement
- Separate PL for each separate product (some grouping possible)

Ingredients Permitted in Class I Complementary Medicines

- New list at start-up of joint agency
- List will include ingredients currently permitted in Listable medicines in Australia, plus those added as a result of Permitted Ingredients List project
- Process for adding new ingredients to list

Expert Advisory Committee on Complementary Medicines

- Appointed by Ministerial Council
- Members chosen for their expertise
- Provide advice to the Managing Director

Post-market Monitoring and Surveillance

- Product testing programme
- Adverse reactions monitoring
- Complaints investigations
- Recalls

Fees and Charges

- Agency to operate on full cost recovery
- Fees and charges prescribed in Rules
- Fees and charges model is under development
- Consultation to occur on a set of proposals

Review of Decisions

- **Merits review**
 - Internal review
 - Review by independent merits review tribunal
- **Judicial review**
 - Existing judicial review arrangements maintained
 - Review in one country or the other
 - Decision has effect in both countries

Next Steps

- Exposure drafts of regulatory requirements
- Rules finalised after stakeholders consulted
- Bills passed 2005
- Treaty ratified
- Agency opens doors mid-2005

Keeping up to date

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