

Regional Meeting: Traditional and Complementary Medicine's Contributions towards Universal Health

June 6-7, 2017
Managua, Nicaragua



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Natural Health Products (NHPs) in Canada

EXPERIENCE EXCHANGE 2:

T&CM Regulation: professional training, service provision, production and distribution of products, resource sustainability.

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Country: Canada



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Canada's Health Care System

- Publicly funded health care system
- Administered through health care insurance plans
- *Reasonable* access to medically necessary services without paying out-of-pocket



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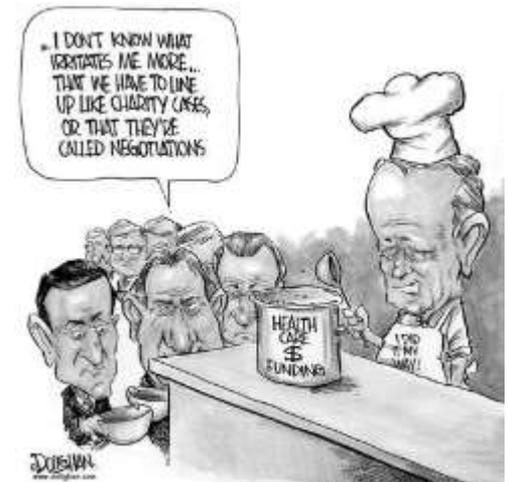
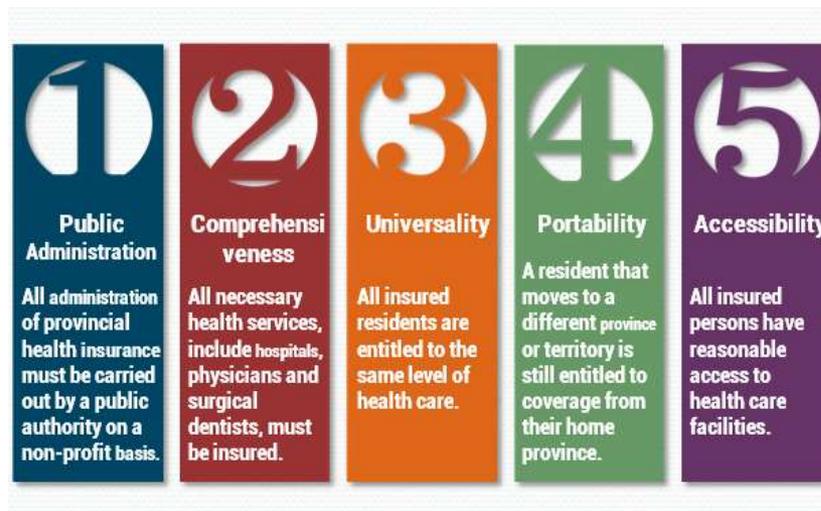


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Canada's Health Care System (cont'd)

- Shared roles and responsibilities - provincial and territorial governments (PTs) and Health Canada
- PTs oversee the management, organization and delivery of health care services for their residents



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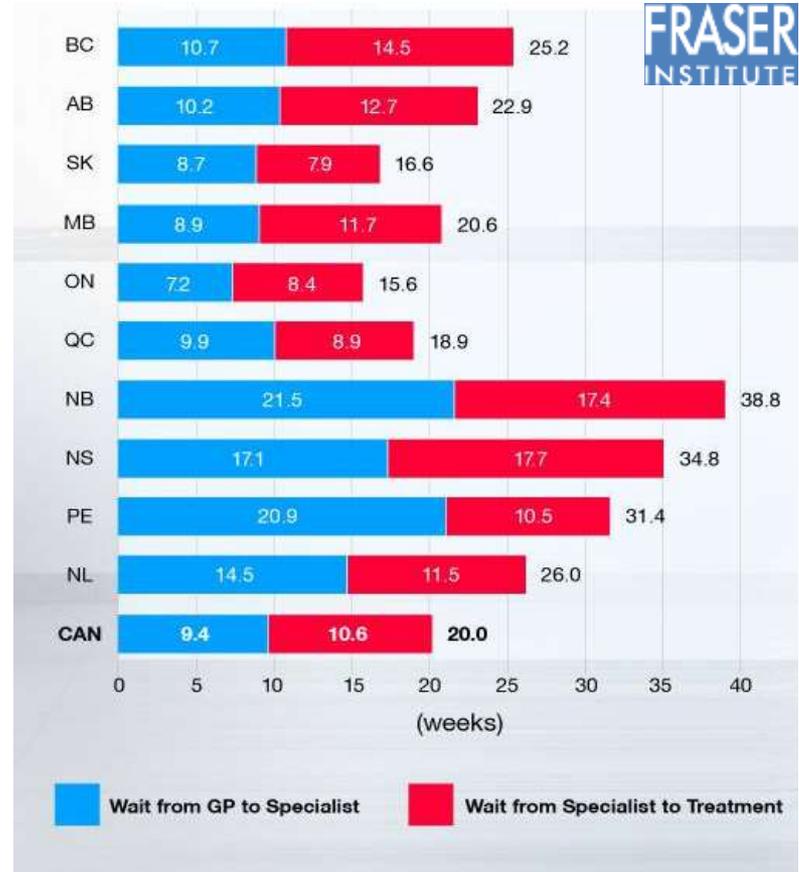
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Waiting Your Turn



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Federal Government Responsibilities

- Regulation of products
- Supports:
 - health research
 - health promotion and protection
 - disease monitoring and prevention



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Federal Responsibilities

- Professional training
- Service provision
- Production and distribution of products
- Resource sustainability



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Provinces and Territories Responsibilities

- Regulate the practice of medicine:
 - Setting standards (professional training)
 - Strategic direction (service provision)
 - Making disciplinary decisions



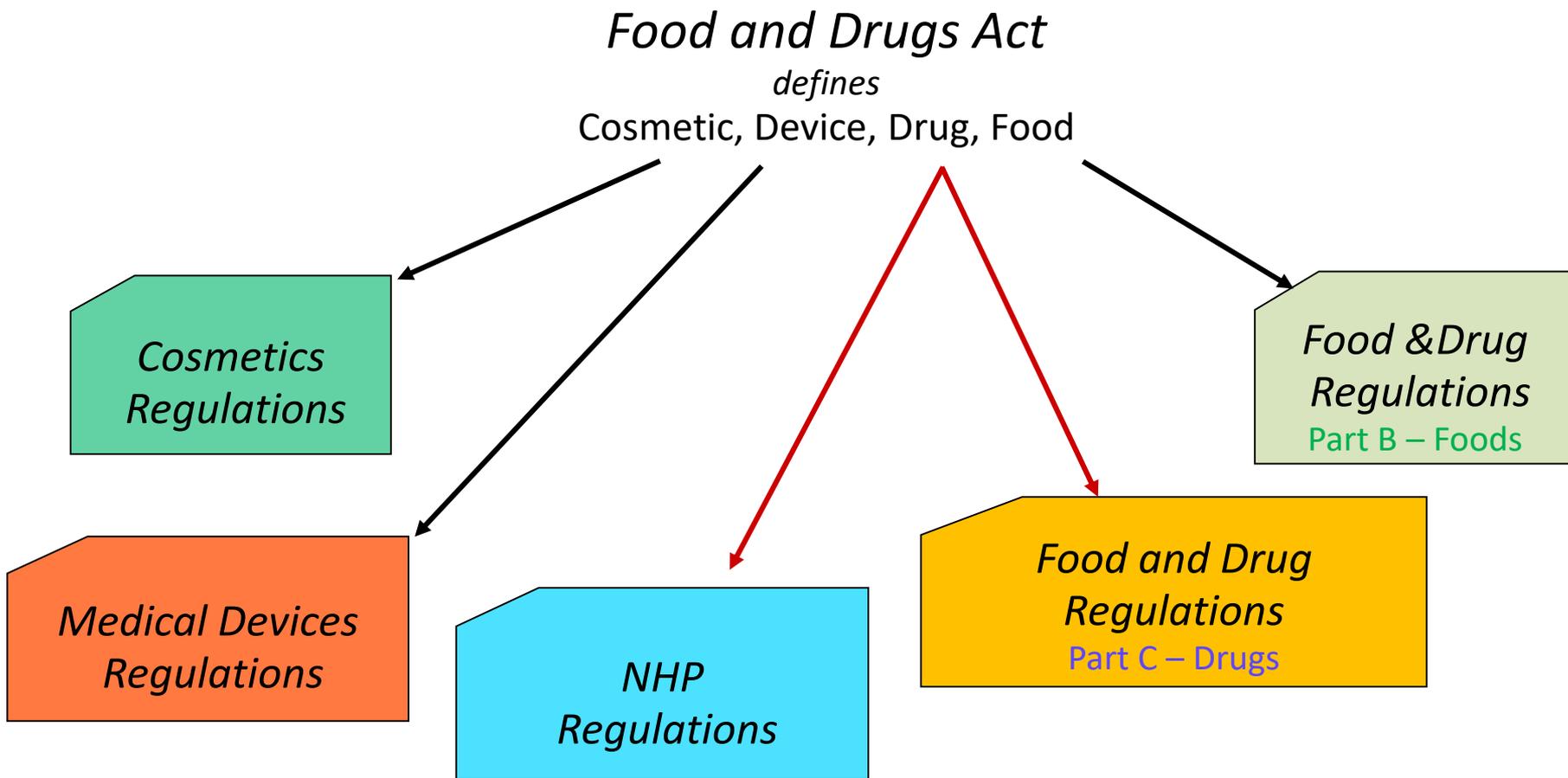
College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario
Ordre des praticiens en médecine traditionnelle chinoise et des acupuncteurs de l'Ontario



COLLEGE OF KINESIOLOGISTS OF ONTARIO



Product Regulation – Federal Authority



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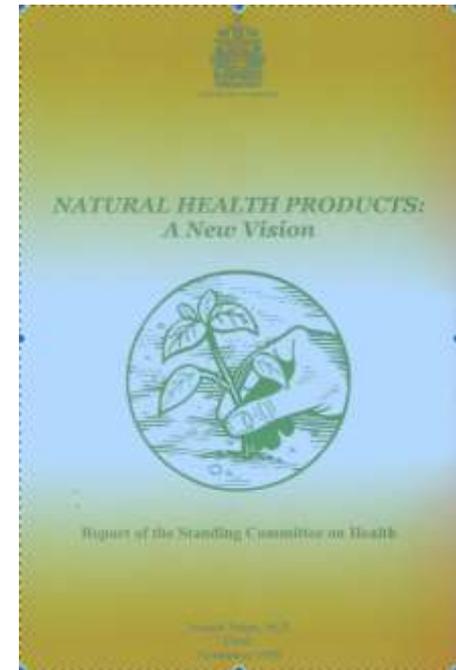


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Natural Health Products Regulations

- Definitions
- Part 1 – Product Licences
- Part 2 – Site Licences
- Part 3 – GMPs
- Part 4 – Clinical Trials
- Part 5 – Packaging and Labelling
- Part 6 – Transitional Provisions



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Natural Health Products includes:

- Herbals, plant material
- Algae, Bacteria, Fungus
- Non-human animal material
- Vitamins
- Amino acid
- Essential fatty acids
- Synthetic duplicates of above
- Probiotics
- Minerals
- Homeopathic medicines
- Traditional medicines



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Natural Health Products excludes:

- Radiopharmaceuticals
- Biologics (some exceptions)
- Tobacco
- Controlled Drugs and Substances
- Injectables
- Antibiotics
- Products requiring prescription



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T&CM: Self-Care

Inclusion on the PDL* based on 3 broad principles:

- a. Supervision by a practitioner is necessary
 - for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms...
 - to monitor a disease, disorder or abnormal physical state, or its symptoms...
- b. The level of uncertainty respecting the drug, its use or its effects justifies supervision by a practitioner.
- c. Use of the drug can cause harm...or a risk to public health that can be mitigated by a practitioner's supervision.

*Prescription Drug List



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Premarket Review for NHPs

CLASS I

Highest Certainty

- Applicants attest to existing information pre-cleared by Health Canada.
- Risks associated with various class I products will vary, but the level of certainty is the same.
- Target of 10 days.

CLASS II

Moderate Certainty

- Evidence (e.g. published literature required in addition to pre-cleared information).
- Ex. New claim for existing authorised product.
- Target of 30 days.

CLASS III

Lowest Certainty

- Clinical trial evidence and full pre-market assessment.
- Ex. New product claiming to reduce the risk of liver dysfunction.
- Target of 180 days.

Performance standards aligned to level of certainty.



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Challenges & Opportunities

- What are other jurisdictions/regulatory agencies?
 - FDA (US), MHRA (UK), TGA (Australia), HSA (Singapore), BfArM (Germany), EMA (Europe), SwissMedic (Switzerland)...
- Industry Concerns
- Consumer Awareness
- Media attention
- Product Classification
- Detection of ADRs
- Compliance & Enforcement



"The active ingredient is marketing."



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Future Direction

- Reducing regulatory burden and aligning with international counterparts
- Sustainability of current NHP Program?
- Regulatory modernization across all OTC health product lines
 - Over 100,000 NHPs authorized for sale in Canada and 5000 Non-prescription drugs (NPDs)



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Traditional and Complementary Medicines - currencies of health.



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- Regulations, Amendments, Monographs, Guidance Documents, Forms and Tools are on the Health Canada web site at www.healthcanada.gc.ca/nhp
- Acts and Regulations available at <http://laws-lois.justice.gc.ca/>
- All information is available in English and French



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Thank you to PAHO/WHO for the opportunity...