

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

June 6-7, 2017  
Managua, Nicaragua



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas

# Natural Health Products (NHPs) in Canada

## EXPERIENCE EXCHANGE 2:

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

**Name:** Nana Bafi-Yeboah, Natural and non-prescription Products Directorate (NNHPD), Health Canada

**E-mail:** [nana.bafi-yeboah@canada.ca](mailto:nana.bafi-yeboah@canada.ca)

**Country:** Canada



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas

# 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



Universal health  
Access and coverage for all



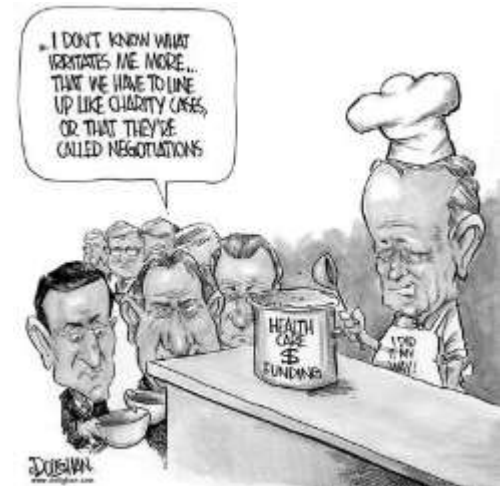
Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 3

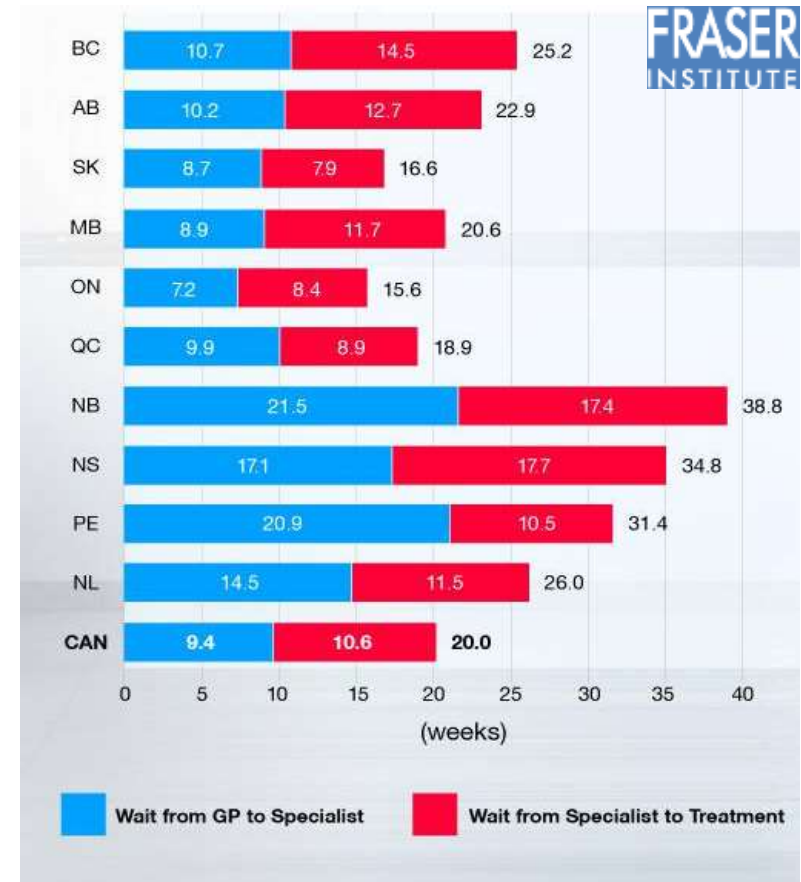
# Canada's Health Care System (cont'd)

- 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





# Waiting Your Turn



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization

REGIONAL OFFICE FOR THE Americas 5

# Federal Government Responsibilities

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



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 6

# Federal Responsibilities

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



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas



# 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



Universal health  
Access and coverage for all



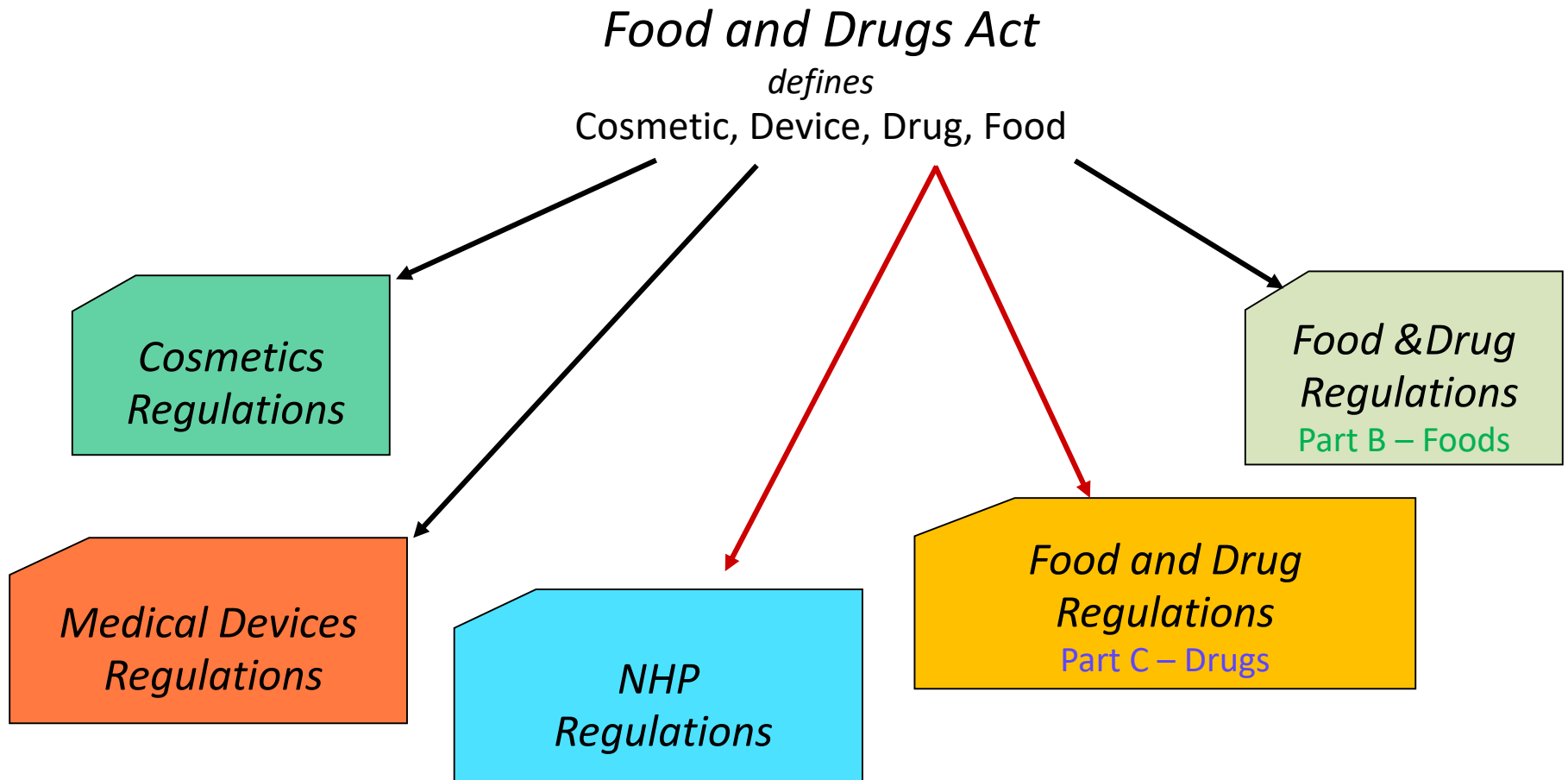
Pan American Health Organization



World Health Organization  
REGIONAL OFFICE FOR THE Americas

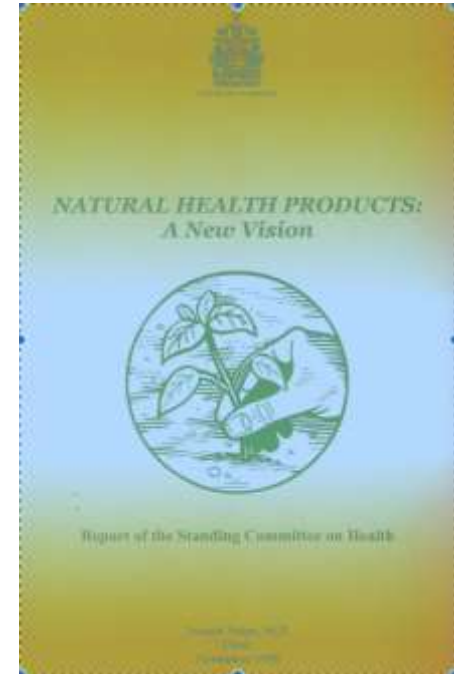


# Product Regulation – Federal Authority



# 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



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 10

# 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



# Natural Health Products excludes:

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



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 12



# 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



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 13

# 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.



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization

REGIONAL OFFICE FOR THE Americas 14

# 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."*



# 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)



Universal health  
Access and coverage for all



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE Americas 16





**Traditional and Complementary  
Medicines - currencies of health.**



**Universal health**  
Access and coverage for all



**Pan American  
Health  
Organization**



**World Health  
Organization**  
REGIONAL OFFICE FOR THE  
**Americas**



# Universal health

Access and coverage for all

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



# Universal health

Access and coverage for all

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