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

June 6-7, 2017
Managua, Nicaragua
EXPERIENCE EXCHANGE 2:
T&CM Regulation: professional training, service provision, production and distribution of products, resource sustainability.

Name: Nana Bafi-Yeboa, Natural and non-prescription Products Directorate (NNHPD), Health Canada
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Country: Canada
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
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
Federal Government Responsibilities

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

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

• Regulate the practice of medicine:
  • Setting standards (professional training)
  • Strategic direction (service provision)
  • Making disciplinary decisions
Product Regulation – Federal Authority

Food and Drugs Act

defines

Cosmetic, Device, Drug, Food

- Cosmetics Regulations
- Medical Devices Regulations
- NHP Regulations
- Food & Drug Regulations
  Part B – Foods
  Part C – Drugs
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
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
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
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.
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)
Is there a common feature among all? Is the common feature that is more global?

**Exercise:** TMs Use Claims in Non-Trad. Traditional and Complementary Medicines - currencies of health.
• Regulations, Amendments, Monographs, Guidance Documents, Forms and Tools are on the Health Canada web site at www.healthcanada.gc.ca/nhp


• All information is available in English and French
Thank you to PAHO/WHO for the opportunity...