Modernizing the *Food and Drugs Act* to Accommodate a Product Lifecycle Approach

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Presentation Objectives

- Overview of the Product Lifecycle Approach
- Current Regulatory System in Canada
- Proposed Modernization of the *Food and Drugs Act*
- Proposed Modernization to the Regulation of Therapeutic Products
- Drug Safety and Effectiveness Network
Product Lifecycle – Project Objectives

To develop a modern regulatory framework that supports:

- Access to new therapies;
- The continuous monitoring, assessment, and communication of product information (benefits and risks) throughout the product lifecycle; and
- The optimal use of therapeutic products to maximize benefits and minimize risks.

The primary objectives of the framework itself are:

- To protect the public from the marketing of unsafe health products; and
- To support the safest use of health products.
Supporting objectives:

- Align the product lifecycle with the system of health care in Canada to achieve positive health outcomes;
- Ensure that the new regulatory structure enables Health Canada to implement best international regulatory practices and maintain appropriate oversight without unduly increasing regulatory burden;
- Encourage and make best use of evolutions in the science of therapeutic product development and regulation; and
- Increase legislative support for inspection capabilities and border surveillance.
Regulating Therapeutic Products in Canada – The *Food and Drugs Act*

- Main legislative instrument is the *Food and Drugs Act*
- Includes food, drugs, devices, cosmetics
  - Food and Drug Regulations (includes clinical trial regulations)
  - Medical Device Regulations
  - Natural Health Product Regulations
  - Safety of Cells, Tissues, and Organs for Transplantation Regulations
- Under the current Act “drug” encompasses
  - Pharmaceuticals
  - Biologics
  - Radiopharmaceuticals
  - Natural health products
  - Cells, tissues, organs
  - Blood and blood components
Regulating Therapeutic Products in Canada – The Current System
Federal and provincial/territorial responsibilities and challenges

- The assessment of therapeutic products for market approval is done at the federal level.
- Provinces and territories are responsible for delivering health care services, including reimbursement plans.
- The *Food and Drugs Act* was created long before there was universal health care in Canada; the systems were not designed to “work together”.
- Some provinces have moved ahead with their own “orphan drug policies”.
Drivers for change

- Modernization efforts in other regulatory jurisdictions
- Increased scrutiny of regulatory activities, openness and transparency
- Pattern of disease and product use have changed – Canadians are living longer with chronic conditions, including children
- Highly educated patient and consumer groups who want to be informed and involved; demands for access to new therapies
- Health care practice has evolved – patient/professional partnerships, “new” professional groups
- Our role as a regulator has changed – more than just a “gatekeeper”, also an information provider
Recent Events

• The Food and Consumer Safety Action Plan was announced in December 2007 by Prime Minister Harper
• In April 2008, Bill C-51 (*An Act to amend the Food and Drugs Act*) was tabled
  • Proposed amendments to the *Food and Drugs Act* would modernize our regulation of health products and food; provide new tools that more quickly and effectively protect Canadians; and, provide better information that empowers Canadians to play a more active role in their own health and safety
• As a result of the election call, Bill C-51 expired on the orders paper
Legislative Proposals: Authorizations and Licences

Market Authorizations

- A market authorization would be required to sell, advertise or import a therapeutic product.
- Market authorizations would be issued on the basis of a favourable benefit-risk profile, and could be subject to specific terms and conditions.
- Market authorizations could be amended, suspended or revoked.
- Market authorization holders could be required to conduct a reassessment of the therapeutic product to which the authorization relates.
- Holders could be required to compile information, conduct studies and monitor experience in relation to therapeutic products and to report information, the results of tests or studies, and monitoring to Health Canada.
Legislative Proposals: Post-Market Authorities

- Power to require information
- Power to require tests or studies, etc.
- Power to require information after discontinuance or revocation of clinical trials
- Power to require labels to be revised
- Power to require reassessment
- Power to disclose risk information
Legislative Proposals: General Provisions

- Consultations - Minister may establish committees and remunerate committee members
- Information –
  - Required information - serious risk
  - Required Information - Health Care Institutions
  - Register
- Personal Information
Benefits of a Lifecycle Approach for Patients

• A lifecycle approach will enable us to better serve patients, consumers and health care professionals by supporting them in making informed decisions based on the best possible information available
• It will support us in early identification of risks, and in implementing successful risk management activities
• There will be more opportunities for professionals, patients and consumers to be involved in decision-making regarding therapeutic products
• Will be able to address a wide range of needs, including those of patients with rare diseases.
Lifecycle Approach Model

Drug Safety and Effectiveness Network

Integration of new information

Clincial Trial Review
- clinical trial applications
- registration of clinical trials
- GCP ADR Reporting

DSEN
Drug Safety and Effectiveness Network

Drug Submission
- CUG
- benefit-risk assessment
- basic scientific information
- results of clinical studies
- product information: label, product monograph, package leaflet
- risk management plan including pharmacovigilance plan

License
- type of authorization
- obligations on MAH
  - reporting
  - post-market studies
  - risk mitigation measures

Ongoing Reporting
- submissions
- for new indications
- ADR reporting including PSURs
- post-market studies / trials
- risk reviews if necessary

Re-evaluation
- opportunity to re-evaluate benefit-risk profile when necessary
- safety
- efficacy
- utilization
- use in special populations

Removal of product

Monitoring

Pharmacovigilance and Risk Management