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

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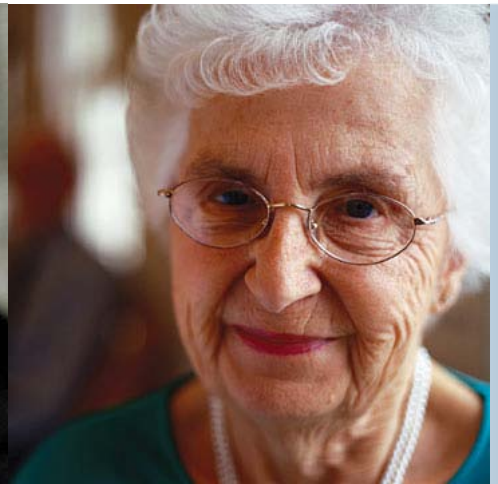
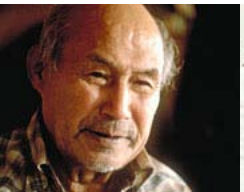


Canada

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



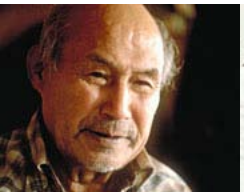

Product Lifecycle – Project Objectives

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.

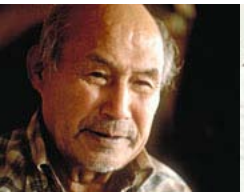
The primary objectives of the framework itself are:

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



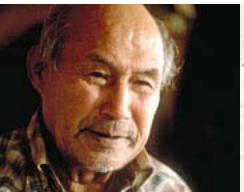

Supporting objectives:

- 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.



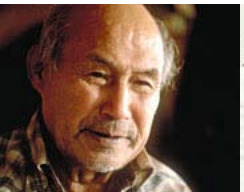

Regulating Therapeutic Products in Canada – The *Food and Drugs Act*

- 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

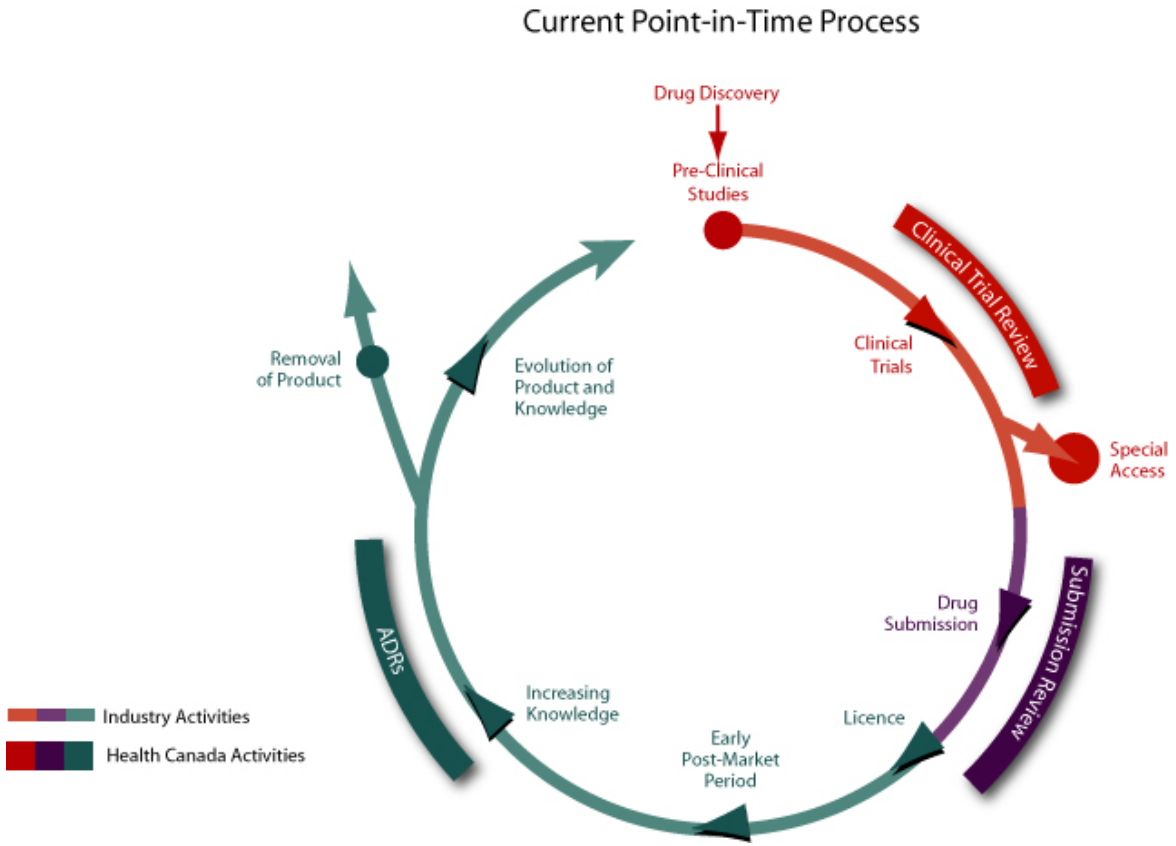


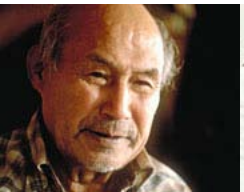

Regulating Therapeutic Products in Canada – The *Food and Drugs Act* and *Regulations*

- Last major revisions made in 1960's in response to the discovery of birth defects associated with the use of thalidomide
- Focus is almost entirely on the pre-market evaluation of the safety, efficacy, and quality of drugs – requirements to conduct clinical trials and for drug submissions
- Post-market requirements are minimal, such as requirements for market authorization holders to report adverse drug reactions
- Other post-market provisions are linked to "stop sale" or product withdrawal
- Few abilities with respect to the post-marketing period



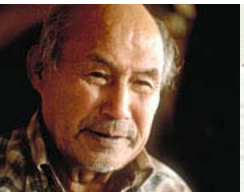

Regulating Therapeutic Products in Canada – The Current System





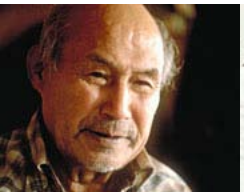

Federal and provincial/territorial responsibilities and challenges

- 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

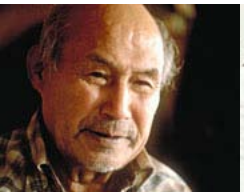
- The Food and Consumer Safety Action Plan was announced in December 2007 by Prime Minister Harper
- In April 2008, *An Act to amend the Food and Drugs Act (Bill C-51)* was tabled
  - Proposed amendments to the *Food and Drugs Act* would modernize our regulation of health products and food; provide new 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 in the Fall of 2009, Bill C-51 expired on the orders paper

Legislative Proposals: General Prohibitions

- False or misleading information
- Tampering
- Hoaxes
- Counterfeiting of therapeutic products

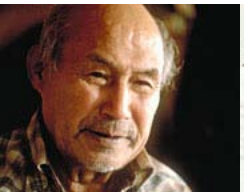
Legislative Proposals: Prohibitions for Therapeutic Products

- Adulterated products
- Unsanitary conditions
- No clinical trial without authorization
- No clinical trial contrary to regulations
- Selling, advertising and importing
- Conducting controlled activity
- Deception, etc.
- Counterfeiting
- Prescription therapeutic products
- Samples – drugs




Legislative Proposals: Improving Inspection Powers

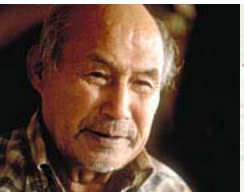
- Recall Authority
  - The Bill would introduce an authority to recall unsafe health products, to correct the Government's current reliance on voluntary recall of therapeutic products and cosmetics by industry;
- Prohibition on Counterfeit and Tampering
  - Tampering can lead to serious harms or fatalities, and recent years have seen a rise in counterfeit prescription medicines, in some cases leading to the death of Canadians;
- Modern and Effective Fines and Penalties
  - We need to strengthen fines and penalties, correcting outdated and irrelevant fine levels; and
- Manufacturing and Imports
  - Stronger controls are needed for manufacturing and imports, particularly for food (e.g., allowing to proactively identify importers)




Legislative Proposals: Authorizations and Licences

Market Authorizations

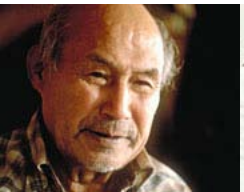
- A market authorization would be required to sell, advertise or import a therapeutic product.
- Market authorizations would be issued on the basis of a favourable benefit-risk profile, and could be subject to specific terms and conditions.
- Market authorizations could be amended, suspended or revoked.
- 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: Authorizations and Licences

Establishment licenses

- An establishment licence would be required to manufacture, package, label, store, wholesale or import for sale a therapeutic product.
- It would be prohibited to sell a therapeutic product that was manufactured, packaged, labelled, stored, wholesaled or imported for sale in an unsanitary or unsafe manner.
- Establishment licences could be amended, suspended or revoked.
- Terms and conditions could be imposed on such licences.
- Specific information regarding establishments would be included in a registry.

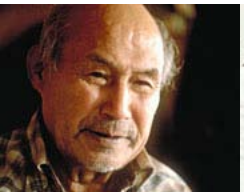



Legislative Proposals: Post-Market Authorities

- 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

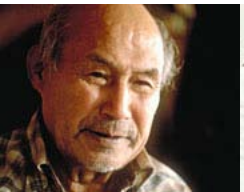
Legislative Proposals: General Provisions

- Consultations - Minister may establish committees and remunerate committee members
- Information –
  - Required information – serious risk
  - Required Information – Health Care Institutions
  - Register
- Personal Information




Legislative Proposals: Regulation-Making Authorities

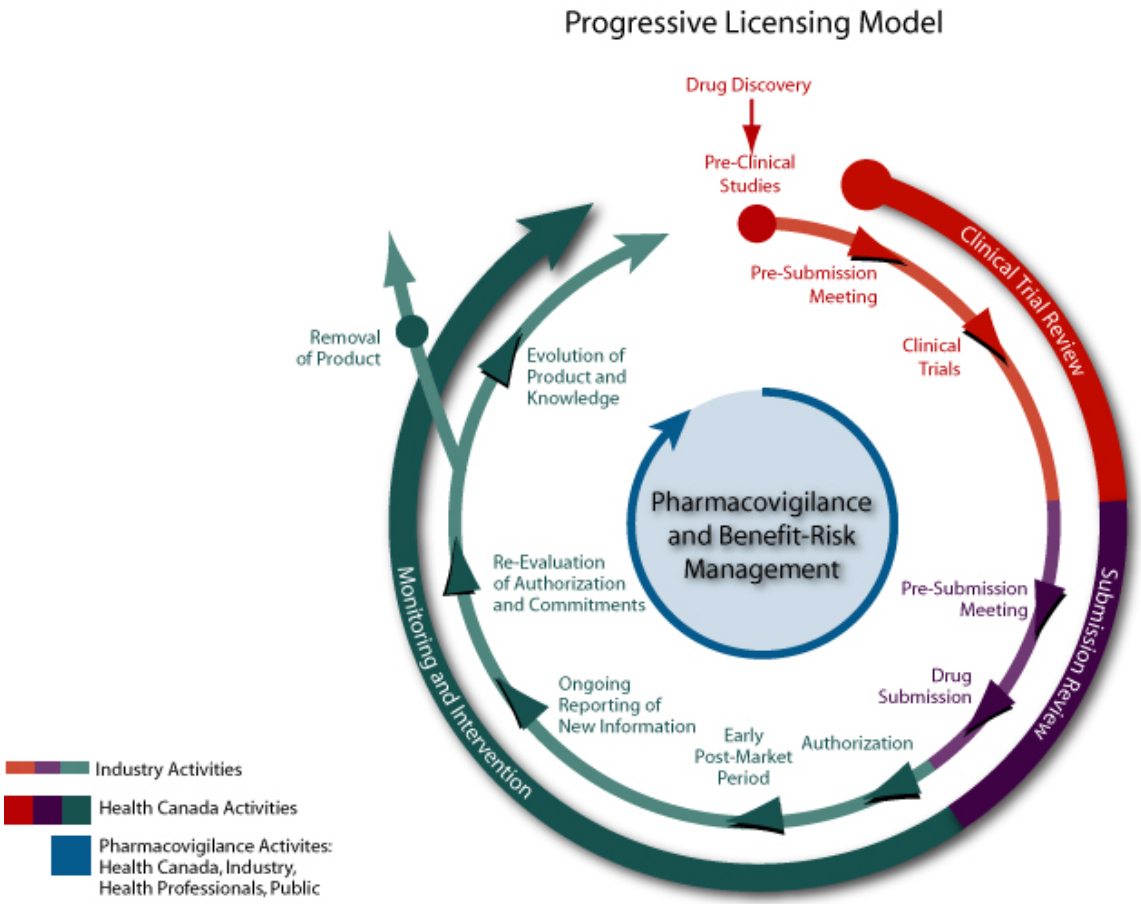
- defining controlled activities in regulations
- designated therapeutic products
- specifying false, misleading, deceptive
- terms and conditions
- establishing classes of authorizations
- respecting applications
- being bound to scientific and regulatory advice
- Minister’s powers




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.

Progressive Licensing – The Future



Product Lifecycle – The Future

Anticipated changes in a new regulatory framework:

- Lifecycle approach becomes explicit
- Formal incorporation of benefit-risk assessment in addition to safety, efficacy, quality
- Ability to authorize with with post-market commitments
- Increased emphasis on product information (labels, product monographs, package leaflet)

Regulatory Development – Chemistry & Manufacturing

- Incorporate principles of ICH Q7,Q8, Q9 and Q10
- Provide for different types of amendments defined by the level of risk associated with the change
- Provide an updated definition of “pharmaceutical equivalent” that can be applied to different types of drugs (pharmaceuticals, biologics)
- Allow for the use of recognized standards and monographs

Drug Safety and Effectiveness Network

- January 2009, federal funding for the Drug Safety and Effectiveness Network (DSEN) announced
  - total investment of $32 million over five years and $10 million per year ongoing
- DSEN will link centres of excellence in post-market pharmaceutical research across Canada, to:
  - increase knowledge about the post-market safety and effectiveness of drugs to support decision making throughout the health care system
  - increase capacity within Canada to undertake research in this area
- DSEN will provide an important source of additional evidence to Health Canada for use in the ongoing risk-benefit assessment of drug products throughout their lifecycle.

Lifecycle Approach Model