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

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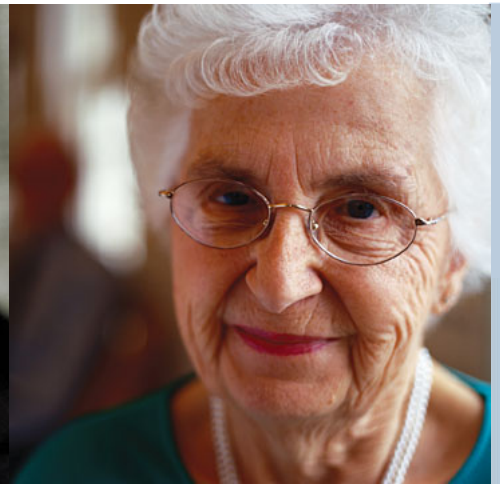


Presentation Objectives

- Overview
- Describe the current regulatory system in Canada
- Describe some of the drivers for change, including international developments
- Proposed modernization of the *Food and Drugs Act*
- Challenges and opportunities for Canada and its fellow regulators

Guiding Objectives of the Product Lifecycle Approach

The primary objectives of the framework itself are:

- To protect the public from the marketing of unsafe drugs; and,
- To support the safest use of drugs.

Three supporting objectives:

- Align the Progressive Licensing Framework 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; and,
- Encourage and make best use of evolutions in the science of drug development and regulation.

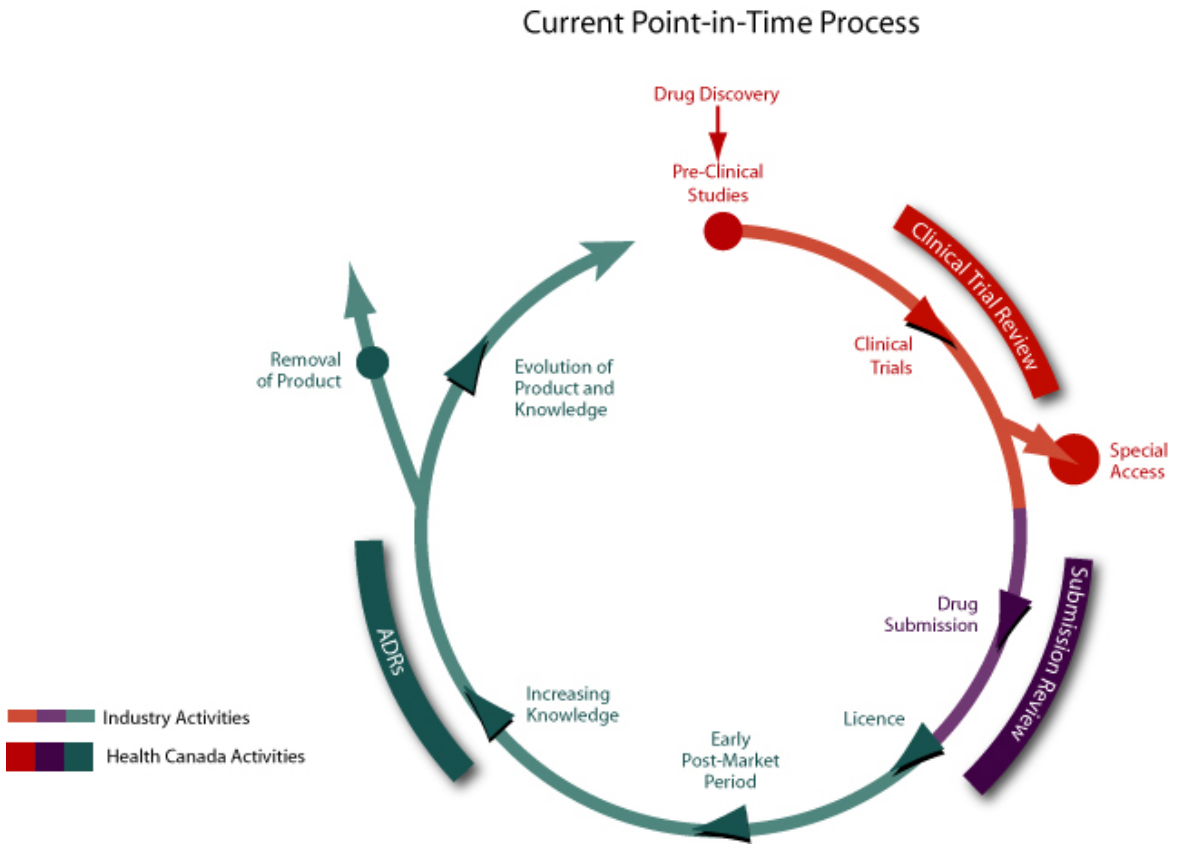
Regulating Drugs in Canada – The *Food and Drugs Act*

- Main legislative instrument is the *Food and Drugs Act*
- Includes food, drugs, devices, cosmetics
- “Drugs” encompasses
  - Pharmaceuticals
  - Biologics
  - Radiopharmaceuticals
  - Natural health products
  - Cells, tissues, organs, blood

Regulating Drugs 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

Regulating Drugs in Canada – the current system



Canada's Unique Situation - Drivers for Change

- Complex health care system with different federal and provincial/territorial roles
- Outdated legislation and regulation
- Modernization efforts in other regulatory jurisdictions
- Impact of International Conference of Harmonization (ICH), where Canada has observer status
- Increased scrutiny of regulatory activities – expectations have gone beyond prevention of birth defects (thalidomide)

Canada's Unique Situation - Drivers for Change

- Expectations for timely decisions, comparable with other agencies
- Increased expectations for openness and transparency
- Highly educated patient and consumer groups who want to be involved in decision-making
- Pattern of disease and drug use have changed – more Canadians living with chronic diseases, longer-term use of drugs
- As a regulator we have adopted best practices, but have not yet incorporated these into a formal regulatory structure

Product Lifecycle – Why Now?

Unique Time

- High-profile drug withdrawals
- Increasing importance of biologically-derived products
- Drug development is evolving from the traditional phase 0-IV approach
- Rapid evolution in fields of pharmacovigilance and pharmacoepidemiology
- Appetite for change is high

International Developments

European Union

- New pharmaceutical legislation introduced in 2004
- Directive 2001/83/EC, Regulation 726/2004, Regulation 507/2006
- Market authorization based on positive benefit-risk balance
- Ability to issue conditional market authorizations
- Requirements for risk management systems
- Person qualified in pharmacovigilance

International Developments

United States

- Food, Drugs and Cosmetics Act
- Institute of Medicine Report on Drug Safety released 2006
- “PDUFA IV/FDAAA” recently passed (September 2007)
  - Enhanced authorities regarding postmarket safety of drugs
  - Ability of Secretary to require postmarket studies and clinical trials
  - Ability of Secretary to require labelling changes
  - Ability of Secretary to require Risk Evaluation and Mitigation Strategy

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

Approach to the *Food and Drugs Act*

- The Progressive Licensing Framework was developed as a strategy for the modernization of the existing framework for the regulation of drugs (pharmaceuticals and biologics), the bulk of which is set out in the *Food and Drug Regulations*.

- Modernization of the *Food and Drugs Act* is required to support revisions to the *Food and Drugs Regulations* that will be required to implement a lifecycle approach to regulating products.

- All sections of *Food and Drugs Act* were examined to determine the scope of changes needed to introduce a structure to support a Product Lifecycle.

Prohibitions - General

- False or misleading information
- Tampering
- Hoaxes

Prohibitions – 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

Authorizations and Licences

Purpose

- Provide a mechanism through which Health Canada can regulate a range of therapeutic products with the ability to tailor the appropriate amount of continued regulatory oversight to the nature and risk of the product

Common structure:

- Issuance
- Amendments
- Suspension
- Revocation

Authorizations and Licences

Clinical Trial Authorizations

- A clinical trial authorization would be required for the investigational use of therapeutic products that has not been marketed in Canada.
- Clinical trial authorizations could be amended, suspended or revoked for therapeutic products.
- Terms and conditions could be imposed on such authorizations.
- Holders or former holders of clinical trial authorizations would be required to continue to report information about a therapeutic product to Health Canada following the discontinuance or cancellation of a clinical trial.

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.

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.

Powers of the Minister

- 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

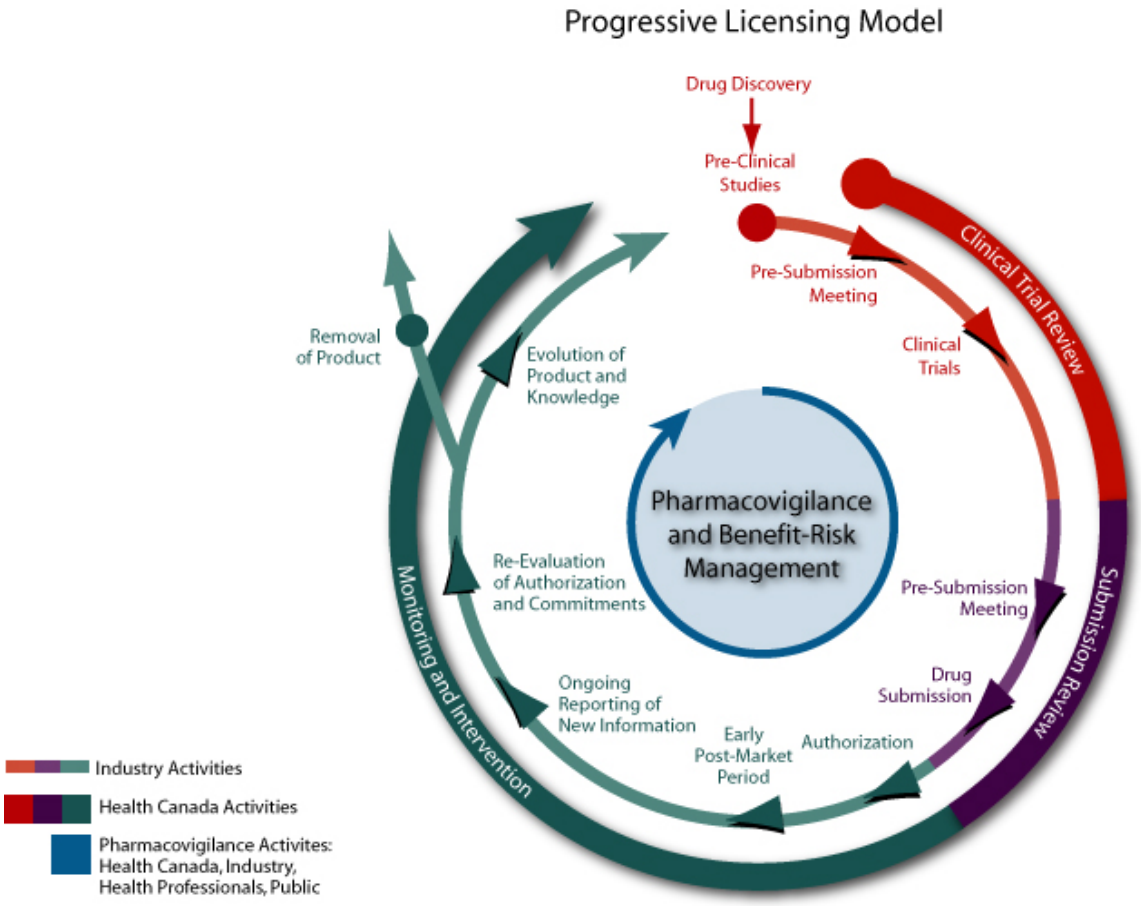
General Provisions

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

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

Progressive Licensing – The Future



Product Lifecycle – The Future

Anticipated changes in a new regulatory framework:

- Life-cycle 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)

Product Lifecycle – The Future

Anticipated changes in a new regulatory framework:

- Enhanced post-market authorities and activities
  - Pharmacovigilance
  - Risk management
  - Risk communications
- Ability to do a formal re-assessment
- Increased emphasis on evaluation of activities and evaluation of the regulatory framework

Challenges and Opportunities

Challenge: Data Collection over the life-cycle

- Drug development is a global enterprise
- Regulators need data relevant to their populations
- Post-market data especially important for chronic use drugs
- Special populations – children, elderly, pregnant, rare diseases
- Real-world use – concomitant drug use, co-morbidity
- Early interaction with the regulator is critical - planning
- Work with involved stakeholders, such as highly-motivated patient groups

Challenges and Opportunities

Challenge: Evaluation

- Of a new framework as well as the drugs themselves
- Identify our goals and objectives
  - These may be simple!
  - May be different for pre- and post-market activities
- Roles and responsibilities
- Learn from professionals and patients - what metrics we should use?
- Learn from other regulators
- Planning for evaluation

Challenges and Opportunities

Challenge: Communication

- How regulators make decisions
  - Summary Basis of Decision
  - Policy on Public Input
- Two-way communication is critical : **Knowledge Exchange**
- “Balanced” information about drugs
  - Benefits as well as risks
  - To health care professionals
  - To patients
- Objectives and evaluation of communication tools

Please visit our website at:

www.healthcanada.gc.ca/progressive_licensing

Progressive Licensing Model