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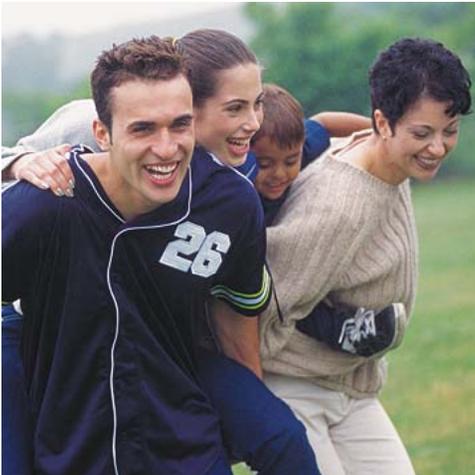
Modernizing the *Food and Drugs Act* to Accommodate a Product Lifecycle Approach

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Canada 

Presentation Objectives

- Overview of the Product Life-cycle Approach
- Describe the current regulatory system in Canada
- Proposed modernization of the *Food and Drugs Act*
- Challenges and opportunities for Canada and its fellow regulators
- Drug Safety and Effectiveness Network



Product Lifecycle Approach – Project Objective

To develop a modern drug regulatory framework that supports:

- Access to new drugs;
- The continuous monitoring, assessment, and communication of drug information (benefits and risks) throughout the product life-cycle; and,
- Optimal use of drugs to maximize benefits and minimize risks.



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.



Evidence-Based

- The intention of the framework is to support **evidence-based** decision-making.
- There has been a generally accepted scientific standard of evidence for clinical efficacy and safety traditionally used by regulators worldwide to provide the scientific basis in the assessment of benefits and risks for drug products considered for market authorization.
- Proposal is that the new standard would continue to require safety and efficacy data, but would incorporate other kinds of evidence as well for a full benefit-risk assessment.
- The new standard would remain evidence-based while providing flexibility to accommodate decision makers' overall considerations about the acceptability of drugs for the marketplace and their use.
- Such a shift would serve to clarify the actual basis of decision making, so long as the principles and methods are clearly stated and widely available.

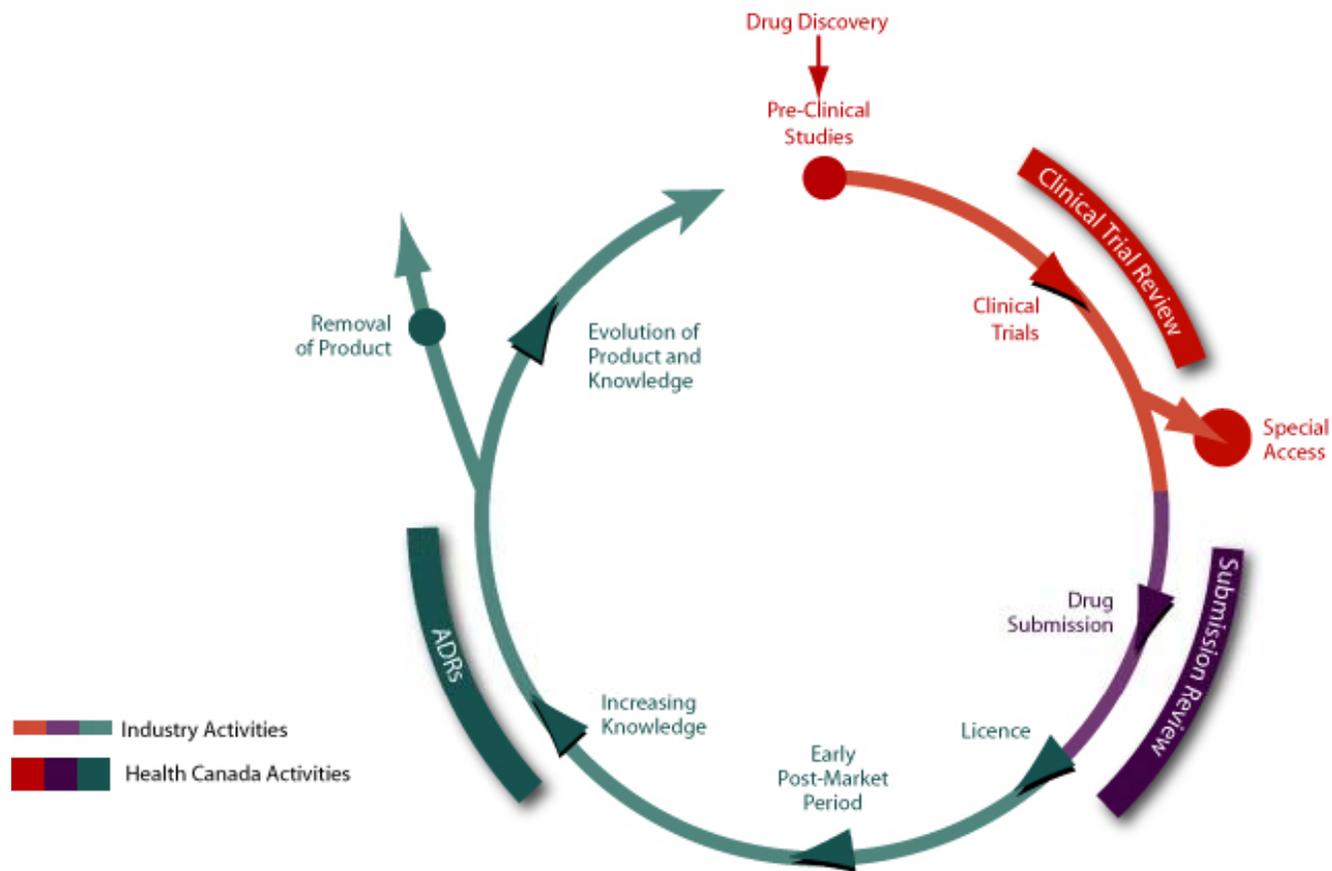


Life-Cycle

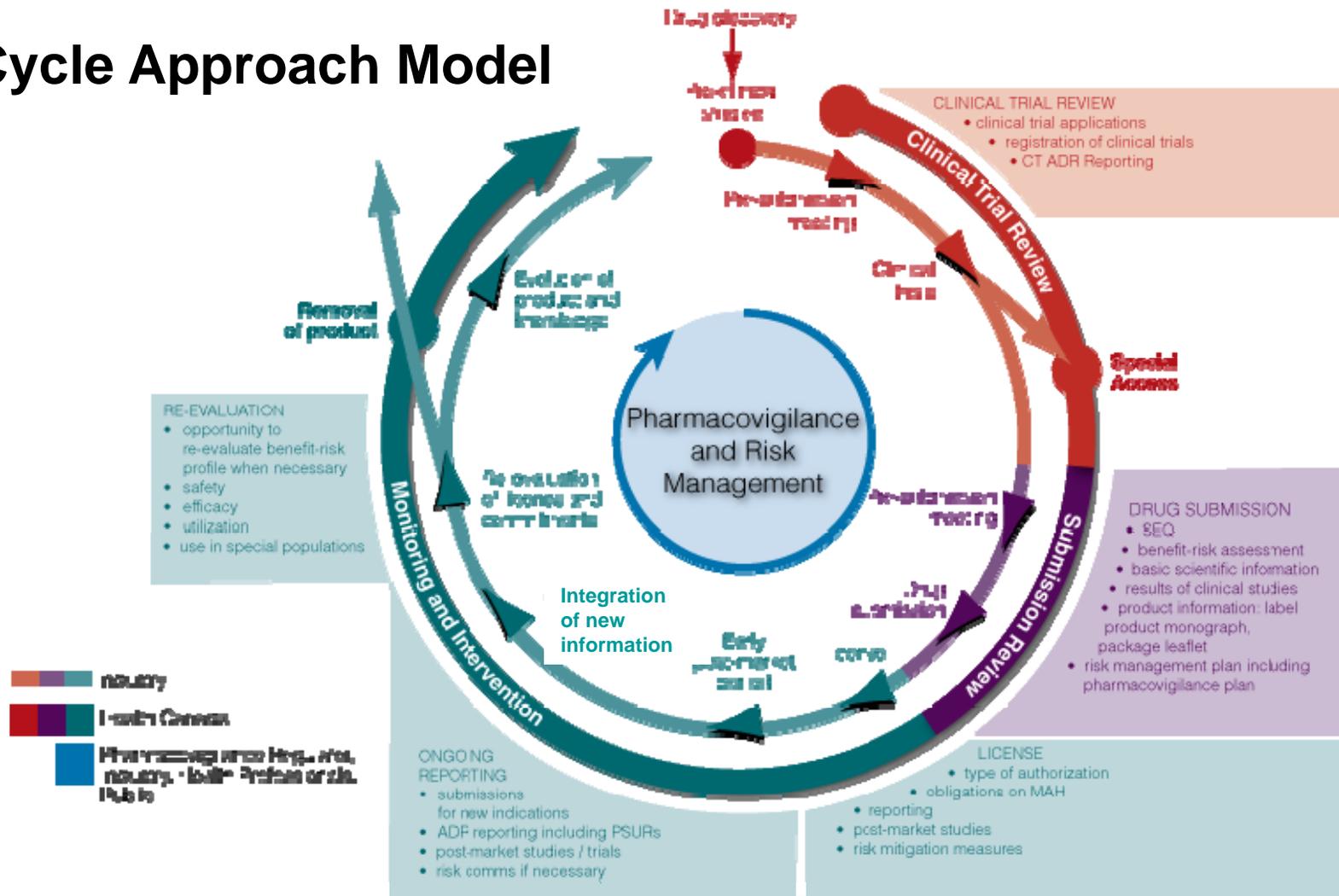
- The central concept of Progressive Licensing is that over time there is a progression in knowledge about a drug.
- The emphasis of the new framework is to identify opportunities within this progression over the full life-cycle of a drug, rather than placing the regulatory focus primarily upon pre-market assessment.
- This represents a fundamental shift from the idea that the pre-market testing of a drug assures its safety and efficacy.
- The new proposed model is that a drug should be evaluated throughout its life-cycle for its benefit-risk profile.



Regulating Drugs in Canada – The Current System



Life-Cycle Approach Model



- Industry
- Industry Canada
- Pharmacovigilance Reg. and Safety System (Public)



Food and Consumer Safety Action Plan

December 2007, Prime Minister Harper announced Canada's Food and Consumer Safety Action Plan

- An integrated strategy to enhance the safety system for food, health and consumer products
- Recognizes that safety is a shared responsibility involving industry, consumers and government
- Legislative modernization is a key component of the plan
- Budget 2008: funding of \$458.5M over five years, \$117M ongoing



Bill C-51 - *An Act to amend the Food and Drugs Act*

- April 8th 2008, Bill C-51 was introduced in the House of Commons
- Proposed amendments to the *Food and Drugs Act* would support new regulations for health products and food, including:
 - Authorization structures with terms and conditions
 - Enhanced post-market surveillance requirements
 - Modern enforcement and compliance powers
- Bill C-51 expired on the order paper with the dissolution of Parliament in fall 2008
- Intent is to reintroduce proposed legislation as reasons for modernization are still valid



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



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

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.
- Type and amount of information required to establish a favourable benefit-risk profile depends on the nature of the product and its intended use
- Safety, efficacy and quality data will remain the foundation for assessment for prescription drugs and some classes of non-prescription products.



Authorizations and Licenses

Market Authorizations (cont'd)

- **In some restricted cases, surrogates may be used to successfully demonstrate a favourable benefit-risk profile**
- **For any authorization or license, 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.**
- **Market authorization holders could be required to conduct a reassessment of the therapeutic product to which the authorization relates.**



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



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



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.



Life-Cycle Approach Model

