Health Canada's Progressive Licensing Framework

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Progressive Licensing Framework (PLF)

- Part of the Blueprint for Renewal, the Progressive Licensing Framework was developed to establish a drug regulatory system for the future

- Focuses on pharmaceuticals and biologics, including prescription and non-prescription

- Four key elements
  - Life-cycle approach
  - Evidence-based decision making
  - Good Planning
  - Accountability

Health Canada's Approach to PLF

Design Goals

- Align with National Health system
- Align with International Requirements
  - Research what is being done in other jurisdictions
  - Look for best practices
- Science-based to encourage the evolution of science

Process

- Extensive consultation with stakeholders including Industry

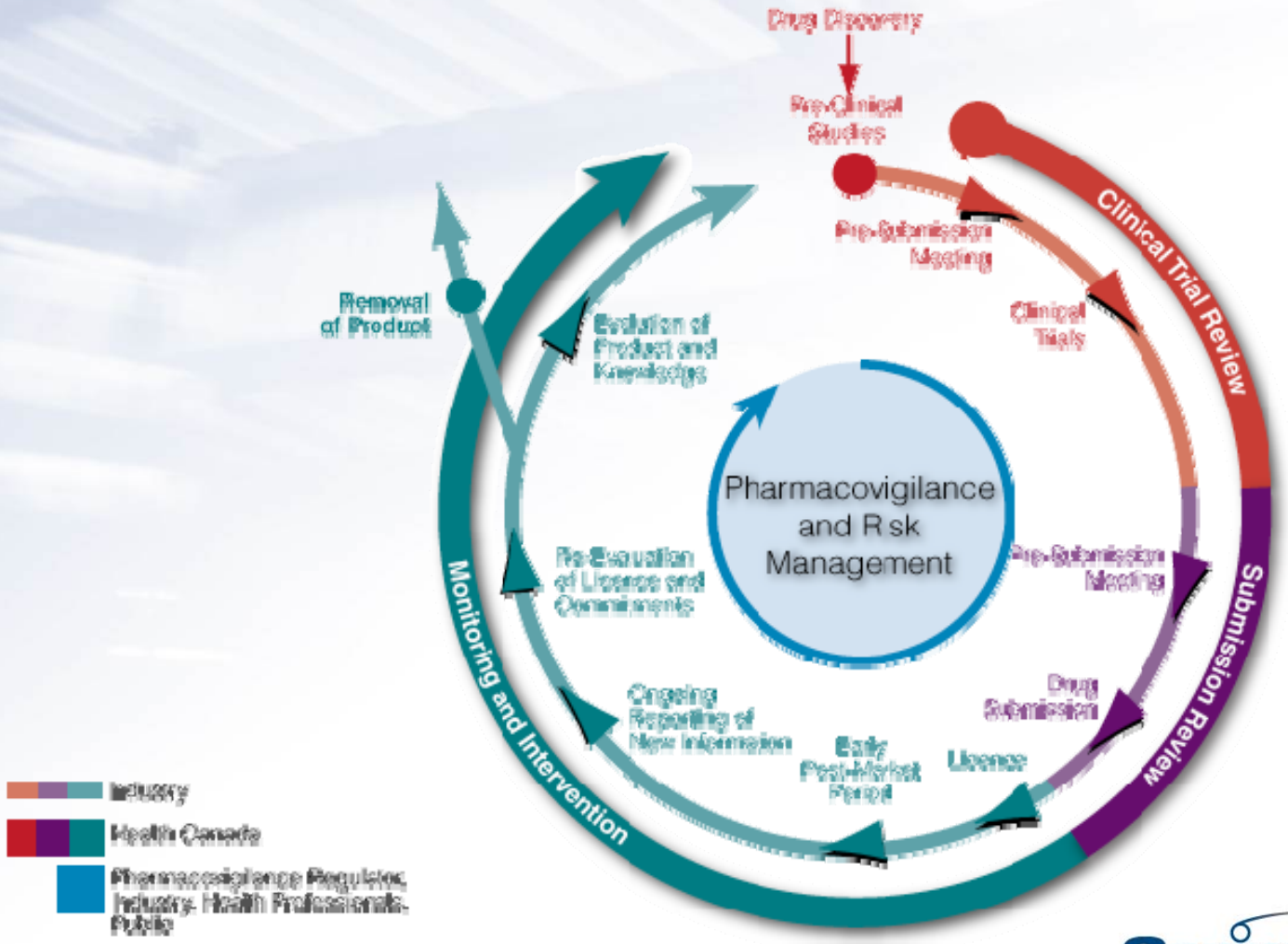
Result

- Development of a framework based on themes and concepts
  - Expected to be released for consultation once new government is in place

Progressive Licensing Framework

- The central concept is that, over time, there is a progression in knowledge about a product
- Allows for the benefits of a drug to be maximized and its risks minimized
- Fundamental shift will allow Health Canada to assess the safety, efficacy and quality of products before, during and after their introduction to the Canadian market, and therefore provide an increased body of knowledge, improving decision making and enhanced risk management

Progressive Licensing Model



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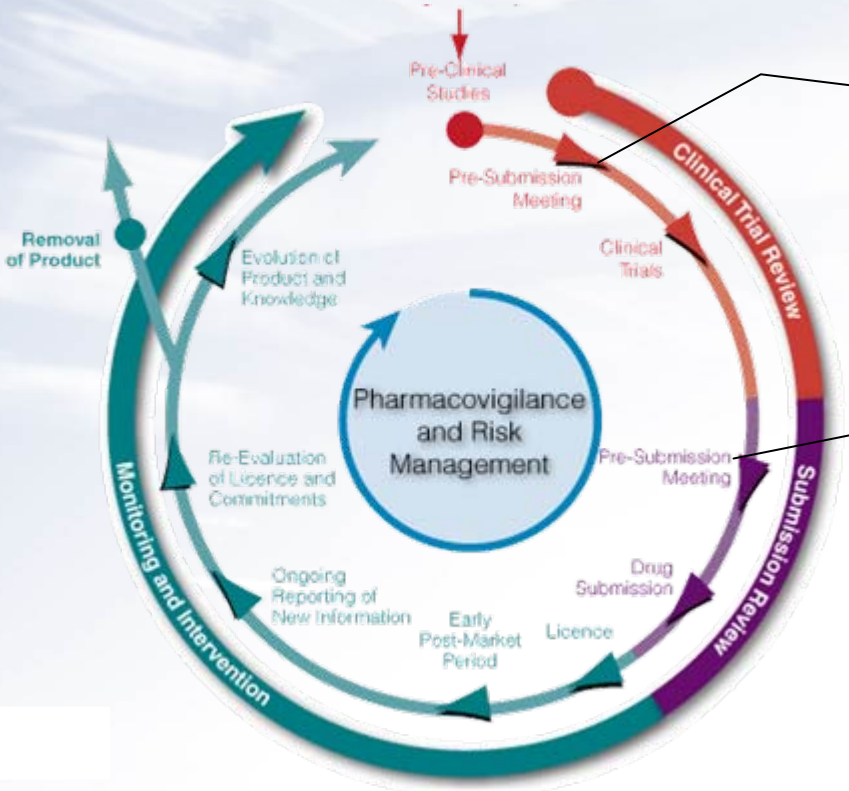
*Health Canada model: Used with permission

PLF Framework Components

- Scientific and Regulatory Advice Meetings
- Submission Requirements
- Authorization
- Post-Authorization
- Re-Evaluation

Scientific and Regulatory Advice Meetings



Pre-submission meetings

- Not required for every drug
- Could be relied upon subject to amendment only where the science underpinning the advice has demonstrably changed

Establishment of Committees for the purpose of seeking advice

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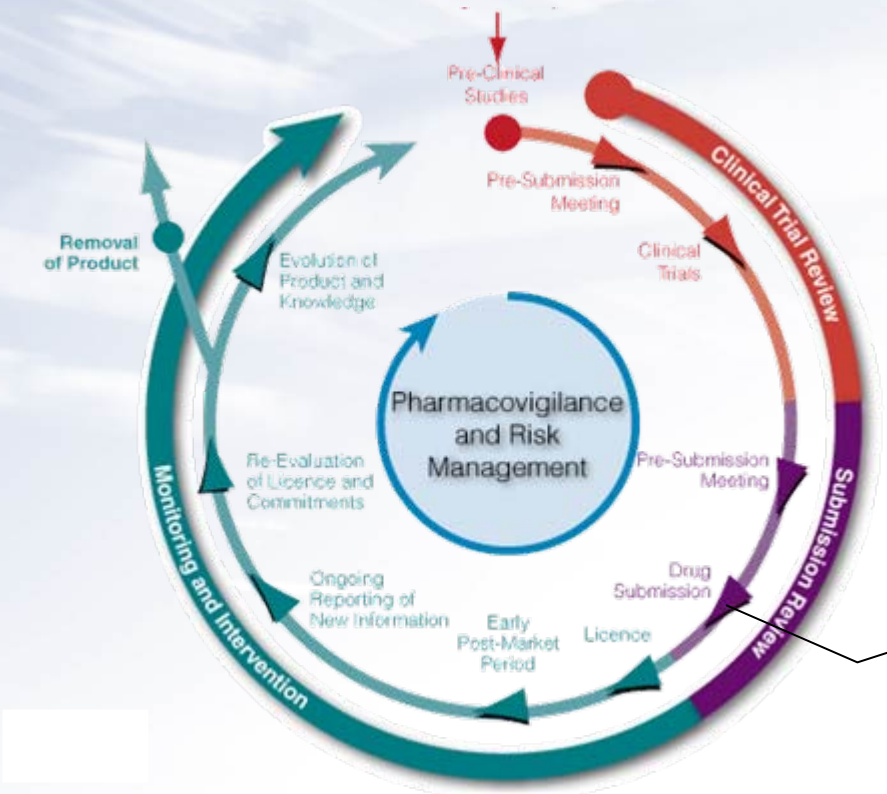
Submission Requirements



Drug Submission

- Safety, Efficacy, Quality
- Benefit-Risk Assessment
- Basic Science Information
- Results of Clinical Studies
- Product Information, Label, Product Monograph, Package Insert
- Risk Management Plan including pharmacovigilance plans
- Publicly register any clinical trials relied upon in drug submission

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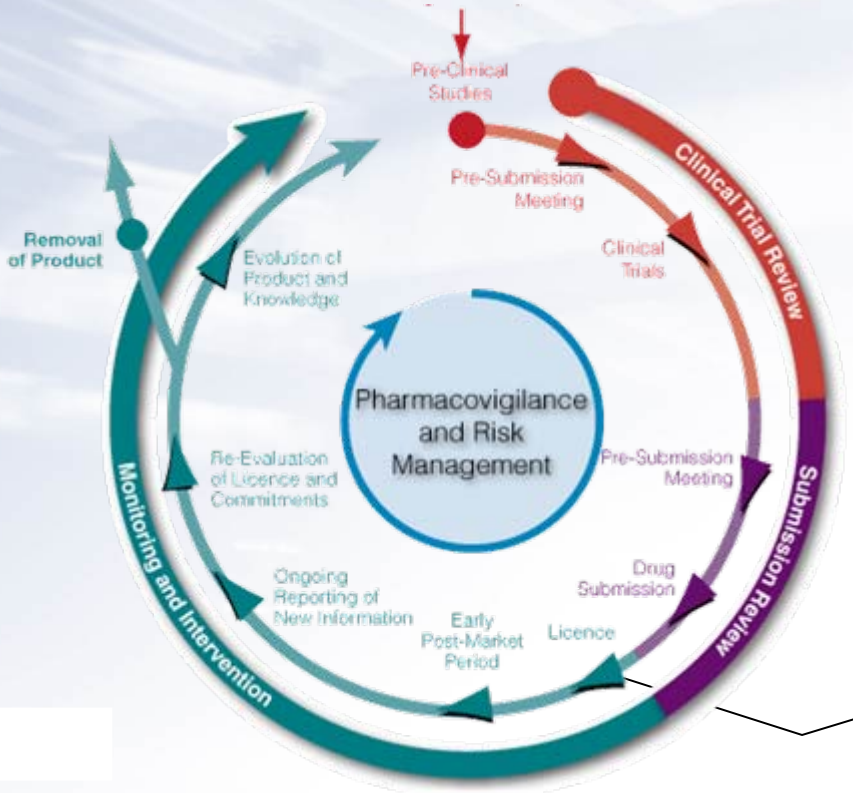
Authorization



Types of Authorizations
- Standard
- Provisional
  - Conditional, Exceptional Needs

Obligations of MAH
- Reporting, PSURs
- Post-market Studies
- Risk Mitigation Measures
- Obligations could be amended depending on the benefit-risk profile

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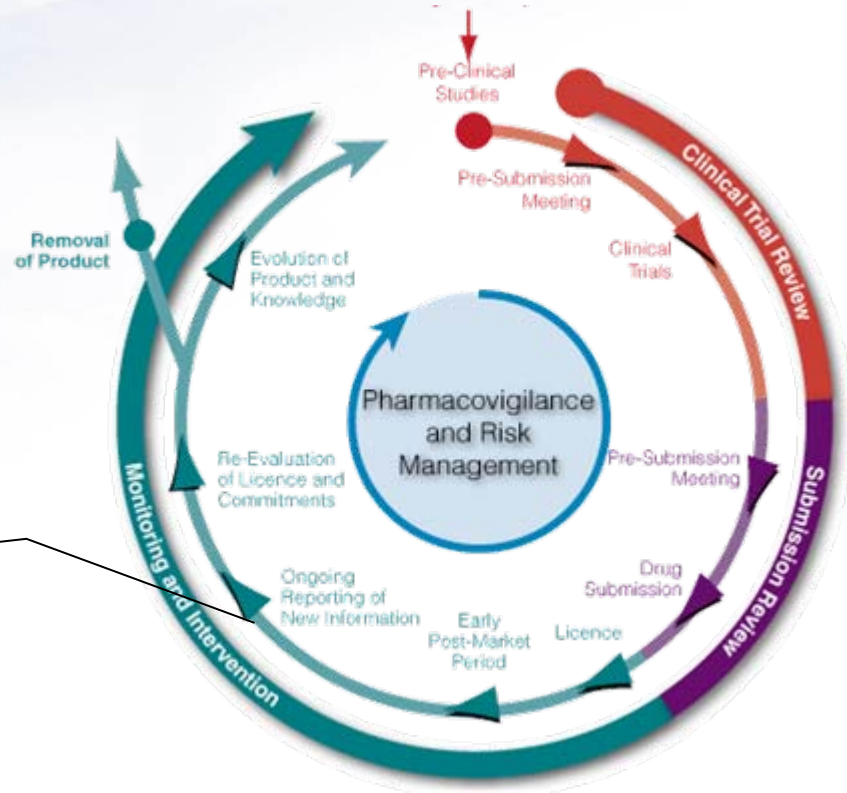
Post-Authorization

Ongoing Reporting
- Submissions for New Indications
- ADR Reporting including PSURs
- Post-market Studies and Trials
- Risk Communication, if necessary



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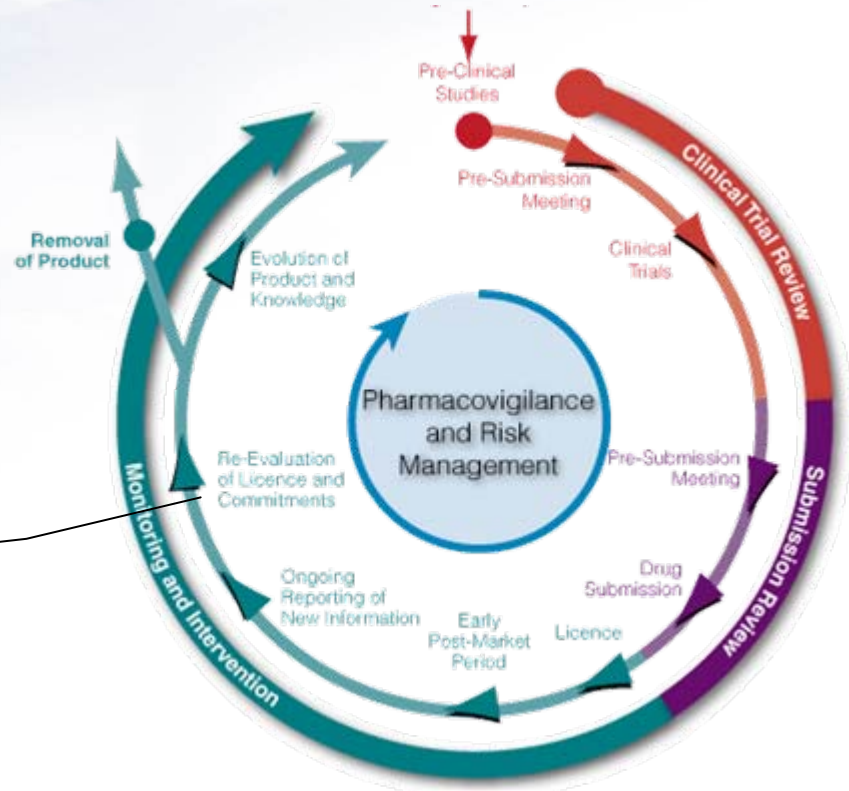
Re-Evaluation

Re-Evaluation
- Opportunity to re-evaluate benefit-risk profile when necessary
- Safety
- Efficacy
- Utilization
- Use in Special Populations



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How different is Health Canada's approach?

Regulatory Initiatives underway with EU

- Roadmap to 2010
  - Developed in 2005 to contribute to better protection and promotion of public and animal health, improve the regulatory environment for medicinal products, and help to stimulate innovation, research and development in the EU
- Five Objectives
  - Top Quality Scientific Assessment
    - Scientific advice: new procedure
    - Scientific Advisory Groups (SAGs)
    - Specific guidance for advanced therapies
    - Incentives for Small and Medium size enterprises
  - Timely Access to Safe and Effective Innovative Medicines
    - Conditional MA, Exceptional Circumstances, Accelerated Evaluation, Compassionate Use

Regulatory Initiatives underway with EU

- Objectives cont.
  - Ensure the Safety of Medicinal Products
    - EMEA Risk Management Strategy
    - Continuous monitoring of medicinal products
  - Increase Transparency and Communication
    - New EU legislation on access to documents
    - EPARs available on website
    - Europharm, Eudravigilance will be key channels
  - Information
    - Tailored to patients, health care professionals, stakeholders

Regulatory Initiatives underway in FDA

- Critical Path to New Medicines
  - Initiated by FDA in 2004 as a nationwide effort to move medical product development and patient care into the 21st century
- Six Priorities
  - Better Evaluation Tools
    - Developing new biomarkers and disease models
    - Safety biomarkers, Personalized medicine, Surrogate endpoints
  - Streamlining Clinical Trials
    - Advancing innovative clinical trial design
      - Adaptive Clinical Trials, Exploratory INDs, Non-inferiority trials
    - Improving measurement of patient responses
    - Streamlining and automating clinical trials

Regulatory Initiatives underway in FDA

- Six Priorities cont.
  - Harnessing Bioinformatics
    - Model-based drug development
    - Facilitate the exchange of regulatory product information using an electronic information supply chain
  - Moving Manufacturing into the 21st Century
    - Quality by Design (for example)
  - Developing innovative approaches to addressing urgent public health needs
    - Rapid Pathogen Identification
    - Better Predicative Disease Models
  - At-Risk Populations - Pediatrics

Scientific and Regulatory Advice Meetings

Health Canada	US FDA	Europe
Establish committees for the purpose of seeking advice	Similar	Similar
Not included	Specific guidance development for advanced therapies	Specific guidance development for advanced therapies
Pre-submission Meetings		
Not required for every drug	Similar – multiple meetings per product and various types	Similar
Binding agreements unless the science underpinning the advice has demonstrably changed	Similar	Similar

Submission Requirements

Health Canada	US FDA	Europe
Information necessary to establish a favourable benefit-risk profile	Similar	Similar
Risk Management Plans, including pharmacovigilance plans	Not required for every drug	Required for every drug
Publicly register any clinical trial relied upon in a drug submission	Available at www.clinicaltrials.gov	Available at www.ifpma.org

Authorization

Health Canada	US FDA	Europe
Provisional License (NOC/c equivalent) Exceptional Needs	Accelerated Approval Approval with Restrictions Animal Rule	Conditional Approval Exceptional Circumstances
Standard License Safety, Efficacy and Quality plus 2nd tier of evidence showing clinical benefit	Safety, Efficacy, Quality	Safety, Efficacy, Quality
Not included	Orphan Drug Designation	Orphan Drug Designation

Post-Authorization

Health Canada	US FDA	Europe
Obligations for filing of PSURs, active surveillance, post-market studies would be assigned within the authorization	PSURs required RiskMAPS	PSURs required RPMS
Authority to require MAH to issue risk communications and revise labels due to safety issues	FDA posts risk alerts/ communications on website Request MAH to issue risk communications	Similar

Re-Evaluation

Health Canada	US FDA	Europe
Not for all drugs only where necessary based upon risk or nature of drug	No re-evaluation requirement	All products have a 5 year re-evaluation requirement
Use in Special Populations	Pediatrics	Pediatrics

Conclusions

- Progressive Licensing Framework will serve to modernize Health Canada's regulatory system
- Many components will utilize similar regulatory tools as both USA and Europe
- True Canadian specific elements will only come to light when the framework is published

Questions

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