Progressive Licensing Project

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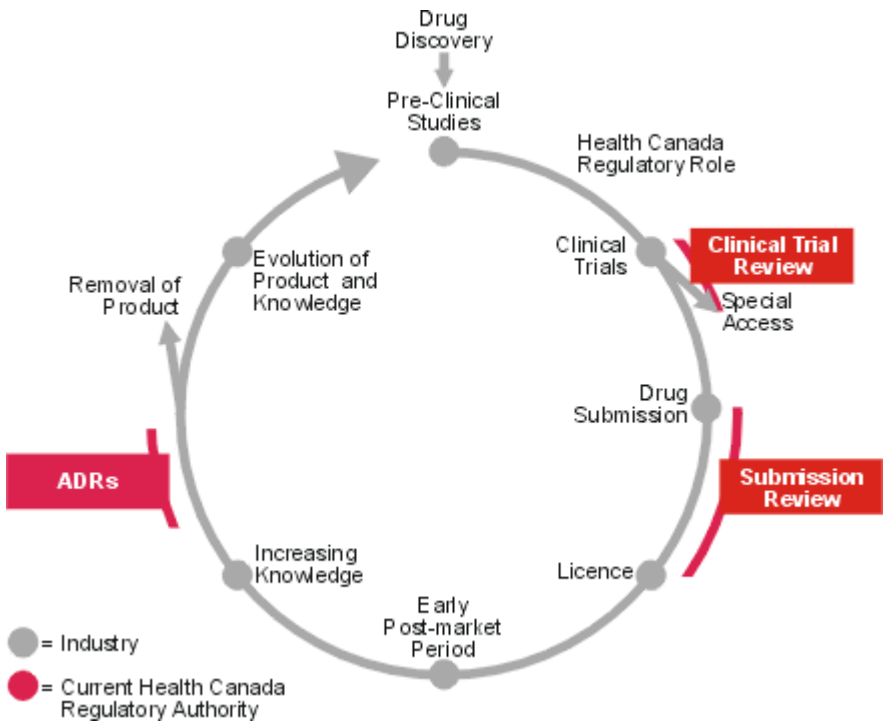
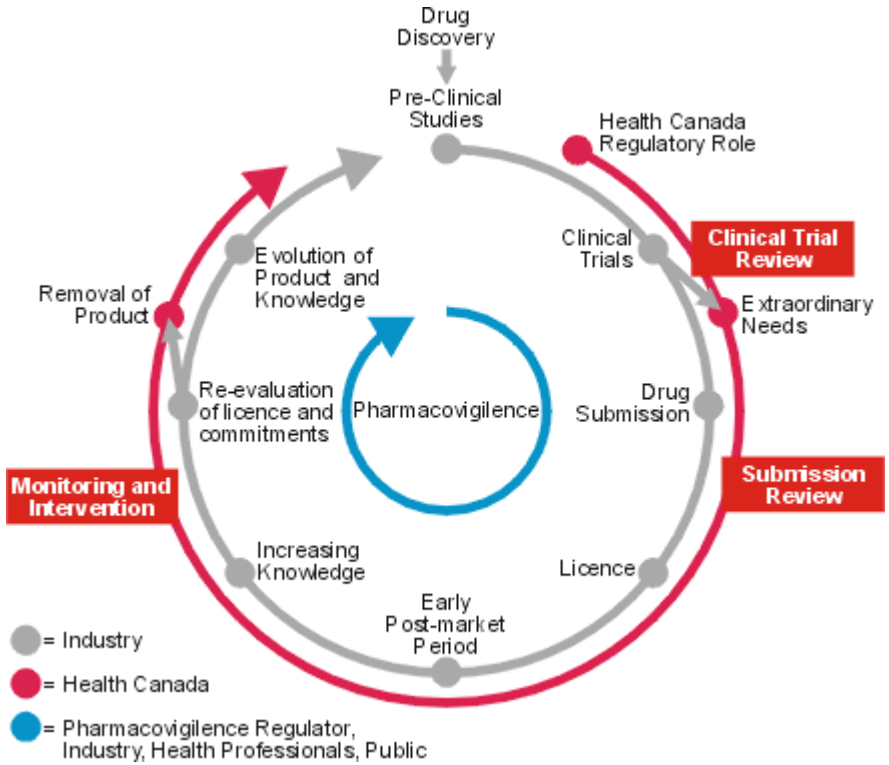
Central Concept of the Progressive Licensing Framework

- Current regulatory model tests a drug *before* it goes to market
- We know now that our knowledge about a drug grows over time, therefore…
- The new model would also evaluate a drug after it is on the market, and throughout its entire life-cycle.

Current Point-in-Time Process



Progressive Licensing Model



Guiding Principles

Four Guiding Principles of the Progressive Licensing Framework:

- Life-cycle management
- Evidence-based approach
- Good planning
- Accountability

1) Life-cycle Management

An approach that continually monitors the potential safety, quality, and effectiveness of a drug, allowing for an ongoing evaluation of the benefits and risks throughout the drug's life-cycle.

2) Evidence-Based Approach

- Decisions are currently made at the pre-market stage, based on evidence of the safety, efficacy and quality of a drug

- In the new Framework, decisions will also include a benefit/risk assessment -- which will allow for the incorporation of other types of evidence over the drug's life-cycle

3) Good Planning

- A mechanism the new Framework will use to manage the collection and analysis of new information that emerges over a drug's life-cycle

- For all drugs, there will be a requirement to file a life-cycle management plan

4) Accountability

Accountability in the PLF is understood to be the ongoing requirement to justify decisions concerning drugs.

Next Steps

Priority Areas Requiring Development:

- **Drug Development**
  - Early Planning and Engagement
  - Alternative Access
- **Licensing**
  - Benefit/Risk Assessments
    - Flexible departure from "normal" licensing process
    - Links to alternative access from previous phase
  - Conditions of License
- **Post-Licensing**
  - Fulfilling post-market commitments
  - Risk management, including risk communication
  - Re-evaluation of market authorizations

Next Steps (cont'd)

- Anticipated areas of interest:
  - Roles and Responsibilities
  - Data coordination
  - Impact assessment
  - Change management

We welcome your feedback and input!

Work Done To Date

- **Consultations**
  - July and November workshops
- **Engagement**
  - Ongoing bilateral meetings and presentations to associations
  - Science Forums
- **Concept paper**
  - created to introduce issues and to stimulate discussion in a wider stakeholder audience
- **Web Site to be launched April 2007**