Health Canada Santé Canada

Your health and safety… our priority. Votre santé et votre sécurité… notre priorité.

Regulatory Considerations for Oncology Biologics Development in Canada

iSBTc Global Regulatory Symposium

San Diego, California

October 29, 2008

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Canada

- **In Canada oncology biologics are regulated under the Food and Drugs Act and Regulations**

- **The Biologics and Genetic Therapies Directorate, part of Health Canada, is responsible for ensuring the safety, efficacy and quality of all biologics for human use marketed in Canada**




BGTD Responsibilities

- **Part of Health Canada's Health Products & Food Branch**

- **BGTD is the Canadian federal authority responsible for regulating biological drugs and radiopharmaceuticals for human use**

  - **Clinical Trial Review and Authorization**
  - **Product review and assessment**
    - **Includes laboratory testing and On-Site Evaluation**
  - **Develops new policies and regulatory framework as needed and keeps existing ones updated**
    - **Collaborates with clients, stakeholders and the general public**
  - **Active research laboratories**
  - **Departmental biotechnology coordination**




Life Cycle of a New Biological Drug

Research

Create/Isolate Active Ingredient
(14,000 tested to have one marketable)
(e.g. carcinogenicity, reproductive studies)

Tissue/Culture
small animals



More Specific animal
testing and in vitro tests
(e.g. carcinogenicity, reproductive studies)

Human Testing (Clinical Trial)

HC approval required
(*Food & Drug Act & Regulations* 30 day default)

All testing is done, drug company completes analysis of data, prepares New Drug Submission (NDS)

Health Canada Review Decision

Post-Market Surveillance

Provincial Formulary Decisions

PMPRB (price controls)



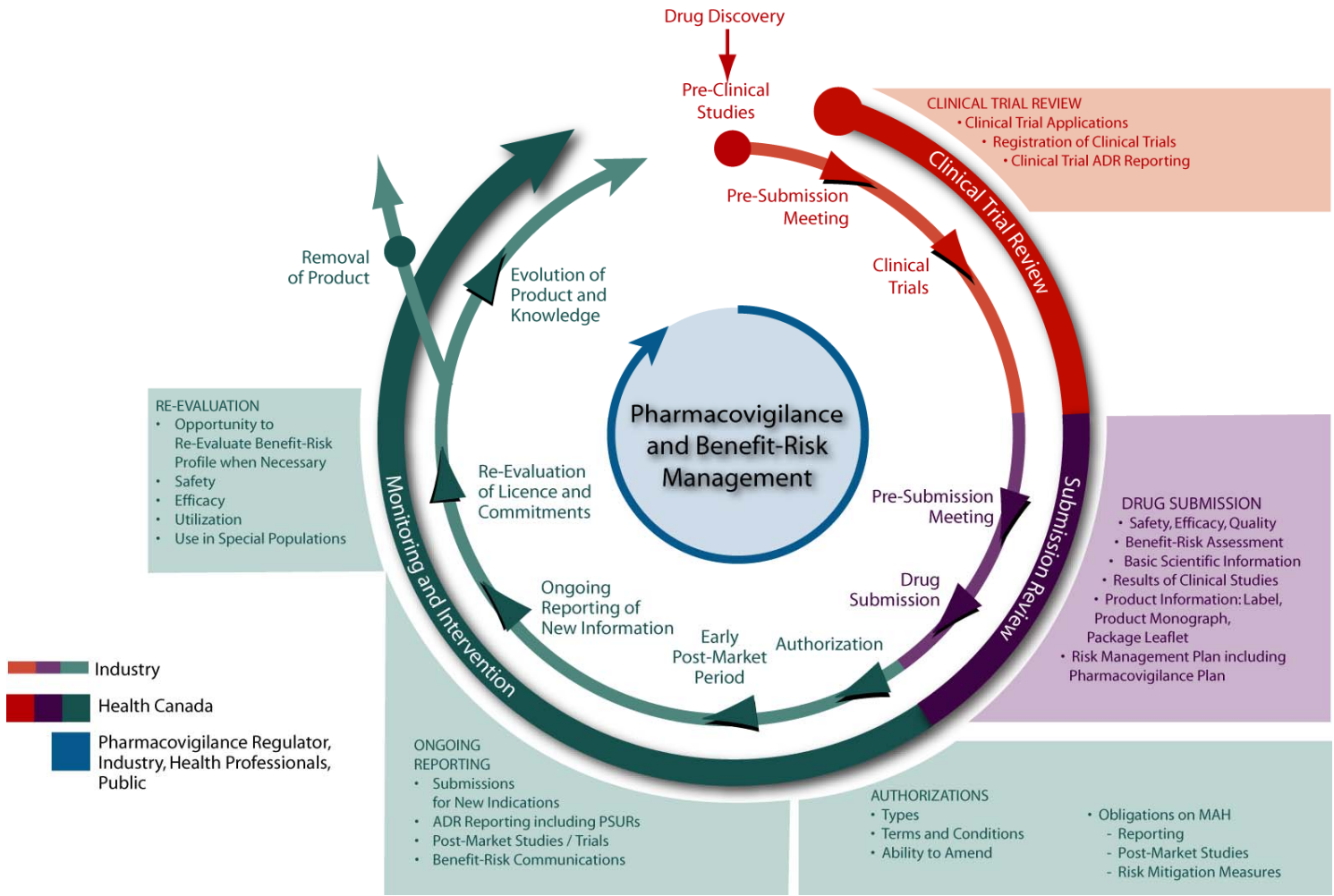

Specifics for regulatory review of biologics in Canada

In addition to paper review, biological drug review includes:

- **Lot-release**
  - Laboratory work on samples received from drug companies to confirm potency, purity and safety.
- **On-site evaluations**
  - Assessment of the production process and facility for a specific product which ensures that the manufacturing process conforms to information described in the submission.
  - Only high risk products are tested (new products and vaccines).
- **Additional GMP (Good Manufacturing Practices)**
  - Special considerations and issues pertinent to manufacturing and control of biological drugs, blood and blood components.




Progressive Licensing Model







Questions


Thank You
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