



Health
Canada

Santé
Canada

Your health and safety...our priority

Votre santé et votre sécurité... notre priorité

Helping the people
of Canada maintain and
improve their health

Aider les Canadiens et
les Canadiennes à maintenir
et à améliorer leur santé

Modernizing Canada's Regulatory System for Health Products and Food

Association of Food and Drug Officials (AFDO)
June 19, 2007



Canada

Volume and scope of our business

<p>There are thousands of products currently on the market that require ongoing efforts</p>	<ul style="list-style-type: none">• 22,000 human drug products• 1,450 veterinary drug products• 50,000+ medical devices• 400 biologic products, including blood, cells, tissues, and organs• 28 categories of food and more than 400 food additives• 42,000 natural health products, which require evidence-based guidelines, policies and standards
<p>... which also generate significant monitoring and regulatory compliance work</p>	<ul style="list-style-type: none">• 650 inspections completed / 2,800 incidents reported and investigated / 2,150 establishment licences issued per year• Average of 8,000 Adverse Drug Reaction reports received each month
<p>... and intense scrutiny by the public, media and other 'watchdogs'</p>	<ul style="list-style-type: none">• Media: 2,000+ media enquiries a year related to HPFB• ATI Requests: 80 percent of HC total relate to HPFB• Over 76 percent of Health Canada's litigation involves HPFB (291 cases)• Recent OAG reports on HPFB programs

Currently on market



Challenges of the modern regulator

- **A severely limited, inflexible and outdated legislative and regulatory toolkit** – Food and Drugs Act was last modernized in the 1960s following the thalidomide tragedy
- **High profile safety incidents in recent years** (e.g., global withdrawal of Vioxx) and related public concerns have led to an international shift toward:
 - increased emphasis on post-market surveillance and continuous re-assessment of the risk and benefits of products throughout the life-cycle
 - moving away from “waiting for events” approaches
- **Increasing public expectations** regarding openness and transparency, accountability
- **Industry expectations** regarding predictability, competitiveness and timeliness of the regulatory process
- **Rapid advances in science and medical technology** leading to increased complexity of products being submitted to Health Canada



Health Canada's Blueprint for Renewal

Vision:

Health Canada will be an internationally-recognized regulatory leader, with an **adaptable and sustainable regulatory system** and capacity. HC will:

- Enable timely access to safe, effective and high quality health products and food
- Strengthen safety oversight through a product lifecycle approach
- Sustain and improve efficiency; maintain safety standards
- Increase transparency and openness
- Contribute to better alignment of regulatory and reimbursement decision-making



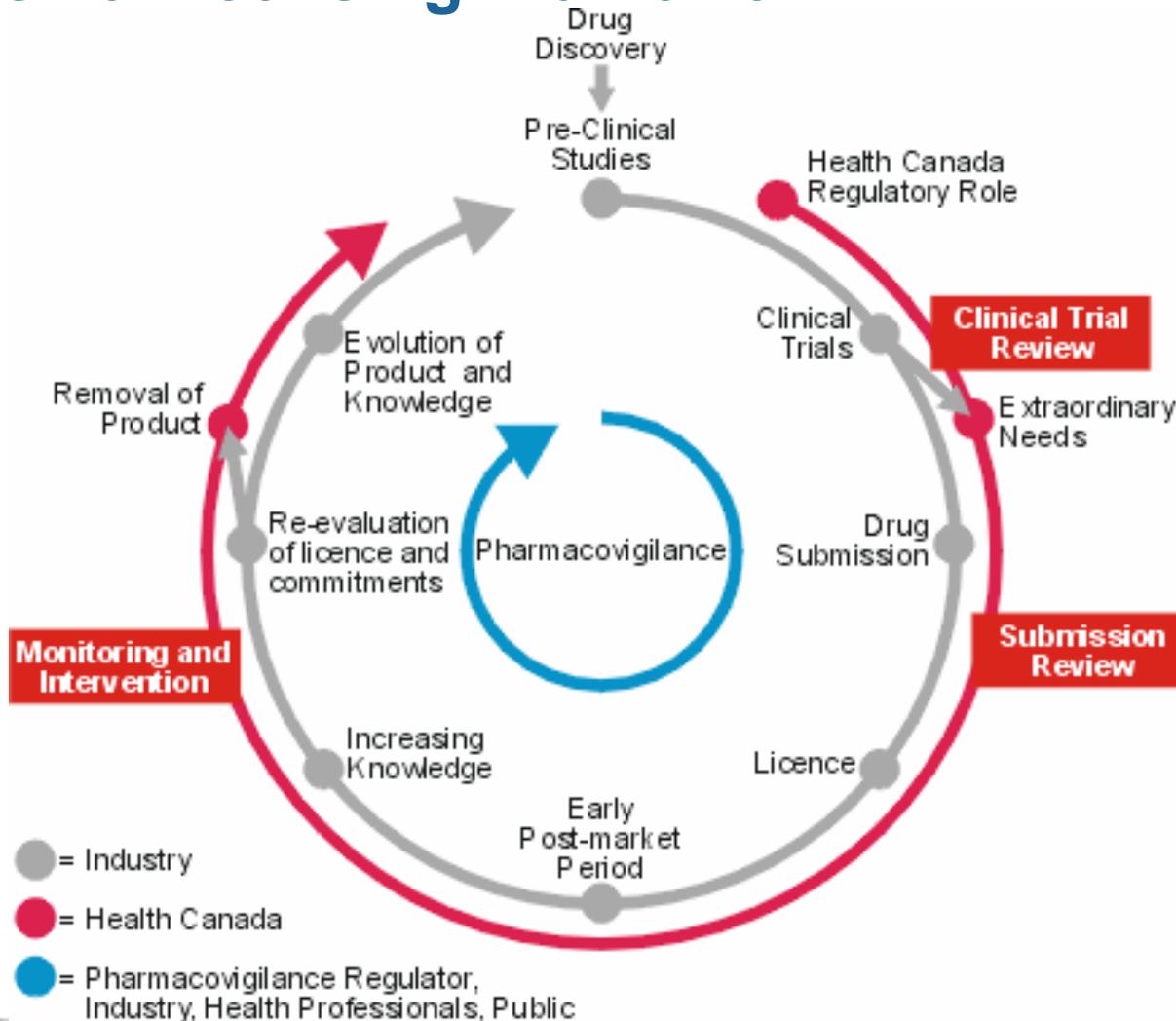
Health Canada's Blueprint for Renewal (cont'd)

Objectives:

1. Life cycle approach
2. Interventions proportional to risk
3. Strengthened compliance and enforcement tools
4. Modern approach to food safety and nutrition
5. Make best use of all types of evidence
6. Pro-active and enabling regulatory system
7. Special emphasis on specific populations
8. Transparency, openness and accountability
9. More and better information to consumers
10. Partner in an integrated system



Progressive Licensing Framework



Regulatory modernization strategy for food and nutrition – policy goals

1. Improve predictability, effectiveness, efficiency, and transparency in Health Canada's regulatory system
2. Promote regulatory responsiveness to food innovation and promote consumer access to foods with assessed health benefits
3. Modernize the regulatory toolkit to address “food contributors” to chronic disease
4. Improve Health Canada's responsiveness to acute food safety health risks – responding to new threats while managing ongoing risks
5. Promote a sustainable and integrated system for food safety and nutrition in Canada



Thank you!

Debra Young
Health Canada
1-613-957-6349
debra_young@hc-sc.gc.ca

For more information on the Blueprint:
www.healthcanada.gc.ca/hpfb-blueprint

