Health Canada Santé Canada

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

Regulatory Modernization Overview

CAPRA Regulatory Modernization Workshop
October 4, 2011

Canada

Objectives:

- Provide an overview of the Health Products and Food Regulatory Modernization; and

- Identify next steps

Context – chronology

- **December 2007** – Prime Minister announced Food and Consumer Safety Action Plan
  - Included a proactive approach to the regulation of food, health and consumer products
- **April 2008** – Bill C-51, *An Act to Amend the Food and Drugs Act,* tabled as a key element of the Action Plan
- **Fall 2008** – Bill C-51 expired on the order paper due to election
- **Next Steps** – Direction to modernize the *Food and Drugs Act* is yet to be determined; in the meantime, Health Canada continues to develop a regulatory modernization agenda for food and health product regulation that builds on previous work

Building on a Solid Foundation

Technical Discussion Sessions (Oct. 2010 – Jan. 2011) introduced a model for the regulation of therapeutic products through the lifecycle, including proposals such as:

- general market authorization requirements
- standard and special conditions for market authorizations
- plain language labelling/packaging
- post-market authorities (e.g. ability to request mfrs to conduct tests and studies, and ability to request label changes, etc.)

What is Regulatory Modernization?

- A **strategy** to produce a sustainable regulatory future for health products and food

- The **vision** to transform nearly a dozen outdated frameworks into an efficient, transparent, and comprehensively aligned regulatory system
  - Product lines include food, NHPs, Rx drugs, non-Rx drugs, veterinary drugs, biologics, vaccines, blood products, cells, tissues and organs, medical devices, disinfectants, etc.

- A **plan** to prioritize and achieve this ambitious regulatory transformation

Where We Are Today

- Current regulatory frameworks are:
  - Based on rigid classification by product types;
  - Not always risk based;
  - Not consistent across product lines; and
  - Often require time consuming and inefficient processes to make even small changes
- Global Pressures:
  - Recognition that current systems are unsustainable and require greater international cooperation
  - Movement towards flexible outcome based regulation
- Domestic Opportunities:
  - Federal priority to reduce regulatory burden with Red Tape Reduction Commission and Regulatory Cooperation Council
  - Looking for greater regulatory efficiencies with Strategic and Operating Review

Where We Are Going

- Moving away from:
  - Rigid product categorization
- Moving towards:
  - Management of benefits, harms, uncertainties
    - Oversight will consider the type and amount of evidence based on the nature, intended use and exposure of the product
  - Positive health outcomes through lifecycle approach
  - International alignment as appropriate

The Ultimate Destination

- Regulatory Frameworks designed to:
  - Support transparency
  - Allow predictability of regulatory processes
  - Permit rapid intervention when required
  - Be adaptable to science and technology innovation
  - Ensure regulatory and operational sustainability

Questions?