Health Canada Santé Canada

Strengthening Post-Market Surveillance in Canada

Presentation to Canadian Association of Regulatory Affairs

May 22, 2003

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Marketed Health Products Directorate

Health Products and Food Branch

Overview

- What is the Marketed Health Products Directorate (MHPD)?
- What is MHPD positioning in Health Products & Food Branch (HPFB)?
- How is MHPD structured?
- What are the primary roles & responsibilities of MHPD?
- How does MHPD work with product specific Directorates?
- What are the current activities to strengthen surveillance?

Marketed Health Products Directorate (MHPD)

- Coordinates post-market monitoring of marketed health products, previously centered in the Bureau of Licensed Product Assessment
- Builds on 40 plus year history of pre- and post-market activities in Health Protection Branch and later Health Products and Food Branch (HPFB)
- Works to assure HPFB programs take a consistent approach to monitor, assess, and intervene concerning marketed health products
- Regulatory responsibility for marketed health product lines remains with currently responsible product specific Directorates:
  - Biologics & Genetic Therapies Directorate (Blood, Vaccines, Biotechnology Products)
  - Therapeutic Products Directorate (Pharmaceuticals & Medical Devices)
  - Veterinary Drugs Directorate

Health Products and Food Branch Mandate

- Take an integrated approach to the management of the risks & benefits to health related to health products & foods:
  - Minimize health risk factors to Canadians while maximizing safety provided by the regulatory system for health products & foods;
  - Promote conditions that enable Canadians to make healthy choices & provide information so that they can make informed decisions about their health

MHPD Divisions

- Marketed Pharmaceuticals
- Marketed Biologicals and Biotechnology Products
- Marketed Natural Health Products
- Marketed Medical Devices
- Marketed Health Products Safety and Effectiveness Information
- Active Surveillance and Clinical Epidemiology
- Therapeutic Effectiveness and Product Utilization
- Patient Safety, Outreach and Partnerships
- Operations and Policy

Health Canada's Post-Market Surveillance Program

- Carried out in several Branches and Directorates:
  - Spontaneous adverse reaction and medication incident reporting for pharmaceuticals, biologic and biotechnology products, natural health products (MHPD)
  - Immunization schedule vaccine surveillance - Population and Public Health Branch (PPHB)
  - Medical Device complaint reporting – Health Products and Food Branch Inspectorate (HPFBI)
  - Acute transfusion reaction monitoring for blood and blood products – Biologics and Genetic Therapies Directorate (BGTD)
  - Transfusion Transmitted Injuries Surveillance System (PPHB)

Health Canada's Post-Market Surveillance Program

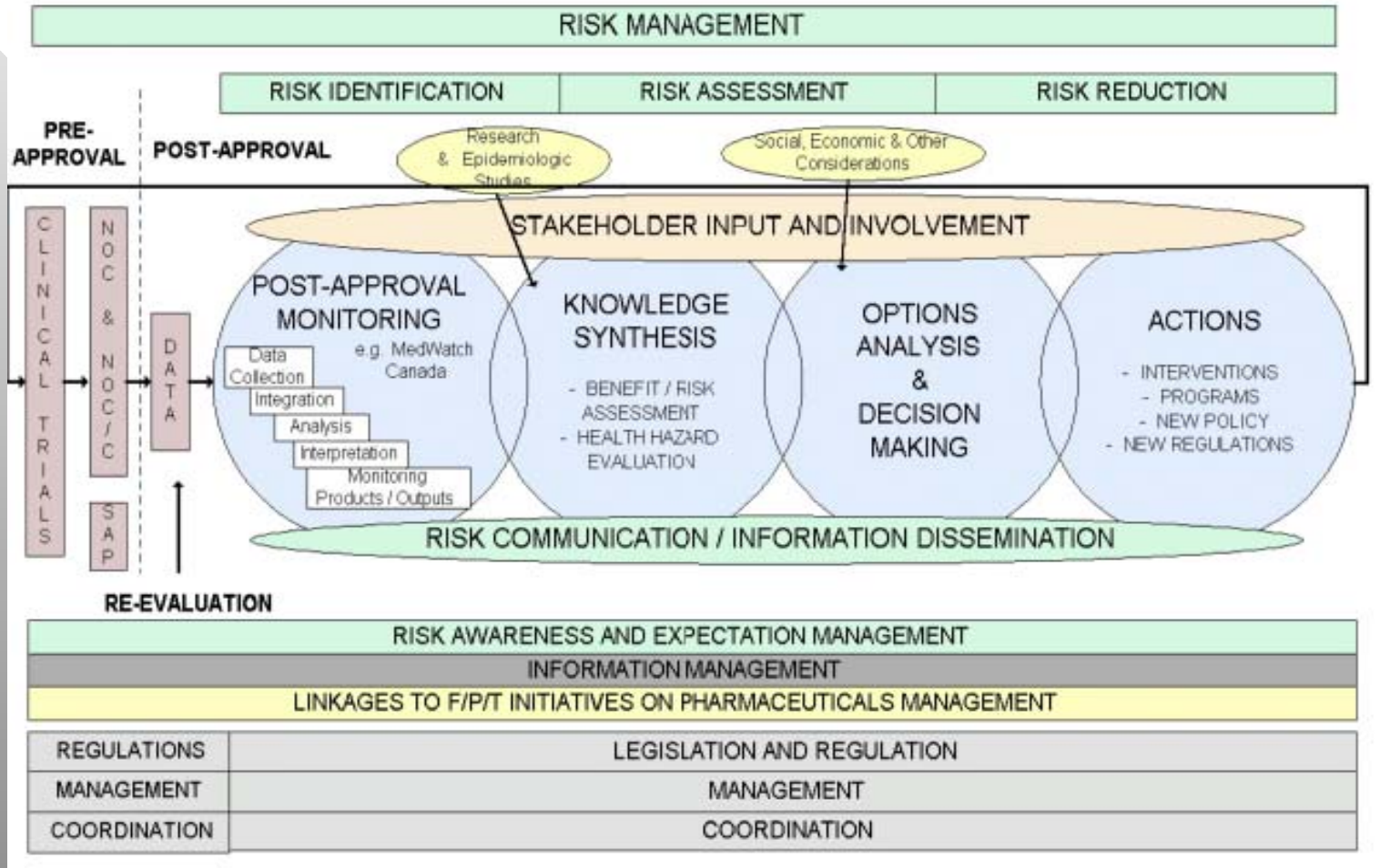
- Voluntary reporting by health professionals, with mandatory reporting by manufacturers
- Encourages pre- and post-approval surveillance partnerships among Health Canada's regulatory and public health organizations
- Highlights importance of risk management (including risk communication) methodologies
- Responds to international obligations and opportunities concerning post-market surveillance of marketed health products

Main Goals of Health Canada's Post-Market Surveillance Program

- Recognize as early as possible - new safety and effectiveness information (ex. signal detection)
- Refine and add to information on suspected or known adverse reactions
- Review the benefits and risks of one product compared with others and other types of therapy to enable informed evidence-based decision-making
- Communicate the information in a way that improves therapeutic practice

Post-Approval Assessment Activities

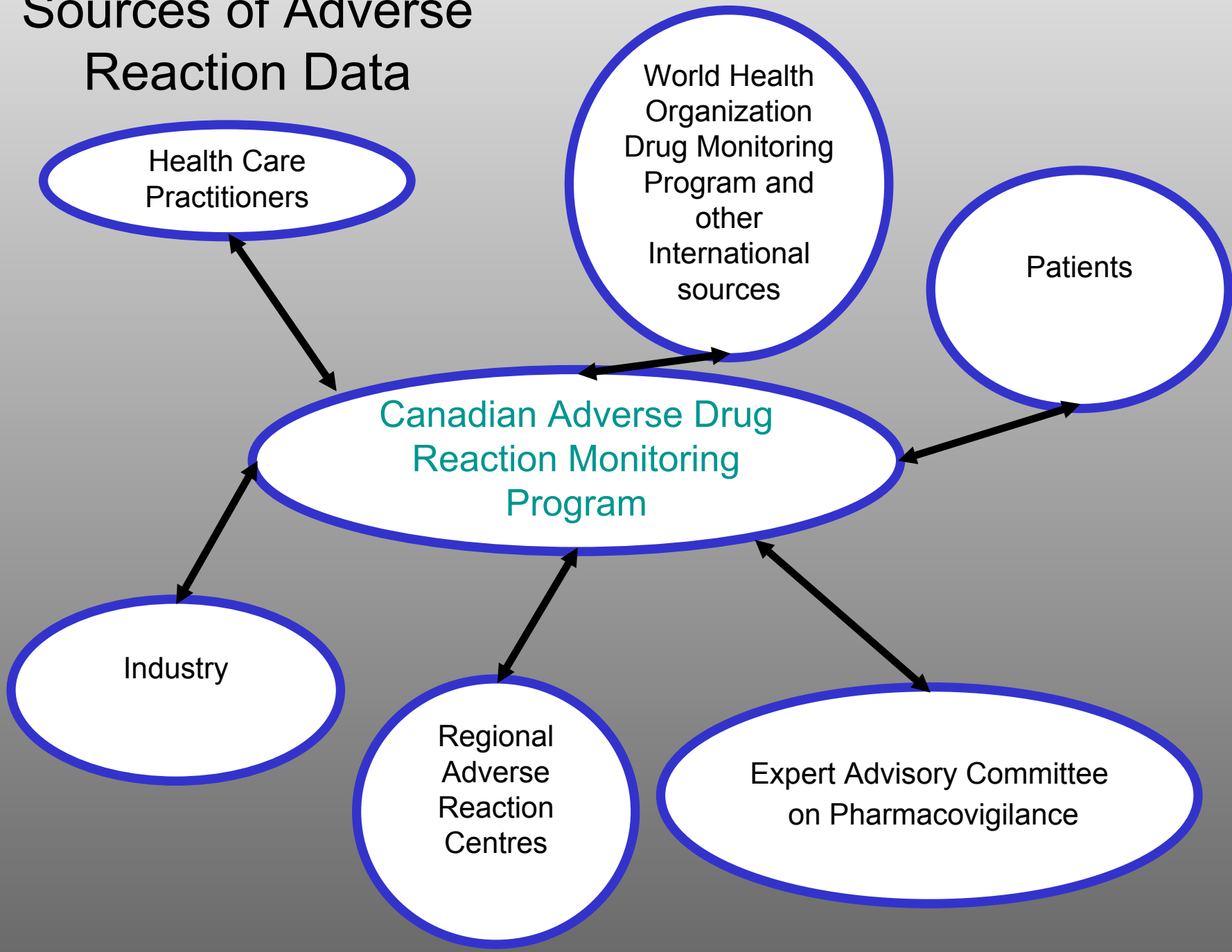
FIGURE 3. POST-APPROVAL ASSESSMENT ACTIVITIES



Post-market Surveillance Activities Summary

- Risk Management:
  - Risk Identification – information collection and monitoring, signal generation
  - Risk Assessment – information integration and analysis
  - Risk Reduction and Mitigation - market interventions
  - Risk Communication to consumers and health care providers
- Other Activities:
  - Utilization and therapeutic effectiveness activities
  - Partnerships with patient groups, health care providers & organizations
  - Regulatory review as it pertains to post-market surveillance issues

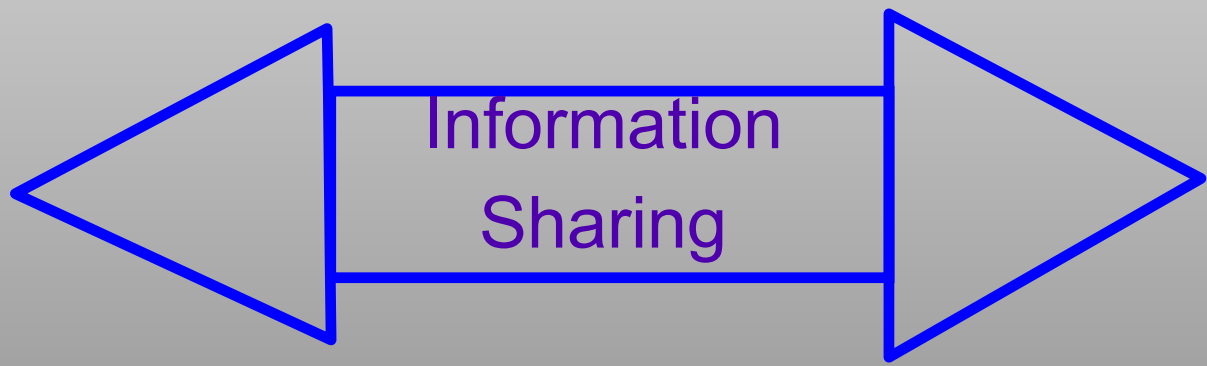
Sources of Adverse Reaction Data



Continuum of Information Sharing

Pre-market drug review

Post-market surveillance



Decision-Making Framework

- Decision-making process;
- Risk-Management Committees at Directorate, Branch and Departmental levels;
- Team-work used to make written summaries of reasons for decisions;
- Management decisions on ways to communicate new risks (e.g. advisories, notices).

Collaboration between MHPD and other Directorates

- Membership at risk management meetings
  - Working groups on product specific risk issues
- Regular bilateral meetings
- Sharing of results of post-market safety assessments
- Coordinated risk communication plans

Current Activities to Strengthen Post-Market Surveillance

- Risk Communication
- Therapeutic Effectiveness
- Medication Incident Reporting & Prevention

Risk Communication

- Workshops to address communication of new safety information about marketed health products
- Research to assess the effectiveness of current risk communication tools and mechanisms
- Examples of current tools used for risk communication

Communicating Drug Safety Information

- November 2001, stakeholder workshop generated two key messages on which to build:
  - There is need for a culture shift to a shared responsibility for drug safety issues
  - New safety information must be developed and disseminated in a manner to ensure it is targeted, timely, and available at the point of care
  - Summary proceedings available at: http://www.hc-sc.gc.ca/english/protection/drugs.html

Communicating Drug Safety Information II

Follow up Stakeholder Workshop March 2003

- Part of HPFB's mandate is to minimize health risk factors while maximizing safety provided by the regulatory system
- Industry has a responsibility to provide products consistent with the regulatory framework
- Health professionals ensure consumers receive appropriate information to ensure safe & effective use of those products
- Consumers have a responsibility to make informed choices about their health

… a shared responsibility

Identified Priorities

- Primary are crafting & packaging messages, dissemination, & integrating information into daily practice & use
- Be strategic, choose actions to deliver significant results:
  - do fewer things but do them well
- Most critical areas to direct effort & resources:
  - effective, recognizable, easily accessed tools, graded to importance
  - working relationships with professionals & associations
  - build awareness among providers of importance of reporting adverse events & using new safety information
  - undertake awareness campaigns at all levels including consumers
- Participants demonstrated commitment to “shared responsibility”

Public Opinion Survey Project

- MHPD is conducting a survey on several key issues involving post-market surveillance & marketed health product risk communication including:
  - Effectiveness of current methods for communicating new safety information about marketed health products
  - Mandatory reporting of serious adverse drug reactions by health care professionals
  - Requirement to obtain informed consent from patients before reporting adverse drug reactions

Risk Communication Mechanisms

- Health Canada website
  - www.hc-sc.gc.ca/english/protection/drugs.html
- Dear Health Care Professional Letters
- Canadian Adverse Reaction Newsletter
- Public advisories and warnings
- It's Your Health newsletter
- Product Monographs and Patient Package Inserts and labels
- Subscribe to Health_Prod_Info for up to date information by e-mail
  - www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/mail_list.html
- Toll-free numbers for consumer & health professional adverse event reporting - Telephone (866) 234-2345 or Fax (866) 678-6789

Therapeutic Effectiveness Initiative

- Options being developed & analyzed regarding establishment of a National Program for Therapeutic Effectiveness Surveillance that would:
  - add to risk information (safety surveillance) to permit benefit-risk assessments of marketed health products
  - be shared with product-specific Directorates in evaluation of similar (class) new drug submissions
  - be shared with Common Drug Review process as part of the F/P/T process concerning drug benefit plan formulary decision recommendations
  - assist in preparation of Benefit-Risk Management, Health Product Promotion and Risk Communication vehicles
  - enhance transparency of surveillance of marketed health products; enabling health professionals & consumers to make informed decisions

Canadian Medication Incident Reporting & Prevention System

- Health Canada leads a Coalition of health care organizations, including consumers, with a mandate to develop a business plan for a comprehensive, viable, sustainable, & affordable medication incident reporting & prevention system that will:
  - Enhance the safety of the Canadian medication use system by focusing on the reduction of harm caused by preventable medication incidents;
  - Address need for a collaborative approach among health care providers & organizations, including governments;
  - Address the federal / provincial / territorial nature of the delivery of health care in Canada; &
  - Collaborate & integrate with broader patient safety initiatives - *Medication incidents are the largest (known) cause of medical error & the most common preventable cause of patient injury*

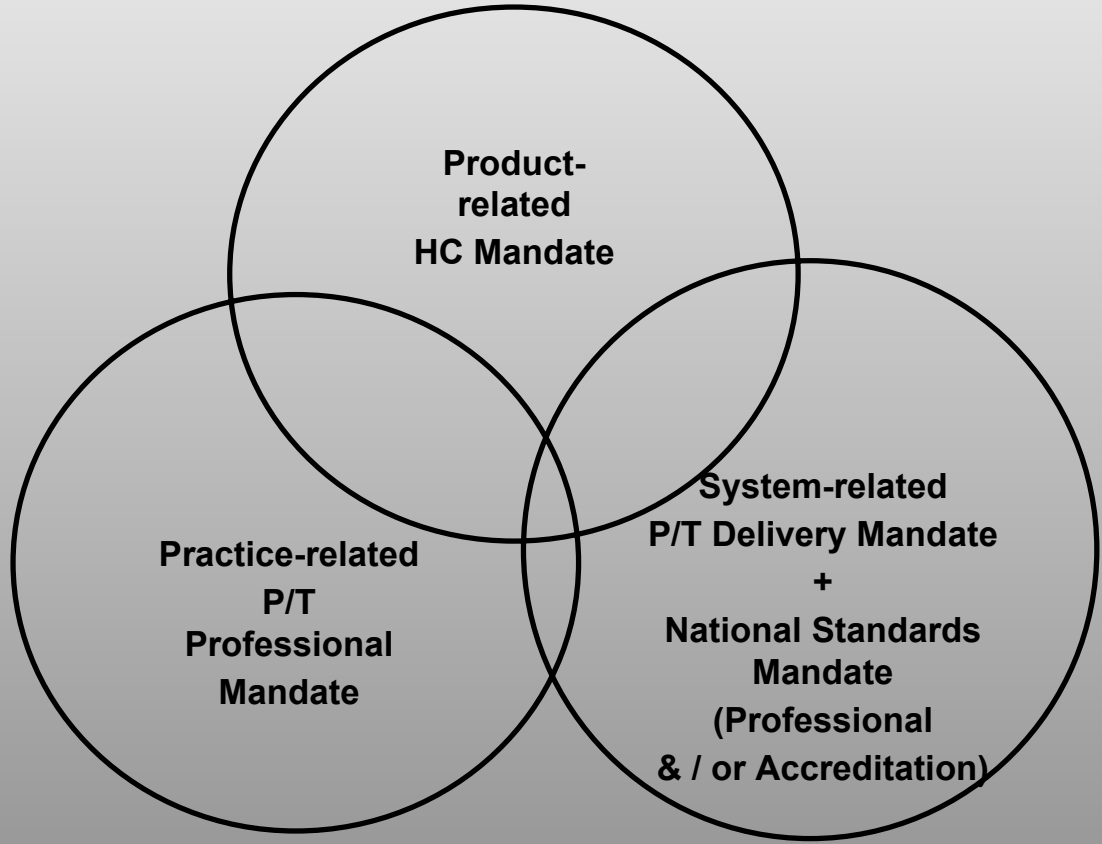
Canadian Coalition on Medication Incident Reporting & Prevention

- Marketed Health Products Directorate, Health Canada - Chair
- Canadian Association of Chain Drug Stores
- Canadian Healthcare Association
- Canadian Institute for Health Information - May 2001
- Canadian Medical Association – Dec. 2001
- Canadian Nurses Association
- Canadian Pharmacists Association
- Canada's Research Based Pharmaceutical Companies
- Canadian Society of Hospital Pharmacists
- College of Family Physicians of Canada – Oct. 2002
- Consumers Association of Canada
- Pharmaceutical Issues Committee - *participating observer*
- Institute for Safe Medication Practices Canada
- The Royal College of Physicians and Surgeons of Canada – Dec. 2001

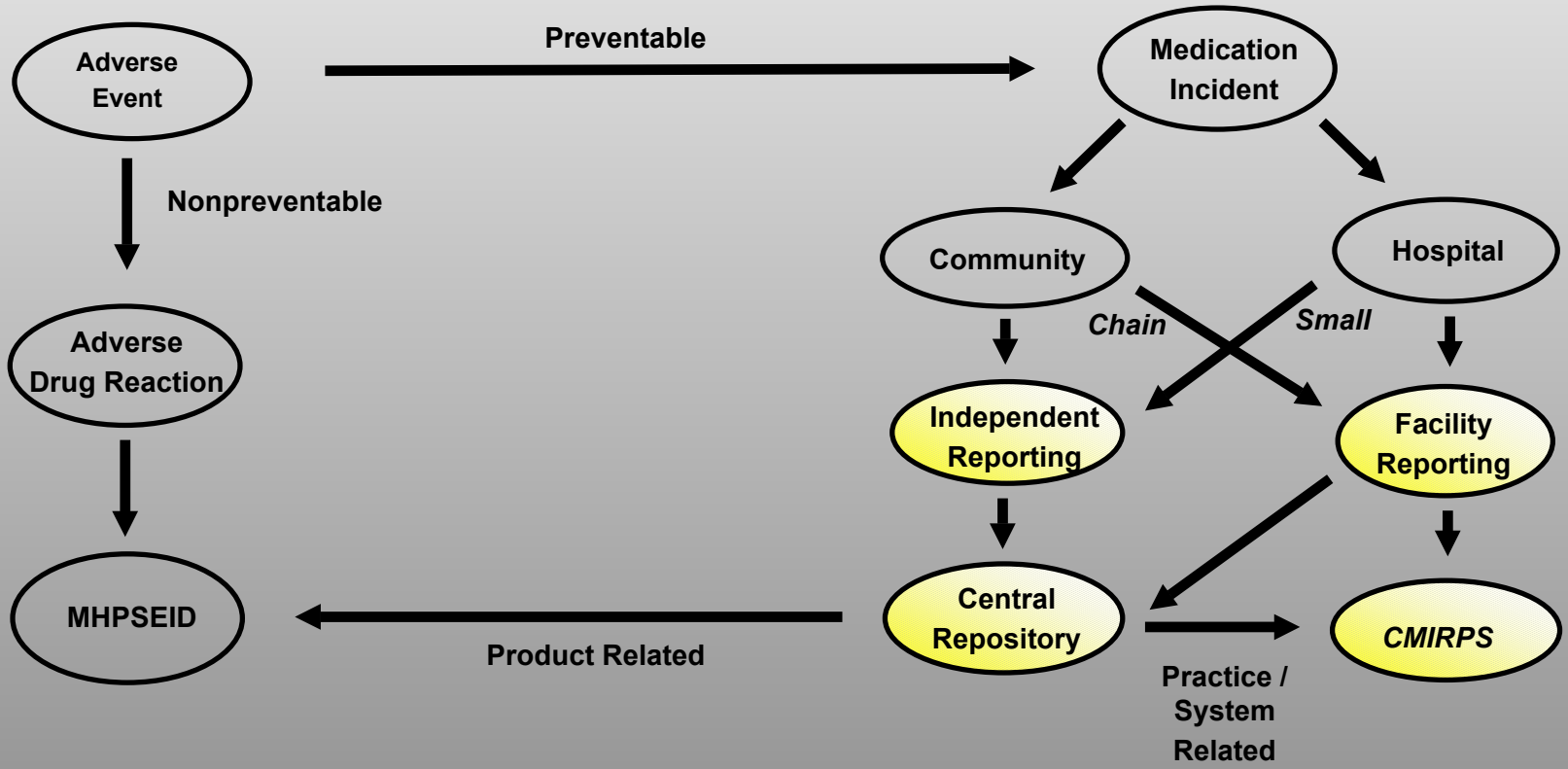
Key Elements of CMIRPS

- Reporting - *of medication incidents*
- Analysis - *of the information from incident reports*
- Dissemination - *of the results of the analysis*
- Leadership - *of efforts to meet defined goals*
- Risk Management Approach

Mandate Overlaps
Joint / Shared Responsibilities



What is Missing?
The "Shaded" Elements



(MHPSEID = Marketed Health Products Safety & Effectiveness Information Division)

Ratio of drug use and provision of care is 90% community to 10% hospital

Proposed Model

- Partnered approach to deliver a system consistent with key principles, goals & attributes of a proposed *Canadian Medication Incident Reporting & Prevention System (CMIRPS)*
- Proposed partnership builds on strengths, core competencies & missions of relevant organizations in Canada
- Purpose of CMIRPS is to:
  - Coordinate capture, analysis & dissemination of information on medication incidents;
  - Enhance the safety of the medication use system for Canadians; and
  - Support effective use of resources through reduction of potential or actual harm caused by preventable medication incidents

Health Canada's Role

- Leadership
  - Identified champion through development, testing & implementation
  - Leading & funding the Coalition
- Product-related aspects of medication incidents
  - Part of role in post-market surveillance of market health products
  - Look-Alike Sound-Alike (LASA) Medication Names - FDA action
  - Compatible with role in Adverse Reaction Reporting, and new initiatives in enhanced & active surveillance
- Joint role with health care professionals
  - Vincristine administration errors: *outcome = death*

CMIRPS - Status

- Sierra Report & Coalition Consensus Response circulated in late July 2002
  - www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpr/cmirps_e.html
- All Coalition member organizations have expressed support in principle for:
  - Establishment of a Medication Incident Reporting & Prevention System
  - The key principles, goals, & attributes expressed in the Sierra Report
  - Continued participation on the Coalition
- Report is a significant milestone in the evolution of a proposed system
- The Coalition will coordinate it's work with that of the National Steering Committee on Patient Safety
  - Support for CMIRPS is consistent with the Health Accord 2003 and Federal Budget 2003 commitments related to patient safety

Questions?