Drug Safety and Effectiveness Network

Canadian Association for Population Therapeutics
April 21, 2009

Cynthia Sunstrum
Manager, DSEN Project,
Strategic Policy Branch, Health Canada
Outline

• Genesis of the Drug Safety and Effectiveness Network (DSEN)

• Public Policy Objectives for the DSEN

• DSEN Design and Implementation (Diane Forbes)
Driving Force

• Large gaps in the evidence available about the safety and effectiveness of drugs based on their use in the “real world” by diverse patient groups, outside the controlled experimental environments of clinical trials.

• Evolution of knowledge about medicines demands that governments and other decision-makers seek better evidence about the balance of benefit and risk throughout the product life cycle.
Current Environment

• Post-market studies are largely *ad hoc* – predominantly driven by investigator interest

• Evidence generated does not always correspond to the needs of decision-makers (e.g., public payers, etc)

• Limited coordination and collaboration among researchers and decision makers to identify and address the most urgent evidence gaps

• Need for more rapid response to important policy concerns related to drug safety and/or effectiveness
A Public Policy Priority

• 2004 First Ministers Health Accord – the “10 year plan”
• Strengthening evaluation of real-world drug safety and effectiveness (RWSE) included as one of the five priority elements in the **National Pharmaceuticals Strategy** (NPS)
  - Recognition that RWSE knowledge gaps are a clear barrier to effective, evidence-based decision making
  - Need for greater coordination of efforts to generate and transfer information necessary to fill evidence gaps and support decision makers in a timely manner
NPS

• Provided opportunity for collaborative development of options to improve our knowledge of RWSE

  • Collaborative effort among NPS partners, Canadian Institutes of Health Research (CIHR), and the Canadian Drug Policy Development Coalition
Post NPS

• DSEN included in the Government of Canada’s *Food and Consumer Safety Action Plan* (December 2007)
  
  • Support product life-cycle approach to drug regulation by providing key evidence to Health Canada for use in ongoing risk-benefit assessment of drug products
  
  • Complement other pharmacosurveillance activities – provide additional tool

  [http://www.healthycanadians.gc.ca/pr-rp/action-plan_e.html](http://www.healthycanadians.gc.ca/pr-rp/action-plan_e.html)
Government of Canada Works to Improve Knowledge About the Safety and Effectiveness of Drugs

January 14, 2009
TORONTO – The Honourable Leona Aglukkaq, Minister of Health, today announced that the Government of Canada is continuing to support the Drug Safety and Effectiveness Network (DSEN), first announced in July 2008.

“Canadians can be confident that this Government is taking the steps necessary to ensure that our drug safety system remains one of the best in the world,” said Minister Aglukkaq. “The Drug Safety and Effectiveness Network complements Canada’s rigorous pre-testing of new drugs by studying how Canadians respond over time to already-approved drugs. The results will help in decision-making and enhance overall consumer safety.”
Public Policy Objectives

• Promote safe and effective use of pharmaceuticals by filling gaps in knowledge required to make effective evidence-based decisions about drugs
  ▪ Decisions made at different points throughout the regulatory and health care system including post-market surveillance; reimbursement; prescribing, utilization

• Increase capacity within Canada to undertake high-quality post-market studies of RWSE
  ▪ To support increased availability of needed evidence
Public Policy Objectives

• Leverage greater value from existing investments in post-market research within Canada by:
  ▪ Building on what already exists
  ▪ Improving coordination of research efforts, both nationally and internationally
  ▪ Promoting greater collaboration

• Contribute to improved system efficiency to support accessible and sustainable health system responsive to the health needs of Canadians
DSEN – A Partnership Initiative

• Many players in Canada’s “drug safety and effectiveness system”
  ▪ from many sectors - governments, academia, industry, health care providers, patients

• Many different roles
  ▪ regulatory, reimbursement, data holders, knowledge generators, treatment providers, prescribers, users
Intersect of RWSE Interests

- Patients
- Health Care Providers
- Researchers
- CIHR
- Health Canada
- Drug Plan Managers
- Industry

DSEN
DSEN Federal Partners

• CIHR and Health Canada, leading establishment of the DSEN, working with other partners and stakeholders:
  ▪ HC providing policy leadership and coordination among DSEN program partners and integrating DSEN research findings into its existing drug regulatory and drug plan management activities
  ▪ CIHR responsible for implementing, facilitating and coordinating DSEN operations and funding research
Thank you!

Cynthia Sunstrum
Project Manager,
Drug Safety and Effectiveness Network Project
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch, Health Canada
(613) 954-3356
cynthia_sunstrum@hc-sc.gc.ca