



Health
Canada

Santé
Canada

*Your health and
safety...our priority.*

*Votre santé et votre
sécurité...notre priorité.*

Knowledge Translation The Marketed Health Products Directorate Perspective

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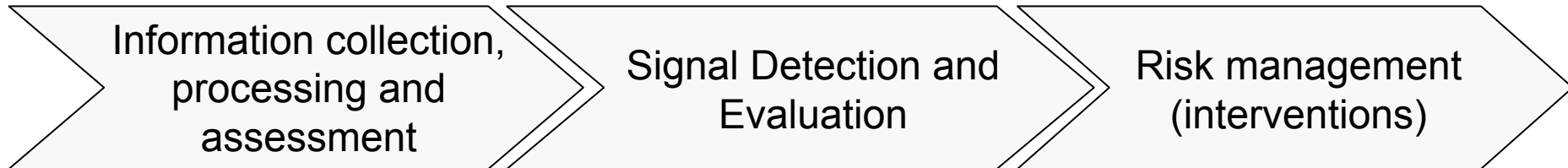
Marketed Health Products Directorate, Health Products and Food Branch

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Canada 

Post-market surveillance is composed of three major activities:



Adverse events occur and information is gathered. Reports are assessed for completeness and assigned medical terminology. New risks are discovered with increased use of product in real world. Information is compiled from literature scan, other regulatory agencies, companies (PSURs, registries, clinical trials), etc.

Many information sources combine to create a signal: a suspicion there is a connection between a product and reported adverse reactions. Evaluation consists in the scientific/medical review of multiple data sources to analyse risks and benefits, considering risk profiles of therapeutic alternatives.

A risk management approach is defined which may include interventions such as: product recall, labelling changes, communicating risk information to health care professionals and the public. Interventions are normally communicated broadly as a mechanism to show accountability.

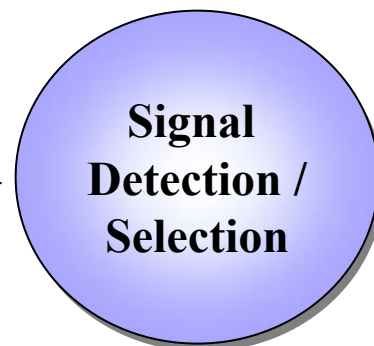


1. Knowledge Creation and Distillation

Monitoring Inputs



**Risk
Identification**



Risk Assessment



Challenges:

- Scientific certainty versus precautionary principle
- Public health versus subpopulation impacts
- Timeliness- expectations management
- Monitoring multiple product lines
- Expectations for transparency



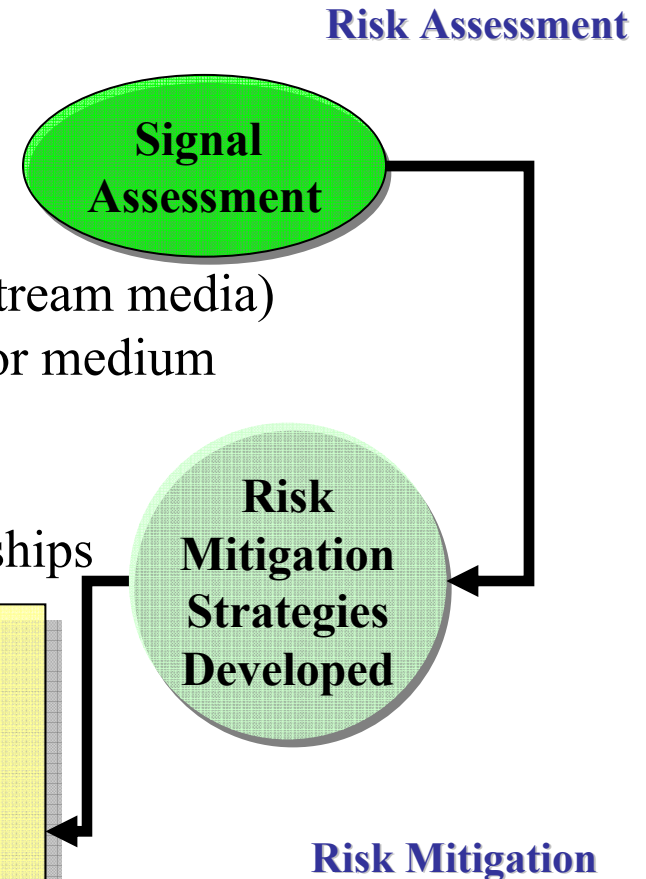
2. Dissemination

Challenges:

- Multiple target audiences
- Multiple media are required (email, fax, mail, mainstream media)
- Keep uniform message but reformulate to audience or medium
- Shared responsibility for risk communications
- Credibility (optics) of information source
- Time lag for dissemination mechanisms and partnerships

RISK COMMUNICATIONS

- Label changes
- Public Advisory
- Health Professional Letter
- Notice to Hospitals
- Spokespersons
- Press Release, Media Lines
- Can Adv Reaction Newsletter
- Listserv – MedEffect e-Notice



3. Uptake

Challenges:

- Risk perception and risk tolerance of consumers
- Health Canada does not have a practice of medicine mandate
- Overload versus over-filtering
- Information versus knowledge
- Our ability to measure the effectiveness of risk communications
- Getting new safety information into normal healthcare business practices



Vision for the Future

- Will require information technology (IT) support
- MedEffect e-Notice
 - Better demographic data on subscribers
 - Support for an individual to self-filter preferences
- Linkage to EHR/EMR
 - Linking at the business process level the new and previous safety information to the prescribing systems

