Government of Canada's

HEALTH PRODUCTS POST-MARKET SURVEILLANCE CYCLE

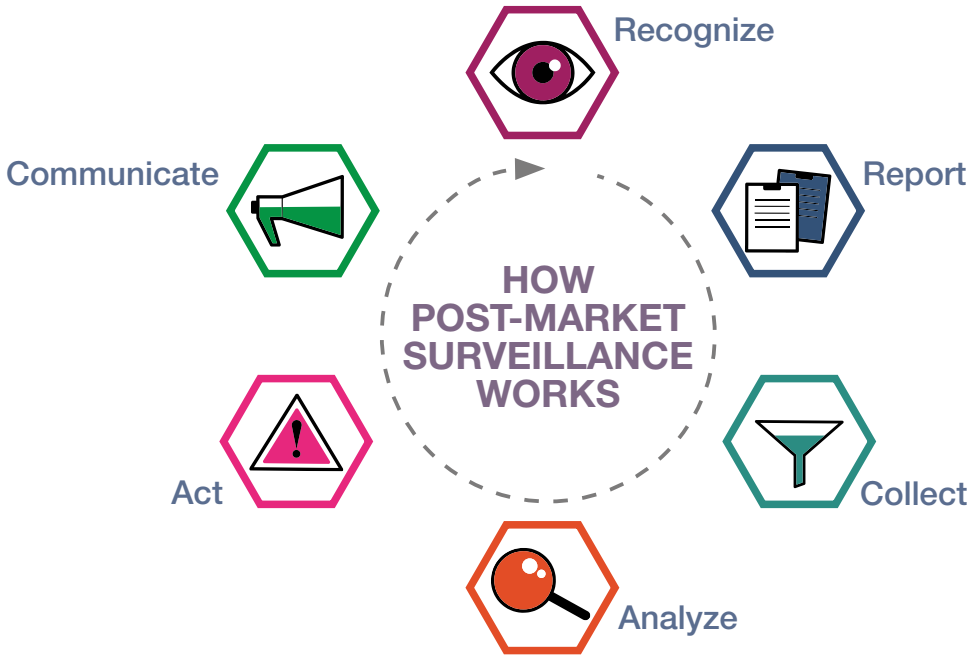

Image source: Adapted from the Uppsala Monitoring Centre's Pharmacovigilance Cycle.

Recognize

- All health products have risks and benefits associated with their use.
- Drug and medical device safety knowledge and issues evolve over time. New risks can become evident once a product is used by broader populations, for longer durations and under different conditions than those studied before being approved for sale.
- Side effects and complications are known as **adverse reactions (ARs)** and **medical device incidents (MDIs)**. Health Canada monitors ARs and MDIs to keep up-to-date on new information related to the safety and effectiveness of health products.

Report

- Anyone can report ARs and MDIs.
- Health care providers and consumers report voluntarily. Market authorization holders (manufacturers and distributors) and hospitals must report under the *Food and Drugs Act*.

Collect

- AR and MDI reports are entered into the Canada Vigilance Adverse Reaction Online Database and the Medical Devices Incident Database.
- These databases allow users to search for AR and MDI reports

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Analyze

- We look at AR and MDI reports received and other sources of product-related safety information, such as:
  - pre-market trials and tests
  - medical and scientific literature
  - additional reports from manufacturers
  - information from foreign regulatory agencies
- We carefully assess the available safety information to look for a possible cause-effect link between the health product and the AR or MDI.

Act

- When Health Canada identifies new safety issues, we take action. We use the most appropriate level of intervention to manage the risks and help people in Canada make informed decisions.
- We may:
  - continue to monitor safety information
  - reassess at a future date if new information becomes available
  - ask the manufacturer to supply additional post-market safety and effectiveness information
  - request post-market tests and studies
  - restrict access to and distribution of the drug or device
  - update the product label
  - issue a risk communication
  - withdraw from the market the drug or device
- We also monitor and respond to advertising complaints to ensure that companies don't make false and misleading claims, or engage in illegal marketing of health products.

Communicate

- We let people in Canada know about safety information in several ways:
  - Recalls and safety advisories
  - Summary safety reviews
  - Health Product InfoWatch (monthly safety bulletin)
  - Advertising complaints database
- You can also look up information for specific drugs or medical devices through our:
  - Canada Vigilance Adverse Reaction Online Database
  - Medical Devices Incident Database
  - Drug and Health Product Portal

If you experience an **AR** or **MDI** with a drug or a medical device, we want to hear from you.

Report to Health Canada