

Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Hospitals

Educational Support for Mandatory Reporting

**Module 4:
Health Canada's Review and
Communication of Safety Findings**

Module 4 – Learning Outcomes

Completion of Module 4 will enable you to:

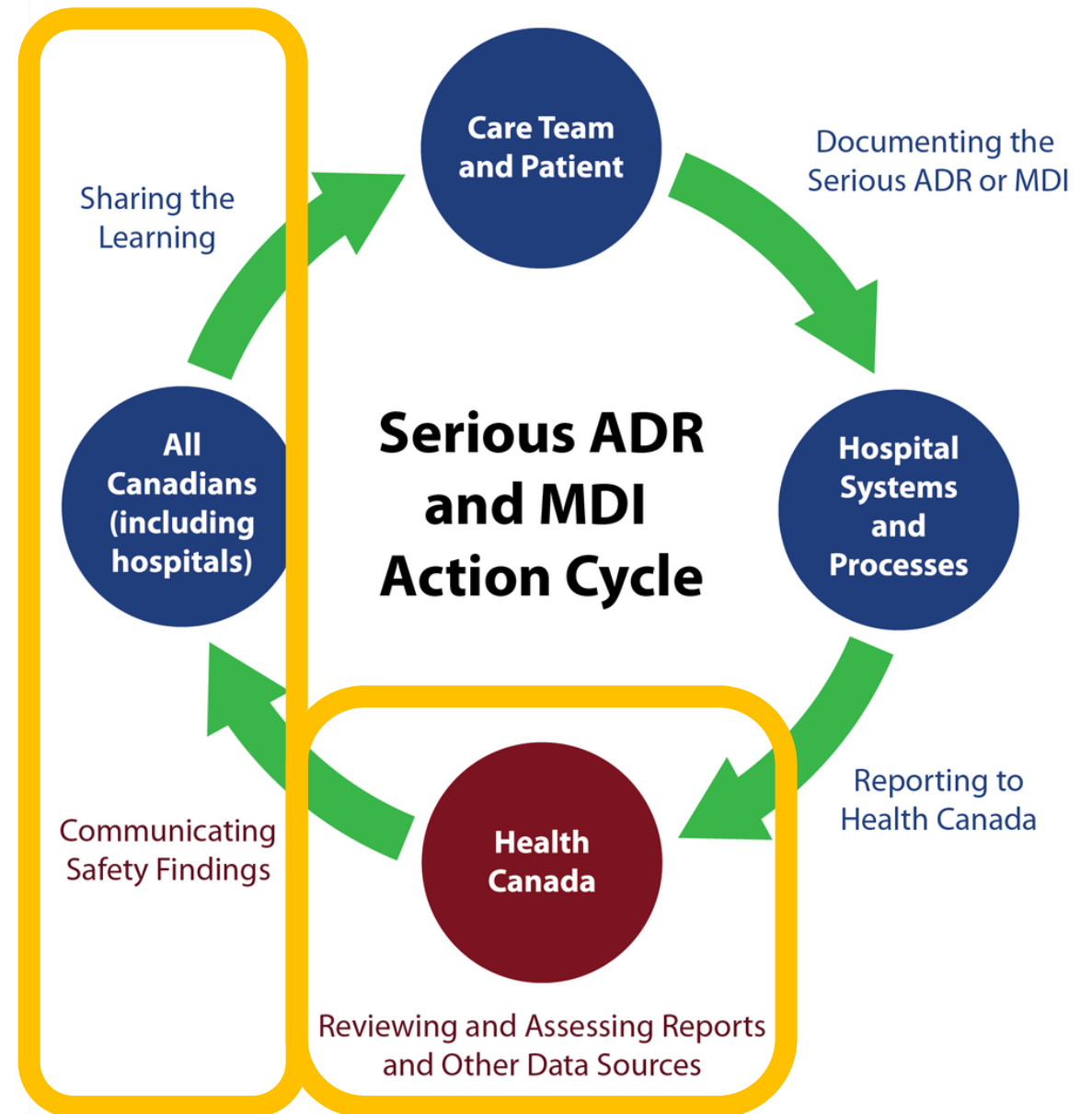
- Provide an overview of health product vigilance in Canada
- Identify the stages of adverse reaction (AR) and medical device problem (MDP) report management
- Describe post-market surveillance activities, including signal detection, signal prioritization, signal assessment/safety review, and risk mitigation
- Describe risk communications from Health Canada
- Recognize the various resources provided by Health Canada to share AR and MDP data and findings
- Understand Health Canada's principles for the security and sharing of AR and MDP report data

Module 4 – Outline

- Health Product Vigilance
- Health Canada's AR and MDP Report Management
- Information Sharing from AR and MDP Reporting
 - AR and MDP Online Databases
 - Health Canada Safety Reviews
 - Health Canada Recalls and Safety Alerts
 - Health Product InfoWatch
 - Drug and Health Product Register (DHPR)
- Data Security and Data Sharing from AR and MDP Reports
- Key Points to Remember
- Abbreviations
- Resources

Conceptual Model of Serious ADR and MDI Reporting by Hospitals

Module 4 describes Health Canada's review and communication of safety findings.



Health Product Vigilance

Health Product Vigilance

- Health Canada builds post-market safety knowledge, which is integral to effective clinical use, from several data sources, including serious adverse drug reaction (serious ADR) and medical device incident (MDI) reports.
- In addition to serious ADR and MDI reports, a variety of other data sources contribute to therapeutic product safety monitoring, including:
 - mandatory reports from regulated parties,
 - voluntary reports from health care professionals and consumers,
 - foreign data such as manufacturer assessment of worldwide safety data,
 - information sharing with foreign regulatory agencies,
 - medical literature, and
 - information generated from the Drug Safety and Effectiveness Network (DSEN).
- This module reflects the broad scope of Health Canada's product vigilance activities beyond mandatory reporting by hospitals (e.g., serious ADRs and MDIs); which is reflected in the use of the AR and MDP report terminology.

Health Canada's Health Product Vigilance Life Cycle

1. MARKET AUTHORIZATION SUBMISSION

- Product submission (pharmaceuticals, natural health products, biologics and biosimilars, radiopharmaceuticals, disinfectants and sanitizers with disinfectant claims, and medical devices) by market authorization holder (MAH)

2. PRE-MARKET REVIEW

- Reviews product submissions to assess for safety, efficacy and quality
- Review risk management plans with MAH to mitigate potential risks (as applicable)
- Assesses product name and label (depending on class for medical devices)

5. COMPLIANCE AND ENFORCEMENT

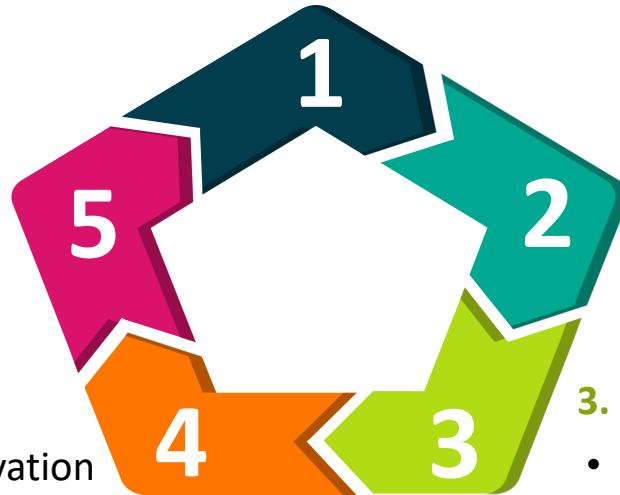
- Monitors quality of adverse reaction/ medical device problem reports through compliance promotion and enforcement (e.g., inspections)
- Enforce regulations

4. RISK MITIGATION

- Continuing observation
- Labelling changes
- Risk communications
- Product recall
- Educational activities
- Market withdrawal
- Other

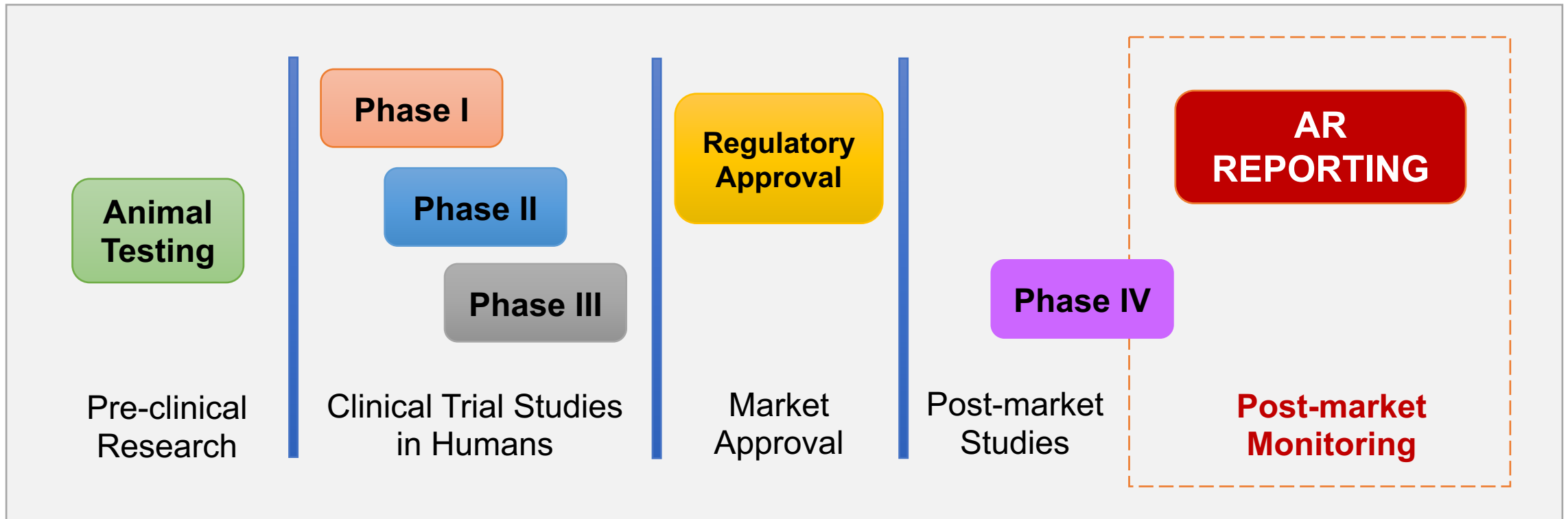
3. POST-MARKET SURVEILLANCE

- Monitors safety and effectiveness of health products by identifying and assessing potential safety signals through multiple sources including spontaneous reporting of adverse reactions to health products and medical device problems reports, literature review, annual safety summaries, DSEN, liaising with other regulators, etc.



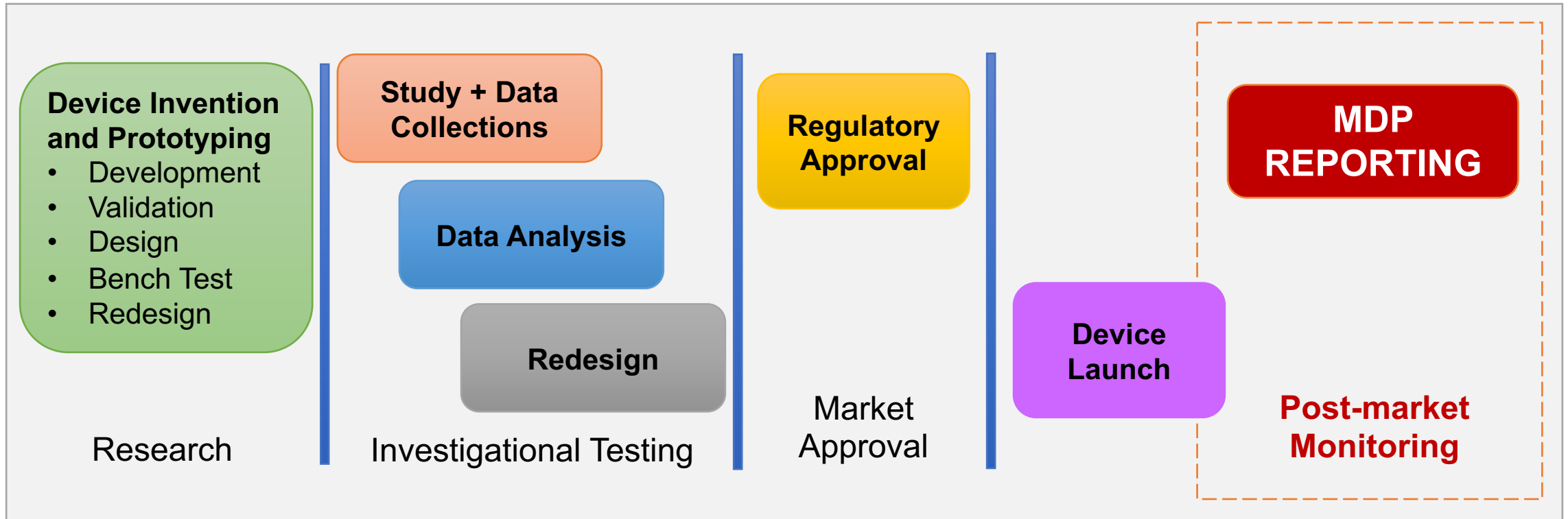
AR Reporting Is Essential to Post-market Surveillance

- Many safety issues are **ONLY** detected after market approval due to use of the health product in larger populations.



MDP Reporting Is Essential to Post-market Surveillance

- Many harms from medical devices are **ONLY** detected after market approval due to use of the device in larger populations.

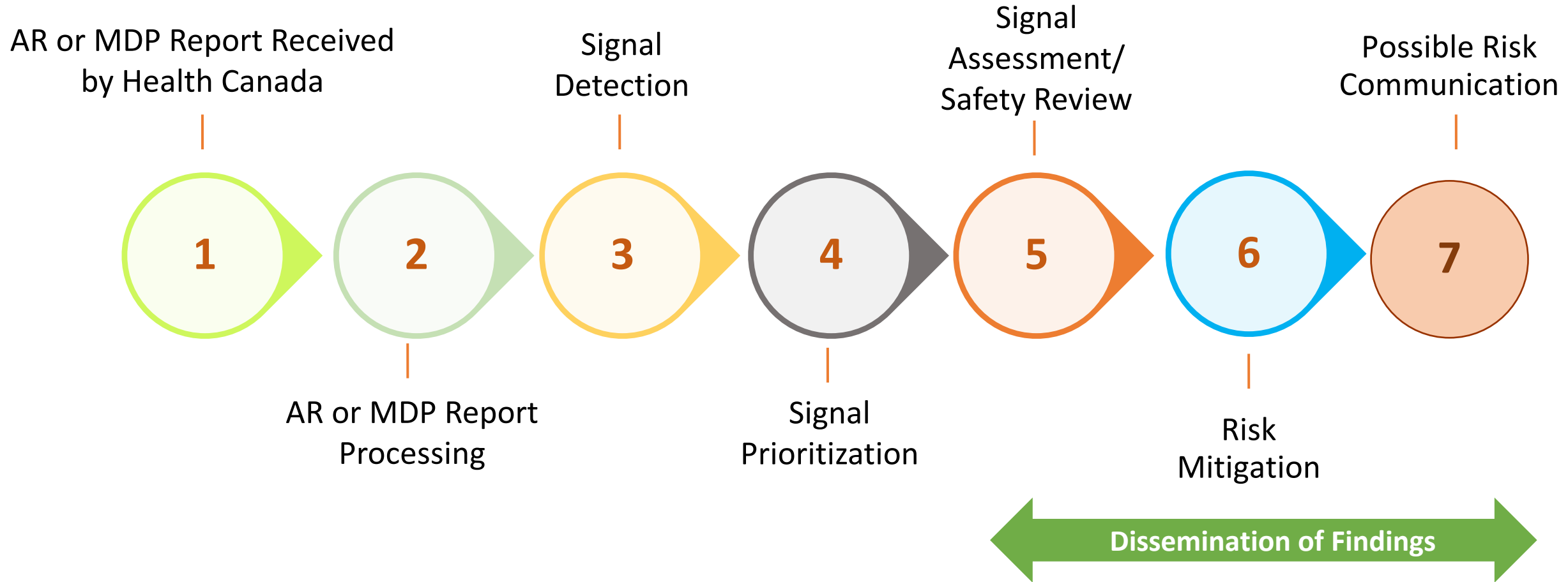


AR and MDP Reporting Is Essential to Post-market Surveillance

Clinical Trials / Investigational Testing Have Limited Scope	Post-market Surveillance Identifies Emerging Safety Issues
<ul style="list-style-type: none">• Highly controlled environment• Limited number of patients• Short trial duration• Highly selected patients• Selected cases and diseases• May not identify rare events	<ul style="list-style-type: none">• Real world use• Varied and large population• Long term use• Off-label use in different patient groups• Patients with multiple co-morbidities• Rare events can be detected

Health Canada's AR and MDP Report Management

Stages of AR and MDP Report Management



Signal Detection and Assessment

- Safety signals (preliminary indications of product-related safety issues) are identified through data scanning, including review of AR and MDP reports.
- Potential signals are reviewed by an internal committee of scientists, pharmacists and physicians to determine if a signal assessment will be completed.
- Assessment from all data sources is used to consider possible risk mitigation activities.
- Risk considerations include strength of evidence, manageability of risk, dissemination of information, and communication targets.
- Following the completion of a signal assessment, recommendations are made and can include changing labels, including indication, recalling or withdrawing a product from the market, and communicating risks to stakeholders.

***Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* improves Health Canada's ability to collect post-market safety information and take appropriate action when a serious risk to health is identified.¹**

¹<https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/protecting-canadians-unsafe-drugs-act-vanessa-law-amendments-food-drugs-act.html>

Risk Communications

Target Audience: Health Care Professionals / Hospitals

- **Health Product Risk Communication**

- Ad hoc communication about safety issues
- Broad dissemination (web posting, RSS feed, MedEffect™ e-Notice)
- Targeted dissemination by the Market Authorization Holder or by Health Canada (fax, email, mail)

- **Health Product InfoWatch**

- Monthly publication to raise awareness of safety issues and stimulate reporting of the same
 - Each publication includes a monthly recap of health product advisories and summary safety reviews, as well as a growing selection of new health product safety information.
- Broad dissemination (web posting, Twitter, RSS feed, MedEffect™ e-Notice)

Risk Communications

Target Audience: General Public

- **Recall Notice**

- Written and distributed by industry; an “extract” of the information posted by Health Canada
- Posted at regular intervals on Health Canada’s Recalls and Safety Alerts database

- **Public Advisory**

- Written by Health Canada for urgent, high risk issues
- Broad dissemination (Newswire, Twitter, RSS feed, MedEffect™ e-Notice)
- Targeted distribution to stakeholders as needed

- **Information Update**

- Written by Health Canada for less urgent, lower risk issues (e.g., labelling updates)
- Broad dissemination (Newswire, Twitter, RSS feed, MedEffect™ e-Notice)

- **Foreign Product Alerts**

- Health Canada communicates information as needed about unauthorized products from other countries which may have been brought into the country by travellers or purchased online

Information Sharing from AR and MDP Reporting

Information Sharing with Health System Partners

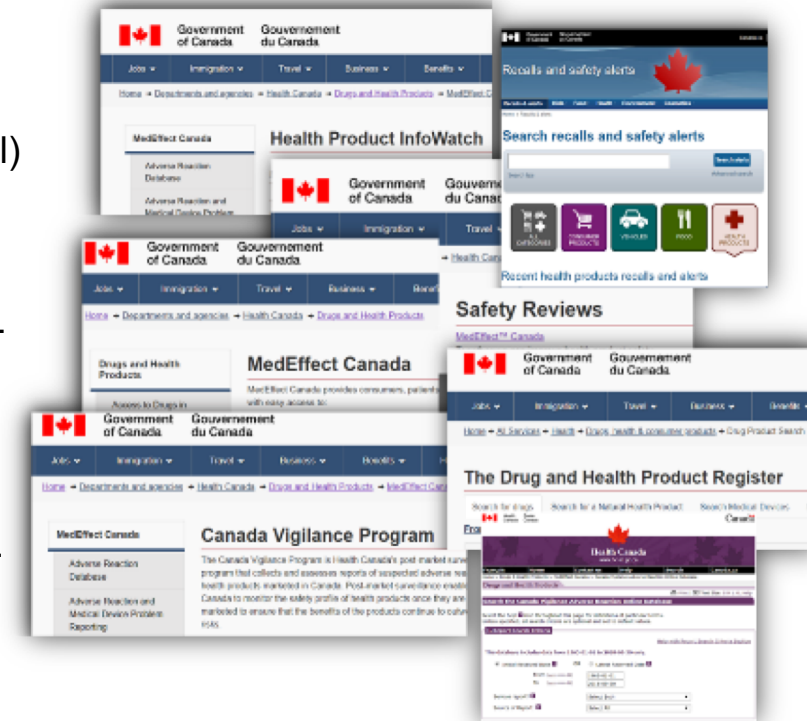
- Health Canada makes AR and MDP data available online, produces an annual trend report and publishes risk communications to health care stakeholders through a number of forums.
- Health Canada plans to continually improve its AR and MDP data analytics, ensuring health system partners have timely access to key information.
 - Data analytics:
 - Invest in information technology to support the timely analysis of the AR and MDP data and streamline the identification of potential safety signals
 - Invest in the optimization of the existing AR/MDP searchable databases
 - Sharing of information with partners, including:
 - Health Canada's annual AR and MDP report
 - Outreach and education activities on reporting and post-market surveillance

Examples of AR and MDP Safety Information Sharing

Health Canada disseminates findings to health care providers and the public to **alert** and **educate** them about identified health risks related to health products.

Multiple sources of safety information are available to provide up-to-date information on ARs and MDPs:

- [Adverse Reaction Online Database](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html)
- [Medical Device Incidents Database](https://hpr-rps.hres.ca/mdi_landing.php) (https://hpr-rps.hres.ca/mdi_landing.php)
- [Annual AR/MDP Trends Report](https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html) (https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html)
- [Health Canada Safety Reviews](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html)
- [Health Canada Recalls and Safety Alerts](http://www.healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3) (http://www.healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3)
- [Health Product InfoWatch](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html)
- [Drug and Health Product Register \(DHPR\)](https://hpr-rps.hres.ca/) (https://hpr-rps.hres.ca/)



Adverse Reaction Online Database

Canada Vigilance Adverse Reaction Online Database

- Searchable database that contains information from post-market AR reports since 1965
- Contains suspected adverse reactions to health products
- Files can be exported and saved in various formats

AR reports can be [searched](#) by:

- report date, seriousness and source
- patient information (gender, age and outcomes)
- suspect health product by brand name and active ingredient
- adverse reaction term or by system organ class



The screenshot shows the official website for the Canada Vigilance Adverse Reaction Online Database. At the top, there is a header with the Government of Canada logo and a search bar. Below the header, a breadcrumb trail indicates the current location: Home > Drugs & Health Products > MedEffect Canada > Canada Vigilance Adverse Reaction Online Database. The main heading is "Search the Canada Vigilance Adverse Reaction Online Database". Below this, it says "From Health Canada". A grey box contains instructions: "Select the help icon throughout this page for definitions of particular terms. Unless specified, all search criteria are optional and set to default values." The section "1. Report Search Criteria" is highlighted in blue. It states: "This database includes data from 1965-01-01 to 2019-03-31 only." Below this, there are radio buttons for "Initial Received Date" (selected) and "Latest Received Date". There are also input fields for "From (yyyy-mm-dd)" with the value "1965-01-01" and "To (yyyy-mm-dd)" with the value "2019-03-31". A link "Help with Report Search Criteria Section" is visible on the right.

Source: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html>

Medical Devices Online Database

Medical Device Incident Database

- Searchable database that contains information from post-market MDP reports since 1980
- Includes devices approved for the Canadian market
- Downloadable full extract available

MDP reports are searched by free text and the following data is returned:

- incident ID
- receipt date
- device name
- device type
- company name
- hazard severity
- description
- code types assigned

Source: https://hpr-rps.hres.ca/mdi_landing.php

The screenshot shows the Government of Canada's Medical Devices Online Database. The top navigation bar includes the Canadian flag, the text 'Government of Canada' and 'Gouvernement du Canada', a search bar, and a language selector for 'Français'. Below this is a menu with categories: Jobs, Immigration, Travel, Business, Benefits, Health, Taxes, and More services. The breadcrumb trail reads: Home > All Services > Health > Drugs, health & consumer products > Medical Device Incidents.

The main section is titled 'Medical Devices' and includes links for Drugs, Natural Health Products, Medical Devices, Review Decisions, Report a side effect, and About. Below this is a link for 'Medical Devices Active Licence Listing (MDALL)' and a search bar for 'Search Medical Device Incidents'. The search bar contains the text 'bed'.

Below the search bar, a list of search results is shown:

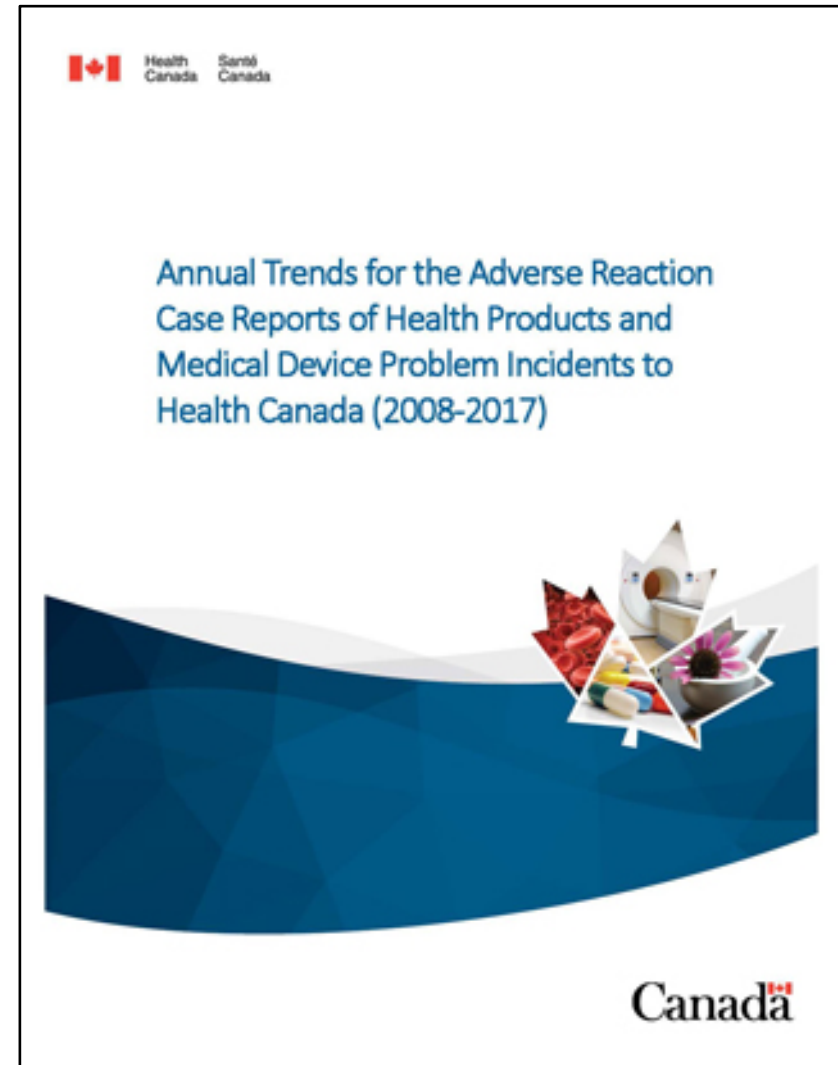
- AC POWERED ADJUSTABLE HOSPITAL BED, INCLUDING RAILS [device]
- CAREASSIST HOSPITAL BED MODEL P1170 [device]
- HILL-ROM 4 MOTOR ADVANCE BED [device]
- VERSACARE BED WITH ACTIVE INTEGRATED RESPONSE TREATMENT SURFACE [device]

The 'Medical Device Incident Results' section shows a 'New Search' button and the text 'Results for: bed'. Below this is a table with the following columns: Incident ID, Devices, Device Type, Company Name, Hazard Severity, Description, Code Type, and Receipt Date. The table contains three rows of data:

Incident ID	Devices	Device Type	Company Name	Hazard Severity	Description	Code Type	Receipt Date
169518	SECURE 3 MED/SURG BED	GENERAL HOSPITAL GENERAL CODE	STRYKER CANADA LP STRYKER MEDICAL	UNASSIGNED	Pending Assessment	Health Effect Medical Device Problem	2018-09-17
169508	CAREASSIST HOSPITAL BED MODEL P1170	BED, AC-POWERED ADJUSTABLE HOSPITAL	HILL-ROM CANADA LTD. HILL-ROM, INC.	POTENTIAL FOR DEATH/INJURY	No Consequences Or Impact To Patient Use of Device Problem Defective Device Break	Health Effect Medical Device Problem Manufacturer Investigation Findings	2018-09-21

Annual Trends Report

The annual trends report provides a descriptive analysis of adverse reaction case reports of health products and medical device problem incidents that have been submitted to Health Canada between 2008 and 2017.



Source: <https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html>

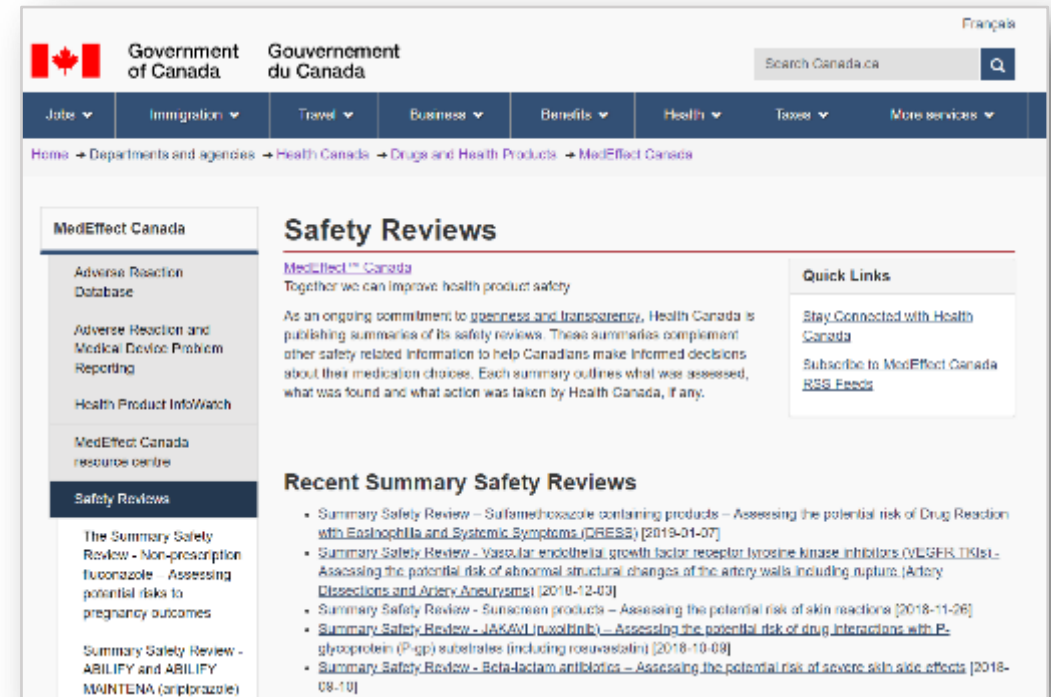
Health Canada Safety Reviews

Health Canada regularly publishes summaries of post-market signal assessment.

Summary Safety Reviews (SSRs) provide a more complete understanding of:

- What was assessed
- What was found
- What action was taken

These summaries can help Canadians make informed decisions about their medication choices and medical devices.



Recalls and Safety Alerts

The recalls and safety alerts database provides centralized access to **recalls** and **safety alerts** from:

- Health Canada
- The Canadian Food Inspection Agency
- Transport Canada

Recalls & alerts Kids Food Your Health Environment Consumer products

Home > Recalls & alerts

Medtronic Stent Graft Systems (2019-02-07)

Starting date: February 10, 2019
Posting date: February 22, 2019
Type of communication: Medical Device Recall
Subcategory: Medical Device
Hazard classification: Type II
Source of recall: Health Canada
Issue: Medical Devices
Audience: General Public, Healthcare Professionals, Hospitals
Identification number: RA-69120

Reason Affected products

Affected Products

A. Reliant Stent Graft Balloon Catheter
B. Endurant II Stent Graft System
C. Talent Endoluminal Occluder System

Reason
This voluntary recall is being conducted due to the potential that the sterile barrier of the products may be compromised during demo product use and demo product labeling.
This issue does not affect any other Medtronic shipments, products or implantable devices.

Recalls & alerts Kids Food Your Health Environment Consumer products

Home > Recalls & alerts

Alburex-25 (2019-02-07)

Starting date: February 7, 2019
Type of communication: Drug Recall
Subcategory: Drugs
Hazard classification: Type II
Source of recall: Health Canada
Issue: Product Safety
Audience: General Public, Healthcare Professionals, Hospitals
Identification number: RA-69014

Reason Depth of distribution Affected

Recalled Products

Alburex-25 Solution

Reason
Appearance may be out of specification in the affected lot.

Depth of distribution

Government of Canada / Gouvernement du Canada Canada.ca Services Departments Français

Recalls and safety alerts

Recalls & alerts Kids Food Health Environment Cosmetics

Home > Recalls & alerts

Search recalls and safety alerts

Search tips Search alerts Advanced search

Featured alert
Unauthorized products may pose serious health risks

Access information when and where you need it
Add the Recall & Safety Alerts to your Web site
Subscribe to health and safety updates
Report side effects, injuries, and other safety concerns

Recent health products recalls and alerts

Health Canada encourages Canadians to report incidents involving medical devices to help strengthen patient safety	Advisory
2019-01-15 Health Products	
Health Canada safety review finds possible link between Fibrinol and risk of liver injury	Advisory
2019-01-11 Health Products	
Bridine Solution (2018-12-27)	Recall
2018-12-27 Health Products	
Panocell-10, Flon Treated and Panocell-16 (2018-12-26)	Recall
2019-01-11 Health Products	
DUREX RealFeel 20 ct condoms (2018-12-26)	Recall
2018-12-27 Health Products	

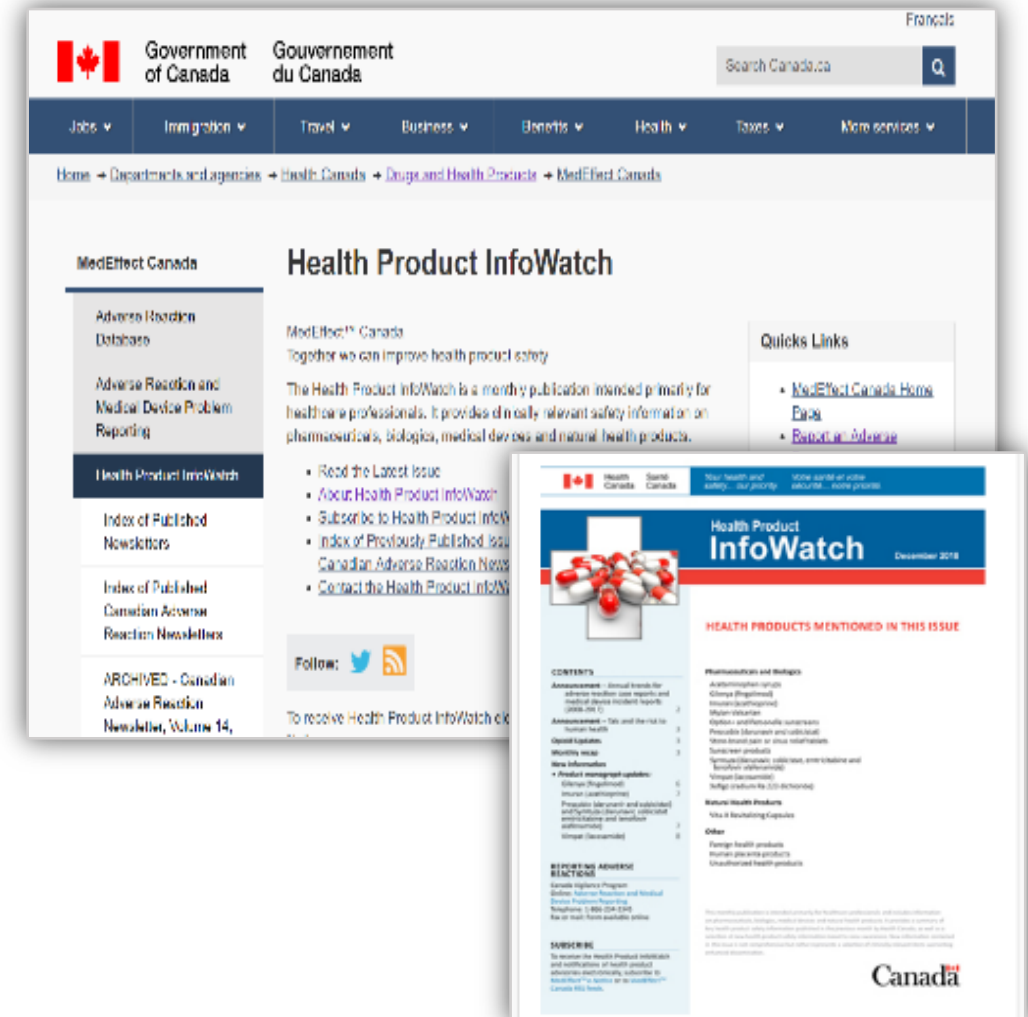
Want to know more?
Why a product is recalled, or

Sign up for e-notifications here!

Source: <https://www.healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3>

Health Product InfoWatch

- A **monthly publication** primarily intended for health care providers
- Provides clinically relevant safety information on
 - pharmaceuticals,
 - biologics,
 - medical devices, and
 - natural health products.
- Each publication includes:
 - recap of health product advisories,
 - recap of summary of safety reviews,
 - new health product safety information, and
 - product monograph updates.



SUBSCRIBE NOW:

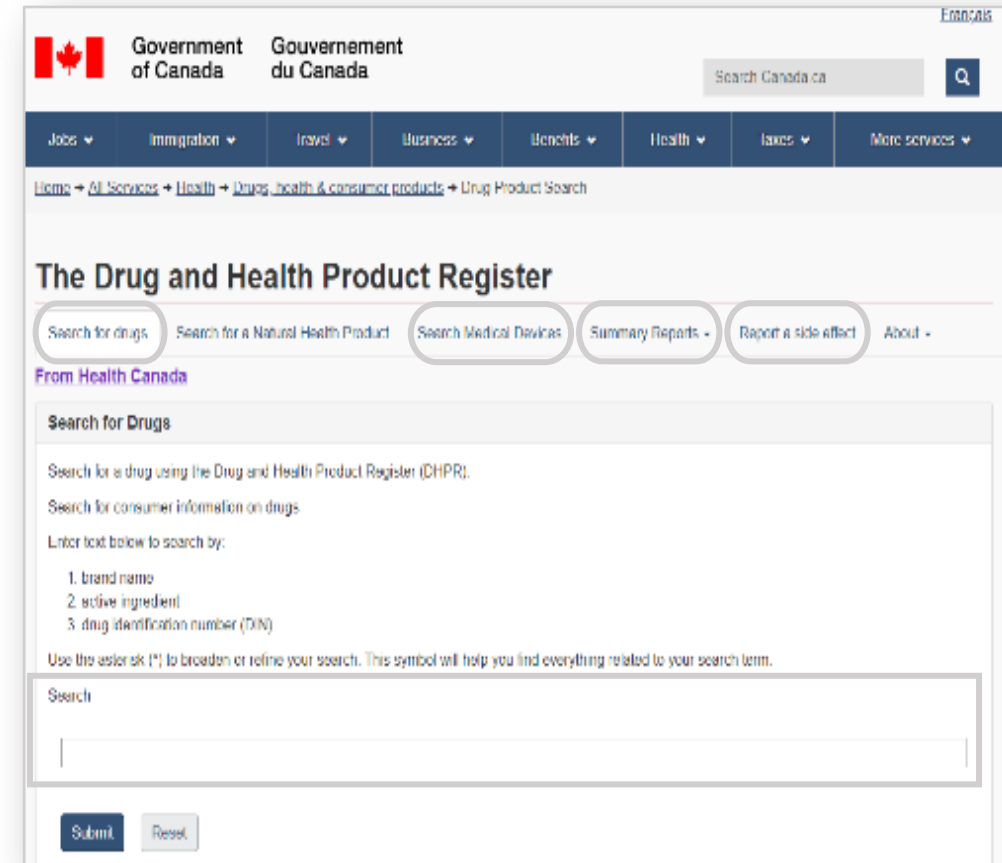
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html>

Drug and Health Product Register (DHPR)

The **DHPR** provides safety information on health products available to Canadians.

The public is able to:

- Access plain language overviews of regulatory decisions:
 - Summary Safety Review
 - Summary Basis of Decision
 - Regulatory Decision Summary
- Search for AR and MDP information
 - Search reported adverse reactions, medical device problems and summary reports of safety information
- Report adverse reactions about health products



The screenshot shows the official website of the Drug and Health Product Register (DHPR) under the Government of Canada. The page is in English, with a French language option available. The header includes the Government of Canada logo and a search bar. A navigation menu lists various services: Jobs, Immigration, Travel, Business, Benefits, Health, Taxes, and More services. The breadcrumb trail indicates the path: Home > All Services > Health > Drugs, health & consumer products > Drug Product Search. The main heading is 'The Drug and Health Product Register'. Below this, there are several search options: 'Search for drugs', 'Search for a Natural Health Product', 'Search Medical Devices', 'Summary Reports', 'Report a side effect', and 'About'. The 'Search for Drugs' section is highlighted, showing instructions to search for a drug using the DHPR, search for consumer information on drugs, and enter text to search by (brand name, active ingredient, or drug identification number). A search box is provided with a 'Submit' button and a 'Reset' button.

Health Canada's Post-market Publication Portal

MedEffect Canada provides health care professionals and consumers with access to safety information (advisories, alerts, recalls, etc.) generated by Health Canada following post-market monitoring and assessment activities.

This portal can be used to access additional resources for health products.

The screenshot shows the MedEffect Canada website. At the top, there is a header with the Canadian flag, the text 'Government of Canada' and 'Gouvernement du Canada', a search bar with 'Search Canada.ca', and a 'Français' link. Below the header is a 'MENU' button. A breadcrumb trail reads: 'Home > Departments and agencies > Health Canada > Drugs and Health Products'. On the left, a sidebar titled 'Drugs and Health Products' lists four categories: 'Access to Drugs in Exceptional Circumstances', 'Biologics, Radiopharmaceuticals and Genetic Therapies', 'Classification of Health Products at the Device-Drug Interface', and 'Compliance and Enforcement'. The main content area is titled 'MedEffect Canada' and contains the text: 'MedEffect Canada provides consumers, patients, and health professionals with easy access to:'. Below this text is a bulleted list of three links: 'Report an adverse reaction or side effect;', 'Obtain new safety information on drugs and other health products; and', and 'Learn and better understand the importance of reporting side effects.'. To the right of the main content is a 'Features' box containing four bulleted links: 'Stay Connected with Health Canada', 'Subscribe to MedEffect Canada RSS Feeds', and 'Recalls and Safety Alerts Widget'. At the bottom of the main content area, the text 'Latest Advisories and Recalls' is visible.

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Home > Departments and agencies > Health Canada > Drugs and Health Products

Drugs and Health Products

Access to Drugs in Exceptional Circumstances

Biologics, Radiopharmaceuticals and Genetic Therapies

Classification of Health Products at the Device-Drug Interface

Compliance and Enforcement

MedEffect Canada

MedEffect Canada provides consumers, patients, and health professionals with easy access to:

- [Report an adverse reaction or side effect;](#)
- [Obtain new safety information on drugs and other health products;](#) and
- [Learn and better understand the importance of reporting side effects.](#)

Latest Advisories and Recalls

Features

- [Stay Connected with Health Canada](#)
- [Subscribe to MedEffect Canada RSS Feeds](#)
- [Recalls and Safety Alerts Widget](#)

Data Security and Data Sharing from AR and MDP Reports

Use of Collected Data – Security and Privacy

Health Canada:

- Stores AR and MDP reports in a confidential database.¹
- Follows protocols to ensure that identifying patient and reporter information is protected under the federal [Privacy Act](#).¹
- Ensures AR and MDP reports are de-identified before sharing.
 - Sends AR data to the [World Health Organization \(WHO\) Global Pharmacovigilance Database](#).
- Commits to ensure that data are used and shared in a scientifically and socially responsible way.
 - [Procedure - The Release to the Public of Information Obtained from Adverse Reaction and Medical Device Incident Reports](#)



¹<https://hpr-rps.hres.ca/static/content/disclaimers-avisdenonresponsabilite.php>

International Collaboration

- Supports the monitoring and identification of new safety issues caused by health products
- Facilitates identification of safety signals by providing a larger pool of data
- Enhances patient safety by allowing for consistent communication around health product risks
- Includes such regulatory agencies as: USA's FDA, EU's EMA, UK's MHRA, Australia's TGA, Japan's PMDA
- Advances worldwide pharmacovigilance standards, systems and learning with organizations such as IMDRF, ICH, ISoP, ICMRA



Key Points to Remember



- **AR and MDP reporting is essential** because many safety issues are detected after market approval.
- **The stages for management of AR and MDP reports are:**
 - AR or MDP report received by Health Canada;
 - AR or MDP report processing;
 - signal detection;
 - signal prioritization;
 - signal assessment/safety review;
 - risk mitigation; and
 - possible risk communication.
- **Health Canada has multiple mechanisms to share learning from reported ARs and MDPs** such as the Drug and Health Product Register (online searchable databases, summary safety reviews and access to reporting) and MedEffect Canada.

Abbreviations

ADR: Adverse Drug Reaction

AR: Adverse Reaction

DHPR: Drug and Health Product Register

DSEN: Drug Safety and Effectiveness Network

EMA: European Medicines Agency

EU: European Union

FDA: Food and Drug Administration

ICH: International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use

ICMRA: International Coalition of Medicines Regulatory Authorities

IMDRF: International Medical Device Regulators Forum

ISoP: International Society of Pharmacovigilance

MAH: Market Authorization Holder

MDI: Medical Device Incident

MDP: Medical Device Problem (any type of medical device issue; not necessarily MDI)

MHRA: Medicines & Healthcare Products Regulatory Agency

PMDA: Pharmaceuticals and Medical Devices Agency

SSRs: Summary Safety Reviews

TGA: Therapeutic Goods Administration

UK: United Kingdom

USA: United States of America

WHO: World Health Organization

Resources

- [Adverse Reaction Database](#)
- [Annual ADR/MDP Trends Report](#)
- [Drug and Health Product Register \(DHPR\)](#)
- [Health Canada Recalls and Safety Alerts](#)
- [Health Canada Safety Reviews](#)
- [Health Product InfoWatch](#)
- [Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals - Guidance document](#)
- [MedEffect Canada](#)
- [Medical Devices Incident Database](#)
- [Procedure - The Release to the Public of Information Obtained from Adverse Reaction and Medical Device Incident Reports](#)
- [Protecting Canadians from Unsafe Drugs Act \(Vanessa's Law\) Amendments to the Food and Drugs Act \(Bill C-17\)](#)
- [Regulations Amending the Food and Drug Regulations \(Serious Adverse Drug Reaction Reporting — Hospitals\): SOR/2019-190](#)
- [Regulations Amending the Medical Devices Regulations \(Medical Device Incident Reporting — Hospitals\): SOR/2019-191](#)
- [The Privacy Act](#)
- [World Health Organization \(WHO\) Global Pharmacovigilance Database](#)

For additional information, please contact the Canada Vigilance Program at:

Email: hc.canada.vigilance.sc@canada.ca

Telephone: 1-866-234-2345

Acknowledgments

- All materials were developed by the collaborating parties: Health Canada, Institute for Safe Medication Practices Canada (ISMP Canada), Health Standards Organization (HSO), and the Canadian Patient Safety Institute (CPSI).
- Any stakeholder interested in using the materials should acknowledge Health Canada as the owner and source:
Educational Support for Mandatory Reporting. Health Canada; 2019.

