Health Canada Santé Canada

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Health Canada Webinar:
Mandatory Reporting by Hospitals
Spring 2022 Updates

Marketed Health Products Directorate
Health Products and Food Branch
Health Canada

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Health Canada Webinar:
Mandatory Reporting for Hospitals

If you have any questions throughout the webinar, please visit **Slido.com** and enter **code #074631** to submit your questions.

The session will be recorded.

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Objectives

To inform hospitals about the status of the mandatory reporting of medical device incidents (MDIs) and serious adverse drug reactions (ADRs).

At the end of our presentation, you will:

- Have the latest information on Canada Vigilance Program (CVP) news and more
- Know the latest statistics on mandatory reporting by hospitals as well as upcoming statistical products
- Understand how your reports are used for signal detection for ADRs

Agenda

1. • **Introduction** – News
2. • **Statistical Update and Upcoming Products**
3. • **Feature** – Signal Detection for ADRs
4. • **Take-home Messages**
5. • **Live Question & Answers session**

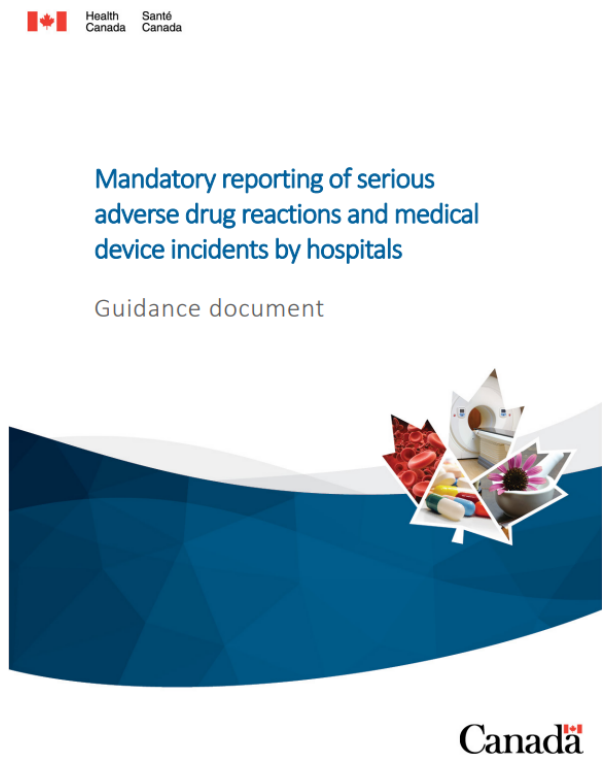
Introduction

CVP News and More

News: Canada Vigilance Program

Guidance Document Consultation

- Updates to the Mandatory reporting of serious ADRs and MDIs by hospitals – Guidance Document
  - Assists hospitals in complying with the federal regulatory requirement for hospitals to report MDIs and serious ADRs to Health Canada
  - Consultation will likely occur in **Winter 2023**
    - Exact date to be confirmed



News: Canada Vigilance Program

MDI Report Notification Tool to Manufacturers

- Currently, hospitals are not required to report MDIs to manufacturers.

- Since **April 18, 2022**, automatic notification letters were sent* to manufacturers upon Health Canada receiving MDI reports from hospitals.

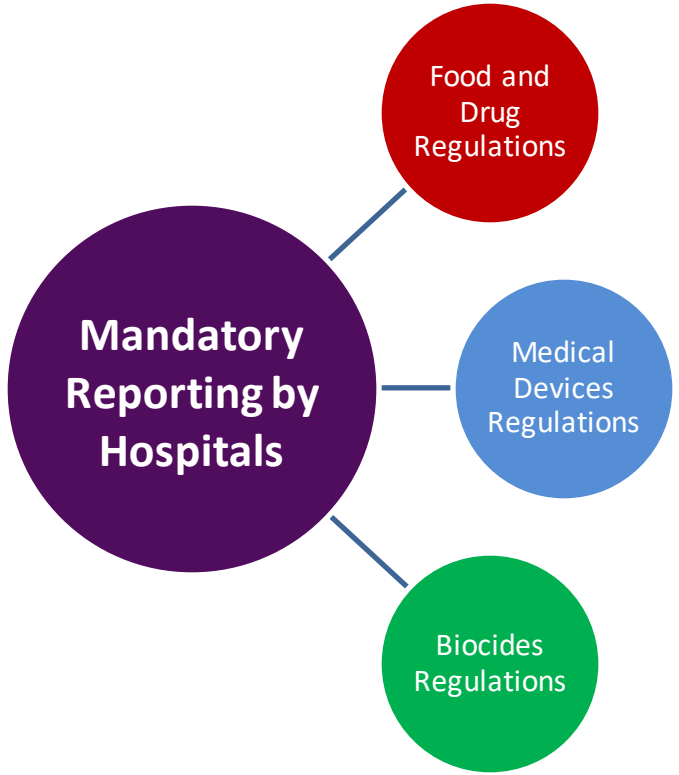
- Notification letters include information about:
  - Device involved
  - Hospital reporter contact information

*On hold pending revisions

News: Biocides Reporting

Biocides Regulations

- Health Canada is proposing to create new *Biocides Regulations* under the *Food and Drugs Act.*
  - Disinfectants currently regulated under the *Food and Drug Regulations* will be transitioned to the new dedicated regulatory framework for biocides.
  - Surface sanitizers currently regulated under the *Pest Control Products Act* will also be transitioned to the biocides regulations.



News: Biocides Reporting

What is a biocide?

- A drug that is sold or represented for use in destroying or inactivating micro-organisms, or in reducing or controlling their number, on a non-living and non-liquid surface.

What is the impact on serious ADR Reporting?

- **Serious Adverse Drug Reaction**
  - Definition modified to better reflect biocide products

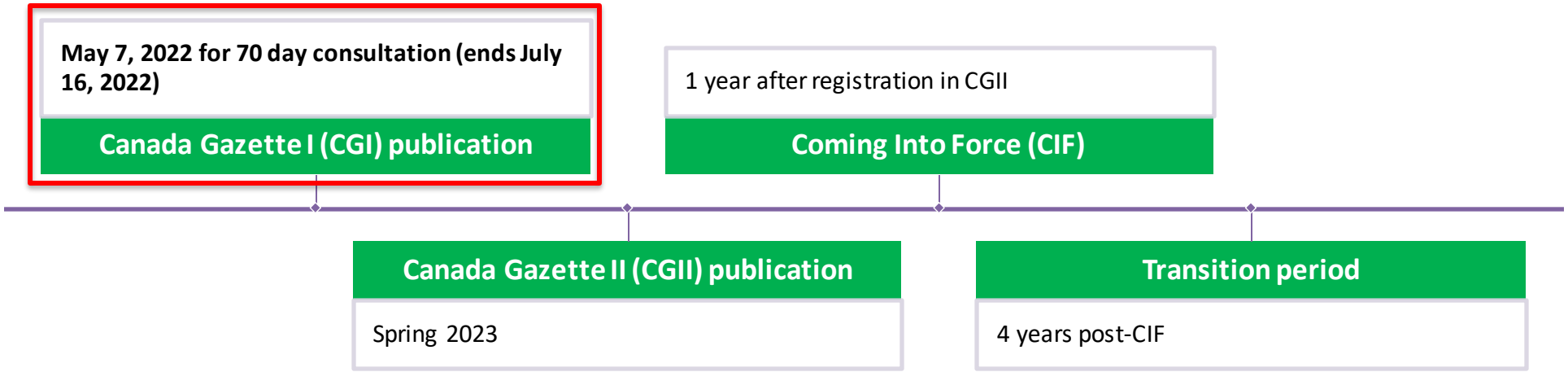
- **Information to Provide**
  - Information requirements will better reflect biocide products

All other reporting requirements remain unchanged

No anticipated changes in reporting volumes

News: Biocides Reporting

- **Timeline**



- **Status**: Canada Gazette I
  - Hospitals are encouraged to review the consultation documents and submit any comments before **July 16, 2022**.

News: Proposed Block Release Regulations

Public or Canadian Armed Forces Health Emergencies — Drugs for Immediate Use or Stockpiling

- Hospital reporting of serious ADRs would be required for drugs allowed under the proposed block release regulations for public health emergencies only.

Purpose:

- Facilitates access to drugs that are not authorised in Canada for use in emergency preparedness and response activities of public health officials (PHOs).
  - E.g. can be used to access a drug from any country, that at a minimum, has passed Phase II Clinical Trial.

News: Proposed Block Release Regulations

Who Can Use It:

- Regulation would permit PHO to stockpile and use drugs to address a public or military health emergency.
  - During a public health emergency, this can be used by PHOs at all levels of government (federal, provincial, territorial or municipal).
  - Main users are expected to be the Public Health Agency of Canada (Chief Public Health Officer) and the Canadian Armed Forces (Surgeon General).

News: Proposed Block Release Regulations

Impact on Serious ADR Reporting:

- The updated regulations propose changes to how serious ADRS are reported for public health emergencies only.
  - Hospitals would be required to report to Health Canada.

Reason:

- For public health emergencies, Canadians will likely present themselves to the hospital if they experience a serious ADR.
- Provides consistency in serious ADR reporting.

Timeline

- **Status:** Canada Gazette II, early 2023

News: Proposed Block Release Regulations

Impact on Hospitals:

- Deployment and use of drugs stockpiled under the block release regulations to address a public health emergency is expected to be a *rare event*.

- The PHO authorised by Health Canada to use the drug would inform the hospitals that the drug is being used to address a public health emergency.
  - The authorised PHO would also be responsible to ensure appropriate labelling of the drug.

- Hospitals would report the serious ADR according to procedures already in place for mandatory reporting.

Statistical Update and Upcoming Products

Summary of all Mandatory Reports (MDIs and serious ADRs)
December 16, 2019 to April 30, 2022

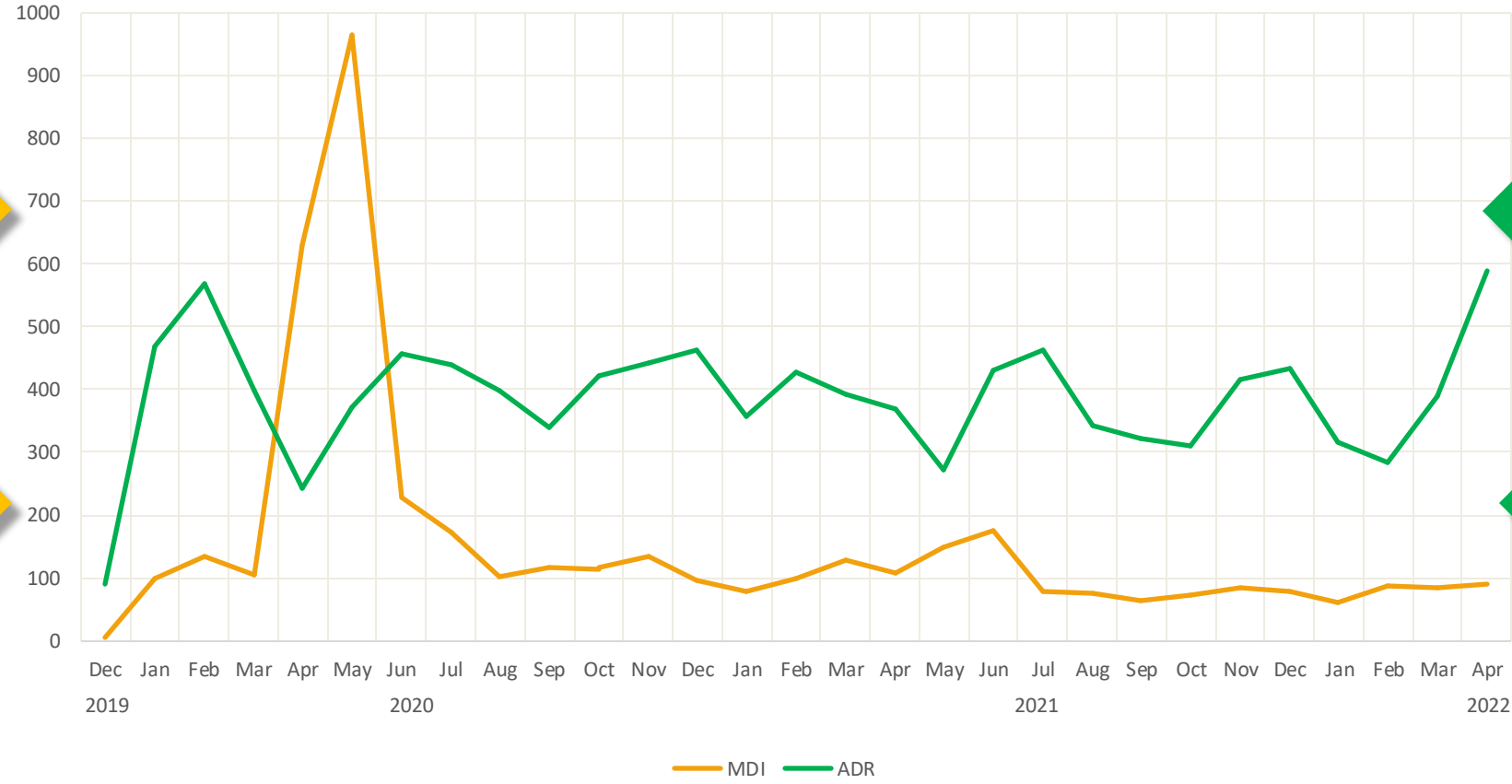
Statistical Summary: Hospital Dashboard

Number of MDI and serious ADR reports submitted by hospitals to Health Canada since the regulations came into effect

MDI

Total: 4,408 reports

Average: 152 reports / month



ADR

Total: 11,216 reports

Average: 386 reports / month

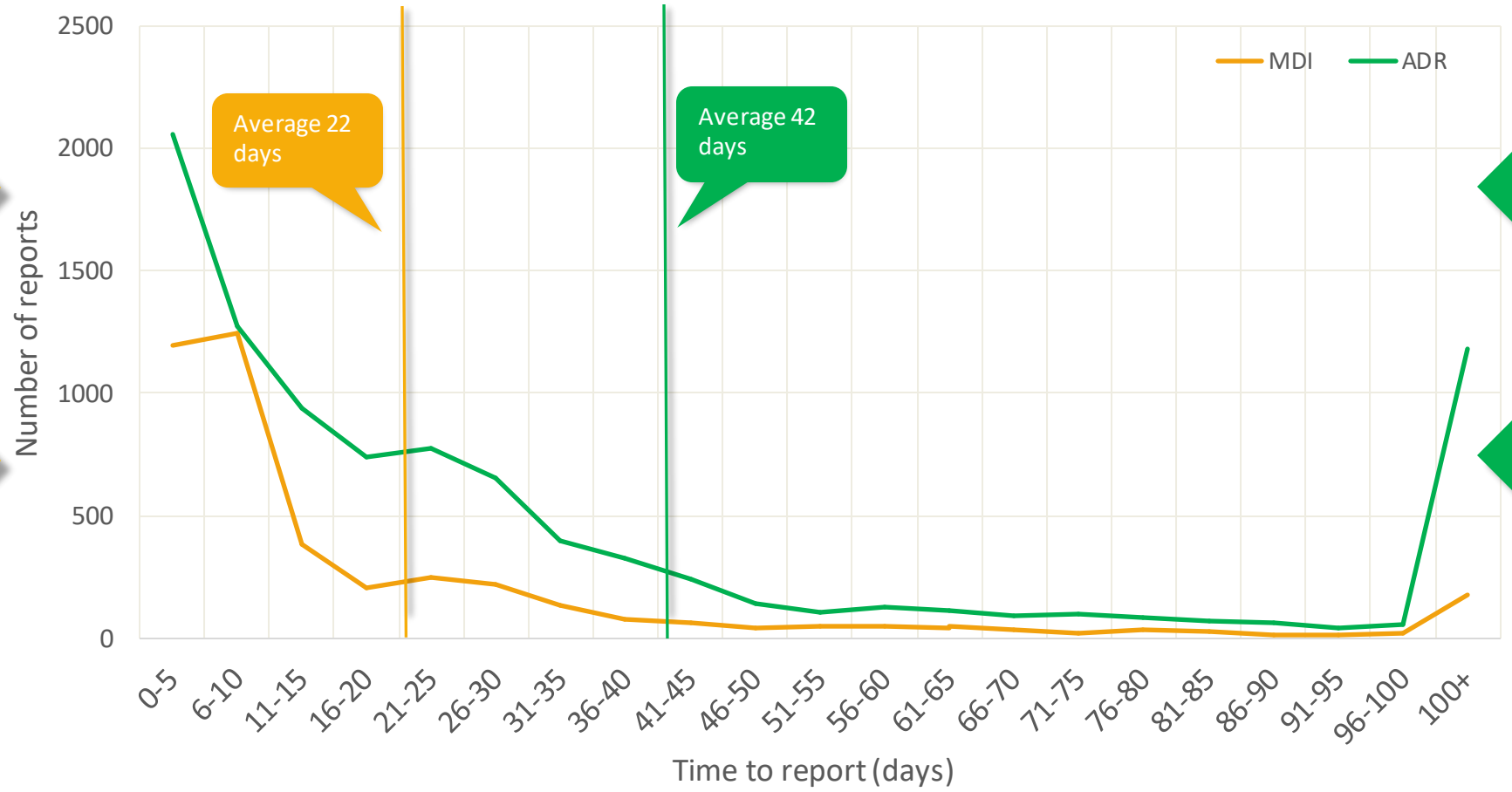
Statistical Summary: Hospital Dashboard

Number of days taken to submit an MDI and serious ADR report over time

MDI

Median: 8 days

On time: 81%



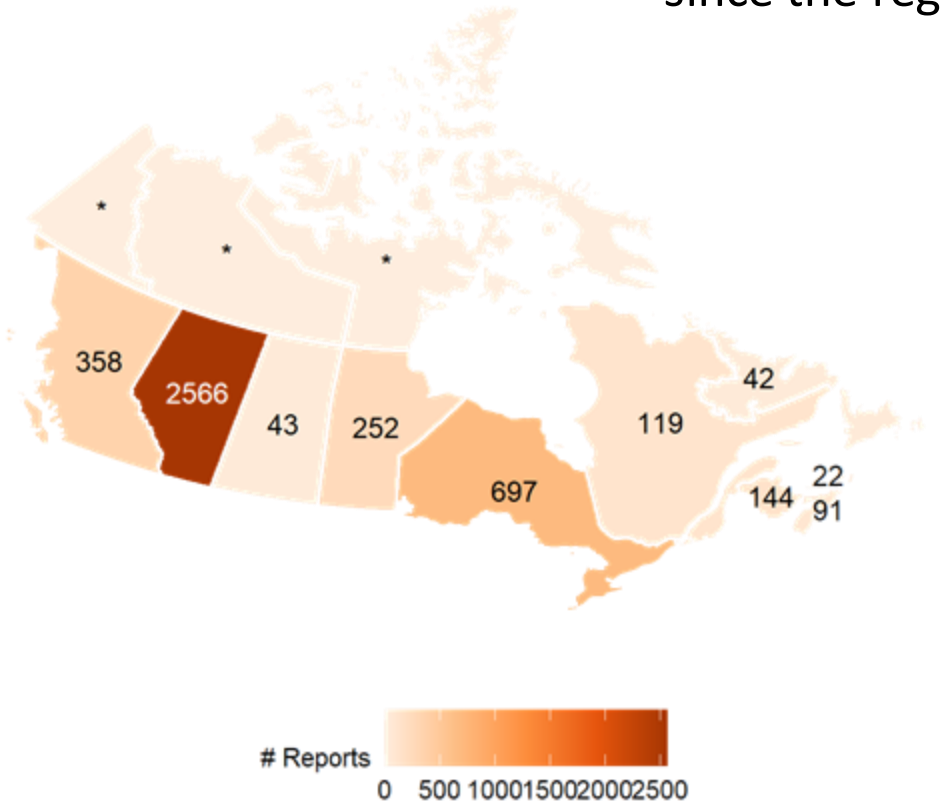
ADR

Median: 19 days

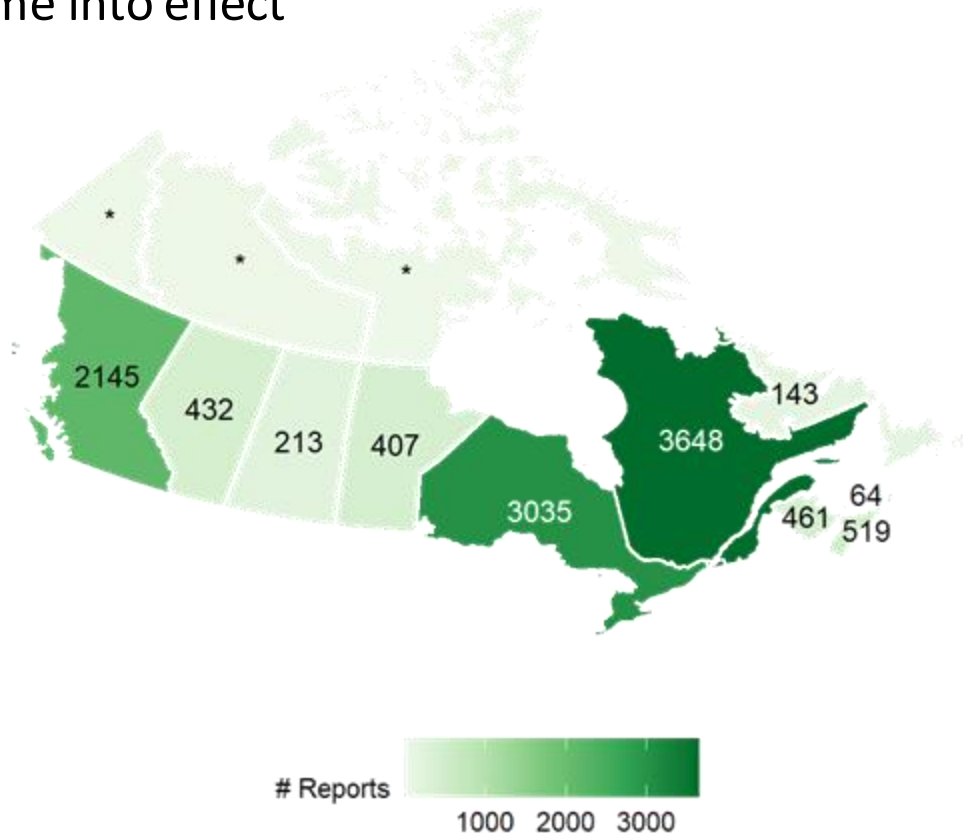
On time: 67%

Statistical Summary: Hospital Dashboard

Number of MDI and serious ADR reports submitted by hospitals, by province and territory, since the regulations came into effect



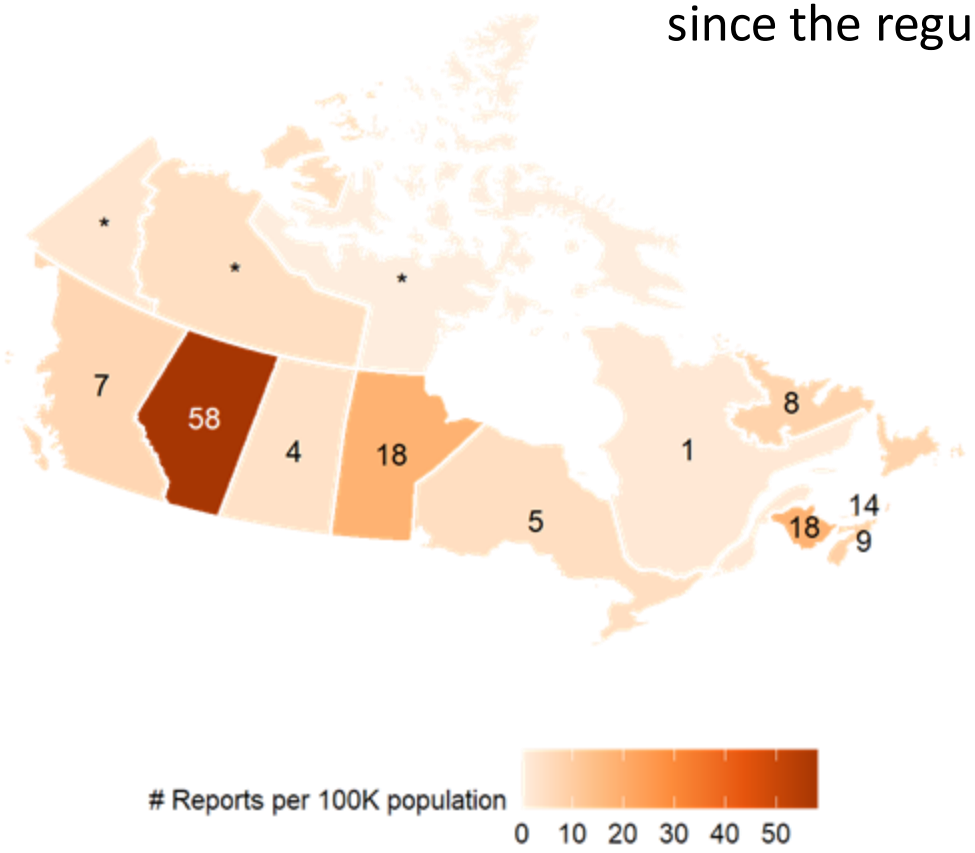
Number of MDI reports



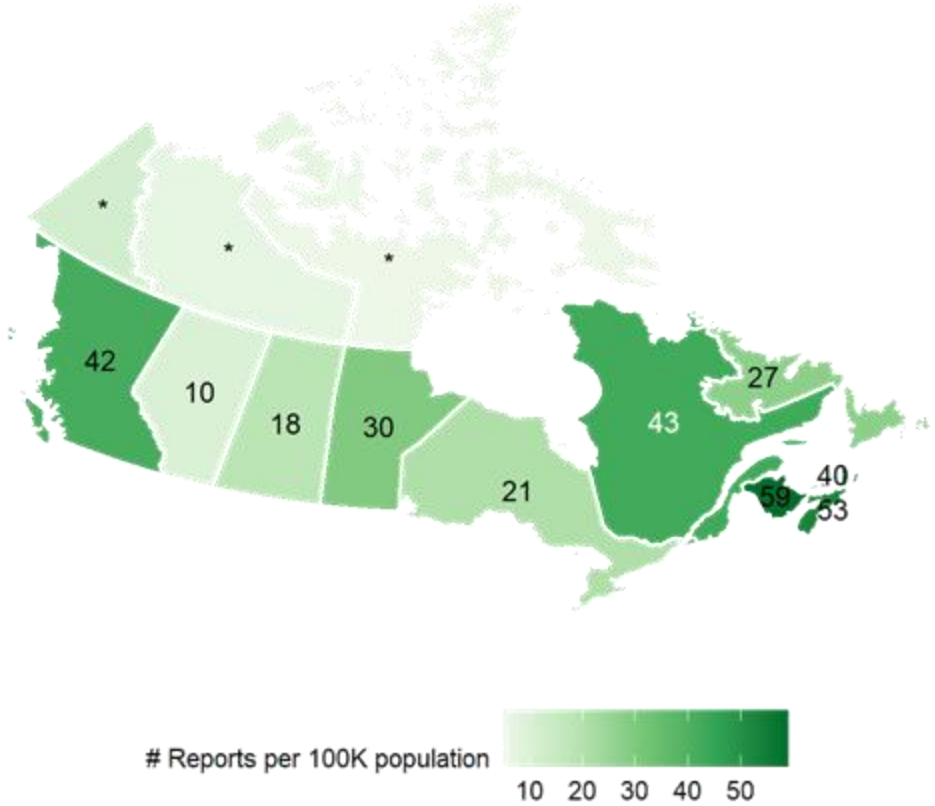
Number of ADR reports

Statistical Summary: Hospital Dashboard

Rate of MDI and serious ADR report submission per 100,000 population, by province and territory, since the regulations came into effect



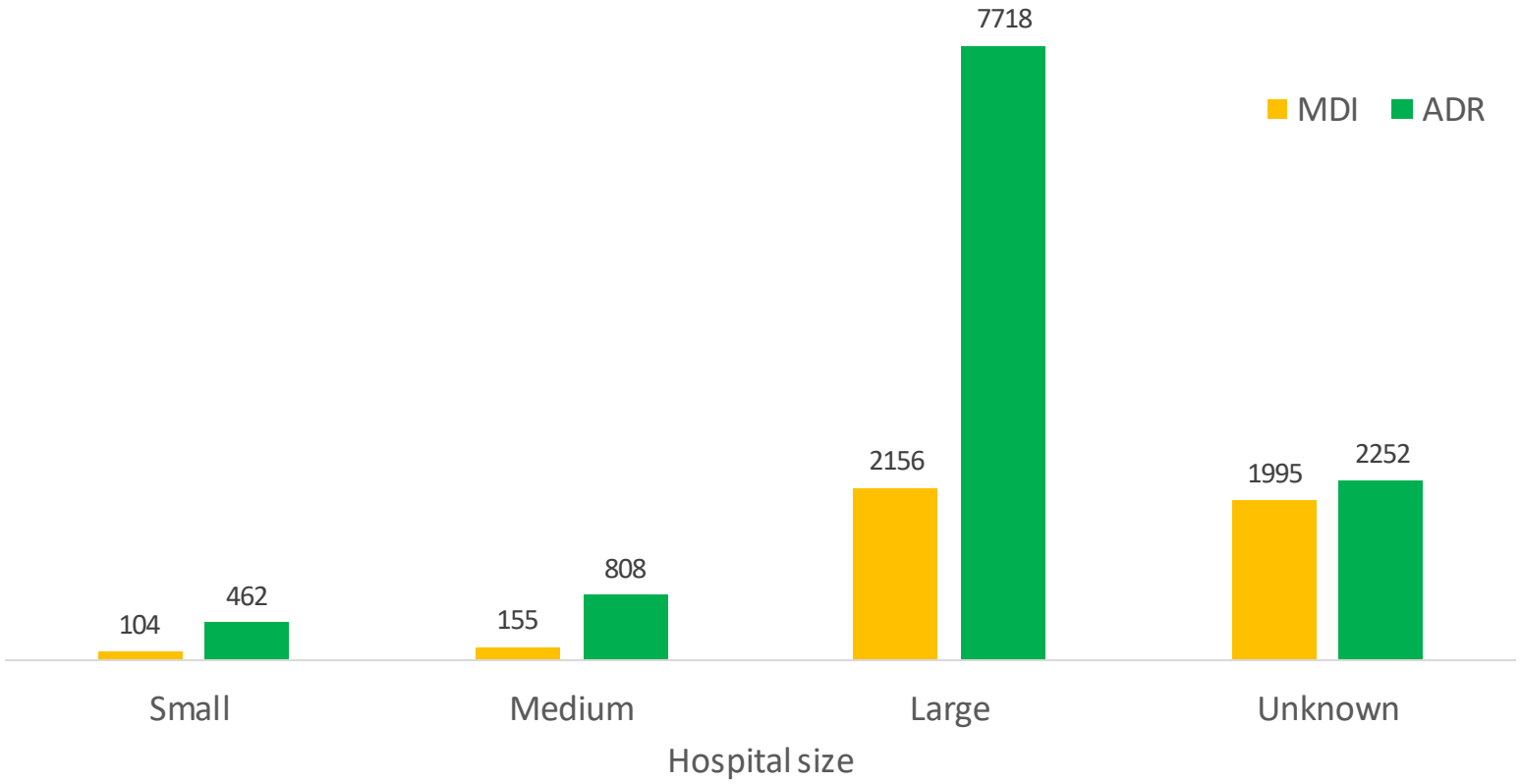
MDI reporting rate per 100,000



ADR reporting rate per 100,000

Statistical Summary: Hospital Dashboard

Number of MDI and serious ADR reports submitted by hospitals to Health Canada, by hospital size, since regulations came into effect



Category	Number of beds
Small	0 – 30
Medium	31 – 99
Large	100 +

Statistical Summary: Hospital Dashboard

Top 5 medical device categories reported in MDI reports

Medical device category[1]	Reports
Non-specialized/general hospital	2,852
Cardiovascular	340
General surgery and plastic surgery	331
Gastroenterology and urology	261
Anesthesiology	179

[1] Categories based on main use or purpose of a medical device according to the International Medical Device Regulators Forum. More information at www.imdrf.org

Top 5 ATC classification groups of suspect products reported in serious ADR reports

ATC[2] Group	Reports
Antineoplastic agents	4,714
Antibacterials For Systemic Use	1,674
Antithrombotic Agents	1,460
Analgesics	650
Drugs Used In Diabetes	607

[2] The Anatomical Therapeutic Chemical system (ATC) is a drug classification system. It divides drugs into different groups based on their properties and the organ or system they act upon. More information at www.whocc.no website.

Upcoming Products

Hospital Summary of Mandatory Reporting

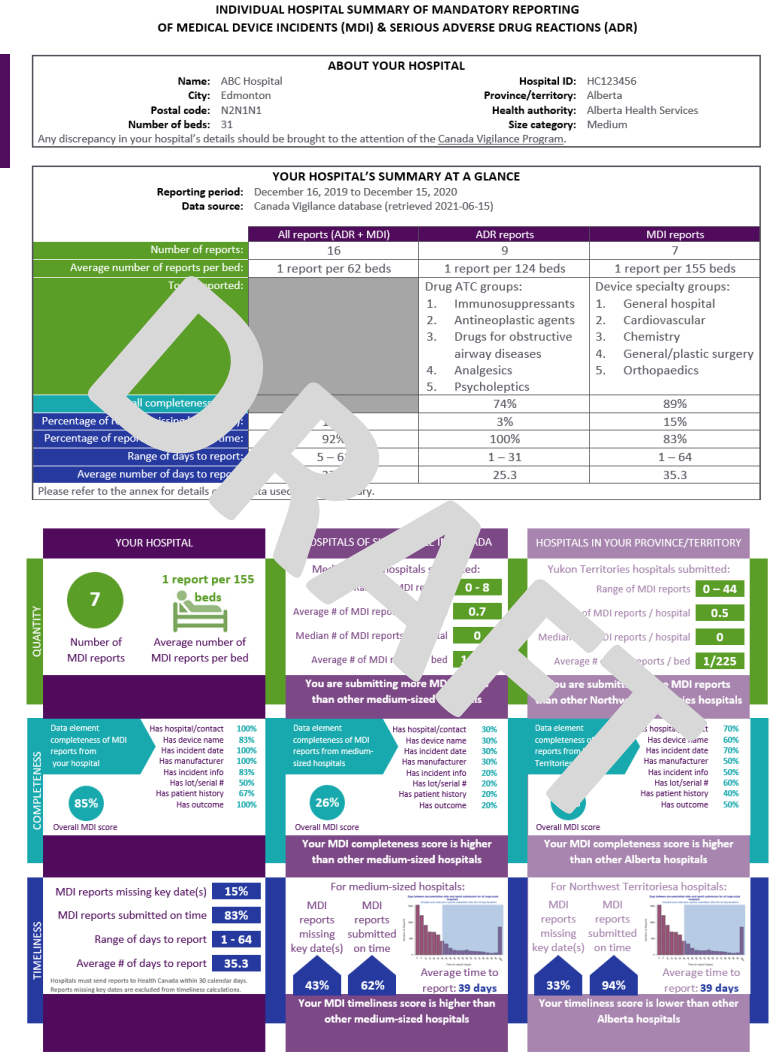
Mandatory Reporting by Hospitals Dashboard

2021 ADR Annual Report

Statistical Summary: Upcoming Products

1. Hospital Summary of Mandatory Reporting

- Individualized 4-page document
  - Only sent to hospitals who have reported at least 1 serious ADR or MDI report
- Combined, serious ADR, and MDI statistics:
  - For your hospital
  - For similarly sized hospitals
  - For hospitals in your province/territory
- **Release date**: To be determined
  - Report frequency not yet determined



INDIVIDUAL HOSPITAL SUMMARY OF MANDATORY REPORTING
OF MEDICAL DEVICE INCIDENTS (MDI) & SERIOUS ADVERSE DRUG REACTIONS (ADR)

ABOUT YOUR HOSPITAL

Name: ABC Hospital
City: Edmonton
Postal code: N2N1N1
Number of beds: 31
Hospital ID: HC123456
Province/territory: Alberta
Health authority: Alberta Health Services
Size category: Medium
Any discrepancy in your hospital's details should be brought to the attention of the Canada Vigilance Program.

YOUR HOSPITAL'S SUMMARY AT A GLANCE

Reporting period: December 16, 2019 to December 15, 2020
Data source: Canada Vigilance database (retrieved 2021-06-15)

	All reports (ADR + MDI)	ADR reports	MDI reports
Number of reports:	16	9	7
Average number of reports per bed:	1 report per 62 beds	1 report per 124 beds	1 report per 155 beds
To [illegible] reported:		Drug ATC groups: 1. Immunosuppressants 2. Antineoplastic agents 3. Drugs for obstructive airway diseases 4. Analgesics 5. Psycholeptics	Device specialty groups: 1. General hospital 2. Cardiovascular 3. Chemistry 4. General/plastic surgery 5. Orthopaedics
[illegible] completeness:		74%	89%
Percentage of r[illegible] reported:		3%	15%
Percentage of repo[illegible]time:	92%	100%	83%
Range of days to report:	5 – 6	1 – 31	1 – 64
Average number of days to rep[illegible]	[illegible]	25.3	35.3

Please refer to the annex for details [illegible]ata used [illegible]ary.

YOUR HOSPITAL

QUANTITY: 7 Number of MDI reports; 1 report per 155 beds — Average number of MDI reports per bed

COMPLETENESS: Data element completeness of MDI reports from your hospital — 85% Overall MDI score

Has hospital/contact	100%
Has device name	83%
Has incident date	100%
Has manufacturer	100%
Has incident info	83%
Has lot/serial #	50%
Has patient history	67%
Has outcome	100%

TIMELINESS

MDI reports missing key date(s)	15%
MDI reports submitted on time	83%
Range of days to report	1 - 64
Average # of days to report	35.3

Hospitals must send reports to Health Canada within 30 calendar days.
Reports missing key dates are excluded from timeliness calculations.

[illegible] HOSPITALS OF [illegible]ADA

[illegible]ospitals [illegible]ed:

Range of MDI reports	0 - 8
Average # of MDI repo[illegible]	0.7
Median # of MDI reports[illegible]	0
Average # of MDI r[illegible]bed	1

QUANTITY: You are submitting more MDI [illegible] than other medium-sized [illegible]

COMPLETENESS: Data element completeness of MDI reports from medium-sized hospitals — 26% Overall MDI score

Has hospital/contact	30%
Has device name	30%
Has incident date	30%
Has manufacturer	30%
Has incident info	20%
Has lot/serial #	20%
Has patient history	20%
Has outcome	20%

COMPLETENESS: Your MDI completeness score is higher than other medium-sized hospitals

TIMELINESS: For medium-sized hospitals: MDI reports missing key date(s) 43% — MDI reports submitted on time 62% — Average time to report: 39 days

TIMELINESS: Your MDI timeliness score is higher than other medium-sized hospitals

HOSPITALS IN YOUR PROVINCE/TERRITORY

Yukon Territories hospitals submitted:

Range of MDI reports	0 – 44
[illegible] of MDI reports / hospital	0.5
Median [illegible]DI reports / hospital	0
Average # [illegible]eports / bed	1/225

QUANTITY: [illegible] MDI reports [illegible] other Northw[illegible]es hospitals

COMPLETENESS: Data element completeness o[illegible] reports from [illegible] Territorie[illegible] — Overall MDI score

Has hospita[illegible]t	70%
Has device [illegible]ame	60%
Has incident date	70%
Has manufacturer	50%
Has incident info	50%
Has lot/serial #	60%
Has patient history	40%
Has outcome	50%

COMPLETENESS: Your MDI completeness score is higher than other Alberta hospitals

TIMELINESS: For Northwest Territoriesa hospitals: MDI reports missing key date(s) 33% — MDI reports submitted on time 94% — Average time to report: 39 days

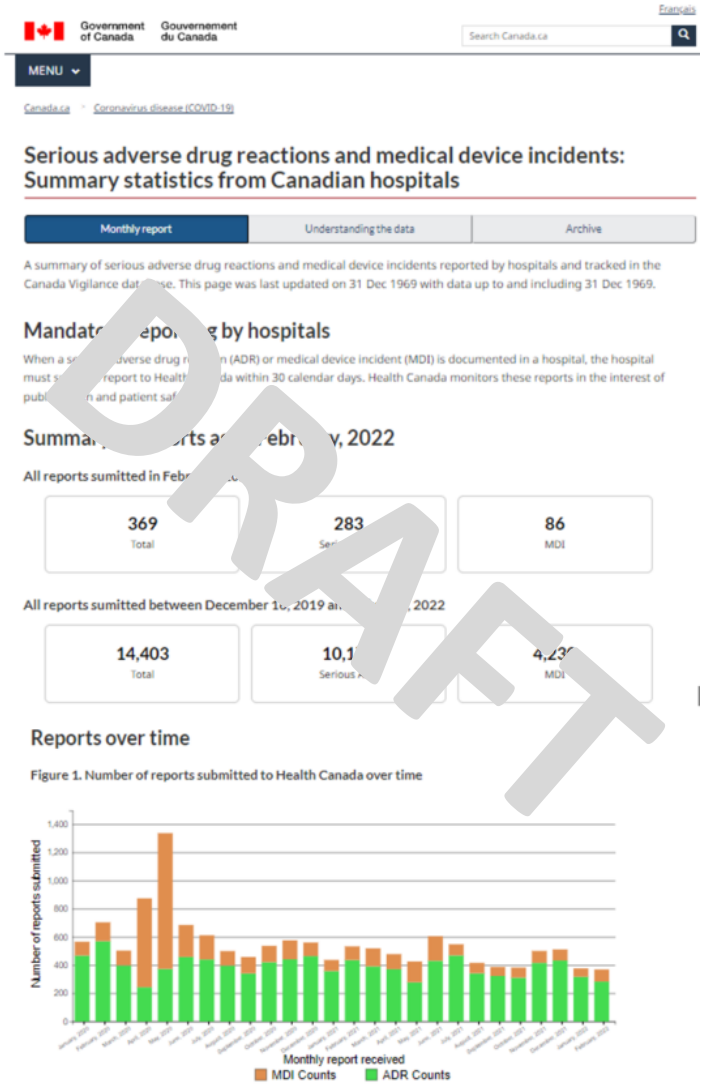
TIMELINESS: Your timeliness score is lower than other Alberta hospitals

DRAFT

Statistical Summary: Upcoming Products

2. Mandatory Reporting by Hospitals Dashboard

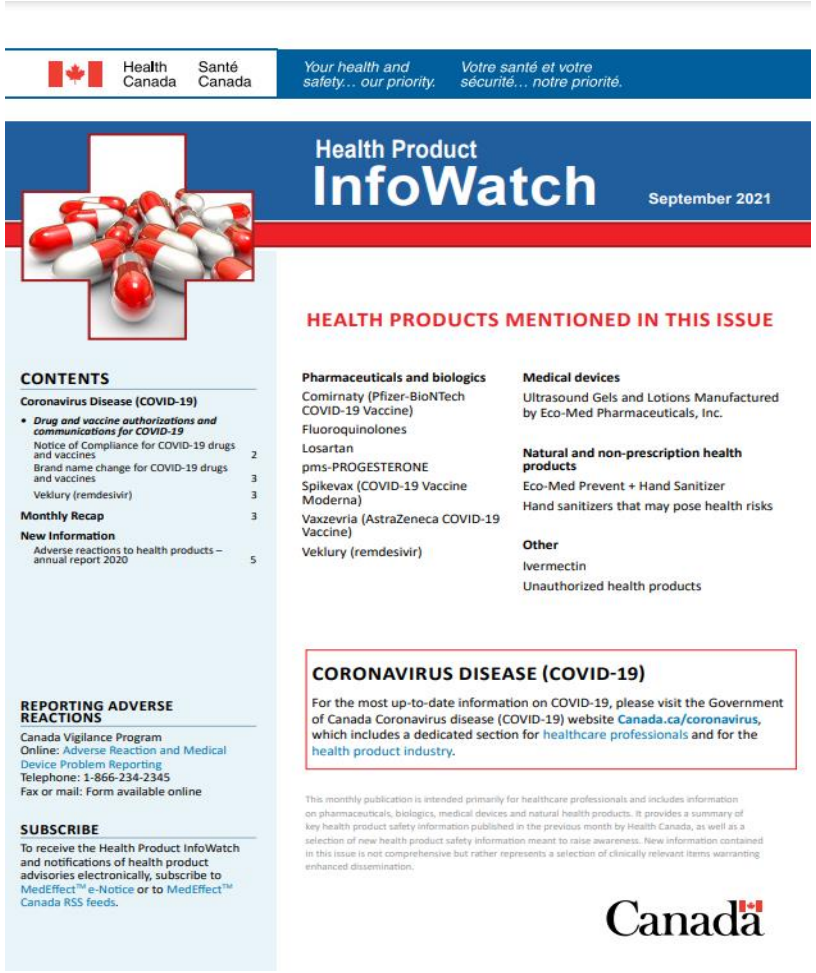
- Publicly accessible webpage
  - Updated monthly.
- Aggregated statistics on mandatory reporting by hospitals.
  - Same statistics as those found in the Hospital Quarterly Updates.
  - Provincial and product level statistics.
  - Data can be downloaded.
- **Release Date:** Spring/summer 2022



Statistical Summary: Upcoming Products

3. 2021 Adverse Drug Reaction Annual Report

- Publicly accessible article published in the Health Product InfoWatch
  - Updated annually
- High-level text-based summary of all CV reports submitted in 2021
- MDI report is currently on hold
- **Release date:** To be determined



Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Health Product
InfoWatch
September 2021

CONTENTS

REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
Telephone: 1-866-234-2345
Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to MedEffect™ e-Notice or to MedEffect™ Canada RSS feeds.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and biologics
Comirnaty (Pfizer-BioNTech COVID-19 Vaccine)
Fluoroquinolones
Losartan
pms-PROGESTERONE
Spikevax (COVID-19 Vaccine Moderna)
Vaxzevria (AstraZeneca COVID-19 Vaccine)
Veklury (remdesivir)

Medical devices
Ultrasound Gels and Lotions Manufactured by Eco-Med Pharmaceuticals, Inc.

Natural and non-prescription health products
Eco-Med Prevent + Hand Sanitizer
Hand sanitizers that may pose health risks

Other
Ivermectin
Unauthorized health products

CORONAVIRUS DISEASE (COVID-19)

For the most up-to-date information on COVID-19, please visit the Government of Canada Coronavirus disease (COVID-19) website Canada.ca/coronavirus, which includes a dedicated section for healthcare professionals and for the health product industry.

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

Canada

Reminder to submit your questions!

Please visit **Slido.com** and enter **code #074631** to submit your questions.

Click the  beside questions you would like us to prioritize.

We will answer questions at the end of the presentation.

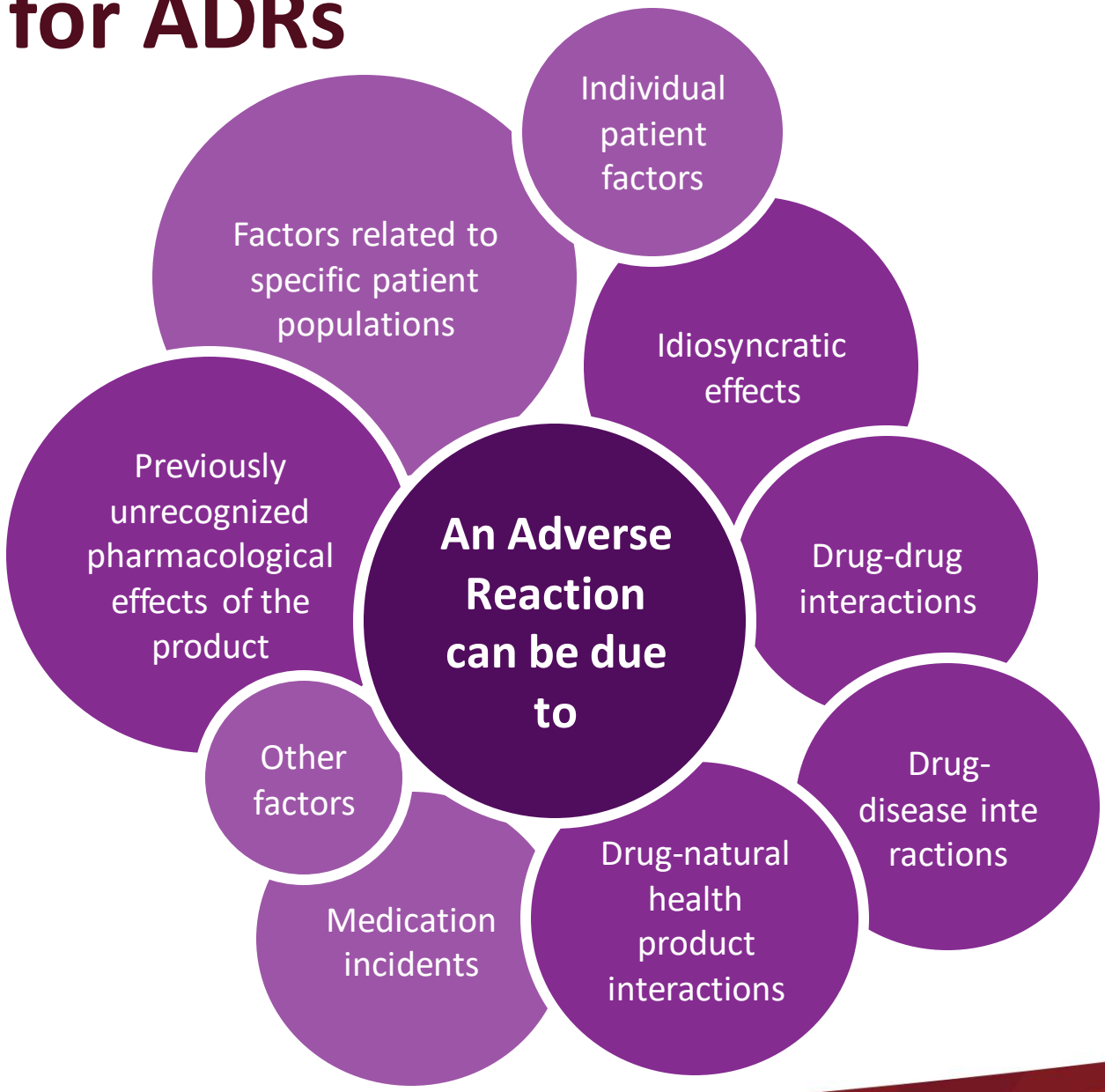
Feature

Signal Detection for ADRs

Feature: Signal Detection for ADRs

What is Signal Detection?

- Health products undergo a **thorough safety, efficacy and quality review** by Health Canada.
- However, due to the nature of clinical trials, there are potential serious adverse reactions (ARs) that may not be identified until only after approval.
- A **pharmacovigilance program** collects AR data which will be evaluated and analyzed to search for potential safety concerns (i.e. for signal detection)
  - A **signal** is a hypothesis of a health product risk with data and arguments that support it
  - An example of a **safety signal** could be a new AR or a change in the frequency and/or severity of a known AR associated with a certain product
  - A potential signal requires further investigation



Feature: Overview of Safety Surveillance Activities

Surveillance

- **Information is collected** from:
  - Domestic and international media and literature scans
  - Foreign regulatory agencies
  - Canada Vigilance Program (CVP) database
  - Industry safety reports
- **New risks are discovered** with the increased use of products in the real world

Signal Detection & Prioritization

- Many information sources combine to create a potential **signal**
- **Evaluation** includes a scientific/medical review of multiple data sources
- Request for additional safety information from market authorization holders (MAHs)/manufacturers

Signal Assessment

Risk Mitigation Strategies

- A **risk management** approach may include interventions such as:
  - Product recalls
  - Labelling changes
  - Risk communications for health care professionals and the public

Regulatory Advertising Oversight - Policy Development

Feature: Surveillance Activities

- The CVP is Health Canada's post-market surveillance (pharmacovigilance) program that collects AR reports submitted by hospitals, health professionals, consumers and manufacturers.
  - The CVP lies within the Marketed Health Products Directorate (MHPD) of Health Canada.

- Timely, routine, targeted, as well as ad-hoc surveillance is conducted by a designated team; safety concerns and potential signals are then referred to the evaluation bureaus.

- Upon signal confirmation, the evaluation bureaus undertake further review of the data in order to inform potential actions for risk mitigation, as necessary.

Feature: Surveillance Activities

Safety Surveillance Activities

Surveillance | Signal Detection & Prioritization | Signal Assessment | Risk Mitigation Strategies

Monitoring Strategy	Description/Scope
All fatal or life-threatening reports	AR reports with seriousness criteria of fatal or life-threatening.
Designated medical events	Rare, serious ARs associated with a high drug-attributable risk. e.g. Hepatic disorders, Anaphylactic reaction
Interactions	Reports coded with a reaction term indicating an interaction. e.g. Drug-food, drug-natural health product (NHP)
Pediatric	Specific reactions for patients 18 years of age or less. e.g. Congenital, Fetal, Neonatal events, Myocardial disorders

- MHPD conducts **routine, scheduled targeted surveillance** for:
  - Pre-specified reactions,
  - Outcomes, or,
  - Populations of special interest or concern.

Feature: Assessment of Safety Information

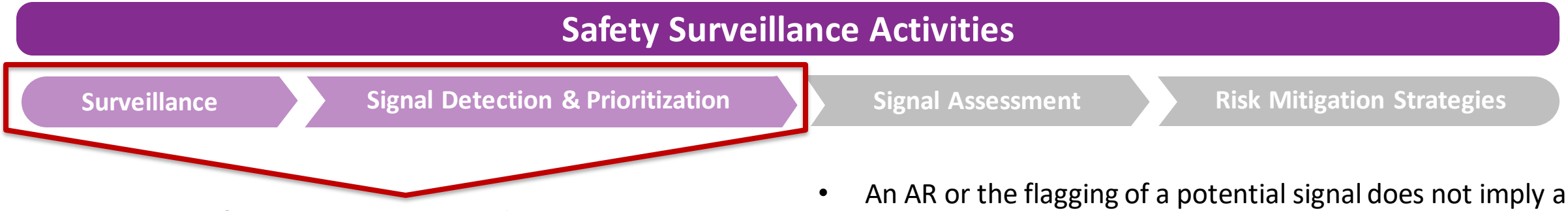
Safety Surveillance Activities

Surveillance | Signal Detection & Prioritization | Signal Assessment | Risk Mitigation Strategies

Monitoring Strategy	Description/Scope
Health Product-Targeted Medical Event (HP-TME)	Monitor a specific health product(s) and set of reactions on a pre-determined schedule. • HP-TMEs often represent identified potential risks that require more information for validation that a safety issue exists. This strategy would not monitor all reactions for a specific product.
New Active Substance* (NAS) Review *NAS: health product that includes an active substance that has never before been approved for marketing in any form in Canada.	Preparation of summaries for specific health product(s) and set of reactions for products identified as a NAS. • When a NAS product enters the market, there is relatively limited information about their safety from clinical. Spontaneous reporting programs usually receive the most adverse reaction reports for a product in the first few years after marketing.

- MHPD additionally conducts **product-specific and ad-hoc monitoring.**

Feature: Surveillance Activities



Information Gathering

- Details of the AR(s)
- Patient's medical history
- Concomitant drug(s)
- Other potential confounders

- An AR or the flagging of a potential signal does not imply a direct causal relationship.
- When a potential safety concern is identified, more in-depth information is gathered through documented sequential review steps to validate the potential signal.
- The **preliminary review** includes a verification of the suspect product's labelling and information provided in the AR report.
- Comprehensive **additional information** may be reviewed.

One of MHPD's key objective is the **early detection of new safety concerns or potential signals** through the review and assessment of **AR.**

Feature: Signal Detection & Prioritization

Pharmacovigilance Activities within the MHPD Review Bureaus

Surveillance → **Signal Detection & Prioritization** → Signal Assessment → Risk Mitigation Strategies

Signal Detection Activities:

- Canada Vigilance cases (e.g. referral from targeted, and/or ad-hoc surveillance)
- Safety literature
- Foreign agency actions (e.g. FDA)
- Info submitted by manufacturers
- Other Emerging safety issues

→

Do we need to investigate it further?

- Previously unknown or incompletely documented adverse event?
- Possible causal relationship?
- Whether there is corroboration from other sources?
- Potential impact on clinical practice
- Public health related issue?
- Canadian context and experience?

Feature: Signal Assessment

Pharmacovigilance Activities within the MHPD Review Bureaus

Surveillance → Signal Detection & Prioritization → **Signal Assessment** → Risk Mitigation Strategies

Signal Assessment Components

- Previous regulatory assessments and/or actions in Canada and internationally
- Analysis of Adverse Events in Canada and internationally
- Causality Assessment – case causality performed by a Medical Team
- Product Utilisation in Canada
- Scientific Literature

Signal Assessment Considerations

- Shift in the benefit/risk ratio based on the new information
- Strength and limitations of available data
- Need for a precautionary approach (e.g. vulnerable population)
- Availability of other therapeutic options
- Actions by other regulatory agencies
- Feasability of risk mitigation actions

Feature: Risk Mitigation Strategies

Pharmacovigilance Activities within the MHPD Review Bureaus

Surveillance → Signal Detection & Prioritization → Signal Assessment → **Risk Mitigation Strategies**

Possible Actions stemming from a Signal Assessment

- Standard monitoring
- Request to continue monitoring issue through Canada Vigilance Program
- Request a Periodic Safety Update Report from the MAH
- Stakeholder engagement
- Request additional studies
- Recommend changes to the product labelling
- Issuance of a risk communication
- Drug Identification Number (DIN) cancellation/product withdrawal from market

Feature: Case Study

Safety Surveillance Activities

Surveillance

- **2013**: Canadian case of rhabdomyolysis associated with donepezil, reported by a health care professional
- Detected through referral from targeted surveillance strategy
  - Rhabdomyolysis was not labelled in the Canadian Product Monograph for ARICEPT ®

Signal Detection & Prioritization

- Signal prioritized for assessment
- Examined Canadian and international case reports and other data
- **Conclusion**: rhabdomyolysis may occur with donepezil use

Signal Assessment

Risk Mitigation Strategies

- Risk communicated to the public
- Product Monograph was updated

Feature: Signal Detection for ADRs

Safety Surveillance Activities

Surveillance → Signal Detection & Prioritization → Signal Assessment → Risk Mitigation Strategies

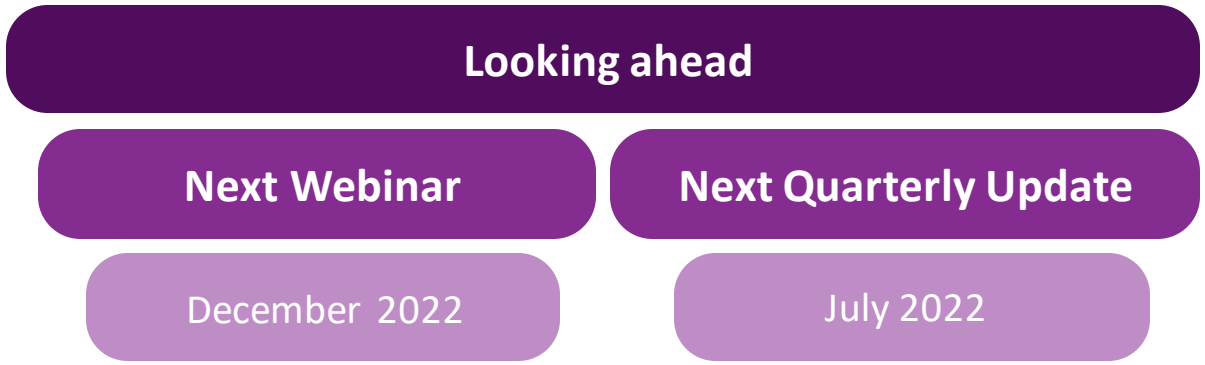
Summary

- Our Directorate takes an early and proactive role in surveillance and signal detection activities.
- Our Directorate's activities contribute to actions taken by Health Canada either directly or indirectly, e.g.:
  - Labelling update;
  - Risk communication, e.g. article in Health Product InfoWatch;
  - Other regulatory action, e.g. removal of product from market
- Our activities contribute to risk management activities and regulatory action. These regulatory actions help to:
  - protect the health of Canadians by minimizing and managing the risks associated with health products
  - facilitate both patients and health care providers in making informed decisions

Take-home Messages

Take-home Messages

- The Mandatory reporting of serious ADRs and MDIs by hospitals – Guidance Document is going to be updated.
- Automatic notification letters were sent to manufacturers upon receiving MDI reports from hospitals.
- New regulations impacting mandatory reporting are coming out in the future.
- Mandatory reporting by hospitals directly contribute to signal detection, supporting post-market safety surveillance.



Frequently Asked Question

If we are already reporting adverse reactions to vaccines to Public Health, are we still required to submit these to Health Canada?

Hospitals **do not** have to submit a report to Health Canada for vaccine-related adverse events if they have already submitted an Adverse Events Following Immunization (AEFI) report to their local public health unit.

- Refer to Section 4.3.2 in the Mandatory reporting of serious ADRs and MDIs by hospitals – Guidance Document for more information.

LIVE Q&A Session

Please visit **Slido.com** and enter **code #074631** to submit your questions.

We will do our best to provide you an answer.

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