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Health Canada

Mandatory Reporting for Hospitals
Your Role in Patient Safety

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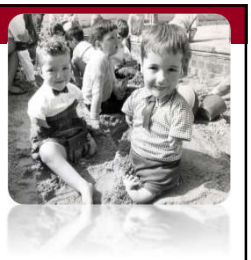
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Objectives



- Support the implementation of a key provision of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) by providing stakeholders with information on Health Canada's new regulatory requirements for serious ADR and MDI reporting
- Describe the reporting processes for hospitals to meet the mandatory reporting requirements
- Describe considerations for reporting using examples
- Describe Health Canada's review and communication of safety findings
- Describe risk communications and various resources provided by Health Canada

Vanessa's Law
Protecting Canadians from Unsafe Drugs (and devices…)

Vanessa Young died in 2000 of a cardiac arrhythmia after being prescribed cisapride (Prepulsid®).

Her father, Terrance Young, embarked on a campaign for increased regulation of therapeutic products which has resulted in greater powers for Health Canada to request data from hospitals and industry about medications and devices.

Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

The *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) introduces amendments to the *Food and Drugs Act* to improve Health Canada's ability to:

- collect post-market safety information;
- take appropriate action when a serious risk to health is identified; and
- promote greater confidence in the oversight of therapeutic products by increasing transparency.

Key amendments to the *Food and Drugs Act* include:

1. Power to require information, tests or studies
2. Power to require a label change/package modification
3. Power to recall unsafe therapeutic products
4. Ability to require and disclose information in certain circumstances
5. Tougher measures for those that do not comply
6. **Mandatory reporting of serious adverse drug reactions and medical device incidents by health care institutions***

*Regulatory amendments give effect to this authority and further define health care institutions as hospitals under section C.01.020.1 of the *Food and Drug Regulations* and section 62 of the *Medical Device Regulations*.

ADR and MDI Reporting in Canada and Abroad: Current Status

- Health Canada is continuously looking for ways to strengthen its knowledge base on product safety in the interest of improving patient outcomes and public health.
- Serious ADR and MDI reports are important sources of information for identifying emerging safety issues.
- Under-reporting and poor quality of reports is an issue in all countries. An international systematic review estimated that only 2-18% (median of approximately 6%) of ADRs are reported.[1]

[1] Hazell, *et al. Drug Safety* 2006

Mandatory Reporting: Details

WHO Is Required to Report?

Hospitals

The regulations define a hospital as a facility that:

- is licensed, approved or designated as a hospital by a province or territory, in accordance with the laws of the province or territory, to provide care or treatment to persons suffering from any form of disease or illness; or
- is operated by the Government of Canada and that provides health services to in-patients.

Notes:

- Outpatient clinics are subject to the regulations if they are legally part of the hospital, even if they are physically separate from the hospital. On the other hand, clinics that may be physically located within a hospital, but that are not legally part of the hospital, will not be subject to the regulations.
- Health care institutions that are outside the scope of the definition of hospitals, such as private clinics or long-term care facilities (e.g., nursing homes), continue to be encouraged to report on a voluntary basis.

Mandatory Reporting: Details

WHAT Events are Reportable?

Serious ADR: a noxious and unintended response to a drug that occurs at any dose and that:

- requires in-patient hospitalization;
- prolongs existing hospitalization;
- causes congenital malformation;
- results in persistent or significant disability or incapacity; or
- is life-threatening or results in death

Medical device incident (MDI) is an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

Note: Hospitals are not required to establish causality; the information to be submitted by the hospital to Health Canada only needs to represent the suspicions of a health care professional that a serious ADR or MDI has been observed.

Mandatory Reporting: Details

WHAT Products are in Scope?

The mandatory reporting requirements for hospitals apply to therapeutic products, including:

- Pharmaceuticals (which includes prescription and non-prescription pharmaceutical drugs),
- Biologic drugs (which includes biotechnology products, fractionated blood products, plasma proteins),
- Radiopharmaceutical drugs,
- Disinfectants,
- Drugs for an urgent public health need, and
- Medical devices (Classes I – IV).

EXCLUDED Products:

- Vaccines administered as part of a routine immunization program
- Natural health products
- Cannabis
- Blood and blood components
- Cells, tissues and organs
- Semen and ova
- Drugs for clinical trials, devices for investigational testing, and drugs/devices accessed via Special Access Programme

Mandatory Reporting: Details

WHEN Must Hospitals Report?

The regulations require hospitals to report serious ADRs or MDIs in writing to Health Canada **within 30 calendar days of first documentation** of the serious ADR or MDI within the hospital.

Coming into Force

Serious ADR Report - Required Data Elements

Reporter:

- Contact information: The name of the hospital and the contact information of a representative of that hospital

Suspect product:

- Name: The drug's brand name, proper name or common name
- Drug Number/Code: In the case of a drug imported under Part C, Division 10 of the *Food and Drug Regulations* (subsection C.10.001(2)), the identifying number or code of the drug, if any, assigned in the country in which the drug was authorized for sale
- DIN: The drug identification number (DIN) assigned for the drug, if applicable
- Concomitants: Any concomitant therapeutic products used by the patient

Patient information:

- Age/Sex: The patient's age and sex
- Medical history: Any medical condition of the patient that directly relates to the serious adverse drug reaction

SADR information:

- Serious ADR description: A description of the adverse drug reaction
- Documentation date: The date on which the serious adverse drug reaction was first documented
- Start/End therapy date: The date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug
- Start/End Serious ADR date: The date on which the serious adverse drug reaction first occurred and, if applicable, the date on which the patient's health was restored to its state prior to the reaction
- Outcome: The effect of the serious adverse drug reaction on the patient's health

Note: minimal essential information required to submit a report. The hospital is exempt from reporting if it does not have in its control all of the information for any of the **4 essential data elements**.

MDI Report - Required Data Elements

Submitter:

- Contact information: The name of the hospital and the contact information of a representative of that hospital

Suspect Product:

- Name or Identifier: The name or identifier of the medical device, so that it is uniquely identifiable.
- Manufacturer Name: The name of the manufacturer of the medical device
- Lot/Serial Number: The lot number of the device or its serial number

MDI information:

- MDI description: A description of the medical device incident
- Documentation date: The date on which the medical device incident was first documented
- Contributing factors: Any contributing factors to the medical device incident including any medical condition of the patient that directly relates to the medical device incident
- Outcome: The effect of the medical device incident on the patient's health

Note: minimal essential information required to submit a report. The hospital is exempt from reporting if it does not have in its control all of the information for any of the **2 essential data elements**.

Criteria for Serious ADRs

Threshold for 'serious'

Consider the following questions:

Has the ADR resulted in:

- In–patient hospitalization or prolongation of existing hospitalization?
- Congenital malformation?
- Persistent or significant disability or incapacity?
- Is the ADR life-threatening or has it resulted in death?
- Does the ADR require significant medical intervention in order to prevent any of the outcomes listed above?

When in doubt, Health Canada encourages hospitals to report

Case Example: Is the Hospital Required to Report?

A patient had been taking warfarin, among other medications, and presented to the emergency department with a life-threatening gastrointestinal bleed. The patient required hospitalization in order to be stabilized.

RATIONALE

Life-threatening condition 

Resulted in in-patient hospitalization  ADR meets the criteria of "serious" 

Case Example: Is the Hospital Required to Report?

A patient experienced dizziness and sweating after a dose of insulin. The patient required glucose tablets to recover. It was discovered that a short-acting insulin had been provided instead of the patient's usual long-acting insulin.

RATIONALE

- A medication incident, also referred to as a medication error, is a mistake with medication or a problem that could cause a mistake with medication.
- Medication incidents are generally preventable and include errors such as receiving the wrong medication or dose, or using the wrong route of administration.

Note: Medication incident-related reporting and learning occurs through a separate and complementary program: the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

Criteria for MDIs

Threshold for 'serious'

What is an MDI?

An incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

What is considered *a serious deterioration in the state of health*?

A life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.

When in doubt, Health Canada encourages hospitals to report

Criteria for MDIs

A useful checklist/procedure to review incidents for MR should include a review of key terms in the MDI definition:

Mandatory Reporting Criteria for Medical Device Incidents (MDIs):

1. **Does your report incident involve a Medical Device?** Medical Device Active License Listing (MDALL) database to search for all Class II-IV licensed medical devices (Class I medical devices do not need a license and will not be searchable)
   - ☐ Yes
   - ☐ No
2. **Is there a (suspected) failure of device, deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use?**
   - ☐ Yes
   - ☐ No
3. **Has the incident resulted in the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur (potential for serious harm)?**
   - ☐ Yes
   - ☐ No
4. **Does the report originate from a hospital as defined by the Mandatory Reporting for Hospitals Law?**
   - ☐ Yes
   - ☐ No

Case Example: Is the Hospital Required to Report?

A health care professional reported that the sewing cuff was discovered to be defective during a heart valve implant. The defective valve was abandoned, a new valve was implanted, and pumping time during surgery was extended. This defect had the potential to cause serious harm.

RATIONALE

Potential for death or serious deterioration in the state of health of this patient due to extended surgical time and this possible defect being missed prior to surgical close on other patients leading to emergency failure

Reportable MDI

Case Example: Is the Hospital Required to Report?

A user performed an inflation test prior to inserting the balloon catheter into the patient, as required in the instructions for use accompanying the device. A malfunction on inflation was detected and another balloon was used.

RATIONALE

- This device deficiency would <u>always</u> be found by the user prior to patient use and is an expected potential deficiency noted in the product's instructions for use.
- If the user performed the testing prior to use, as per the instructions, no harm would come to a patient.

AR and MDP Reporting Is Essential to Post-market Surveillance

Clinical Trials / Investigational Testing Have Limited Scope	Post-market Surveillance Identifies Emerging Safety Issues
• Highly controlled environment • Limited number of patients • Short trial duration • Highly selected patients • Selected cases and diseases • May not identify rare events	• 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 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).

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]**

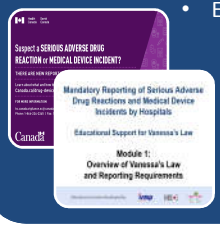
What Are the Benefits of Serious ADR and MDI Reporting?

Serious ADR and MDI Reporting Contributes to:

IDENTIFICATION	ASSESSMENT	SHARING	IMPROVEMENT
of emerging safety issues related to drugs and medical devices	of harm vs. benefit of drugs and medical devices	of learning, including warnings and advisories for health care providers, patients, and stakeholders	of safety of products through risk mitigation such as a labelling change, a product information update, or a recall

Key Resources for Hospital Readiness

- Guidance and forms
  - Guidance Document for hospitals
  - PDF forms for serious ADRs and MDIs
  - https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html



- Educational materials
  - **Posters and postcards to promote mandatory reporting (MR) by hospitals**
    - contact hc.canada.vigilance.sc@canada.ca
  - **HC in partnership with CPSI, ISMP, HSO published 4 Education Modules for MR**
    - Module 1 – Overview of Vanessa's Law and Reporting Requirements
    - Module 2 – Reporting Processes to Health Canada
    - Module 3 – Strategies to Promote and Support Mandatory Reporting
    - Module 4 – Health Canada's Review and Communication of Safety Findings

- Health Canada has put in place education and awareness tools to support hospitals in complying with these new regulations, including:
  - HC single window
  - Case study examples, infographics
  - Updated PDF and new online reporting forms

Examples of 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)
- Medical Device Incidents Database (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)
- Health Canada Safety Reviews (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html)
- Health Canada Recalls and Safety Alerts (http://www.healthycanadians.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)
- Drug and Health Product Register (DHPR) (https://hpr-rps.hres.ca/)

Mandatory Reporting Resources…

Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) Amendments to the Food and Drugs Act (Bill C-17)

- 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

Mandatory Reporting CGII publication

- http://gazette.gc.ca/rp-pr/p2/2019/2019-06-26/html/sor-dors190-eng.html (serious ADRS)
- http://gazette.gc.ca/rp-pr/p2/2019/2019-06-26/html/sor-dors191-eng.html (MDIs)

Guidance Document for ADR/MDI hospital reporting (June 2019)

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html

Report an adverse reaction or medical device problem (landing page)

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

Mandatory reporting hospital summary page

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting.html

Mandatory Reporting Resources

Single window environment

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html?utm_campaign=hospital-reporting-1920&utm_medium=email-en&utm_source=announcement-sw

Education Modules

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/education.html?utm_campaign=hospital-reporting-1920&utm_medium=email-en&utm_source=announcement-em

Case Study Examples

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/case-studies.html?utm_campaign=hospital-reporting-1920&utm_medium=email-en&utm_source=announcement-cs

Medical Devices Active Licence Listing (MDALL)

- https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/licences/medical-devices-active-licence-listing.html

Key Points to Remember

- The ***Protecting Canadians from Unsafe Drugs Act*** (Vanessa's Law) introduces amendments to the *Food and Drugs Act*, including mandatory reporting of serious adverse drug reactions (**serious ADRs**) and medical device incidents (**MDIs**) by health care institutions.
- The Act aims to improve the quality and quantity of serious ADR and MDI reports to **strengthen the safety oversight** of therapeutic products.
- The reporting of serious ADRs and MDIs contributes to **identification** of emerging safety issues, **assessment** of harm vs. benefit, **sharing** of learning, and **improvement** of product safety.
- Health care professionals have an **important role** in serious ADR and MDI reporting.
- The **Guidance Document** offers information to help hospitals comply with the regulatory requirements for serious ADR and MDI reporting to Health Canada.
- A **shared commitment to health product safety** includes many key partners with important and complementary roles.

Questions and Contact Information

Please forward any questions or comments to:
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