Health Canada Webinar Presentation: Mandatory Reporting for Hospitals – November 8, 2019, 10:30-12:00 PM EST

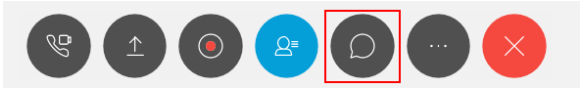
Welcome to Health Canada's webinar on the topic of mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals. The presentation will begin shortly.

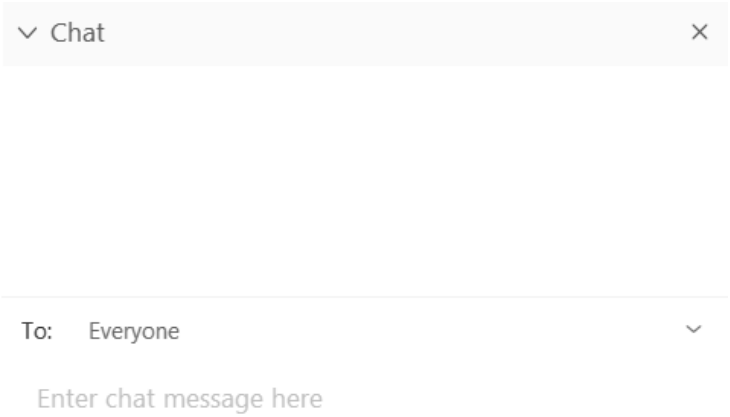
This session will be recorded.

Mandatory Reporting Update Webinar

- We will mute your phone lines for the entirety of the presentation.
- If you have questions, please send them through the WebEx Chat function.

1. Hover your mouse over the Webex presentation.
2. Click on the chat icon at the bottom of the screen.
3. Select ‘Host’ from the “To:” drop down list.
4. Type your question.
5. Hit Enter on your keyboard to send.





- Questions submitted will be read and answered aloud by a facilitator from Health Canada following the presentation.

Health Canada Santé Canada

Canada

Health Canada

Mandatory Reporting for Hospitals
Regulatory Update

Marketed Health Products Directorate
Health Products and Food Branch
Health Canada

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Objectives

Provide information on:

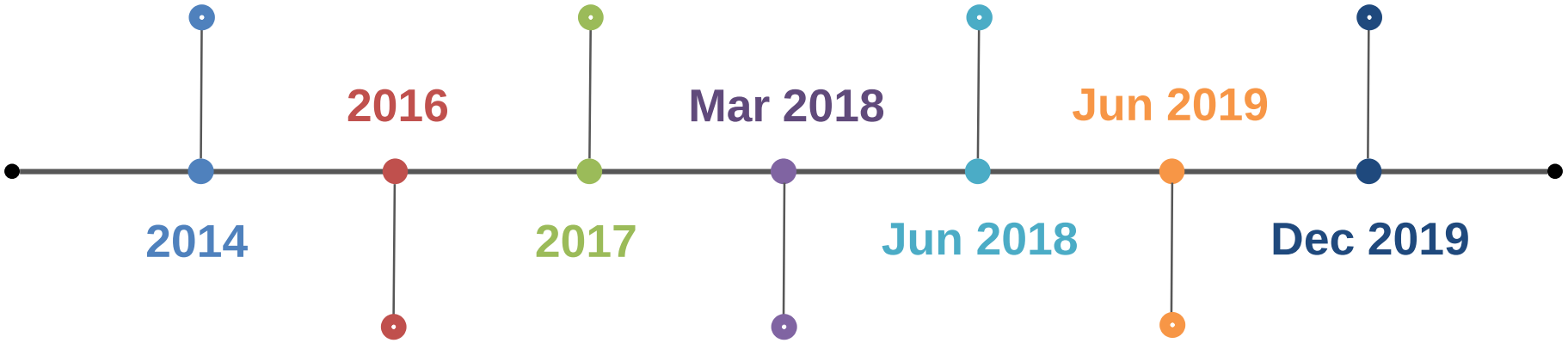
- The regulations for mandatory reporting
- The guidance document
- The reporting forms
- The reporting methods and systems update

Mandatory Reporting – Final Regulations

WHY: Provide more and better data for Health Canada's monitoring of therapeutic products throughout their life cycle

- Pre-market knowledge may be limited (e.g. clinical trials)
- Reports are often the first sign of emerging safety problems
- Reporting was previously only mandatory for industry
- Voluntary underreporting is an international issue (estimated 1 – 10%)
- Hospitals are uniquely positioned to identify serious adverse drug reactions (ADRs) and medical device incidents (MDIs)

Mandatory Reporting – Timeline



Royal Assent

Vanessa's Law received Royal Assent on November 6, 2014.

Issue Identification Paper

Issue Identification Paper to solicit early views on mandatory reporting was published in May 2016.

Discussion Paper

Consultation paper to inform the design of the regulations was published online between June 28 to August 11. "What We Heard" report was published in December 2017.

System Consultation

System consultation to identify IT requirements and processes to facilitate seamless reporting was conducted in March 2018.

Regulatory Proposal in CGI

Proposed mandatory reporting regulations published in *Canada Gazette, Part I* on June 16, 2018.

Final Regulations in CGII

Final mandatory reporting regulations published in *Canada Gazette, Part II* on June 26, 2019.

Coming Into Force

Mandatory reporting regulations come into force on December 16, 2019.

Mandatory Reporting: Details

WHO: All hospitals, as regulated by P/T legislation

- 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 provides health services to in-patients.

WHAT: Serious ADRs and MDIs

- **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)** means 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.

Mandatory Reporting: Details

- **WHEN:** Hospitals are required to report serious ADRs and MDIs to Health Canada, in writing, **within 30 calendar days** of first documentation of the reaction or incident within the hospital

- **INCLUDED PRODUCTS:**
  - Pharmaceuticals (which includes prescription and non-prescription pharmaceutical drugs),
  - Biologic drugs (which includes biotechnology products, fractionated blood products, plasma proteins),
  - Radiopharmaceutical drugs,
  - Disinfectants and
  - Medical devices.

- **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

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
- New! 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:

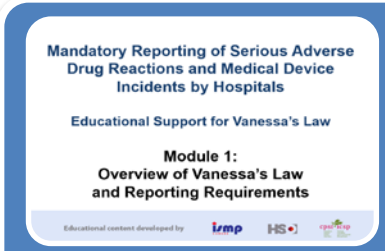
- MDI description: A description of the medical device incident
- New! Documentation date: The date on which the medical device incident was first documented
- Contributing factors: Any contributing factors to the medical device incident including any medical condition of the patient that directly relates 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.

Dates to Note:

June 2019

- **Health Canada (HC) published**
  - New Amended *Food and Drug Regulations* / *Medical Devices Regulations*
  - Updated Guidance Document
  - New Reporting Forms for SADRs and MDIs



July 2019

- **HC in partnership with CPSI, ISMP, HSO will publish**
  - 4 Education Modules for MR - https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx

Fall 2019

- **HC will:**
  - Update HC webpage
  - Post case studies, video, infographics
  - Send out posters and postcards to promote MR in your hospitals
  - Provide more webinars on MR

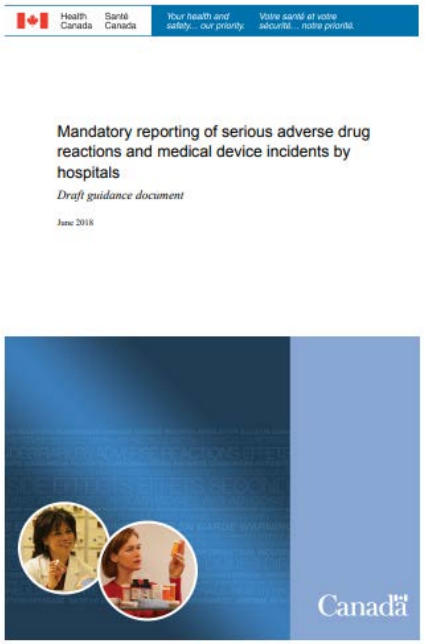
December 16th, 2019

- **Coming into Force Date:**
  - Hospitals are required to submit in writing, all SADR/MDI to Health Canada

Guidance Document for Hospitals

Overview

- As part of the implementation plan associated with mandatory reporting of serious ADRs and MDIs, Health Canada committed to providing **guidance**, outreach, and education to all hospitals and health care professionals working within hospitals responsible for reporting.
- As such, this guidance document, written in plain language, was developed to provide hospitals with information that may be useful in **achieving compliance** with the federal **regulatory requirement for hospitals to report serious ADRs and MDIs to Health Canada**, mainly by outlining the type of information that should be submitted and the different methods available for submitting reports.



Who is this guidance for?

- This guidance is intended for regulated parties (**hospitals**) who are affected by the regulations as they pertain to the mandatory reporting of serious ADRs and MDIs for therapeutic products.

Guidance Document for Hospitals

June 2018

- Draft Guidance Document for mandatory reporting by hospitals published

Summer 2018

- 75-day consultation period

Fall/Winter 2018

- Analyzed stakeholder comments and revised Draft Guidance Document

June 2019

- Updated Guidance Document published

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

Guidance Document for Hospitals

Table of Contents

Appendices

Guidance Document for Hospitals

1. **Introduction:** Objective, scope and application

2. **The regulations and their purpose**
   - Purpose
   - Serious ADR and MDI definitions

3. **Roles and responsibilities**
   - Role of hospitals/HCPs
   - New! – Other types of facilities (e.g. private clinics, nursing homes, outpatient clinics)
   - New! – Hospital's requirement to report in other situations (examples)

4. **Applicability of the regulations according to product type**
   - New! – Applicable therapeutic products/ medical devices
   - New! – Non-applicable therapeutic products/ medical devices
   - New! – Determination of applicability for combination products

5. **Serious ADRs or MDIs to be reported by hospitals**
   - New! – SADR/MDI reportability considerations
   - New! – SADR/MDI examples
   - New! – Outcomes associated with MDIs
   - Causality assessment/hospital investigations
   - Documentation examples

Guidance Document for Hospitals

6. Information requirements for serious ADR and MDI reports

- ADR/MDI data elements: essential minimal information and information required if known

7. When and how to submit serious ADR and MDI reports

- Reporting timeline
- Health Canada follow-up requests
- New! How to send reports (submission methods and formats)
- New! Links to ADR/MDI reporting forms
- New! Use of third-party reporters
- New! Feedback

8. Privacy: Privacy considerations when submitting reports

9. Additional reporting considerations

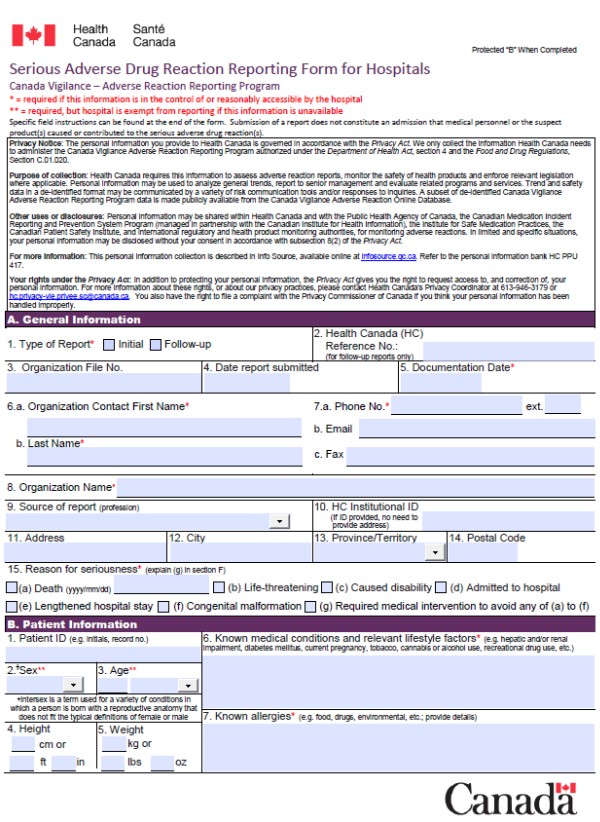
- Submission of reports to manufacturers
- Submission of reports to CMDSNet

New! **10. Compliance and enforcement:** Health Canada compliance and enforcement actions for hospitals

Appendices:

- **Appendix 1**: Acronyms, Definitions and Terminology
- New! **Appendix 2**: Third-party Reporting Authorization Form
- New! **Appendix 3**: Reporting requirements for therapeutic products not subject to the new regulations for hospitals
- New! **Appendix 4**: Quick Reference Guide - Regulations, What, Why, Who, Products within/outside of scope, When, How, Contact

Serious ADR Reporting Form for Hospitals



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Protected "B" When Completed

Serious Adverse Drug Reaction Reporting Form for Hospitals

Canada Vigilance – Adverse Reaction Reporting Program

* = required if this information is in the control of or reasonably accessible by the hospital

** = required, but hospital is exempt from reporting if this information is unavailable

Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

Privacy Notice. The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance Adverse Reaction Reporting Program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance Adverse Reaction Reporting Program data is made publicly available from the Canada Vigilance Adverse Reaction Online Database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information), the Institute for Safe Medication Practices, the Canadian Patient Safety Institute, and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

A. General Information

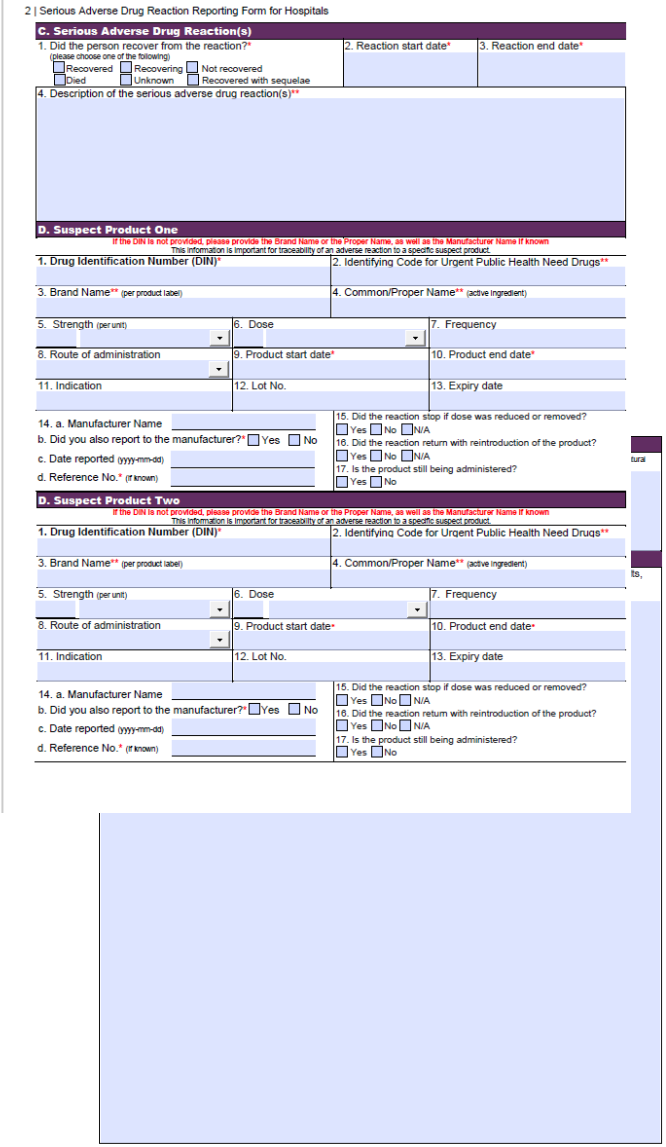
1. Type of Report* ☐ Initial ☐ Follow-up
2. Health Canada (HC) Reference No.: (for follow-up reports only)
3. Organization File No.
4. Date report submitted
5. Documentation Date*
6.a. Organization Contact First Name*
7.a. Phone No.* ext.
b. Last Name*
b. Email
c. Fax
8. Organization Name*
9. Source of report (profession)
10. HC Institutional ID (If ID provided, no need to provide address)
11. Address
12. City
13. Province/Territory
14. Postal Code
15. Reason for seriousness* (explain (g) in section F)

☐ (a) Death (yyyy/mm/dd) ☐ (b) Life-threatening ☐ (c) Caused disability ☐ (d) Admitted to hospital ☐ (e) Lengthened hospital stay ☐ (f) Congenital malformation ☐ (g) Required medical intervention to avoid any of (a) to (f)

B. Patient Information

1. Patient ID (e.g. initials, record no.)
2.*Sex**
3. Age**
*intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male
4. Height cm or ft in
5. Weight kg or lbs oz
6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.)
7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details)

Canada



2 | Serious Adverse Drug Reaction Reporting Form for Hospitals

C. Serious Adverse Drug Reaction(s)

1. Did the person recover from the reaction?* (please choose one of the following) ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Died ☐ Unknown ☐ Recovered with sequelae
2. Reaction start date*
3. Reaction end date*
4. Description of the serious adverse drug reaction(s)**

D. Suspect Product One

If the DIN is not provided, please provide the Brand Name or the Proper Name, as well as the Manufacturer Name if known

This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug Identification Number (DIN)*
2. Identifying Code for Urgent Public Health Need Drugs**
3. Brand Name** (per product label)
4. Common/Proper Name** (active ingredient)
5. Strength (per unit)
6. Dose
7. Frequency
8. Route of administration
9. Product start date*
10. Product end date*
11. Indication
12. Lot No.
13. Expiry date
14. a. Manufacturer Name
b. Did you also report to the manufacturer?* ☐ Yes ☐ No
c. Date reported (yyyy-mm-dd)
d. Reference No.* (if known)
15. Did the reaction stop if dose was reduced or removed? ☐ Yes ☐ No ☐ N/A
16. Did the reaction return with reintroduction of the product? ☐ Yes ☐ No ☐ N/A
17. Is the product still being administered? ☐ Yes ☐ No

D. Suspect Product Two

If the DIN is not provided, please provide the Brand Name or the Proper Name, as well as the Manufacturer Name if known

This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug Identification Number (DIN)*
2. Identifying Code for Urgent Public Health Need Drugs**
3. Brand Name** (per product label)
4. Common/Proper Name** (active ingredient)
5. Strength (per unit)
6. Dose
7. Frequency
8. Route of administration
9. Product start date*
10. Product end date*
11. Indication
12. Lot No.
13. Expiry date
14. a. Manufacturer Name
b. Did you also report to the manufacturer?* ☐ Yes ☐ No
c. Date reported (yyyy-mm-dd)
d. Reference No.* (if known)
15. Did the reaction stop if dose was reduced or removed? ☐ Yes ☐ No ☐ N/A
16. Did the reaction return with reintroduction of the product? ☐ Yes ☐ No ☐ N/A
17. Is the product still being administered? ☐ Yes ☐ No

4 | Serious Adverse Drug Reaction Reporting Form for Hospitals

Instructions on completing the Serious Adverse Drug Reaction (SADR) Reporting Form for Hospitals

A. General information

This section must be completed by the hospital.

A1. **Initial or follow-up***: Indicate whether the report is the first one submitted for this specific adverse drug reaction (i.e. initial) or a follow-up to a previously submitted report.

A2. **Health Canada (HC) Reference Number**: If the report is identified as a follow-up in A1, provide the reference number of the SADR report generated by Health Canada and provided to the submitter further to initial report submission.

A3. **Organization File Number**: Indicate the hospital's identification number for the case. For follow-up reports, the report number should be the same as the number assigned to the initial report.

A4. **Date submitted**: Indicate the date the report was sent to Health Canada.

A5. **Documentation date***: Indicate the date when the hospital first documented this SADR.

A6. **Organization Contact First & Last Name***: Enter the first and last name of a contact for the hospital.

A7. **Phone number, Email or Fax***: Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A8. **Organization Name***: Enter the full name of the reporting hospital.

A9. **Source of report**: Indicate the profession of the hospital employee who first flagged this as a potential SADR.

A10. **HC Institutional ID**: Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canada.vigilance.sc@canada.ca. Address details do not need to be completed if this unique number is provided.

A11. **Hospital address**: Enter the civic address for the hospital.

A12. **City**: Indicate the city in which the hospital is located.

A13. **Province/Territory**: Select the province or territory in which the hospital is located.

A14. **Postal Code**: Provide the postal code of the hospital.

A15. **Reason for seriousness***: Select a criterion that makes the report a serious adverse reaction. More than one can be selected. Enter the date of death if known.

B. Patient information

B1. **Patient ID**: Provide a patient identifier in order to readily locate the case for follow-up purposes. This can be the patient initials or the record number. Please do not provide the full name of the patient.

B2. **Sex***: Enter the patient's biological sex.

B3. **Age***: Provide the patient's age at the time of the reaction.

B4. **Height**: Enter the patient's height.

B5. **Weight**: Enter the patient's weight.

B6. **Known medical conditions and lifestyle factors***: If available, provide information on the patient's history and other known conditions.

B7. **Known allergies***: Provide the allergies the patient is known to have experienced, whether to food, drugs, environmental components, etc.

C. Serious adverse drug reaction

C1. **Recovery status***: Indicate the outcome of the SADR.

C2. **Reaction start date***: Provide the date of onset of the SADR. Partial dates are acceptable

C3. **Reaction end date***: Provide the end date of the SADR if applicable. Do not provide this for reports involving death. Partial dates are acceptable.

C4. **Description of the serious adverse drug reaction****: List the serious adverse drug reaction(s) that the patient experienced. Please try to avoid use of acronyms in this section.

D. Suspect product(s)

Up to two suspected products may be reported on one form. Attach additional forms if there are more than two suspected products for the reported SADR.

Reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect product. The Drug Identification Number (DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their Brand Name. Generic drugs can be uniquely identified by providing both the Generic Name and the Manufacturer Name. Please also include the Lot Number if known.

D1. **Drug Identification Number (DIN)***: Provide the drug identification number of the product the patient took, if available. For drugs accessed under an Urgent Public Health Need, provide the identifying code or number for the country in which the product is marketed. If DIN is provided, it is not necessary to provide manufacturer, product name, active ingredient(s), strength, or dosage form.

D2. **Identifying Code for Urgent Public Health Need Drugs****: If the drug was imported as part of the Access to Drugs in Exceptional Circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

D3. & D4. **Brand Name, Common/Proper Name****: Provide the brand name as per the product label if the DIN is not known. If the brand name cannot be provided, or is not specific (e.g. an active ingredient as brand name), please provide the proper name (active ingredients) and the manufacturer name.

D5. **Strength**: Provide the amount of active ingredient per single dosage form of the drug. For example, if the patient took two tablets of a medication, please provide the strength of only one tablet. Strength is defined as the amount of an active ingredient that the product contains.

D6. **Dose**: Indicate the amount of the product taken by the patient per the dosing regimen. Dose is normally expressed as a quantity.

D7. **Frequency**: Indicate how often the dose was taken by the patient. Shorthand text, such as b.i.d., is acceptable in this field.

D8. **Route of administration**: Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D9. **Product start date***: Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D10. **Product end date***: Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D11. **Indication**: Enter the therapeutic reason for use.

D12. **Lot No.**: If known, indicate the lot number(s) of the suspect product.

D13. **Expiry date**: If known, indicate the expiry date.

D14. **Manufacturer Details***: Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D15. **Reaction stopped if dose was reduced or removed**: Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D16. **Reaction returned with reintroduction**: Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

D17. **Product still administered**: Indicate if the product is still being administered.

E. Concomitant therapeutic product(s)

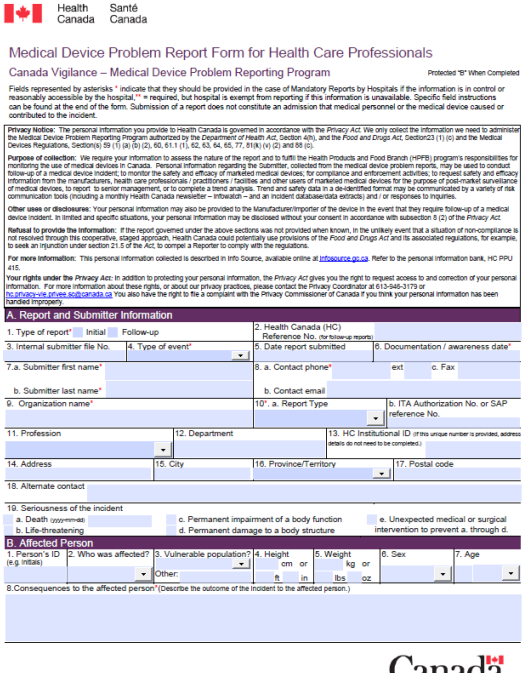
E1. **Known therapeutic products***: List all known health products, other than the suspect product, the patient was taking at the same time (i.e. concomitantly) the reaction occurred. Information related to therapy of these products is not required but encouraged. Do not include health products used to treat the reaction.

F. Additional Information

F1. This section can be used to provide a narrative summary of the serious adverse drug reaction, additional information on the underlying diagnosis that is pertinent to the reaction, or information that did not fit in the structured fields that could help to determine why the reaction occurred. For serious cases involving death, this section can also be utilized to provide details on the official cause of death and autopsy results.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices.html

MDI Reporting Form for Health Care Professionals



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Medical Device Problem Report Form for Health Care Professionals

Canada Vigilance – Medical Device Problem Reporting Program

Protected "B" When Completed

Fields represented by asterisks * indicate that they should be provided in the case of Mandatory Reports by Hospitals if the information is in control or reasonably accessible by the hospital.** = required, but hospital is exempt from reporting if this information is unavailable. Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the medical device caused or contributed to the incident.

Privacy Notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the Medical Device Problem Reporting Program authorized by the *Department of Health Act*, Section 4(d), and the *Food and Drugs Act*, Section23 (1) (c) and the Medical Devices Regulations, Section(s) 59 (1) (a) (b) (2), 60, 61.1 (1), 62, 63, 64, 65, 77, 81(k) (v) (2) and 88 (c).

Purpose of collection: We require your information to assess the nature of the report and to fulfil the Health Products and Food Branch (HPFB) program's responsibilities for monitoring the use of medical devices in Canada. Personal information regarding the Submitter, collected from the medical device problem reports, may be used to conduct follow-up of a medical device incident; to monitor the safety and efficacy of marketed medical devices; for compliance and enforcement activities; to request safety and efficacy information from the manufacturers, health care professionals / practitioners / facilities and other users of marketed medical devices for the purpose of post-market surveillance of medical devices, to report to senior management, or to complete a trend analysis. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools (including a monthly Health Canada newsletter – Infoactch – and an incident database/data extracts) and / or responses to inquiries.

Other uses or disclosures: Your personal information may also be provided to the Manufacturer/Importer of the device in the event that they require follow-up of a medical device incident. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8 (2) of the *Privacy Act*.

Refusal to provide the information: If the report governed under the above sections was not provided when known, in the unlikely event that a situation of non-compliance is not resolved through this cooperative, staged approach, Health Canada could potentially use provisions of the *Food and Drugs Act* and its associated regulations, for example, to seek an injunction under section 21.5 of the *Act*, to compel a Reporter to comply with the regulations.

For more information: This personal information collected is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank, HC PPU 415.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

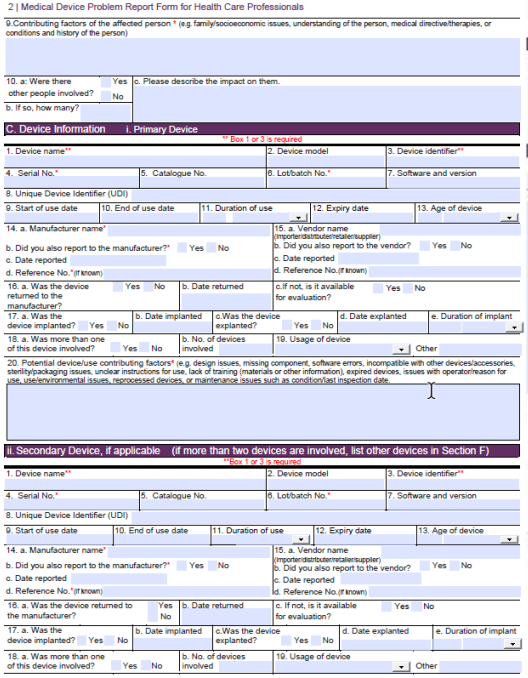
A. Report and Submitter Information

1. Type of report* ☐ Initial ☐ Follow-up
2. Health Canada (HC) Reference No. (for follow-up reports)
3. Internal submitter file No.
4. Type of event*
5. Date report submitted
6. Documentation / awareness date*
7.a. Submitter first name*
b. Submitter last name*
8. a. Contact phone* ext c. Fax
b. Contact email
9. Organization name*
10*. a. Report Type
b. ITA Authorization No. or SAP reference No.
11. Profession
12. Department
13. HC Institutional ID (if this unique number is provided, address details do not need to be completed.)
14. Address
15. City
16. Province/Territory
17. Postal code
18. Alternate contact
19. Seriousness of the incident
a. Death (approximate)
b. Life-threatening
c. Permanent impairment of a body function
d. Permanent damage to a body structure
e. Unexpected medical or surgical intervention to prevent a. through d.

B. Affected Person

1. Person's ID (e.g. initials)
2. Who was affected?
3. Vulnerable population? Other:
4. Height cm or ft in
5. Weight kg or lbs oz
6. Sex
7. Age
8. Consequences to the affected person* (Describe the outcome of the incident to the affected person.)

Canada



2 | Medical Device Problem Report Form for Health Care Professionals

9 Contributing factors of the affected person * (e.g. family/socioeconomic issues, understanding of the person, medical directive/therapies, or conditions and history of the person)

10. a: Were there other people involved? ☐ Yes ☐ No
b. If so, how many?
c. Please describe the impact on them.

C. Device Information i. Primary Device

** Box 1 or 3 is required

1. Device name**
2. Device model
3. Device identifier**
4. Serial No.*
5. Catalogue No.
6. Lot/batch No.*
7. Software and version
8. Unique Device Identifier (UDI)
9. Start of use date
10. End of use date
11. Duration of use
12. Expiry date
13. Age of device
14. a. Manufacturer name*
b. Did you also report to the manufacturer?* ☐ Yes ☐ No
c. Date reported
d. Reference No.* (if known)
15. a. Vendor name (importer/distributer/retailer/supplier)
b. Did you also report to the vendor? ☐ Yes ☐ No
c. Date reported
d. Reference No. (if known)
16. a. Was the device returned to the manufacturer? ☐ Yes ☐ No
b. Date returned
c. If not, is it available for evaluation? ☐ Yes ☐ No
17. a. Was the device implanted? ☐ Yes ☐ No
b. Date implanted
c. Was the device explanted? ☐ Yes ☐ No
d. Date explanted
e. Duration of implant
18. a. Was more than one of this device involved? ☐ Yes ☐ No
b. No. of devices involved
19. Usage of device ☐ Other
20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date.

ii. Secondary Device, if applicable (if more than two devices are involved, list other devices in Section F)

** Box 1 or 3 is required

1. Device name**
2. Device model
3. Device identifier**
4. Serial No.*
5. Catalogue No.
6. Lot/batch No.*
7. Software and version
8. Unique Device Identifier (UDI)
9. Start of use date
10. End of use date
11. Duration of use
12. Expiry date
13. Age of device
14. a. Manufacturer name*
b. Did you also report to the manufacturer?* ☐ Yes ☐ No
c. Date reported
d. Reference No.* (if known)
15. a. Vendor name (importer/distributer/retailer/supplier)
b. Did you also report to the vendor? ☐ Yes ☐ No
c. Date reported
d. Reference No. (if known)
16. a. Was the device returned to the manufacturer? ☐ Yes ☐ No
b. Date returned
c. If not, is it available for evaluation? ☐ Yes ☐ No
17. a. Was the device implanted? ☐ Yes ☐ No
b. Date implanted
c. Was the device explanted? ☐ Yes ☐ No
d. Date explanted
e. Duration of implant
18. a. Was more than one of this device involved? ☐ Yes ☐ No
b. No. of devices involved
19. Usage of device ☐ Other

3 | Medical Device Problem Report Form for Health Care Professionals

ii. Secondary Device – continued

20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date.

D. Incident Information (Continue in Section F if necessary)

1. Date of incident
2. Source of report
3. a. Is this a recurring issue? ☐ Yes ☐ No
b. If so, how many times?
4.In which country did the incident occur?
5. Location of the incident
6. Incident details** (Please ensure there is no personal information including names of affected persons/patients/staff involved)

E. Actions Taken

1. Actions taken by hospital, if applicable (e.g retested/calibrated device, called for service for device, discontinued use of device, treatment of injured party, education provided to staff or reported elsewhere, and development of new clinical guidelines.)

2. Actions taken by manufacturer/vendor, if applicable. (e.g pick up of device for investigation, on site servicing of device/training of the staff, recalling products, replacement devices provided)

F. Additional Details

1. Insert any additional details, including additional affected persons or devices involved. Use the fields in section B, C, and D to guide the content.

3 | Medical Device Problem Report Form for Health Care Professionals

ii. Secondary Device – continued

20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date.

D. Incident Information (Continue in Section F if necessary)

1. Date of incident
2. Source of report
3. a. Is this a recurring issue? ☐ Yes ☐ No
b. If so, how many times?
4.In which country did the incident occur?
5. Location of the incident
6. Incident details** (Please ensure there is no personal information including names of affected persons/patients/staff involved)

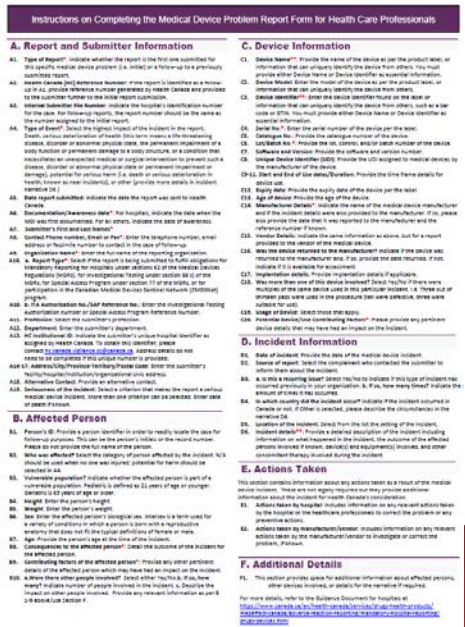
E. Actions Taken

1. Actions taken by hospital, if applicable (e.g retested/calibrated device, called for service for device, discontinued use of device, treatment of injured party, education provided to staff or reported elsewhere, and development of new clinical guidelines.)

2. Actions taken by manufacturer/vendor, if applicable. (e.g pick up of device for investigation, on site servicing of device/training of the staff, recalling products, replacement devices provided)

F. Additional Details

1. Insert any additional details, including additional affected persons or devices involved. Use the fields in section B, C, and D to guide the content.



Instructions on Completing the Medical Device Problem Report Form for Health Care Professionals

A. Report and Submitter Information

A1. Type of Report*: Indicate whether the report is the first one submitted for this specific medical device problem (i.e. initial) or a follow-up to a previously submitted report.

A2. Health Canada (HC) Reference Number: If the report is identified as a follow-up in A1, provide reference number generated by Health Canada and provided to the submitter further to the initial report submission.

A3. Internal Submitter File Number: Indicate the hospital's identification number for the case. For follow-up reports, the report number should be the same as the number assigned to the initial report.

A4. Type of Event*: Select the highest impact of the incident in the report. Death, serious deterioration of health (this term means a life-threatening illness, 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 illness, disorder or abnormal physical state or permanent impairment or damage), potential for serious harm (i.e. death or serious deterioration in health, known as near incidents), or other (provide more details in incident narrative D6.)

A5. Date report submitted: Indicate the date the report was sent to Health Canada.

A6. Documentation/Awareness date*: For hospitals, indicate the date where the MDI was first encountered by users, indicate the date of awareness.

A7. Submitter's First and Last Names*:

A8. Contact Phone number, Email or Fax*: Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A9. Organization Name*: Enter the full name of the reporting organization.

A10. a. Report Type*: Select if the report is being submitted to fulfill obligations for Mandatory Reporting for hospitals under sections 62 of the Medical Devices Regulations (MDR), for investigational Testing under section 66 (c) of the MDR, for Special Access Program under section 77 of the MDR, or for participation in the Canadian Medical Devices Sentinel Network (CMDSNet) program.

A10. b. ITA Authorization No./SAP Reference No.: Enter the investigational Testing Authorization number or Special Access Program Reference Number.

A11. Profession: Select the submitter's profession.

A12. Department: Enter the submitter's department.

A13. HC Institutional ID: Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canada.vigilance.vigilance@canada.ca. Address details do not need to be completed if this unique number is provided.

A14-17. Address/City/Province-Territory/Postal Code: Enter the submitter's facility/hospital/institution/organizational civic address.

A18. Alternative Contact: Provide an alternative contact.

A19. Seriousness of the Incident: Select a criterion that makes the report a serious medical device incident. More than one criterion can be selected. Enter date of death if known.

B. Affected Person

B1. Person's ID: Provide a person identifier in order to readily locate the case for follow-up purposes. This can be the person's initials or the record number. Please do not provide the full name of the person.

B2. Who was affected? Select the category of person affected by the incident. N/A should be used when no one was injured; potential for harm should be selected in A4.

B3. Vulnerable population? Indicate whether the affected person is part of a vulnerable population. Pediatric is defined as 21 years of age or younger. Geriatric is 65 years of age or older.

B4. Height: Enter the person's height.

B5. Weight: Enter the person's weight.

B6. Sex: Enter the affected person's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

B7. Age: Provide the person's age at the time of the incident.

B8. Consequences to the affected person*: Detail the outcome of the incident for the affected person.

B9. Contributing factors of the affected person*: Provide any other pertinent details of the affected person which may have had an impact on the incident.

B10. a. Were there other people involved? Select either Yes/No. b. If so, how many? Indicate number of people involved in the incident. c. Describe the impact on other people involved. Provide any relevant information as per B 1-9 above/use Section F.

C. Device Information

C1. Device Name*: Provide the name of the device as per the product label, or information that can uniquely identify the device from others. You must provide either Device Name or Device Identifier as essential information.

C2. Device Model: Enter the model of the device as per the product label, or information that can uniquely identify the device from others.

C3. Device Identifier:** Enter the device identifier found on the back or information that can uniquely identify the device from others, such as a bar code or DTIN. You must provide either Device Name or Device Identifier as essential information.

C4. Serial No.*: Enter the serial number of the device per the label.

C5. Catalogue No.: Provide the catalogue number of the device.

C6. Lot/Batch No.*: Provide the lot, control, and/or batch number of the device.

C7. Software and Version: Provide the software and version number.

C8. Unique Device Identifier (UDI): Provide the UDI assigned to medical devices by the manufacturer of the device.

C9-11. Start and End of Use dates/Duration: Provide the time frame details for device use.

C12. Expiry date: Provide the expiry date of the device per the label.

C13. Age of device: Provide the age of the device.

C14. Manufacturer Details*: Indicate the name of the medical device manufacturer and if the incident details were also provided to the manufacturer. If so, please also provide the date that it was reported to the manufacturer and the reference number if known.

C15. Vendor Details: Indicate the same information as above, but for a report provided to the vendor of the medical device.

C16. Was the device returned to the manufacturer? Indicate if the device was returned to the manufacturer and, if so, provide the date returned. If not, indicate if it is available for assessment.

C17. Implantation details: Provide implantation details if applicable.

C18. Was more than one of this device involved? Select Yes/No. If there were multiples of the same device used in this particular incident, i.e. three out of thirteen pads were used in one procedure (six were defective, three were outdated for use).

C19. Usage of device: Select those that apply.

C20. Potential device/use contributing factors*: Please provide any pertinent device details that may have had an impact on the incident.

D. Incident Information

D1. Date of Incident: Provide the date of the medical device incident.

D2. Source of report: Select the complainant who contacted the submitter to inform them about the incident.

D3. a. Is this a recurring issue? Select Yes/No to indicate if this type of incident has occurred previously in your organization. b. If so, how many times? Indicate the amount of times it has occurred.

D4. In which country did the incident occur? Indicate if the incident occurred in Canada or not. If Other is selected, please describe the circumstances in the narrative D6.

D5. Location of the Incident: Select from the list the setting of the incident.

D6. Incident details*: Provide a detailed description of the incident including information on what happened in the incident, the outcome of the affected persons involved if known, device(s) and equipment(s) involved, and other concomitant therapy involved during the incident.

E. Actions Taken

This section contains information about any actions taken as a result of the medical device incident. These are not always required but may provide additional information about the incident for Health Canada's consideration.

E1. Actions Taken by hospital: Includes information on any relevant actions taken by the hospital or the healthcare professionals to correct the problem or any preventive actions.

E2. Actions taken by manufacturer/vendor: Includes information on any relevant actions taken by the manufacturer/vendor to investigate or correct the problem, if known.

F. Additional Details

F1. This section provides space for additional information about affected persons, other devices involved, or details from the narrative if required.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-problem-reporting-pre-market-devices.html

Required Fields and Privacy Notice

* = required if this information is in the control of or reasonably accessible by the hospital
** = required, but hospital is exempt from reporting if this information is unavailable

Health Canada / Santé Canada

Protected "B" When Completed

Serious Adverse Drug Reaction Reporting Form for Hospitals

Canada Vigilance – Adverse Reaction Reporting Program

* = required if this information is in the control of or reasonably accessible by the hospital
** = required, but hospital is exempt from reporting if this information is unavailable

Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

Privacy Notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance Adverse Reaction Reporting Program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance Adverse Reaction Reporting Program data is made publicly available from the Canada Vigilance Adverse Reaction Online Database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information), the Institute for Safe Medication Practices, the Canadian Patient Safety Institute, and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Health Canada / Santé Canada

Medical Device Problem Report Form for Health Care Professionals

Canada Vigilance – Medical Device Problem Reporting Program

Protected "B" When Completed

Fields represented by asterisks * indicate that they should be provided in the case of Mandatory Reports by Hospitals if the information is in control or reasonably accessible by the hospital.** = required, but hospital is exempt from reporting if this information is unavailable. Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the medical device caused or contributed to the incident.

Privacy Notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the Medical Device Problem Reporting Program authorized by the *Department of Health Act*, Section 4(h), and the *Food and Drugs Act*, Section23 (1) (c) and the Medical Devices Regulations, Section(s) 59 (1) (a) (b) (2), 60, 61.1 (1), 62, 63, 64, 65, 77, 81(k) (v) (2) and 88 (c).

Purpose of collection: We require your information to assess the nature of the report and to fulfill the Health Products and Food Branch (HPFB) program's responsibilities for monitoring the use of medical devices in Canada. Personal information regarding the Submitter, collected from the medical device problem reports, may be used to conduct follow-up of a medical device incident; to monitor the safety and efficacy of marketed medical devices; for compliance and enforcement activities; to request safety and efficacy information from the manufacturers, health care professionals / practitioners / facilities and other users of marketed medical devices for the purpose of post-market surveillance of medical devices, to report to senior management, or to complete a trend analysis. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools (including a monthly Health Canada newsletter – Infowatch – and an incident database/data extracts) and / or responses to inquiries.

Other uses or disclosures: Your personal information may also be provided to the Manufacturer/Importer of the device in the event that they require follow-up of a medical device incident. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8 (2) of the *Privacy Act*.

Refusal to provide the information: If the report governed under the above sections was not provided when known, in the unlikely event that a situation of non-compliance is not resolved through this cooperative, staged approach, Health Canada could potentially use provisions of the *Food and Drugs Act* and its associated regulations, for example, to seek an injunction under section 21.5 of the *Act*, to compel a Reporter to comply with the regulations.

For more information: This personal information collected is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank, HC PPU 415.

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Serious ADRs – General Information

A. General Information

1. Type of Report* ☐ Initial ☐ Follow-up

2. Health Canada (HC) Reference No.: (for follow-up reports only)

3. Organization File No.

4. Date report submitted 2019-06-27

5. Documentation Date*

Date when the adverse drug reaction was documented in the hospital

June, 2019

Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

6.a. Organization Contact First Name*

b. Last Name*

7.a. Phone No.* ext.

b. Email

c. Fax

8. Organization Name*

9. Source of report (profession)

- Physician
- Pharmacist
- Other Health Professional
- Risk Management Coordinator
- Nurse
- Lawyer
- Consumer or other non health professional

10. HC Institutional ID (If ID provided, no need to provide address)

Contact HC to obtain this number

11. Address

12. City

13. Province/Territory

14. Postal Code

15. Reason for seriousness* (explain (g) in section F)

☐ (a) Death (yyyy/mm/dd) Partial date accepted ☐ (b) Life-threatening ☐ (c) Caused disability ☐ (d) Admitted to hospital

☐ (e) Lengthened hospital stay ☐ (f) Congenital malformation ☐ (g) Required medical intervention to avoid any of (a) to (f)

Serious ADRs – Patient and reaction(s) Information

B. Patient Information

1. Patient ID (e.g. initials, record no.)

Do not provide patient's full name

2. †Sex**

3. Age**

†Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male

4. Height

____ cm or

____ ft ____ in

5. Weight

____ kg or

____ lbs ____ oz

6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.)

7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details)

C. Serious Adverse Drug Reaction(s)

1. Did the person recover from the reaction?*

(please choose one of the following)

☐ Recovered ☐ Recovering ☐ Not recovered

☐ Died ☐ Unknown ☐ Recovered with sequelae

2. Reaction start date*

3. Reaction end date*

Partial dates are acceptable

4. Description of the serious adverse drug reaction(s)**

- Avoid using acronyms
- Do not include any information which may identify the patient or staff involved

Serious ADRs – Suspect Product(s)

D. Suspect Product One

If the DIN is not provided, please provide the Brand Name or the Proper Name, as well as the Manufacturer Name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug Identification Number (DIN)*	2. Identifying Code for Urgent Public Health Need Drugs**
3. Brand Name** (per product label)	4. Common/Proper Name** (active ingredient)

5. Strength (per unit)	6. Dose	7. Frequency
8. Route of administration	9. Product start date*	10. Product end date*

Top 5 common routes

- Oral
- Intravenous (not otherwise specified)
- Subcutaneous
- Intramuscular
- Topical
- Other
- Auricular (otic)
- Buccal

11. Indication	12. Lot No.	13. Expiry date

14. a. Manufacturer Name

b. Did you also report to the manufacturer?* ☐ Yes ☐ No

c. Date reported (yyyy-mm-dd)

d. Reference No.* (if known)

15. Did the reaction stop if dose was reduced or removed?
☐ Yes ☐ No ☐ N/A

16. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ N/A

17. Is the product still being administered?
☐ Yes ☐ No

D. Suspect Product Two

If the DIN is not provided, please provide the Brand Name or the Proper Name, as well as the Manufacturer Name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug Identification Number (DIN)*	2. Identifying Code for Urgent Public Health Need Drugs**
3. Brand Name** (per product label)	4. Common/Proper Name** (active ingredient)

Serious ADRs

E. Concomitant therapeutic product(s)

1. Known therapeutic products taken or used proximal to the reaction* (e.g. prescription and non-prescription drugs, medical devices, natural health products, etc. Include details of use if available.)

- List all known health products taken when reaction occurred
- Information related to therapy of these products
- Do not include health products used to treat reaction

F. Additional information

1. Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction.

- Narrative summary
- Additional information
  - Underlying diagnosis pertinent to reaction
  - Information that did not fit structured fields
  - For death cases: details on official cause of death and autopsy results

For more details, refer to Instructions and/or Guidance Document

MDI – Report and Submitter Information

A. Report and Submitter Information

1. Type of report* ☐ Initial ☐ Follow-up

2. Health Canada (HC) Reference No. (for follow-up reports)

3. Internal submitter file No.

4. Type of event*
- Death
- Serious deterioration in the state of
- Potential for death or serious deteri
- Other

Potential for death or serious deterioration in state of health

5. Date report submitted
YYYY-MM-DD

6. Documentation / awareness date*

June, 2019

Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

7.a. Submitter first name*

b. Submitter last name*

8. a. Contact phone* ext c. Fax

b. Contact email

9. Organization name*

10*. a. Report Type
- Mandatory report from hospital
- Mandatory report for ITA
- Mandatory report for SAP
- Voluntary report from CMDSNet

b. ITA Authorization No. or SAP reference No.

11. Profession
- Nurse
- Pharmacist
- Physician
- Risk management coordinator
- Other health care professional
- Lawyer
- Consumer or other non-health care professional

12. Department

13. HC Institutional ID (If this unique number is provided, address details do not need to be completed.)
Contact HC to obtain this number

14. Address

15. City

16. Province/Territory

17. Postal code

18. Alternate contact

19. Seriousness of the incident

☐ a. Death (yyyy-mm-dd) Partial date accepted

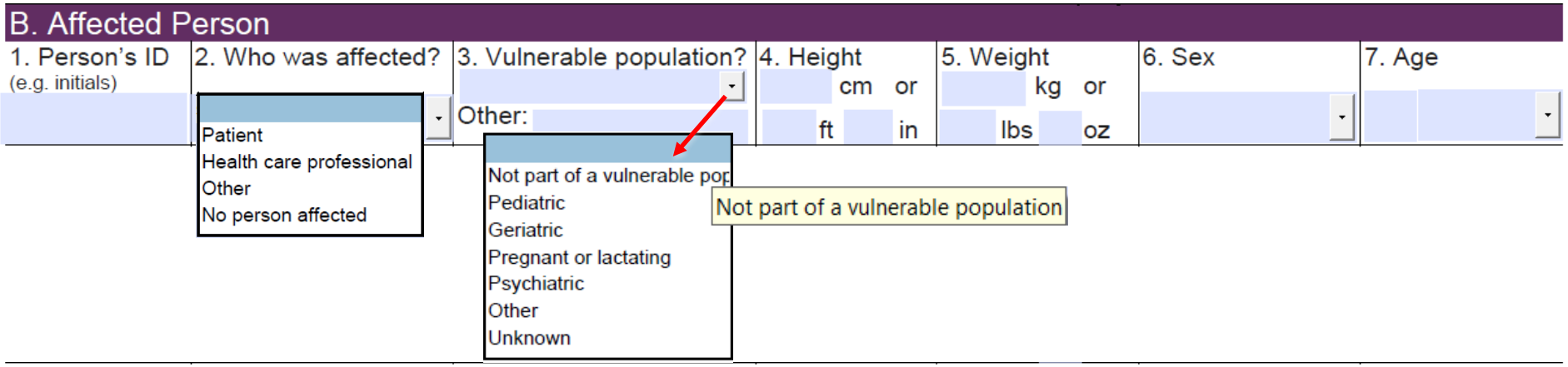
☐ b. Life-threatening

☐ c. Permanent impairment of a body function

☐ d. Permanent damage to a body structure

☐ e. Unexpected medical or surgical intervention to prevent a. through d.

MDI – Affected Person



MDI – Primary Device Information (secondary device, if applicable)

C. Device Information i. Primary Device

** Box 1 or 3 is required

1. Device name**	2. Device model	3. Device identifier**

4. Serial No.*	5. Catalogue No.	6. Lot/batch No.*	7. Software and version

8. Unique Device Identifier (UDI)

9. Start of use date	10. End of use date	11. Duration of use	12. Expiry date	13. Age of device

14. a. Manufacturer name*	15. a. Vendor name (importer/distributer/retailer/supplier)
b. Did you also report to the manufacturer?* Yes No	b. Did you also report to the vendor? Yes No
c. Date reported	c. Date reported
d. Reference No.*(if known)	d. Reference No.(if known)

16. a. Was the device returned to the manufacturer? Yes No	b. Date returned	c.If not, is it available for evaluation? Yes No

17. a. Was the device implanted? Yes No	b. Date implanted	c.Was the device explanted? Yes No	d. Date explanted	e. Duration of implant

18. a. Was more than one of this device involved? Yes No	b. No. of devices involved	19. Usage of device	Other

20. Potential device/use contributing factors* (e.g. design issues, missing component, software errors, incompatible with other devices/accessories, sterility/packaging issues, unclear instructions for use, lack of training (materials or other information), expired devices, issues with operator/reason for use, use/environmental issues, reprocessed devices, or maintenance issues such as condition/last inspection date.

ii. Secondary Device, if applicable (if more than two devices are involved, list other devices in Section F)

**Box 1 or 3 is required

1. Device name**	2. Device model	3. Device identifier**

4. Serial No.*	5. Catalogue No.	6. Lot/batch No.*	7. Software and version

8. Unique Device Identifier (UDI)

9. Start of use date	10. End of use date	11. Duration of use	12. Expiry date	13. Age of device

MDI – Incident Information

D. Incident Information (Continue in Section F if necessary)				
1. Date of incident	2. Source of report	3. a. Is this a recurring issue? Yes No b. If so, how many times?	4.In which country did the incident occur?	5. Location of the incident

6. Incident details** (Please ensure there is no personal information including names of affected persons/patients/staff involved)

MDI – Actions Taken and Additional Details

E. Actions Taken

1. Actions taken by hospital, if applicable.(e.g retested/calibrated device, called for service for device, discontinued use of device, treatment of injured party, education provided to staff or reported elsewhere, and development of new clinical guidelines.)

2. Actions taken by manufacturer/vendor, if applicable. (e.g pick up of device for investigation, on site servicing of device/training of the staff, recalling products, replacement devices provided)

F. Additional Details

1. Insert any additional details, including additional affected persons or devices involved. Use the fields in section B, C, and D to guide the content.

For more details, refer to Instructions and/or Guidance Document

The Reporting Methods and System Update

- In order to meet the new regulatory requirements, Health Canada has ensured there are various submission methods available to hospitals for serious ADR and MDI reporting
  - Fax
  - Mail
  - Online reporting applications
  - Secure electronic submission methods

- Methods of submission must be secure in order to protect the information being exchanged

The Reporting Methods and System Update

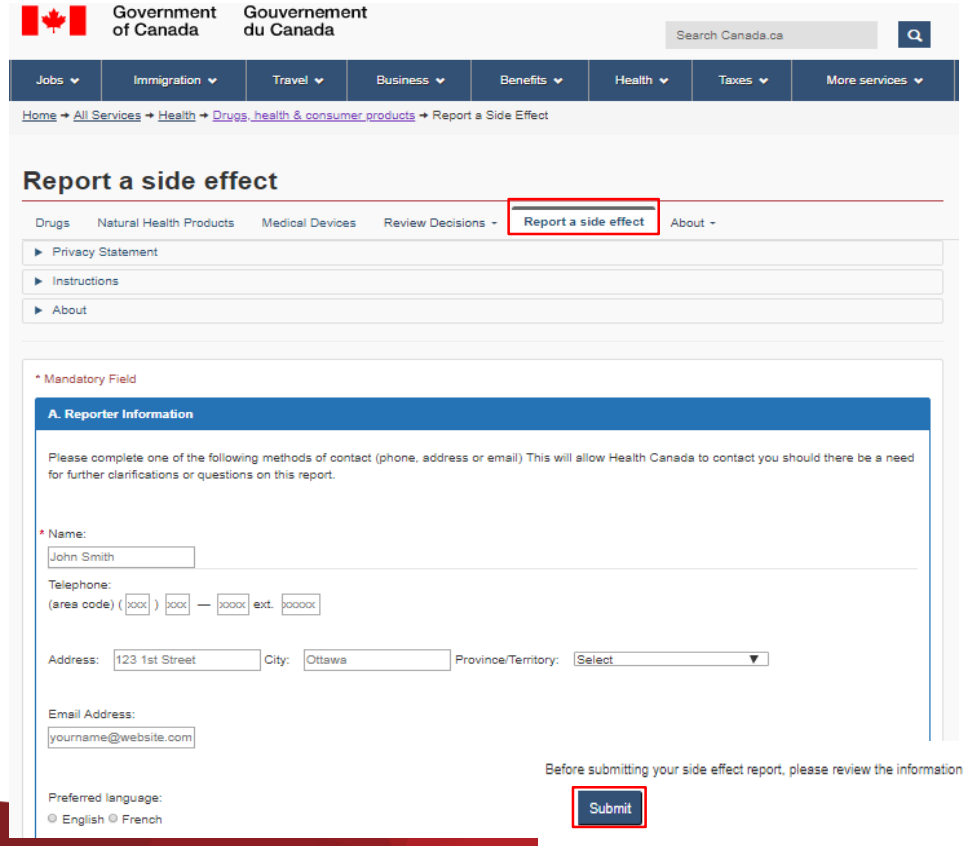
- Health Canada acknowledges that systems and/or internal processes for documenting serious ADRs and MDIs vary by hospital and province

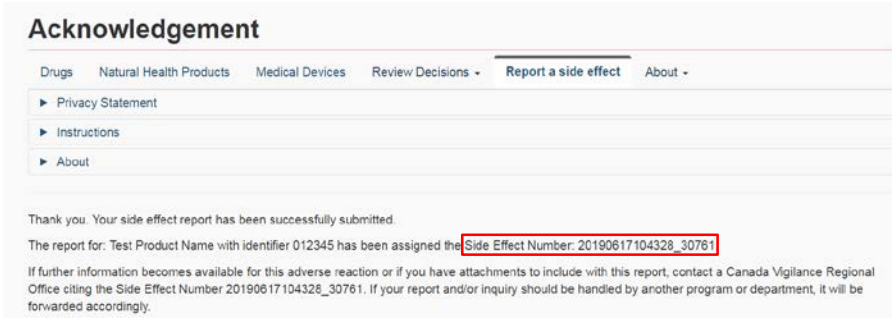
- Health Canada remains flexible and encourages hospitals to select the most efficient option for their circumstances

- Health Canada encourages hospitals to seek opportunities to leverage existing databases (e.g. incident databases, electronic health records) to create efficiencies and facilitate reporting

How can hospitals submit reports to Health Canada?

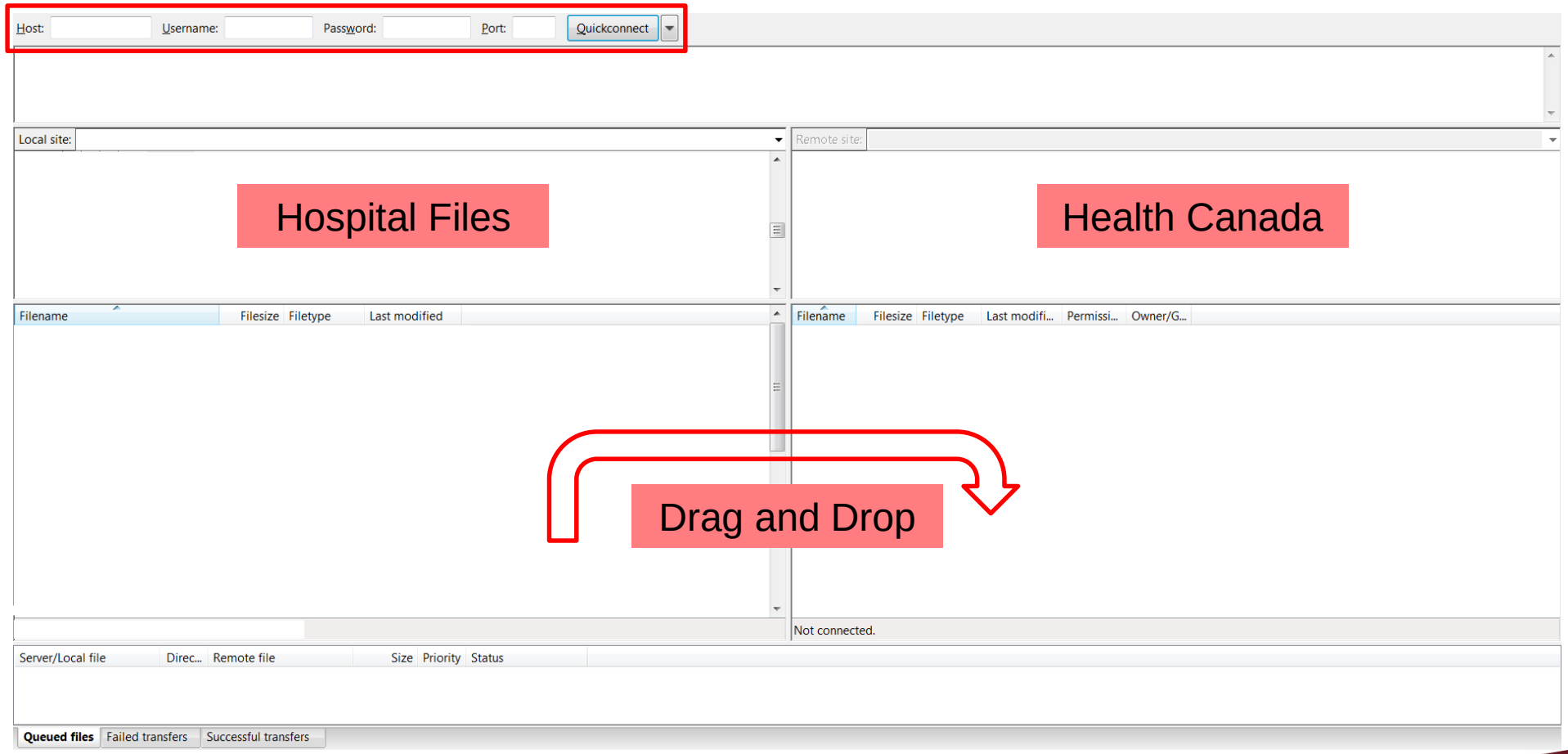
- **Fax or Mail**
  - Download, complete, and print the PDF form
- **Online**
  - Complete and submit a report using the online reporting applications available at: canada.ca/medeffect. Serious ADR and MDI hospital forms available early Fall 2019





How can hospitals submit reports to Health Canada?

- **Electronic reporting**
  - Secure File Transfer Protocol (sFTP): enrollment and submission process



How can hospitals submit reports to Health Canada?

- sFTP and File Formats:
  - Supports: PDF, MS Word, MS Excel, XML, or HTML
  - Ability to bulk submit reports, reduces file size restrictions, and compatible with zipped files
  - Best practices recommendations and templates will be made available to hospitals
    - Examples:
      - Excel: consistent column and row outputs, clear data field names
      - XML: consistent and clear use of tags, structured information blocks

- **Electronic reporting (cont'd.)**
  - Health Canada continues to explore other electronic submission methods such as system-to-system exchanges.

Examples of serious ADR and MDI Reporting Systems

- Health Canada is currently working with hospitals, health authorities, and health organisations to support readiness and provide best practices recommendations to all hospitals

- Examples:
  - British Columbia Patient Safety & Learning System (BC PSLS)
    - Provincial online reporting system (Datix software) that includes serious ADR and MDI (future) reporting
  - Alberta Health Services (AHS)
    - Serious ADR reporting will be fully integrated into the electronic health record (EPIC system). Until integration is completed, will be using the online provincial reporting and learning system (Datix software).
    - MDI reporting supported by centralized Medical Device Safety teams and reporting form linked between electronic health record (EPIC system) and the AHS intranet.

Reporting Methods and Formats – more information to follow

- Health Canada will continue to collaborate with hospitals, health authorities, and health organisations to explore new ways to facilitate reporting of serious ADRs and MDIs

- Health Canada will continue to communicate best practices recommendations to hospitals

- If you are interested in submitting reports electronically, please email the Canada Vigilance Program: hc.canada.vigilance.sc@canada.ca

Questions/ Comments?

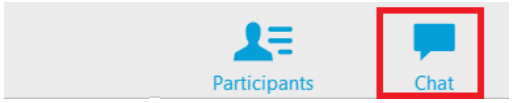
Please send any inquiries to:

hc.canada.vigilance.sc@canada.ca

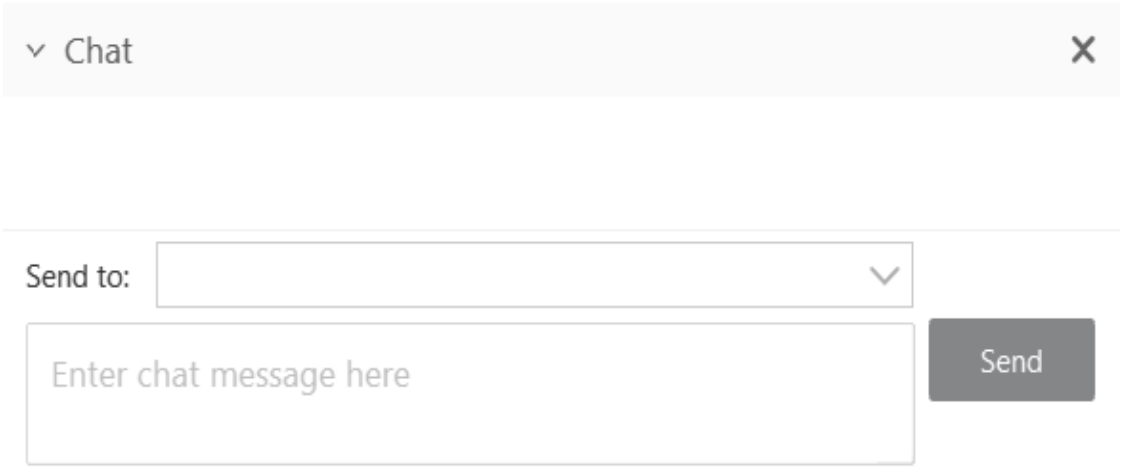
Questions

- If you have questions, please send them through the WebEx Chat function.

1. Click on the Chat Box in the upper right hand corner.



2. Select “Host” from the Send To: drop down list.
3. Type your question.
4. Press send.



- Questions submitted will be answered aloud as time permits.

- Health Canada has muted phone lines