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

Educational Support for Mandatory Reporting

Module 2:
Reporting Processes to Health Canada

Module 2 – Learning Outcomes

Completion of Module 2 will enable you to:

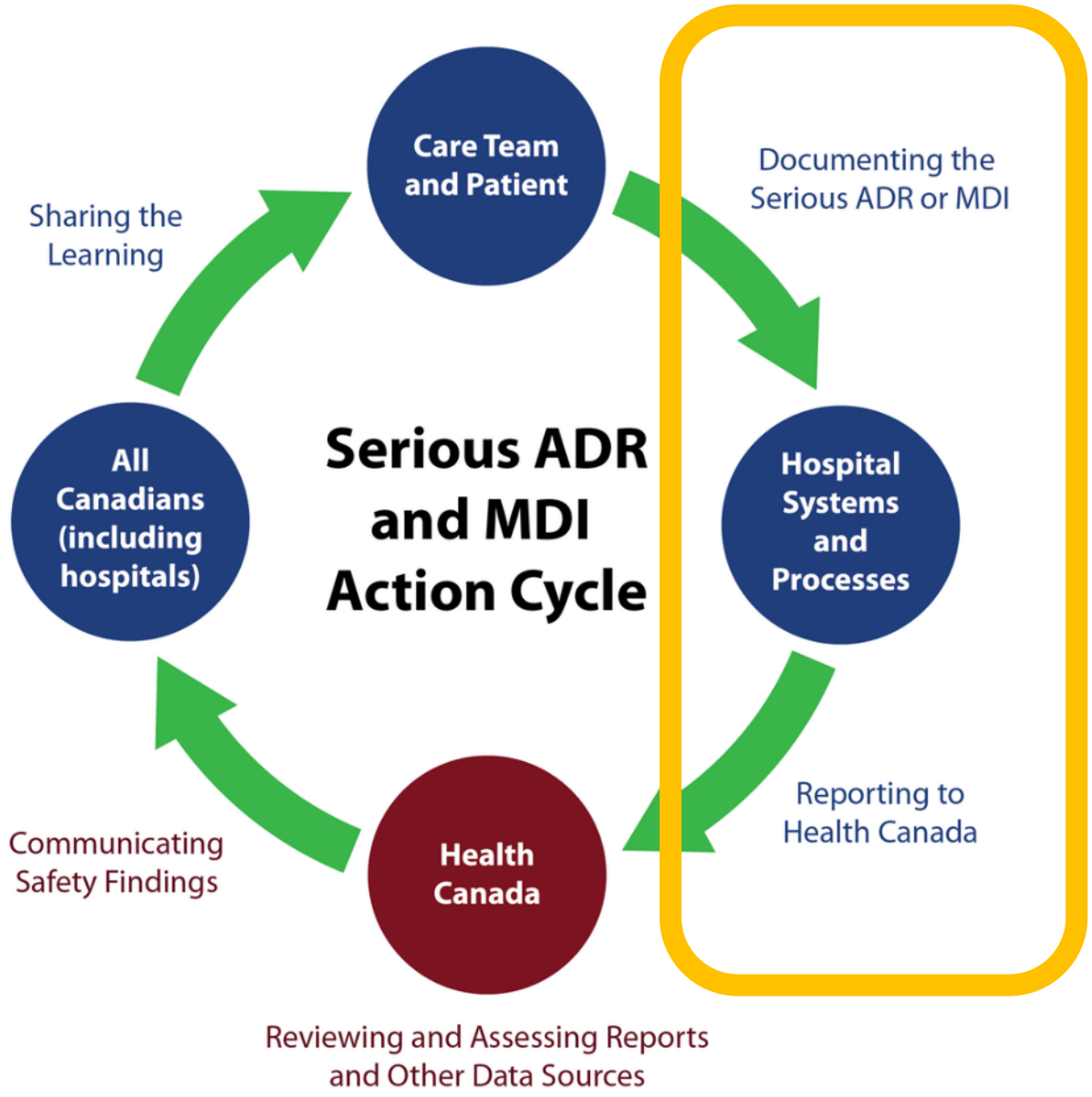
- Describe considerations for mandatory reporting
- Describe reporting options to Health Canada
- Differentiate among the following:
  - Serious adverse drug reaction (serious ADR)
  - Medical device incident (MDI)
  - Medication incident
  - Adverse reaction (AR)
  - Medical device problem (MDP)
- Describe the information contained within the Guidance Document
- Describe voluntary reporting of ARs and MDPs to Health Canada

Module 2 – Outline

- Considerations for Mandatory Reporting
- Submitting Reports to Health Canada
- Case Examples
- Guidance Document
- Voluntary Reporting to Health Canada
- Key Points to Remember
- Abbreviations
- Resources

Conceptual Model of Serious ADR and MDI Reporting by Hospitals

Module 2 describes reporting processes to Health Canada.



Source: Serious ADR and MDI Action Cycle. ISMP Canada, HSO, CPSI; 2019.

Considerations for Mandatory Reporting

Hospital Considerations

- Hospital systems, processes, policies, procedures, and forms may need to be updated to reflect requirements for mandatory reporting of serious ADRs and MDIs to Health Canada.
- Hospitals are expected to:
  - Develop and maintain internal policies and procedures in order to comply with the requirements for mandatory reporting of serious ADRs and MDIs to Health Canada
  - Determine and communicate internal roles and responsibilities of staff in meeting the mandatory reporting requirements

- The mandatory reporting requirements apply to the hospital and not to the individual health care providers working in the hospital. However, health care providers will have an important role in recognizing and documenting serious ADRs and MDIs.

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

Health Care Provider Considerations

- Health care providers have a role in identifying and documenting serious ADRs and MDIs, in accordance with hospital-defined processes.
- Health Canada is interested in reports about a serious ADR or MDI, even if:
  - its association with the drug and/or medical device is only suspected;
  - causality is not confirmed;
  - all the details are not known; and/or
  - it hasn’t caused serious harm but has the potential to cause serious harm if it was to reoccur (only in case of MDIs).

Tips for Recognizing a Serious ADR or MDI

- Serious harm from a drug or from a medical device can be mistaken for a symptom of a disease.
- A high level of suspicion, clinical awareness, and patient dialogue are key components in identifying a serious ADR or MDI. The following can help:
  - Ask about the patient's medical history
  - Consider a serious ADR or MDI if there is:
    - an unexpected change in the patient's clinical condition
    - a new health problem for the patient
    - a need for urgent additional therapies, procedures or surgeries
    - a sudden need for a rescue drug (e.g., naloxone, epinephrine, glucagon)
    - a medical order for an acute change to therapy (e.g., abrupt discontinuation)
- A serious ADR or MDI can occur shortly after beginning treatment or much later

Considerations for Reporting to Industry/Vendors

- Mandatory reporting regulations do not require hospitals to report to industry/vendors; however, reporting to industry/vendors is strongly encouraged.
- Prompt voluntary reporting from hospitals to industry/vendors enables industry/vendors to conduct investigations to determine causes and corrective actions in a timely manner.
    - **MDIs**: the hospital should inform industry/vendors of an MDI as soon as possible. The manufacturers/importers are required to determine causes and corrective actions.
        - Hospitals should consider including a report to industry/vendors in internal reporting policies and procedures.
        - Hospitals should consider sequestering the medical device involved in an MDI; it is important that industry/vendors have the device for further investigation and analysis.
- Communication among all parties is an effective mechanism to ensure product improvement and patient safety.

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

Submitting Reports to Health Canada

Submitting Serious ADR and MDI Reports to Health Canada

- Health Canada remains flexible and is able to receive reports in various formats via multiple secure submission methods, recognizing that hospital systems vary.
  - If interested in submitting reports electronically to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.
  - Health Canada supports report submissions using a secure File Transfer Protocol (sFTP) and continues to explore system-to-system options.
- The reporting forms for serious ADRs and MDIs, together with instructions, are available on the Health Canada website:
  - Serious ADR reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf
  - MDI reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf

Serious Adverse Drug Reaction (Serious ADR)

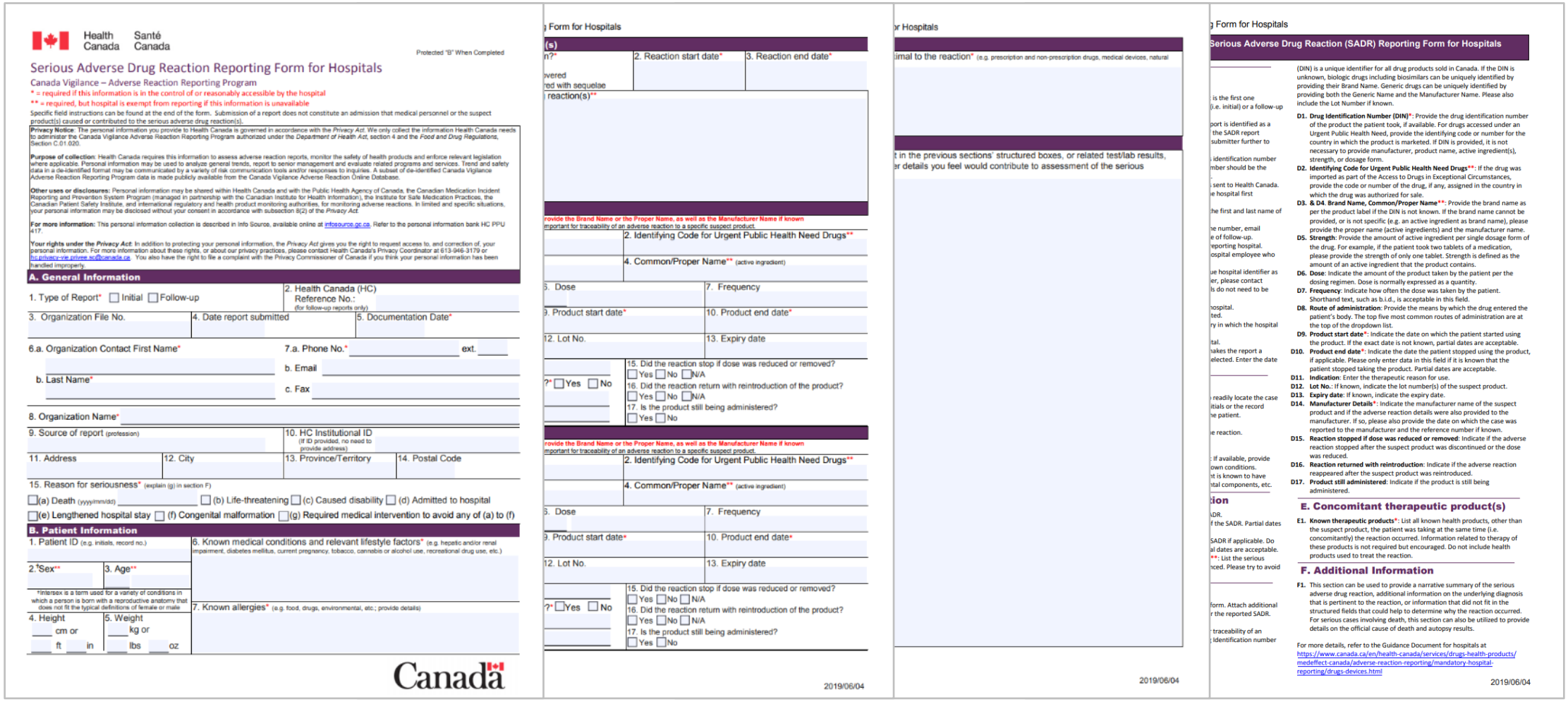
- A noxious and unintended response to a drug that occurs at any dose and that
  - requires in-patient hospitalization or prolongation of existing hospitalization,
  - causes congenital malformation,
  - results in persistent or significant disability or incapacity,
  - is life-threatening, or
  - results in death.[1]

Examples of Serious ADRs

- Kidney damage from a diuretic (water pill) that requires dialysis
- Lung damage from a chemotherapy drug that requires long-term oxygen therapy
- Allergic reaction to an antibiotic that is life-threatening

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

New Form for Mandatory Reporting of Serious ADRs



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.

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*
b. Last Name*
7.a. Phone No.* ext.
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

Form for Hospitals

(s)

n?* 2. Reaction start date* 3. Reaction end date*

overed
ed with sequelae

reaction(s)**

rovide the Brand Name or the Proper Name, as well as the Manufacturer Name if known
mportant for traceability of an adverse reaction to a specific suspect product.

2. Identifying Code for Urgent Public Health Need Drugs**
4. Common/Proper Name** (active ingredient)
6. Dose
7. Frequency
9. Product start date*
10. Product end date*
12. Lot No.
13. Expiry date
?* ☐Yes ☐No
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

rovide the Brand Name or the Proper Name, as well as the Manufacturer Name if known
mportant for traceability of an adverse reaction to a specific suspect product.

2. Identifying Code for Urgent Public Health Need Drugs**
4. Common/Proper Name** (active ingredient)
6. Dose
7. Frequency
9. Product start date*
10. Product end date*
12. Lot No.
13. Expiry date
?* ☐Yes ☐No
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

2019/06/04

or Hospitals

imal to the reaction* (e.g. prescription and non-prescription drugs, medical devices, natural

t in the previous sections' structured boxes, or related test/lab results,
er details you feel would contribute to assessment of the serious

2019/06/04

Form for Hospitals

Serious Adverse Drug Reaction (SADR) Reporting Form for Hospitals

is the first one
(i.e. initial) or a follow-up

port is identified as a
the SADR report
submitter further to

identification number
mber should be the

sent to Health Canada.
e hospital first

he first and last name of

e number, email
e of follow-up.
reporting hospital.
ospital employee who

ue hospital identifier as
er, please contact
ls do not need to be

ospital.
ted.
ry in which the hospital

tal.
akes the report a
elected. Enter the date

readily locate the case
itials or the record
e patient.

e reaction.

: If available, provide
own conditions.
t is known to have
ital components, etc.

tion

ADR.
f the SADR. Partial dates

SADR if applicable. Do
al dates are acceptable.
**: List the serious
nced. Please try to avoid

form. Attach additional
r the reported SADR.

: traceability of an
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

2019/06/04

The new reporting form for serious ADRs, together with instructions, are available on the Health Canada website: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf

Medical Device Incident (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.[1]

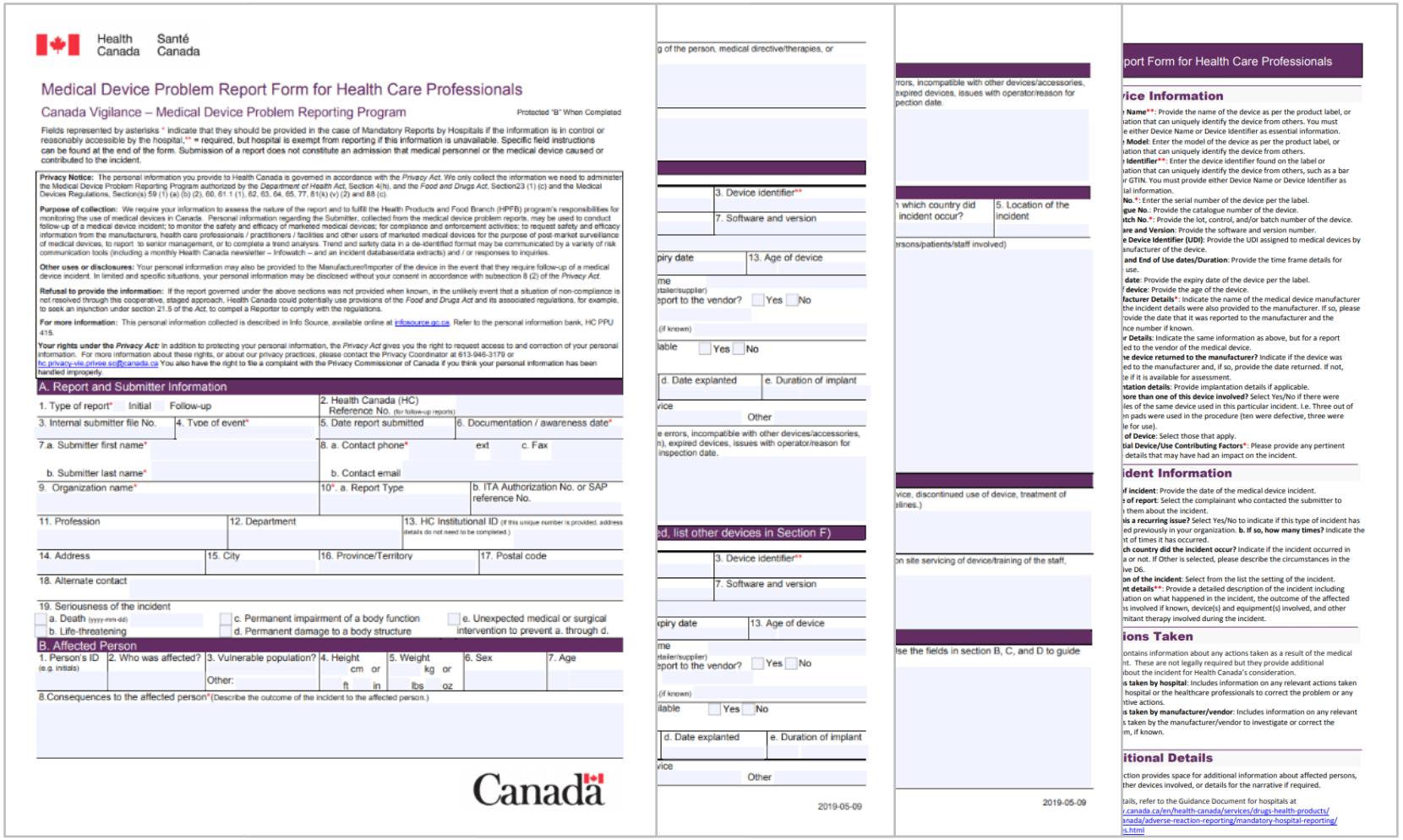
Examples of MDIs

- An infusion pump stopped due to a malfunction, but failed to give an alarm. The patient received an under-infusion of antibiotics; septic shock occurred and prolonged the patient's stay in the hospital's intensive care unit.
- An external defibrillator failed to deliver the programmed level of energy to a patient due to a malfunction. The patient was not revived.

  Note: If the patient was revived, this would be considered a potential to cause serious harm (if it had not been for the timely intervention by a health care provider) and would also be reportable.

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

New Form for Mandatory Reporting of MDIs



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.

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 (yyyy-mm-dd)
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

g of the person, medical directive/therapies, or

3. Device identifier**
7. Software and version
piry date
13. Age of device
me
etailer/supplier)
eport to the vendor? Yes No
(if known)
lable Yes No
d. Date explanted
e. Duration of implant
vice
Other
e errors, incompatible with other devices/accessories, n), expired devices, issues with operator/reason for inspection date.
ed, list other devices in Section F)
3. Device identifier**
7. Software and version
xpiry date
13. Age of device
me
etailer/supplier)
eport to the vendor? Yes No
(if known)
ilable Yes No
d. Date explanted
e. Duration of implant
vice
Other

2019-05-09

rrors, incompatible with other devices/accessories, expired devices, issues with operator/reason for pection date.
which country did incident occur?
5. Location of the incident
rsons/patients/staff involved)
vice, discontinued use of device, treatment of alines.)
on site servicing of device/training of the staff.
lse the fields in section B, C, and D to guide

2019-05-09

port Form for Health Care Professionals

vice Information

Name**: Provide the name of the device as per the product label, or ation that can uniquely identify the device from others. You must e either Device Name or Device Identifier as essential information.
Model: Enter the model of the device as per the product label, or ation that can uniquely identify the device from others.
Identifier**: Enter the device identifier found on the label or ation that can uniquely identify the device from others, such as a bar r GTIN. You must provide either Device Name or Device Identifier as ial information.
No.*: Enter the serial number of the device per the label.
gue No.: Provide the catalogue number of the device.
tch No.*: Provide the lot, control, and/or batch number of the device.
are and Version: Provide the software and version number.
e Device Identifier (UDI): Provide the UDI assigned to medical devices by anufacturer of the device.
and End of Use dates/Duration: Provide the time frame details for use.
date: Provide the expiry date of the device per the label.
f device: Provide the age of the device.
facturer Details*: Indicate the name of the medical device manufacturer the incident details were also provided to the manufacturer. If so, please ovide the date that it was reported to the manufacturer and the nce number if known.
r Details: Indicate the same information as above, but for a report ed to the vendor of the medical device.
e device returned to the manufacturer? Indicate if the device was ed to the manufacturer and, if so, provide the date returned. If not, e if it is available for assessment.
tation details: Provide implantation details if applicable.
ore than one of this device involved? Select Yes/No if there were les of the same device used in this particular incident. I.e. Three out of n pads were used in the procedure (ten were defective, three were le for use).
of Device: Select those that apply.
ial Device/Use Contributing Factors*: Please provide any pertinent details that may have had an impact on the incident.

ident Information

f incident: Provide the date of the medical device incident.
e of report: Select the complainant who contacted the submitter to them about the incident.
is a recurring issue? Select Yes/No to indicate if this type of incident has ed previously in your organization. **b. If so, how many times?** Indicate the nt of times it has occurred.
ch country did the incident occur? Indicate if the incident occurred in a or not. If Other is selected, please describe the circumstances in the ive D6.
on of the incident: Select from the list the setting of the incident.
nt details**: Provide a detailed description of the incident including ation on what happened in the incident, the outcome of the affected s involved if known, device(s) and equipment(s) involved, and other mitant therapy involved during the incident.

ions Taken

ontains information about any actions taken as a result of the medical nt. These are not legally required but they provide additional bout the incident for Health Canada's consideration.
s taken by hospital: Includes information on any relevant actions taken hospital or the healthcare professionals to correct the problem or any ntive actions.
s taken by manufacturer/vendor: Includes information on any relevant s taken by the manufacturer/vendor to investigate or correct the m, if known.

itional Details

ction provides space for additional information about affected persons, ther devices involved, or details for the narrative if required.

tails, refer to the Guidance Document for hospitals at r.canada.ca/en/health-canada/services/drugs-health-products/ anada/adverse-reaction-reporting/mandatory-hospital-reporting/ s.html

The reporting form for MDPs was created for multiple reporting uses:

- Mandatory reporting for
  - hospitals,
  - Special Access Program (SAP),
  - Investigational Testing Authorization (ITA)
- Voluntary reporting to Canadian Medical Devices Sentinel Network (CMDSNet) by participating institutions

The new reporting form for MDPs, together with instructions, are available on the Health Canada website: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf

Case Examples

Case Example 1: 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.

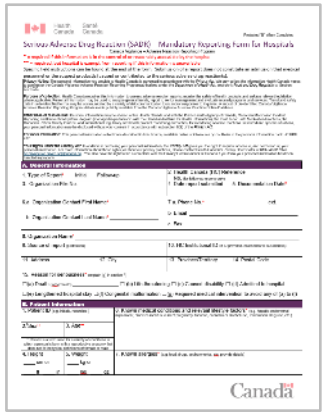
RATIONALE

Life-threatening condition

and/or

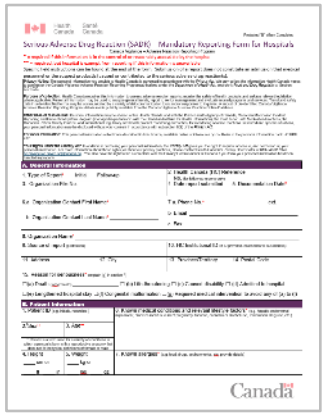
Resulted in in-patient hospitalization

ADR meets the criteria of "serious"



Case Example 2: Is the Hospital Required to Report?

A patient diagnosed with Hodgkin's lymphoma was being treated with doxorubicin, bleomycin, vincristine, and dacarbazine. Following cycle 3, the patient was admitted as an in-patient with complaints of dry cough and shortness of breath on exertion. Bleomycin-induced pulmonary fibrosis was suspected.



RATIONALE

Life-threatening condition

and/or

Resulted in in-patient hospitalization

ADR meets the criteria of "serious"

Note: This ADR also meets the criteria of "serious" because bleomycin-induced pulmonary fibrosis may be considered a persistent and significant disability as it can impact the patient's quality of life, given that it can take a long time for an improvement in pulmonary function.

Case Example 3: Is the Hospital Required to Report?

A patient has been recently started on the oral anticoagulant warfarin and is having international normalized ratio (INR) monitored at an out-patient anticoagulation clinic at a hospital. The patient reported a nosebleed that occurred in the time between clinic appointments. Based on the patient's INR level, the patient's warfarin dose was adjusted. The patient will continue to have INR monitored at the hospital.

RATIONALE While the patient may be at increased risk for another bleed (with an elevated INR and recent nosebleed), the ADR does *not* meet the criteria for “serious”.

Case Example 4: Is the Hospital Required to Report?

A patient was being treated with doxorubicin and cyclophosphamide, and developed neutropenia. After assessing the severity of the neutropenia, a decision was made to continue with chemotherapy at a reduced dose with growth factor support.

RATIONALE While the patient may be at increased risk for potentially fatal infections, the ADR is *not* immediately life-threatening.

Note: This ADR would need to be reported if the patient developed febrile neutropenia and required in-patient hospitalization for treatment (e.g., antimicrobials to prevent infectious complications from febrile neutropenia).

Case Example 5: 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).

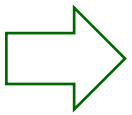
Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/medeffect-canada-role-management-prevention-harmful-medication-incidents.html

Case Example 6: Is the Hospital Required to Report?

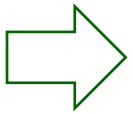
Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs; these burns were due to thin uterine walls and were an unanticipated side effect of ablation. The manufacturer failed to change the ablation device label to warn users of this side effect (which may be produced when the device is working within specification).

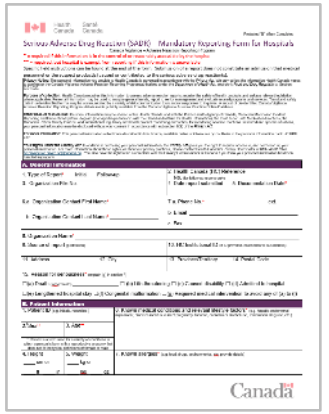
RATIONALE

Serious deterioration in the state of health of a patient



Reportable MDI



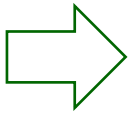


Case Example 7: Is the Hospital Required to Report?

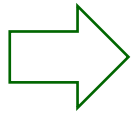
A health care professional reported that the sewing cuff was discovered to be defective during a heart valve implant. The defective valve was abandoned, a new valve was implanted, and pumping time during surgery was extended. This defect had the potential to cause serious harm.

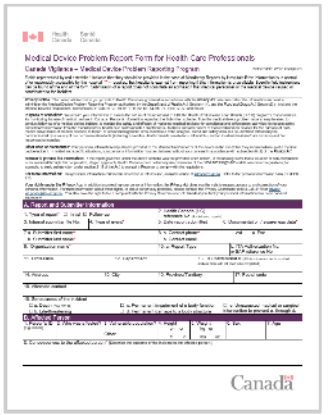
RATIONALE

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



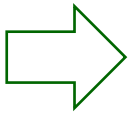


Case Example 8: Is the Hospital Required to Report?

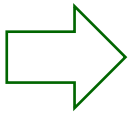
A batch of out-of-specification blood glucose test strips is released by a manufacturer. The patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

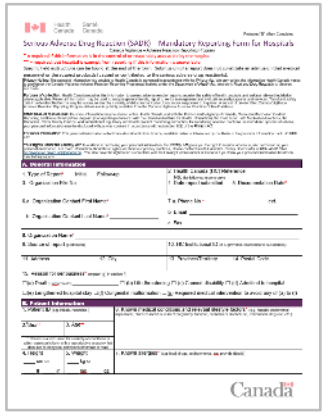
RATIONALE

Serious deterioration in the state of health of a patient



Reportable MDI





Case Example 9: 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 always 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.

Case Example 10: Is the Hospital Required to Report?

A patient died after dialysis treatment. The patient had end-stage renal disease and died of renal failure.

RATIONALE

When the hospital has information that the cause of the incident was definitely due to a patient's condition, the incident does not need to be reported. The patient's condition could be pre-existing or occurring during device use. An incident due to a patient's condition does not meet the requirements of an MDI.

Mandatory Reporting of Serious ADRs and MDIs by Hospitals:

Guidance Document

Guidance Document

1. **Introduction**
2. **The regulations and their purpose**
   - Purpose
   - Serious ADR and MDI definitions
3. **Roles and responsibilities**
   - Role of hospitals / health care professionals
   - Other types of facilities (e.g., private clinics, nursing homes, outpatient clinics)
   - Hospital's requirement to report in other situations (examples)
4. **Applicability of the regulations according to product type**
   - Applicable therapeutic products / medical devices
   - Non-applicable therapeutic products / medical devices
   - Determination of applicability for combination products

Source: 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

5. Serious ADRs or MDIs to be reported by hospitals

- Serious ADR / MDI reportability considerations
- Serious ADR / MDI examples
- Outcomes associated with MDIs
- Causality assessment / hospital investigations
- Documentation examples

6. Information requirements for serious ADR and MDI reports

- Serious ADR / MDI data elements

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

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

Source: 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

8. **Privacy**
    - Privacy considerations when submitting reports
9. **Additional reporting considerations**
    - Submission of reports to manufacturers
    - Submission of reports to CMDSNet
10. **Compliance and enforcement**
    - Health Canada compliance and enforcement actions for hospitals

Appendices

- **Appendix 1**: Acronyms, Definitions and Terminology
- **Appendix 2**: Third-party Reporting Authorization Form
- **Appendix 3**: Reporting requirements for therapeutic products not subject to the new regulations for hospitals
- **Appendix 4**: Quick Reference Guide

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

Voluntary Reporting to Health Canada

Voluntary Adverse Reaction (AR) and Medical Device Problem (MDP) Reporting

- Health Canada builds post-market safety knowledge integral to informing effective clinical use of health products. This safety knowledge is derived from several data sources, including serious ADR and MDI reports.
- Voluntary reporting of suspected ARs or MDPs by health professionals and consumers is another method to monitor the safety and effectiveness of marketed health products.

Adverse Reaction (AR)

- A noxious and unintended effect to a health product.[1]

Examples of ARs

- Reduced kidney function from a diuretic (water pill)
- Reduced lung capacity from a chemotherapy drug
- Allergic reaction to an antibiotic

[1] https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html#a1

Medical Device Problem (MDP)

- A medical device problem is related to:
  - inadequate labelling or instructions for use
  - a failure of the device or a deterioration in its effectiveness
  - an actual or potential deficiency that may affect product performance or safety[1]

Note: Medical device problem reporting includes any type of medical device issue; it does not necessarily meet the definition of an MDI.

Examples of MDPs

- Tubing leaked, causing a delay in treatment, but there was no serious harm to the patient
- Needle broke during a blood draw, but it was removed with minor injury to the patient

[1] https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html#a1

Canada Vigilance Program

The **Canada Vigilance Program** is a national post-market monitoring program that collects and assesses reports of suspected ARs and MDPs involving health products marketed in Canada.

AR Voluntary Reporting for Health Products

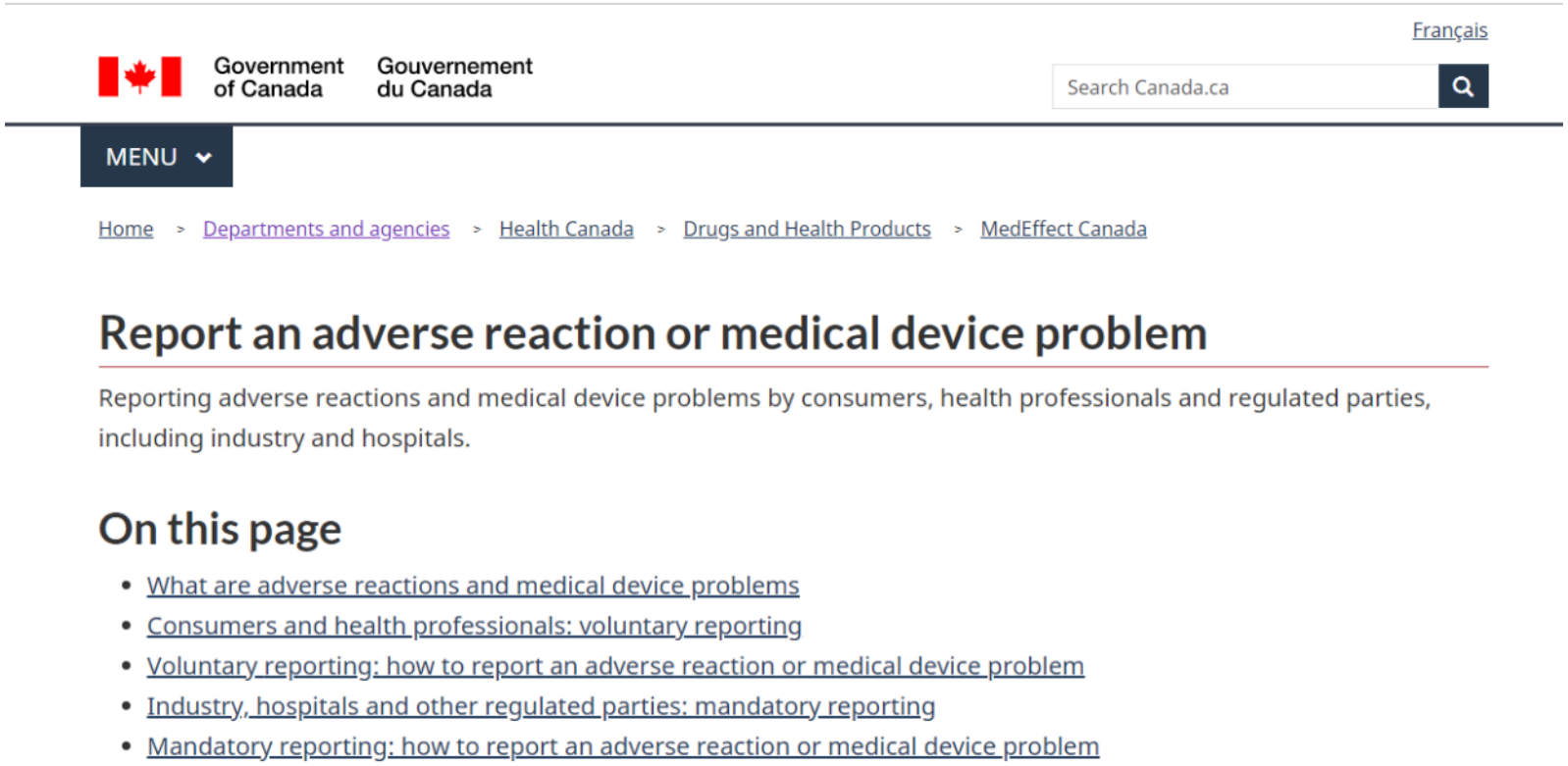
- Online form: https://hpr-rps.hres.ca/static/content/form-formule.php
- Telephone: 1-866-234-2345 (toll-free)
- Fax or Mail: Download, print and complete the Side Effect Reporting Form (please read the instructions before completing the form)
  - Fax: 1-866-678-6789 (toll-free)
  - Mail: Canada Vigilance Office (using the postage paid label)

MDP Voluntary Reporting

- The Canadian Medical Devices Sentinel Network (CMDSNet) is a pro-active surveillance program that encourages the reporting of MDP reports from all types of institutions.
    - Only institutions participating in CMDSNet voluntarily report MDIs occurring within their organizations directly through the Canada Vigilance Program.
- Other voluntary reporting from non-participating CMDSNet institutions, consumers, and health professionals are encouraged to report device-related incidents directly to Health Canada by completing a Health Product Complaint Form via the Regulatory Operations and Enforcement Branch.

Reporting ARs and MDPs to Health Canada

The Report an Adverse Reaction or Medical Device Problem web page provides access to more information and forms.



Key Points to Remember

- **Hospital systems, processes, policies, procedures, and forms** may need to be updated to reflect requirements for mandatory reporting of serious ADRs and MDIs to Health Canada.
- Health care professionals have an **important role** in serious ADR and MDI reporting.
- Health Canada is open to accepting **different formats for reports** of serious ADRs and MDIs, recognizing that hospital systems vary.
- It is important to understand **the differences** between serious ADRs, MDIs, medication incidents, ARs, and MDPs, and how to report them.
- The **Guidance Document** offers information to help hospitals comply with the regulatory requirements for serious ADR and MDI reporting to Health Canada.
- Health Canada values **voluntary reporting** and has programs to support it.

Abbreviations

ADR: Adverse Drug Reaction

AR: Adverse Reaction

CMDSNet: Canadian Medical Devices Sentinel Network

CMIRPS: Canadian Medication Incident Reporting and Prevention System

ITA: Investigational Testing Authorization

MDI: Medical Device Incident

MDP: Medical Device Problem

SAP: Special Access Program

sFTP: Secure File Transfer Protocol

Resources

- Applications for Medical Device Investigational Testing Authorizations Guidance Document - Summary
- Canadian Medical Devices Sentinel Network
- Canadian Medication Incident Reporting and Prevention System
- Canada Vigilance Program
- MedEffect Canada
- Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals - Guidance document
- Health Canada's role in the Management and Prevention of Harmful Medication Incidents
- Health Product Complaint Form
- Medical Devices Regulations
- Medical Devices - Special Access Programme
- Side Effect Reporting Form
- Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) Amendments to the Food and Drugs Act (Bill C-17)
- Regulations Amending the Food and Drug Regulations (Serious Adverse Drug Reaction Reporting — Hospitals): SOR/2019-190
- Regulations Amending the Medical Devices Regulations (Medical Device Incident Reporting — Hospitals): SOR/2019-191
- Report An Adverse Reaction or Medical Device Problem

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

Email: hc.canada.vigilance.sc@canada.ca
Telephone: 1-866-234-2345

Acknowledgments

- All materials were developed by the collaborating parties: Health Canada, Institute for Safe Medication Practices Canada (ISMP Canada), Health Standards Organization (HSO), and the Canadian Patient Safety Institute (CPSI).

- Any stakeholder interested in using the materials should acknowledge Health Canada as the owner and source:
  Educational Support for Mandatory Reporting. Health Canada; 2019.

Health Canada Santé Canada

ismp CANADA

HSO

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients