



Health  
Canada

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# Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals

Guidance document



**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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## Forward

Guidance documents are meant to provide assistance on how to comply with governing statutes and regulations. Guidance documents also provide assistance to Health Canada staff on how our mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, effectiveness or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with relevant sections of other applicable guidance documents.



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# 1 Introduction

Therapeutic products can save lives, reduce suffering and improve the lives of Canadians. However, these products can cause serious adverse drug reactions (ADRs) and medical device incidents (MDIs), and Canadians can be hospitalized as a result of these events. This is a public health concern resulting in significant costs to the health care system as well as individual impacts on Canadians. Health Canada's monitoring of therapeutic product safety plays a vital role in public health and patient safety, providing health care providers and patients with the most up-to-date knowledge for decision making. It also provides Health Canada with information needed to monitor the benefit-risk ratio of products and act to protect Canadians where appropriate.

Like all therapeutic product regulators worldwide, Health Canada recognizes that there are limitations in understanding the benefits and harms of a product even after a product has been authorized for sale. It is generally understood that knowledge about drugs and medical devices over their life-cycle is required to adequately support patient safety. Increasing this knowledge reduces the uncertainty associated with the real-world benefits and harms of a product which may not be evident during the clinical trial or investigational testing phases.

Reports of serious ADRs and MDIs by manufacturers and importers, health care professionals and the public are often the first sign of emerging safety issues. The regulatory amendment for mandatory reporting of serious ADRs and MDIs by hospitals aims to increase the quantity of reporting and improve the quality of these reports, to enable a better understanding of the benefits and harms of therapeutic products being used in Canada. Improving the knowledge base on therapeutic product safety will empower Canadians along with their health care providers to make better, more informed decisions regarding their medical treatment and will support overall patient safety.

## 1.1 Objective

The purpose of this guidance document is 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 as outlined in section C.01.020.1 of the *Food and Drug Regulations* and section 62 of the *Medical Device Regulations*.

## 1.2 Scope and application

This regulatory requirement applies to hospitals that are regulated through provincial or territorial legislation, as well as hospitals operated by the federal government.

The regulations flow from section 21.8 of the *Food and Drugs Act* and apply to serious ADRs and MDIs involving a therapeutic product. A "therapeutic product" is defined in the *Food and Drugs Act* to be a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*. For more information on the types of therapeutic products subject to the mandatory reporting requirements for hospitals, see [section 4](#) of this guidance document.





## 2 The Regulations and their Purpose

### 2.1 Purpose of the amended regulations

Health Canada is continuously looking for ways to strengthen the post-market knowledge base to reduce the uncertainty associated with the real-world benefits and harms of therapeutic products. These regulations put in place new authorities provided through the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) which made several amendments to the *Food and Drugs Act*, including a new requirement in section 21.8 for designated health care institutions to provide Health Canada with information on serious ADRs and MDIs that involve a therapeutic product. The central objective of this authority is to increase the quantity of reporting of serious ADRs and MDIs, improve the quality of these reports, and expand on the real-world data used by Health Canada to monitor the safety and effectiveness of therapeutic products as part of a life-cycle approach to their regulation. The requirement for mandatory ADR/ MDI reporting is effective as of December 16, 2019, with changes to both the *Food and Drug Regulations* and the *Medical Devices Regulations*.

### 2.2 Definition of a serious adverse drug reaction

A serious adverse drug reaction, as defined in Part C, Division 1, subsection C.01.001(1.1) of the *Food and Drug Regulations* and for the purposes of the *Food and Drugs Act*, means 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. This definition implies that the causal relationship between the drug and the occurrence of the adverse reaction is suspected, and for the reaction to be considered serious, a minimum of one or any combination of the aforementioned outcomes should be fulfilled.

Medical and scientific judgement should be exercised in deciding whether reporting is appropriate in situations that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the above definition from the *Food and Drug Regulations*. Examples of such events include intensive treatment in an emergency room for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, or development of drug dependency or drug abuse. These important medical events should also usually be considered serious. Thus, Health Canada encourages hospitals to report the ADRs that led to important medical events.

The regulation requires hospitals to report serious ADRs, regardless of whether the reaction is expected or unexpected.

### 2.3 Definition of a medical device incident

In accordance with section 62(4) of the *Medical Devices Regulations*, a medical device incident refers to 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.

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



## 3 Roles and Responsibilities

### 3.1 The role of hospitals

Under the regulations, all hospitals are required to report serious ADRs and MDIs to Health Canada. The section C.01.020(4) of the *Food and Drug Regulations* and section 61(4) of the *Medical Devices 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.

Hospitals should develop and maintain internal policies and procedures and provide staff training in order to comply with the mandatory reporting requirement. The procedures should provide for a standard process to identify reportable events in a timely fashion and be effective in compiling the information necessary for a complete report. Incorporating how follow-up requests from Health Canada will be addressed should be included in the process.

### 3.2 The role of health care professionals

The mandatory reporting requirement applies to the facility (hospital) rather than individual health care professionals working in the hospital.

While health care professionals play an important role in recognizing and documenting serious ADRs and MDIs, it is the hospital that is responsible for determining clear internal roles and responsibilities for its employees or contract workers/companies in complying with the mandatory reporting obligations.

### 3.3 Outpatient clinics

Outpatient clinics are subject to the regulations if they are legally part of the hospital, even if they are physically separate from the hospital. On the other hand, clinics that may be physically located within a hospital, but that are not legally part of the hospital, will not be subject to the regulations.

### 3.4 Other types of health care institutions

If a health care institution does not fall within the definition of a hospital in the regulations, it is not required to report serious ADRs and MDIs to Health Canada. In other words, only facilities that are licensed, approved or designated as a hospital according to the laws of a province or territory, or that are operated by the Government of Canada to provide health services to in-patients, are subject to these regulations. The rationale for limiting the scope of health care institutions to hospitals is that this is where the treatment of serious ADRs and MDIs is most likely to occur. Health care institutions that are outside the scope of the definition of hospitals, such as private clinics or long-term care facilities (e.g. nursing homes), continue to be encouraged to report to Health Canada on a voluntary basis either directly or via the manufacturer or importer (who must report all serious ADRs and MDIs to Health Canada). For more information on voluntary reporting, please refer to [Adverse Reaction and Medical Device Problem Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>)

### 3.5 Other situations

The hospital is required to report any serious ADR or MDI that it documents, regardless of whether the serious ADR or MDI originated within or outside of a hospital setting, or if the patient is admitted to hospital.

<b>Hospital's requirement to report in other situations</b>	
<b>Situation</b>	<b>Is the hospital required to report the serious ADR/MDI?</b>
<b>What if a serious adverse drug reaction or medical device incident occurred in another health care institution that was not a hospital (e.g., long-term care) and led to the patient's hospitalization?</b>	A facility (e.g., long-term care) which does not meet the definition of a hospital in the regulations would not be required to report to Health Canada. However if the serious ADR or MDI occurred at the long-term care facility, and it was documented at the admitting hospital, that hospital would be required to report the event to Health Canada.
<b>What if a serious adverse drug reaction or medical device incident occurred in the community and led to the patient's hospitalization?</b>	If the serious ADR or MDI occurred in the community (such as at home or in an ambulance), led to the patient's hospitalization for treatment and the reportable event was documented within the hospital, the hospital would be required to report the serious ADR or MDI to Health Canada.
<b>What if a serious adverse drug reaction or medical device incident occurred in the community and the patient was treated in the hospital's emergency room but not admitted as an in-patient?</b>	Even if the patient was not admitted as an in-patient after being treated in the emergency room, as long as the serious ADR or MDI was documented at the hospital, the hospital is responsible for reporting the event to Health Canada.  It should also be noted that, regardless of the specific service area in the hospital where the serious ADR or MDI report was documented, the hospital is responsible for sending all documented serious ADR or MDI reports to Health Canada.
<b>What if the patient had a serious adverse drug reaction or medical device incident at one hospital but is transferred to another hospital?</b>	If a serious ADR or MDI was documented at both hospitals, both hospitals are required to report to Health Canada. If the serious ADR or MDI was only documented at one hospital, then that hospital is required to report to Health Canada. Hospitals are encouraged to identify duplicate reporting when possible to ensure the ADR or MDI is counted as a singular case.

## 4 Applicability of the Regulations According to Product Type

### 4.1 Applicable therapeutic products

The mandatory reporting requirements for hospitals apply to the following products regulated under the *Food and Drug Regulations* and the *Medical Device Regulations*:

- Pharmaceuticals (which includes prescription and non-prescription pharmaceutical drugs);
- Biologic drugs (which includes biotechnology products, fractionated blood products, plasma proteins, as well as vaccines, excluding those administered under a routine immunization program of a province or territory);
- Radiopharmaceutical drugs;
- Disinfectants;
- Drugs for an urgent public health need;
- Medical devices.

While pharmaceutical products that contain ingredients derived from cannabis are subject to these mandatory reporting requirements, cannabis itself is not, regardless if it was used medically or recreationally.

A disinfectant is defined as a substance, or mixture of substances, capable of destroying or irreversibly inactivating pathogenic (disease-causing) and potentially pathogenic (opportunistic) microorganisms, but not necessarily bacterial spores, present on environmental surfaces and inanimate objects due to the antimicrobial action of the active ingredient(s). Disinfectants refer to hard surface disinfectants and not topical antiseptic agents. To determine if a disinfectant is subject to these mandatory reporting requirements, the presence of a DIN should be confirmed.

#### 4.1.1 Drugs for an urgent public health need, regulated under Part C, Division 10 of the *Food and Drug Regulations*

Drugs for an Urgent Public Health Need, regulated under Part C, Division 10 of the *Food and Drug Regulations* are included in section C.01.020(2) of the mandatory reporting requirement under Vanessa's Law. Previously, these drugs (i.e. those set out in the [List of Drugs for an Urgent Public Health Need](https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html>)), had serious ADR reporting requirements that were similar, but not identical to, the requirements outlined in these regulations. To enhance clarity and alignment across the *Food and Drug Regulations*, Health Canada repealed the previous ADR reporting requirements under Part C, Division 10 of the *Food and Drug Regulations* and included drugs regulated under Part C, Division 10 of the *Food and Drug Regulations* in the mandatory reporting regulations of serious ADRs and MDIs for hospitals.

### 4.2 Applicable types of medical devices

The term “medical device”, as defined in Section 1 of the *Food and Drugs Act* and *Medical Devices Regulations* covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Some examples of medical devices include pacemakers, artificial heart valves, hip implants, medical laboratory diagnostic instruments, test kits for diagnosis, bandages, tubing, and contraceptive devices.

Medical devices are classified into Classes I to IV, by means of the classification rules set out in Schedule 1 of the *Medical Devices Regulations*, where Class I represents the lowest risk and Class IV represents the highest risk. Examples of medical devices, by class can include: Class I- hospital beds, Class II- infusion sets, Class III- infusion pumps, Class IV-certain pacemakers/defibrillators. All classes of medical devices are included in mandatory reporting by hospitals.

## 4.3 Non-applicable therapeutic products

### 4.3.1 Drugs and medical devices subject to the Clinical Trial (drugs)/Investigational Testing (medical devices) and Special Access Programme regulatory frameworks

The Clinical Trial or Investigational Testing (IT) and Special Access Programme (SAP) sections C.05.014/C.08.010 of the *Food and Drug Regulations* and 79(3)/69(2) of the *Medical Device Regulations* already have reporting schemes in place, and require investigators and health care providers to report serious adverse events. As such, these categories of drugs and medical devices are excluded from the reporting requirements under Vanessa's Law. Refer to [Appendix 3](#) for links to relevant regulations.

### 4.3.2 Vaccines administered under a routine immunization program of a province/territory

Mandatory reporting requirements under Vanessa's Law do not apply to vaccines that are administered under routine childhood, adolescent or adult immunization programs of a province or territory. Hospitals and health care professionals should submit these reports to their local public health unit.

As part of provincial and territorial immunization programs, adverse events following immunization (AEFI) are monitored by local health units in part so that the Medical Officer of Health can monitor their local programs and provide advice to local health care providers and the community. These reports are also forwarded to provincial and territorial health authorities for jurisdictional review, and then on to the Public Health Agency of Canada for national collation and analysis. The Public Health Agency of Canada then uses the data in these reports and collaborates with Health Canada as part of federal post-market surveillance activities related to vaccines marketed in Canada.

In addition to a longstanding established AEFI network to monitor vaccine safety, AEFI reporting is already mandatory for health care professionals in most provincial and territorial jurisdictions. For these reasons the regulations state that vaccines administered under a routine provincial and territorial immunization program are to be exempted from the scope of the reporting requirements. Therefore, if a hospital submits an AEFI report to their local health unit, they do not have to submit a report to Health Canada as well. The regulations would still apply to vaccines that are administered outside of the context of routine immunization programs and that are not reported through an AEFI network; an example of this could be travel-related vaccines.

Requiring the mandatory reporting by hospitals for ADRs related to vaccines that are part of provincial and territorial immunization programs, would result in the duplication of reporting for this class of therapeutic products.

### 4.3.3 Adverse reactions to cells, tissues and organs, blood and blood components, and semen/ova

Reporting suspected reactions associated with cells, tissues and organs, blood and blood components and assisted human reproduction therapies (semen/ova) are not within scope of this guidance. Reporting for these products is required for certain types of health facilities through other federal regulations (see [Appendix 3](#)).

## 4.4 Determination of applicability of drug/medical device combination products

Hospitals should determine whether the therapeutic product was licensed as a drug or a medical device by Health Canada. If the combination product has a Drug Identification Number (DIN) (e.g., allergy pens), the serious ADR should be reported under the mandatory reporting requirements if there has been an adverse reaction to the drug component, but if there was an issue with the non-drug component, this could be submitted as a voluntary report. On the other hand, if the product was licensed as a medical device and issued a licence number (e.g., stents) and there was an adverse reaction to the drug component, it would be reported as a medical device problem through a voluntary report. Searchable databases for the licensing of therapeutic products are available on the Health Canada website for medical devices (classes II-IV) ([MDALL](https://health-products.canada.ca/mdall-limh/index-eng.jsp)(<https://health-products.canada.ca/mdall-limh/index-eng.jsp>)) and drugs ([DPD](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)(<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>)).

# 5 Serious Adverse Drug Reactions and Medical Device Incidents to be Reported by Hospitals

## 5.1 Serious adverse drug reactions associated with off-label use

All serious ADRs that are documented within the hospital must be reported to Health Canada, even if they occur as a result of off-label use. Off-label use refers to any intentional use of a drug as prescribed by a qualified health care professional, but that is not covered by the terms of its marketing authorization. Examples of off-label uses include the following: use for a different indication, use of a different dosage, dosing frequency or duration of use, use of a different method of administration, or use by a different patient group (e.g., children instead of adults) than what is indicated in the product monograph.

## 5.2 Examples of serious adverse drug reactions

In order to determine whether the ADR meets the threshold of “serious”, the following questions should be considered:

- Has the ADR resulted in:
  - ✓ In-patient hospitalization or prolongation of existing hospitalization?
  - ✓ Congenital malformation?
  - ✓ Persistent or significant disability or incapacity?
- Is the ADR life-threatening or has it resulted in death? The term “life-threatening” in the definition of “serious” refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction which hypothetically might have caused death if it were more severe.
- Does the ADR require medical intervention in order to prevent any of the outcomes listed above?
- The examples below are intended to be instructive in determining whether an ADR meets the criteria of “serious”. When in doubt as to whether or not an adverse drug reaction is serious, Health Canada encourages hospitals to report.

### 5.2.1 Example 1

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.

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> (a) Death  | <input type="checkbox"/> (b) Life-threatening         | <input type="checkbox"/> (c) Caused disability       |
| <input type="checkbox"/> (d) Admitted to hospital                                     | <input type="checkbox"/> (e) Lengthened hospital stay | <input type="checkbox"/> (f) Congenital malformation |
| <input type="checkbox"/> (g) Required medical intervention to avoid any of (a) to (f) |   |  |

Comments: Although this is an ADR, it does not meet the criteria of “serious”.

### 5.2.2 Example 2

A patient had been taking warfarin, among other medications, and presented to the emergency with a life-threatening GI bleed and was required to be hospitalized, in order for the patient to be stabilized.

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> (a) Death  | <input checked="" type="checkbox"/> (b) Life-threatening | <input type="checkbox"/> (c) Caused disability       |
| <input checked="" type="checkbox"/> (d) Admitted to hospital                          | <input type="checkbox"/> (e) Lengthened hospital stay    | <input type="checkbox"/> (f) Congenital malformation |
| <input type="checkbox"/> (g) Required medical intervention to avoid any of (a) to (f) |  |  |

Comments: This ADR meets the criteria of “serious” because it is a life-threatening event that has resulted in the hospitalization of the patient.

### 5.2.3 Example 3

A patient who has recently started chemotherapy but is being managed as an out-patient notes to her physician that one of the ADRs she has noticed is alopecia (hair loss).

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> (a) Death  | <input type="checkbox"/> (b) Life-threatening         | <input type="checkbox"/> (c) Caused disability       |
| <input type="checkbox"/> (d) Admitted to hospital                                     | <input type="checkbox"/> (e) Lengthened hospital stay | <input type="checkbox"/> (f) Congenital malformation |
| <input type="checkbox"/> (g) Required medical intervention to avoid any of (a) to (f) |   |  |

Comments: This adverse drug reaction, although considered serious from the patient’s perspective, does not meet the criteria of “serious” in relation to a reportable ADR.

### 5.2.4 Example 4

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.

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> (a) Death  | <input checked="" type="checkbox"/> (b) Life-threatening | <input checked="" type="checkbox"/> (c) Caused disability |
| <input checked="" type="checkbox"/> (d) Admitted to hospital                          | <input type="checkbox"/> (e) Lengthened hospital stay    | <input type="checkbox"/> (f) Congenital malformation      |
| <input type="checkbox"/> (g) Required medical intervention to avoid any of (a) to (f) |  |   |

Comments: This ADR meets the criteria of “serious” because it is a life-threatening event that has resulted in the patient being hospitalized.

It 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.



## 5.2.5 Example 5

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.

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> (a) Death  | <input type="checkbox"/> (b) Life-threatening         | <input type="checkbox"/> (c) Caused disability       |
| <input type="checkbox"/> (d) Admitted to hospital                                     | <input type="checkbox"/> (e) Lengthened hospital stay | <input type="checkbox"/> (f) Congenital malformation |
| <input type="checkbox"/> (g) Required medical intervention to avoid any of (a) to (f) |   |  |

Comments: This ADR would not meet the criteria of “serious”. While the patient may be at increased risk for potentially fatal infections, the ADR is not immediately life-threatening. However, if the patient develops febrile neutropenia and requires in-patient hospitalization and treatment with antimicrobials to prevent infectious complications, then the ADR would meet the criteria of serious.

## 5.3 Serious adverse drug reaction associated with multiple patients

A serious ADR report submitted to Health Canada should refer to one patient only. If a number of patients have experienced the same serious ADR, separate reports should be submitted for each patient. The same situation would apply for mother and child/foetus reports; separate reports should be submitted for the mother and the child/foetus if both experienced a serious ADR.

## 5.4 Reporting criteria for medical device incidents

### 5.4.1 An incident has occurred

A health care professional working in a hospital suspects that a medical device incident has occurred and documents the details of the incident. The date that is first documented in the hospital is considered Day 0 for the 30 calendar day timeline to report to Health Canada.

### 5.4.2 Considerations in assessing reportability

In assessing the suspected link between the device and the incident, the hospital should take into account:

- the opinion, based on available information, from a health care professional (as appropriate);
- information concerning previous, similar incidents;
- complaint trends; and
- any other information that is in the control of the hospital (see [section 6.2](#)).

This judgement may be difficult when there are multiple devices involved. If, after becoming aware of a potentially reportable incident, there is uncertainty about whether it is reportable, the hospital should submit a report within the timeframe required. The hospital is not required to perform an investigation to determine the root cause.

## 5.5 The incident led to one of the following outcomes

### 5.5.1 Death of a patient, user or other person

When the first two criteria to determine whether an incident is reportable (see [section 5.4](#)) are met, **and** when death is the result of an incident, a report to Health Canada must be submitted within 30 calendar days.

### 5.5.2 Serious deterioration in health of a patient, user or other person

When the first two criteria to determine whether an incident is reportable (see [section 5.4](#)) are met, **and** when serious deterioration in health is the result of an incident, a report to Health Canada must be submitted within 30 calendar days.

Under the regulations, a serious deterioration in health means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage.

The interpretation of the term “serious” should be made in consultation with a medical professional, when appropriate. The term “permanent” means irreversible impairment or damage to a body structure or function, and necessarily excludes minor impairment or damage.

Medical intervention is not in itself a serious deterioration in health. The reason that motivated the medical intervention should be used to assess the reportability of an incident.

### 5.5.3 Potential for death or serious deterioration in health of a patient, user or other person

Not all incidents lead to a death or to a serious deterioration in health, either owing to circumstances or to the timely intervention of health care personnel, for example. These situations are known as “near incidents” or “near misses”. As the words “could do so were it to recur” are found within the definition of medical device incident, “near incidents” with the potential to cause serious harm if they were to recur are included in the definition of MDIs.

This requirement also applies if the examination of the device, or a deficiency noted in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an incident involving death or a serious deterioration in health.

An example of a near incident/near miss is the following:

- A monitor suspension system, that was installed, maintained and used according to the manufacturer’s instructions, fell from the ceiling when the bolts holding the swivel joint broke off. No one was injured in the surgical theatre at that time. However, if there had been a surgical team and a patient with an open surgical site on the table below there could have been serious harm to one or more people.

## 5.6 Medical device incident associated with off-label/abnormal use

All MDIs must be reported to Health Canada, even if they occur as a result of an off-label/abnormal use. In the case of devices, sometimes the term *abnormal use* is used but this is synonymous with *off-label use*. Off-label use refers to any intentional use of a product that is not covered by the terms of its licensing. Examples of off-label uses include the following: use for a different indication, use in different environments or under different conditions, duration of use, use with different devices, or use by a different patient group (e.g., children instead of adults) than what is indicated in the licensing conditions.

## 5.7 Examples of medical device incidents

- 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.
- An infusion pump stopped, due to a malfunction, but failed to give an alarm. The patient received an under-infusion of antibiotics, causing septic shock and a required stay in the hospital’s intensive care unit to correct.
- The loss of sensing after a pacemaker has reached “end of life”. The elective replacement indicator did not show up in due time, although it should have according to device specifications. This has a potential for serious harm.
- During patient examination, the C-arm on an X-ray vascular system had uncontrolled motion. The patient was hit by the image intensifier and was permanently and severely injured. The system was installed, maintained, and used according to manufacturer’s instructions.

- Sterile, single-use implantable device packaging was labelled with the caution, “*Do not use if package is opened or damaged*”. By incorrect design, the label is placed on the inner packaging. The device was subsequently stored only in the inner packaging, which did not offer a sufficient sterile barrier. The outer package was removed, but the device was not used during the procedure. There is a potential for serious harm because of potential sepsis.
- The premature revision of an orthopaedic implant due to loosening. No cause yet determined. The patient has the potential of having serious permanent harm caused by this loosening.
- Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation. The manufacturer does not change the label of the ablation device, and fails to warn users of this side effect which may be produced when the device is working within specification.
- A health care professional reported that during the implant of a heart valve, the sewing cuff was discovered to be defective. The valve was abandoned, a new valve was implanted and pumping time during surgery was extended. This had the potential to cause serious harm.
- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to a malfunction. The patient was not revived.
  - **Note:** If the patient was revived, this would be considered a near incident and would also be reportable.
- A user reported that there were insufficient details in the instructions for use regarding cleaning methods for reusable surgical instruments used in brain surgery, despite the risk of variant Creutzfeldt-Jakob Disease (vCJD) transmission.

## 5.8 Non-applicable medical device incidents

### 5.8.1 Deficiency of a device found by the user prior to patient use

Deficiencies of devices that would always be detected by the user, and where death or serious deterioration in health has not occurred, do not need to be reported, because they do not meet requirements of the definition of medical device incident. In these situations, "always" means that even if the incidents were to recur, the user would, again, always detect the defect or malfunction prior to use.

Example:

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

### 5.8.2 Incident caused by a patient's condition

When the hospital has information that the cause of the incident is definitely due to a patient's condition, the incident does not need to be reported, because it does not meet the requirements of the definition of medical device incident. These conditions could be pre-existing or occurring during device use.

To justify not submitting a report in this case, the hospital should have documented information available to conclude that the device performed as intended and did not cause, or contribute to, death or a serious deterioration in health.

Example:

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

### 5.8.3 Malfunction protection operated correctly

Incidents which did not lead to a death or to a serious deterioration in health because a design feature protected against a malfunction becoming a hazard, do not need to be reported, because they do not meet the requirements of the definition of medical device incident.

Example:

- After a malfunction of an infusion pump that was not related to a manufacturing defect, the pump gives an appropriate alarm and stops. There was no harm to the patient.

## 5.9 Causality assessment between the therapeutic product and serious adverse drug reaction or medical device incident

Hospitals are not required to establish causality between the therapeutic product and a reaction or incident. The information to be submitted by the hospital to Health Canada only needs to represent the suspicions of a health care professional that a serious ADR or MDI has been observed. It is acknowledged that when the serious ADRs and MDIs are documented, there will be some professional judgement exercised in making this assessment. However, there is no need to perform a causality assessment or investigation to determine whether the therapeutic product caused the serious ADR or MDI in order to send the report to Health Canada, although it is encouraged that this information be provided, if available.

In the case of MDIs, the hospital should inform the manufacturer and importer of the incident as soon as possible because they are required to determine root cause and corrective actions, not the hospital or health care professionals.

These approaches for establishing associations are aligned with international best practices for ADR and MDI reporting.

## 5.10 Adverse drug reaction or medical device incident associated with multiple suspect products or devices

If the serious ADR or MDI may be related to a single suspected drug or device, Health Canada would expect the serious ADR or MDI report to be provided for the suspected drug or device with the concomitant therapeutic products identified.

If the serious ADR or MDI may be related to several suspected drugs and/or devices and it could not be determined which of the suspected drugs or devices might have caused the serious ADR or MDI, Health Canada would expect that the ADR or MDI report would be provided with all of the suspected drugs, devices and concomitant therapeutic products identified.

If all of the suspected drugs and/ or devices are subject to these regulations (see sections 4.1 and 4.2 for applicable products), the report would be mandatory.

If none of the suspected drugs and/ or devices are subject to these regulations (see section 4.3 for non-applicable products), the report would not be mandatory.

If some of the suspected drugs and/ or devices are subject to these regulations while others are not, the report would be mandatory.

If there was a serious adverse drug reaction and medical device incident that occurred at the same time in the same patient, a separate ADR and MDI report would each have to be filed

## 5.11 Examples of serious adverse drug reaction and medical device incident documentation in a hospital setting

Hospitals are only required to report serious ADRs and MDIs that are documented within the hospital. Examples of serious ADR and MDI documentation could include:

- A serious ADR or MDI that is identified in a patient's clinical/medical record.
- A serious ADR or MDI that is identified in a separate report form (electronic or hard copy) that has been completed by a health care professional. Some examples of these separate report forms include: ADR form as per internal hospital policy, product complaint form (MDIs), pathology report, report in the incident or patient safety learning database, and a computerized prescription recording system.



## 6 Information Requirements for Serious Adverse Drug Reaction and Medical Device Incident Reports

### 6.1 Information required for serious adverse drug reaction and medical device incident reports

Hospitals can submit reports in either official language.

Based on the regulations, hospitals are required to report certain key pieces of information about serious ADRs and MDIs if the information is in the control of the hospital (see [section 6.2](#)). The information requirements for serious ADRs and MDIs are different from one another due to the differences in the required information for the monitoring of these types of products.

All of the items listed below represent the data elements that are required to be included in reports if the hospital has this information within its control. Additionally, the items marked with a double asterisk (\*\*) represent the data elements that are essential in order for the report to be useful for Health Canada. If a hospital does not have in its control all of the information for the data elements with a double asterisk, it is exempt from having to submit a report.

For serious ADRs, the following information is required:

- (a) the name of the hospital and the contact information of a representative of that hospital;
- (b) \*\*the drug's brand name, proper name or common name;
- (c) \*\*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;
- (d) the drug identification number (DIN) assigned for the drug, if applicable;
- (e) \*\*the patient's age and sex;
- (f) \*\*a description of the serious adverse drug reaction;
- (g) the date on which the serious adverse drug reaction was first documented;
- (h) the date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug;
- (i) 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;
- (j) any medical condition of the patient that directly relates to the serious adverse drug reaction;
- (k) any concomitant therapeutic products used by the patient; and
- (l) the effect of the serious adverse drug reaction on the patient's health.

For MDIs, the following information is required:

- (a) the name of the hospital and the contact information of a representative of that hospital;
- (b) \*\*the name or identifier of the medical device;
- (c) the date on which the medical device incident was first documented;
- (d) the name of the manufacturer of the medical device;
- (e) \*\*a description of the medical device incident;
- (f) the lot number of the device or its serial number;
- (g) any contributing factors to the medical device incident including any medical condition of the patient that directly relates to the medical device incident; and
- (h) the effect of the medical device incident on the patient's health.

### 6.2 Information 'in the control' of the hospital

Information that is 'in the control' of the hospital is information that would be reasonably accessible within the hospital. While it is encouraged for those who document the serious ADR or MDI to take all reasonable steps to retrieve the information listed above to complete as thorough a report as possible, there is no requirement to do

further investigation in order to obtain the pieces of information. Thus, if the information listed above is not reasonably accessible within the hospital, it is encouraged, but not required, to take steps to obtain the missing information by contacting sources outside of the hospital (e.g., a family physician's office, pharmacy, or another health care institution).

## 6.3 Information required to be submitted in the adverse drug reaction report

Section C.01.020.1(2) of the *Food and Drug Regulations* sets out the information requirements for an ADR report, if in control (known) by the hospital. The required information is listed below by section number, with a brief explanation where necessary.

**Hospital name and contact information:** the hospital must submit the name of the hospital and the contact information of a representative of that hospital. When submitting the name of the hospital, including its address and/or Health Canada (HC) Institutional Identifier (ID) would also be helpful to Health Canada to correctly identify the hospital. If the HC ID is provided, the address section does not need to be filled out. The first and last name of a representative of the hospital who can be contacted, along with their phone number and/or email, is also necessary to be included in the event that Health Canada needs to conduct a follow-up for additional information (C.01.020.1(2)(a)).

**Drug's brand name, proper name or common name:** the hospital must submit the drug's brand name, proper name or common name. The reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect drug product. If the drug identification number (DIN) is unknown, biologic drugs including biosimilars can be uniquely identified by providing their brand name. Pharmaceuticals can be uniquely identified by providing their brand name and their generics can be uniquely identified by providing both the generic name and the manufacturer name due to some generics brand names only using the common name as their brand name. Hospitals are encouraged to also include the lot number, if known, to help identify possible quality-related safety issues (C.01.020.1(2)(b)).

**Identifying number or code of the drug:** the hospital must submit, in the case of a drug imported under subsection C.10.001(2) related to Drugs Accessed for an Urgent Public Health Need (UPHN), the identifying code or number of the drug, if any, assigned in the country in which the drug was authorized for sale (C.01.020.1(2)(c)).

**Drug identification number:** the hospital must submit the drug identification number (DIN) assigned for the drug, if applicable. The 8-digit DIN is a unique identifier for all drug products sold in Canada. It serves to uniquely identify the product characteristics, such as its manufacturer, its product name, its active ingredient(s), the strength(s) of active ingredient(s) and its pharmaceutical form (C.01.020.1(2)(d)).

**Patient's age and sex:** the hospital must submit the patient's age and sex. Sex refers to the biological anatomy of the patient, and not necessarily the gender identity (C.01.020.1(2)(e)).

**Description of the serious adverse drug reaction:** the hospital must submit a description of the serious adverse drug reaction (C.01.020.1(2)(f)).

**Date on which the serious adverse drug reaction was first documented:** the hospital must submit the date on which the serious adverse drug reaction was first documented. This date would be considered day zero in the reporting time frames to submit a report to Health Canada within 30 calendar days (C.01.020.1(2)(g)).

**Date on which the patient first used/stopped the drug:** the hospital must submit the date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug (C.01.020.1(2)(h)).

**Date on which the serious adverse drug reaction first occurred/state restored:** the hospital must submit 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 (C.01.020.1(2)(i)).

**Patient's medical condition:** the hospital must submit any medical condition of the patient that directly relates to the serious adverse drug reaction. With the patient's medical history (e.g., hepatic and/or renal impairment, diabetes mellitus, current pregnancy, etc...), the Canada Vigilance Program also requests patient information regarding



lifestyle factors, such as tobacco, cannabis or alcohol use, recreational drug use, etc... These factors can help identify potential pharmacokinetic impacts (C.01.020.1(2)(j)).

**Patient's concomitant therapeutic products:** the hospital must submit any concomitant therapeutic products used by the patient. In other words, any known therapeutic products taken or used proximal to the reaction (e.g., prescription and non-prescription drugs, medical devices, natural health products, etc..., including details of use if available) (C.01.020.1(2)(k)).

**Effect of the serious adverse drug reaction on the patient's health:** the hospital must submit the effect of the serious adverse drug reaction on the patient's health. The relevant recovery status of the patient pertaining to the specific adverse drug reaction may be unknown, fatal, fully recovered, currently recovering, recovered with sequelae or not recovered. If the only information available on an ADR report is that the patient was discharged from the hospital, without any indication on patient's status, the outcome should be considered unspecified and reported as unknown (C.01.020.1(2)(l)).

## 6.4 Information required to be submitted in the medical device incident report

Section 62(2) of the *Medical Devices Regulations* sets out the information requirements for an MDI report, if in control (known) by the hospital. The required information is listed below by section number, with a brief explanation where necessary.

**Hospital name and contact information:** the hospital must submit the name of the hospital and the contact information of a representative of that hospital. When submitting the name of the hospital, including its address and/or Health Canada (HC) Institutional Identifier (ID) would also be helpful to Health Canada to correctly identify the hospital. The first and last name of a representative of the hospital who can be contacted, along with their phone number and/or email, is also necessary to be included in the event that Health Canada needs to conduct a follow-up for additional information (62(2)(a)).

**Medical device name or identifier:** the hospital must submit the name or identifier of the medical device. This is an essential piece of data for a report. Reporting of this information is important for traceability of an incident to a specific suspect medical device. The name of the device includes any information necessary for the user to identify the device and to distinguish it from similar devices. An example of this would be the full trade name that is found on the label of a medical device. In lieu of the name of the device, an identifier can be provided. An identifier is a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. An example of this would be a device catalogue number; this information would be available on the device labelling or packaging (62(2)(b)).

**Date on which the medical device incident was first documented:** the hospital must submit the date on which the medical device incident was first documented. This date would be considered day zero in the reporting time frames to submit a report to Health Canada within 30 calendar days (62(2)(c)).

**Medical device manufacturer's name:** the hospital must submit the name of the manufacturer of the medical device involved in the incident (62(2)(d)).

**Description of the medical device incident:** the hospital must submit a description of the medical device incident. This is an essential piece of data for a report (62(2)(e)).

This section should include any details that might be relevant to understanding the incident such as the following:

- What happened (where, when, how, to whom)? Please do not include any identifying information about the patient or staff involved;
- Information about the affected person(s) and other concomitant therapy involved during the incident;
- Incident details such as date of incident and location;
- Whether this was a reoccurring issue in your organization;
- Details about the use of the device such as implant details, duration of use, how many units were involved, reprocessed single use, expiry dates;

- Any environmental contributing factors such as other device/use concerns such as maintenance issues, physical setting, storage issues, instructions or training issues, and
- Any actions taken as a result of the incident.

**Medical device lot or serial number:** the hospital must submit the lot number of the device or its serial number; this information would be available on the device labelling or packaging (62(2)(f)).

**Medical device incident contributing factors:** the hospital must submit any contributing factors to the medical device incident, including any medical condition of the patient that directly relates to the medical device incident. These can include but are not limited to: medical directives or clinical guidelines on the use of the device, patient therapies such as oxygen, chemo, radiation, dialysis, immunotherapy, pain/sedation/psychiatric/cardiac medication, or patient conditions such as allergies, alcohol-drug use, COPD, diabetes, heart disease, obesity, pregnancy, premature infant, smoking, recent accident, stroke, surgery (62(2)(g)).

**Effect of the medical device incident on the patient's health:** the hospital must submit the effect of the medical device incident on the patient's health. The details of the impact to the affected person should contain details of any serious harmful (or potential for serious harm) health effect(s) from the incident, the severity of the effect(s) and any treatment required (62(2)(h)).

## 6.5 Additional information encouraged to be submitted to Health Canada to enhance the value of an adverse reaction report/medical device incident report

If the hospital has more information than those listed in section 6.1 above as required information for a serious ADR or MDI, Health Canada encourages the hospital to include this information in the serious ADR or MDI report sent to Health Canada.

The mandatory ADR or MDI reporting form templates contain key data elements that enhance the quality of an ADR or MDI report. The hospital is encouraged to provide information on as many listed items as are relevant to the case.

Having the maximum information assists Health Canada in conducting assessment, causality reviews, and signal detection activities, in addition to decreasing the processing time of ADR and MDI reports.

## 7 When and How to Submit Serious Adverse Drug Reaction and Medical Device Incident Reports

### 7.1 Timeline for reporting serious adverse drug reactions and medical device incidents to Health Canada

Serious ADRs and MDIs are required to be reported, in writing, to Health Canada within 30 calendar days from the date of first documentation within the hospital. The date that is first documented in the hospital is considered Day 0. If the report is completed earlier than the 30 days, Health Canada encourages hospitals to report sooner. Serious ADRs and MDIs that were first documented prior to the coming into force date of these regulations (December 16, 2019) are not required to be reported.

If the hospital becomes aware of additional information about a serious ADR or MDI they have previously submitted to Health Canada, they can submit a follow-up report whenever the information becomes available

In order to accurately identify a follow-up report, the hospital should clearly indicate whether this is the first report submitted or a follow-up to a previously submitted report by checking off the appropriate selection on the mandatory ADR or MDI reporting form for hospitals (i.e. initial vs. follow-up). Health Canada also encourages hospitals to reference any number (e.g. internal submitter/organization file number) specific to the initial report, which will help reconcile the information correctly when follow-up information is submitted. The date on which the hospital first documented the adverse drug reaction or medical device incident should also be provided if available. Submitting information that is as complete as possible will minimize the need for Health Canada to conduct a follow-up for additional information.

### 7.2 Follow-up on reports submitted Health Canada

Hospitals should be aware that they may be contacted for additional information in regards to the serious ADR and MDI reports submitted to Health Canada. Thus, hospitals should consider implementing a tracking system for the reports that are submitted to Health Canada. Please consider providing Health Canada with your internal submitter/organization file number so we have an additional report identification mechanism if we have follow-up questions about the case.

As part of quality assurance, surveillance and signal detection activities, Health Canada may need to follow-up with the identified hospital representative, in order to clarify or obtain more information on the case reported. Reasons for a follow-up by Health Canada may include, but not limited to the following considerations:

- Missing key data element(s) as outlined in section 6.1;
- Contradicting information provided;
- Legibility issues requiring clarification;
- Compliance promotion initiatives.

Once a follow-up is identified as necessary, Health Canada will contact the hospital contact provided on the report, via telephone or email, and document any additional information related to the case that is obtained.

### 7.3 Submission methods and formats

To provide the greatest flexibility for hospitals and to allow them to use their existing systems and processes, Health Canada will be able to receive reports via various submission methods and formats and hospitals will be able to select the most efficient ones for their circumstances. Hospitals are encouraged to seek opportunities to leverage their existing databases (e.g. incident databases, electronic health records) to create efficiencies to facilitate reporting.

Health Canada also has [online tools](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for reporting such as the online reporting applications. The ADR and MDI

reporting forms can be found online and can be faxed or can be mailed to Health Canada to satisfy the reporting obligation.

Hospitals may submit serious ADR and MDI reports to the Canada Vigilance National Office using one of the following reporting methods:

- **Electronic reporting**

If you are interested in submitting reports electronically (e.g. secure File Transfer Protocol - sFTP, system-to-system exchanges) to Health Canada, please email the Canada Vigilance Program at [hc.canada.vigilance.sc@canada.ca](mailto:hc.canada.vigilance.sc@canada.ca).

- **Online**

Complete and submit a report using the online reporting applications available at: [canada.ca/medeffect](http://canada.ca/medeffect).

- **Fax or Mail**

Download, print and complete the applicable form: [Serious Adverse Drug Reaction Reporting Form for Hospitals](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf) (<https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf>) or [Medical Device Problem Report Form for Health Care Professionals](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf) (<https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf>)

- Send by fax at: 1-866-678-6789
- Mail it to the Canada Vigilance National Office:

Canada Vigilance Program  
Health Products Surveillance and Epidemiology Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Address Locator 1908C  
Ottawa, Ontario  
K1A 0K9

If you have any questions related to mandatory reporting for hospitals, you may contact the Canada Vigilance Program by:

- Email: [hc.canada.vigilance.sc@canada.ca](mailto:hc.canada.vigilance.sc@canada.ca)
- Toll-free telephone: 1-866-234-2345

## 7.4 Reporting forms

ADR and MDI reporting forms have been created for hospitals. They identify the minimum criteria to report, what is required information if in the control of the hospital and other additional information that Health Canada deems important to collect in order to fully understand the serious ADR or MDI. Please refer to the [Serious Adverse Drug Reaction Reporting Form for Hospitals](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf) (<https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf>) and to the [Medical Device Problem Report Form for Health Care Professionals](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf) (<https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf>).

## 7.5 Submitting reports to Health Canada using a third party such as a regional health authority

The hospital, as per the definition in the mandatory reporting regulations, is the party responsible for reporting serious ADRs and MDIs documented within the hospital to Health Canada. However, a hospital may use a third party such as a regional health authority, other reporting programs or another agent to send reports to Health Canada, on the hospital's behalf. In order to do this, an agreement between the hospital and the third party would need to be set up in order to: (1) authorize the collection of information by the third party on behalf of the hospitals; and (2) to provide that the reports submitted would meet the legal requirements of the regulations such as the timeliness and the required content. This agreement would need to be signed by both the hospital and the third party, and be provided to Health Canada. Please see [Appendix 2](#) for an example of such an agreement.

## 7.6 Feedback

Traditionally, Health Canada has used serious ADR and MDI information submitted to Health Canada primarily to support regulatory decision making within Canada and with our international regulatory colleagues.

Health Canada then shares this information publically through various mechanisms, including summary safety reviews, risk communications and an annual report. Several measures to improve access to timely, useful and relevant health and safety information, while respecting privacy, confidentiality and security considerations are already underway and will continue:

- The [Canada Vigilance Adverse Reaction Online Database](https://open.canada.ca/data/en/dataset/9cbaef00-b52c-4a70-9fed-d9aa8263ab74) (<https://open.canada.ca/data/en/dataset/9cbaef00-b52c-4a70-9fed-d9aa8263ab74>) contains information about suspected adverse reactions that have been reported from all sources. As noted below, Health Canada recently developed a public-facing, searchable [online database](https://hpr-rps.hres.ca/mdi_landing.php) ([https://hpr-rps.hres.ca/mdi\\_landing.php](https://hpr-rps.hres.ca/mdi_landing.php)) for MDIs.
- The Department produces a report to provide the annual numbers and trends of adverse drug reaction case reports and medical device incident reports sent to Health Canada.
- [Health Product InfoWatch](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html>) is a monthly publication intended to alert health professionals and consumers to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk-benefit evaluations and regulatory decisions are undertaken.
- Summaries of [safety reviews](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html#Safety_Reviews) ([https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html#Safety\\_Reviews](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html#Safety_Reviews)) are also posted online. Each summary outlines what was assessed, what was found and what action was taken by Health Canada, if any.
- Health Canada disseminates findings to healthcare professionals and the public to [alert](http://healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php) (<http://healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php>) them about identified health risks related to drugs and medical devices.

Reporting institutions, provinces and territories (PTs) and other decision makers, including patients, can benefit from timely sharing of intelligence gathered by the enhanced reporting through these regulations. As such, Health Canada is undertaking new activities to support expanded sharing of intelligence:

- Health Canada aims to provide reports back to institutions and PTs with the information they need and in the format(s), which will optimize its uptake and use. Consultations are currently underway to finalize the format/content and frequency of reports with the intended end users.
- Health Canada will launch a webinar series that will allow for timely sharing of information on potential safety issues when they arise. This series will capitalize on the existing webinar platforms and established audiences of health care professional partners and will allow Health Canada to provide a forum to share and discuss safety issues with relevant, targeted health professional groups as issues arise.
- Health Canada has recently made available online a searchable MDI database that provides Canadians the opportunity to search the MDI case reports themselves, while maintaining the privacy of the patients who experienced the MDIs. Like the Canada Vigilance database, which is already available to Canadians online,

the MDI database will be updated regularly to support open and transparent sharing of the data.

Together, these activities will serve to ensure partners have timely, appropriate access to that information and that Canadians and reporting institutions understand and experience the benefits of reporting SADR and MDIs to Health Canada. Health Canada will not follow up individually with hospitals to communicate results or conclusions from each report.

## 8 Privacy

### 8.1 Management of potential privacy issues associated with patient information in serious adverse drug reaction and medical device incident reports

When submitting serious ADR or MDI reports, Health Canada encourages reporters to use unique patient identifiers that would not breach privacy (e.g., avoid providing the patient's full name, social insurance number, any social circumstances that do not add valuable clinical information, etc...). While direct identifiers regarding the patient would not be sought under the mandatory reporting requirement, Health Canada has protocols in place to ensure that any information it receives related to the identity of the patient is protected as personal information under the federal *Privacy Act* (<http://laws-lois.justice.gc.ca/eng/acts/P-21/index.html>).

Please refer to the forms instructions for more details about the Privacy Notices regarding the collection of information related to mandatory reporting (see [section 7.4](#) for link to forms).





## 9 Additional Reporting Considerations

### 9.1 Submission of reports to manufacturers by hospitals

The regulations require hospitals to report serious ADRs and MDIs to Health Canada. Health Canada acknowledges the important role that manufacturers play in monitoring the safety of their products and encourages hospitals to continue to report serious ADRs and MDIs to manufacturers (and importers) for patient safety reasons, as well as to Health Canada, since this allows manufacturers to be aware of potential safety for their products. However, hospitals are not required under the regulations to report to the manufacturer. As part of their surveillance activities, manufacturers are expected to consult the Canada Vigilance Adverse Reaction and the Drugs and Medical Devices Online Databases to identify reports for their products that were sent directly to the Canada Vigilance Program. Manufacturers are required to report cases specific to drugs identified from these sources back to Health Canada only when new information is available from the manufacturer, as per the Notice “[Clarification of section 4.3 \(Regulatory Authority Sources\) of the Reporting Adverse Reactions to Marketed Health Products - Guidance Document for Industry](https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry/notice.html)” (<https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry/notice.html>).

For MDIs in particular, Health Canada recognizes the important role that information received from hospitals and health care professionals plays in contributing to the manufacturer or importer’s assessment of the root cause of the incident and plan for the corrective actions taken in respect of the incident, as applicable. As such, reporting to the manufacturer is strongly encouraged.

#### 9.1.2 Identification of duplicate reports associated with the same event submitted by different reporters

Duplicate reports are those that document the exact same case but by different reporters/sources (e.g., a patient could report the same unique event as the hospital and/or the manufacturer). These reports need to be linked as duplicates in the Canada Vigilance Adverse Reaction and the Drugs and Medical Devices Online Databases in order to reflect the accurate number of serious ADR and MDI cases for signal detection purposes. Linking the reports avoids issues related to multiple counting of a single event. In order to help Health Canada identify and link duplicate reports efficiently for both serious ADR and MDI reports, hospitals should include the date on which the hospital first documented the ADR or MDI in the report submission. Information about the patient such as the age and sex are examples of essential ADR identifiers, while device details are essential to be provided for MDIs to help with duplicate conciliation, in addition to other key data elements requested in section 6.1. Hospitals are encouraged to indicate in their report if the case has also been submitted to the manufacturer (section D 13b. on the Mandatory ADR Reporting Form for Hospitals and section C for MDIs) and provide reference numbers unique to the report (e.g. internal submitter/organization file number).

### 9.2 Canadian Medical Devices Sentinel Network (CMDSNet)

CMDSNet uses a proactive approach to surveillance that encourages the reporting of medical device problem reports from all types of institutions so that Health Canada can better identify emerging safety issues and improve the safe use of medical devices. CMDSNet will continue to operate and play an important role in Health Canada’s post-market surveillance of medical devices even with the new regulations. While it is a requirement for hospitals to report MDIs to Health Canada under the regulations for mandatory reporting, CMDSNet-participating institutions (including hospitals) are encouraged to report to this network, on a voluntary basis, incidents occurring with medical devices that fall outside of the scope of mandatory reporting. As well, CMDSNet will aim to continue to expand its network of facilities outside of the hospital setting, which are not subject to the regulations for mandatory reporting, including long-term care facilities and private clinics. In this way, CMDSNet and the regulations for mandatory reporting will complement one another to better inform post-market evaluations.



## 10 Compliance and Enforcement

### 10.1 Health Canada compliance and enforcement actions for hospitals

The primary objective of Health Canada's compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention, proportional to the risk posed to the general public. For the purposes of compliance monitoring, Health Canada has implemented an oversight mechanism to verify that the reports are being received and that they are complete and provide information of sufficient quality to meet the regulatory requirements. When a situation of non-compliance is identified, Health Canada will work with hospitals to help them meet the mandatory reporting requirements under Vanessa's Law, building on guidance, outreach and education efforts, and address any issues that may lead to situations of future non-compliance.

In the event that Health Canada identifies instances of more persistent non-compliance, additional compliance and enforcement measures could be taken by the Regulatory Operations and Enforcement Branch (ROEB) in accordance with the risk-based approach detailed in [Health Canada's Compliance and Enforcement Policy \(POL-0001\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>).

In the unlikely event that a situation of non-compliance is not resolved through this approach, Health Canada may use provisions of the *Food and Drugs Act* and its associated regulations, for example seeking an injunction under section 21.5 of the *Act* to compel a hospital to comply with the regulations. In determining the appropriateness of exercising enforcement measures, the Department would take into consideration whether the non-compliance of a hospital is shown to pose a serious health risk to Canadians, as well as other factors outlined in POL-0001.



# Appendix 1 - Glossary: Acronyms, Definitions and Terminology

**ADR:** Adverse Drug Reaction  
**AEFI:** Adverse Events Following Immunization  
**CMDSNet:** Canadian Medical Devices Sentinel Network  
**CVP:** Canada Vigilance Program  
**DIN:** Drug Identification Number  
**DPD:** Drug Product Database  
**FDA:** *Food and Drug Act*  
**FTP:** File Transfer Protocol  
**HC:** Health Canada  
**ID:** Identifier  
**IT:** Investigational Testing  
**MDALL:** Medical Devices Active Licence Listing  
**MDI:** Medical Device Incident  
**ROEB:** Regulatory Operations and Enforcement Branch  
**SAP:** Special Access Programme  
**vCJD:** Variant Creutzfeldt-Jakob Disease

## Allergy

Exaggerated or pathological reaction (i.e. sneezing, respiratory embarrassment, itching, or skin rashes) to substances, situations, or physical states that are without comparable effect on the average individual.

## Brand name (Food and Drug Regulations)

With reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

- (a) that is assigned to the drug by its manufacturer,
- (b) under which the drug is sold or advertised, and
- (c) that is used to distinguish the drug.

## Common name (Food and Drug Regulations)

With reference to a drug, the name in English and French by which the drug is

- (a) commonly known, and
- (b) designated in scientific or technical journals, other than the publications referred to in Schedule B to the *Food and Drugs Act*.

## Date of documentation

Date on which a serious adverse drug reaction or a medical device incident is first documented in the hospital that is submitting a report.

## Drug (Food and Drugs Act)

According to the *Food and Drugs Act*, a drug includes any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept.

## Expected Adverse Drug Reaction

An adverse drug reaction whose nature (i.e., specificity or outcome), severity or frequency is consistent with the terms or description used in the product labelling should be considered expected.

### **Hospital (Food and Drug Regulations)**

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.

**Health Canada (HC) Institutional Identifier (ID):** Indicates the submitter's unique hospital/institutional identifier as assigned by Health Canada. To obtain this identifier, please contact [hc.canadavigilance.sc@canada.ca](mailto:hc.canadavigilance.sc@canada.ca).

**Health Canada (HC) Reference Number:** Refers to the reference number of an ADR or MDI report, generated by Health Canada and provided to the submitter following the report submission.

### **Identifier (Medical Devices Regulations)**

Identifier means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.

**Internal submitter/organization file number:** Refers to the internal reference number of an ADR or MDI report, generated by the submitter or hospital.

### **Medical device (Section 1 of the *Food and Drugs Act*)**

Device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:

- (a) Diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
- (b) Restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
- (c) Diagnosing pregnancy in human beings or animals,
- (d) Caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
- (e) Preventing conception in human beings or animals;

However, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal; (instrument)

In the *Medical Devices Regulations*, a device within the meaning of the *Act*, but does not include any device that is intended for use in relation to animals.

### **Manufacturer (Medical Devices Regulations)**

Manufacturer means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

### **Medical device incident (Medical Devices Regulations)**

In accordance with section 62(4) of the *Medical Devices Regulations*, a medical device incident refers to 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.

### **Medical intervention**

In medicine, a treatment or action taken to prevent or treat disease, or improve health in other ways.

### **Medication**

See definition for “Drug”.

### **Outcome**

The result of evaluating the final state of a person who experienced an adverse event (examples: recovered/resolved, recovering/resolving, not recovered/not resolved, recovered/resolved with sequelae, fatal, unknown).

- **Outcome death**  
An indication or description that a specific activity resulted in the death of a subject.
- **Recovered or resolved with sequelae**  
One of the possible results of an adverse event outcome where the subject recuperated but retained pathological conditions resulting from the prior disease or injury.
- **Recovered or resolved without sequelae**  
One of the possible results of an adverse event outcome where the subject recuperated and is free of any pathological conditions resulting from the prior disease or injury.
- **Recovering or resolving**  
One of the possible results of an adverse event outcome that indicates that the event is improving.
- **Not recovered or not resolved**  
One of the possible results of an adverse event outcome that indicates that the event has not improved or recuperated.
- **Unknown**  
Not known, not observed, not documented, or refused.
- **Persistent or significant disability or incapacity**  
An indication or description of a continuing and significant impairment (loss or abnormality of psychological, physiological or anatomical function).

### **Proper name (Food and Drug Regulations)**

With reference to a drug, the name in English or French

- (a) assigned to the drug in section C.01.002,
- (b) that appears in bold-face type for the drug in these regulations and, where the drug is dispensed in a form other than that described in this Part the name of the dispensing form,
- (c) specified in the Canadian licence in the case of drugs included in Schedule C or Schedule D to the *Act*,
- (d) or assigned in any of the publications mentioned in Schedule B to the *Act* in the case of drugs not included in subparagraphs (a), (b) or (c) of this paragraph.

For products with multiple ingredients, there is no proper name for the product but there is a proper name for each ingredient. Example of a proper name - acetaminophen, azithromycin capsules

### **Serious adverse drug reaction (Food and Drug Regulations)**

A serious adverse drug reaction, as defined in the *Food and Drug Regulations*, is 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.

**Serious deterioration in the state of health (*Medical Devices Regulations*)**

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

**Serious Unexpected Adverse Drug Reaction (*Food and Drug Regulations*)**

A serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.

**Submitter**

The person submitting on behalf of the hospital that is required to report mandatory adverse drug reaction/ medical device incident reports to Health Canada, in accordance with the *Regulations*.



## Appendix 2 - Authorization for Reporting via a Third Party

This form authorizes the organization named in Section B (third party) to act on behalf of the organization named in Section A (Hospital) in regard to hospital mandatory reporting of serious adverse drug reactions and medical device incidents to the Marketed Health Products Directorate of Health Canada. Upon completion, the hospital should submit this authorization form to Health Canada's Canada Vigilance Program via email ([hc.canada.vigilance.sc@canada.ca](mailto:hc.canada.vigilance.sc@canada.ca)).

### Section A (Hospital)

- I hereby authorize the organization named in Section B to prepare and submit serious adverse drug reactions and/or medical device incident reports according to the requirements defined in section C.01.020(4) of the *Food and Drug Regulations* and section 61(4) of the *Medical Devices Regulations* on my behalf.

Hospital: \_\_\_\_\_  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Title: \_\_\_\_\_

### Section B (Third Party)

- I hereby accept the authorization in regard to hospital mandatory reporting on behalf of the organization named in Section A.

Third Party: \_\_\_\_\_  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_  
Title: \_\_\_\_\_



## Appendix 3 - Summary of the reporting requirements for therapeutic products not subject to the mandatory reporting requirements for hospitals under section C.01.020(4) of the *Food and Drug Regulations* and section 61(4) of the *Medical Device Regulations*

Reporting requirements for therapeutic products not subject to the mandatory reporting requirements for hospitals		
Therapeutic product	Reporting requirement	Who reports to Health Canada
Cells, tissues and organs	Mandatory reporting to Health Canada under the <i>Safety of Human Cells, Tissues and Organs for Transplantation Regulations</i> (pursuant to section 30 of the <i>Food and Drugs Act</i> ) ( <a href="https://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-118/page-8.html">https://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-118/page-8.html</a> )	Source establishment <sup>1</sup>
Blood and blood products	Mandatory reporting of ARs related to the safety or quality of the blood to Health Canada under the <i>Blood Regulations</i> (pursuant to section 30 of the <i>Food and Drugs Act</i> ) ( <a href="http://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/page-10.html">http://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/page-10.html</a> )	Blood establishment responsible for the activity that was the root cause leading to the AR <sup>2</sup>
Semen	Mandatory reporting to Health Canada under the <i>Processing and Distribution of Semen for Assisted Conception Regulations</i> (pursuant to subsection 30(1) of the <i>Food and Drugs Act</i> ) ( <a href="http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-254/page-2.html">http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-254/page-2.html</a> )	Processor of semen <sup>3</sup>
Clinical trial drugs	Mandatory reporting to Health Canada under the <i>Food and Drug Regulations</i> (pursuant to the <i>Food and Drugs Act</i> ) ( <a href="https://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-132.html">https://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-132.html</a> )	Drug sponsor
Investigational trials (medical devices)	Mandatory reporting to Health Canada under the <i>Medical Device Regulations</i> (pursuant to the <i>Food and Drugs Act</i> ) ( <a href="https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html">https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html</a> )	Device Sponsor
Special access programme (SAP) drugs	Mandatory reporting to Health Canada under the <i>Food and Drug Regulations</i> (pursuant to the <i>Food and Drugs Act</i> ) ( <a href="https://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-140.html">https://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-140.html</a> )	Health care practitioner dispensing the SAP drug <sup>4</sup>
Special access programme (SAP) devices	Mandatory reporting to Health Canada under the <i>Medical Device Regulations</i> (pursuant to the <i>Food and Drugs Act</i> ) ( <a href="https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html">https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html</a> )	Health care practitioner dispensing the SAP device
Vaccines	Hospitals and health care professionals submit reports	The Public Health Agency

administered under a provincial/ territorial immunization program	to local health units, who forward these reports to provincial/ territorial health authorities and the Public Health Agency of Canada	of Canada shares data with Health Canada
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<sup>1</sup>Non-source establishments must notify the source establishments or importers of an adverse reaction, while source establishments must notify all other establishments that received or imported the implicated cells, tissues and organs. Furthermore, source establishments must conduct investigations and forward copies of their reports to Health Canada and all other implicated health establishments.

<sup>2</sup>Establishment means a person that conducts any of the following activities in respect of blood: (a) importation; (b) processing; (c) distribution; (d) transformation; or (e) transfusion.

<sup>3</sup>Physicians must report contaminated semen to the processor of semen, who in turn, must investigate and report to Health Canada.

<sup>4</sup>Health care practitioners dispensing SAP drugs must report adverse reactions to the manufacturers, in addition to reporting to Health Canada.

## Appendix 4 - Quick Reference Guide

<b>Quick Reference Guide</b>	
<b>Regulation requirement</b>	Section C.01.020.1 of the <i>Food and Drug Regulations</i> and section 62 of the <i>Medical Devices Regulations</i> , require hospitals to report to Health Canada all serious adverse drug reactions (ADRs) and medical device incidents (MDIs) within 30 days of being documented within the hospital.
<b>What to report</b>	<p>All documented serious ADRs as well as all documented MDIs, where the required information is within the control of the hospital, must be reported in accordance with the regulations.</p> <p>A serious ADR is a noxious and unintended response to a drug that occurs at any dose and that:</p> <ul style="list-style-type: none"> <li>• requires in-patient hospitalization or prolongation of existing hospitalization</li> <li>• causes congenital malformation</li> <li>• results in persistent or significant disability or incapacity, or</li> <li>• is life-threatening or results in death.</li> </ul> <p>A medical device incident 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.</p> <p>Information that is ‘in the control’ of the hospital is information that would be reasonably accessible within the hospital. Additional information on the regulatory requirements related to mandatory reporting can be found in the <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada.html#a2">Guidance Document and Guidelines section of the Reports and Publications - MedEffect Canada page</a> (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada.html#a2">https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada.html#a2</a>).</p> <p>When in doubt, Health Canada encourages hospitals to report.</p>
<b>Why report</b>	Health Canada’s monitoring of therapeutic product safety plays a vital role in public health and patient safety, providing health care providers and patients with the most up-to-date knowledge on product safety so as to prevent and mitigate ADRs and MDIs. By reporting ADRs and MDIs, health care professionals and hospitals are participating in the system that makes health products safer. Reports of serious adverse drug reactions and medical device incidents are often the first sign of emerging safety problems. Improved reporting will help Health Canada take action more quickly against products that may pose a risk to the health and safety of Canadians.
<b>Who is regulated</b>	<p>This regulatory requirement only applies to hospitals.</p> <p>Hospital is defined as a facility that:</p> <ul style="list-style-type: none"> <li>- 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</li> <li>- is operated by the Government of Canada and provides health services to in-patients.</li> </ul>
<b>What therapeutic products are within scope</b>	<p>The mandatory reporting requirements for hospitals apply to the following therapeutic products:</p> <ul style="list-style-type: none"> <li>• pharmaceuticals (prescription and non-prescription);</li> <li>• biologic drugs (biotechnology products, fractionated blood products, plasma proteins, as well as vaccines, excluding those administered under a routine immunization program of a province or territory);</li> <li>• radiopharmaceutical drugs;</li> <li>• disinfectants;</li> </ul>

	<ul style="list-style-type: none"> <li>• drugs for an urgent public health need;</li> <li>• medical devices.</li> </ul>
<b>What therapeutic products are out of scope</b>	<p>These reporting requirements do not apply to the following therapeutic products:</p> <ul style="list-style-type: none"> <li>• drugs and devices used under the Special Access Programme or Clinical Trials/Investigational Testing;</li> <li>• vaccines administered under a routine immunization program of a province or territory;</li> <li>• blood and blood components;</li> <li>• cells, tissues and organs;</li> <li>• semen/ova.</li> </ul>
<b>When to submit</b>	<p>Serious ADRs and MDIs are required to be reported, in writing, to Health Canada within 30 calendar days from the date of first documentation within the hospital. If the report is completed earlier than the 30 days, Health Canada encourages hospitals to report sooner.</p>
<b>How to submit</b>	<ul style="list-style-type: none"> <li>• <b>Electronic reporting</b> If you are interested in submitting reports electronically (e.g. secure File Transfer Protocol - sFTP, system-to-system exchanges) to Health Canada, please email the Canada Vigilance Program at <a href="mailto:hc.canada.vigilance.sc@canada.ca">hc.canada.vigilance.sc@canada.ca</a>.</li> <li>• <b>Online</b> Complete and submit a report using the online reporting applications available at: <a href="http://canada.ca/medeffect">canada.ca/medeffect</a>.</li> <li>• <b>Fax or Mail</b> Download, print and complete the applicable form: <a href="https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf">Serious Adverse Drug Reaction Reporting Form for Hospitals</a> (<a href="https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf">https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf</a>) or <a href="https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf">Medical Device Problem Report Form for Health Care Professionals</a> (<a href="https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf">https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf</a>) <ul style="list-style-type: none"> <li>○ Send by fax at: 1-866-678-6789</li> <li>○ Mail it to the Canada Vigilance National Office: <p>Canada Vigilance Program (CVP) Health Products Surveillance and Epidemiology Bureau Marketed Health Products Directorate Health Products and Food Branch</p> <p>Health Canada Address Locator 1908C Ottawa, Ontario K1A 0K9</p> </li> </ul> </li> </ul>
<b>Contact</b>	<p>For additional information about CVP or mandatory reporting of ADRs/MDIs:</p> <ul style="list-style-type: none"> <li>• Call toll free 1-866-234-2345</li> <li>• Email <a href="mailto:hc.canada.vigilance.sc@canada.ca">hc.canada.vigilance.sc@canada.ca</a></li> </ul>