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

Draft guidance document

June 2018

Canada

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[1], such as drugs and medical devices, 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 risk/benefit 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/ 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 proposal 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 Purpose

The purpose of this draft guidance is to provide hospitals with information that may be useful in achieving compliance with the proposed new regulatory requirement for hospitals to report serious ADRs and MDIs to Health Canada.

1.2 Scope and Application

The proposed regulatory requirement to provide reports of serious ADRs and MDIs to Health Canada will apply to hospitals that are regulated through provincial/ territorial legislation and those operated by the federal government .

The proposed 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.

[1] Section 2 of the *Food and Drugs Act* defines "therapeutic product" 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.*

2 The Proposed Regulations and their Purpose

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. The *Protecting Canadians from Unsafe Drugs Act (*Vanessa's Law*)* made several amendments to the *Food and Drugs Act*, including a new requirement in section 21.8 for prescribed 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 ADR and MDIs, improve the quality of these reports, and to 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. Although Vanessa's Law received Royal Assent in November 2014, this particular requirement will come into effect when accompanying changes are made to both the *Food and Drug Regulations* and the *Medical Devices Regulations*.

3 Roles and Responsibilities

3.1 What is the role of hospitals?

Under the proposed regulations, all hospitals are required to report serious ADRs and MDIs documented within the hospital to Health Canada. These reports are required to be sent to Health Canada within 30 calendar days from the date of first documentation within the hospital. The proposed 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 regulatory requirement to report all serious ADRs and MDIs that are documented within the hospital to Health Canada. 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.

3.2 What is the role of health care professionals?

The mandatory reporting requirement applies to the facility rather than individual health care professionals working in the hospital. However, health care professionals will have 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 staff in meeting the mandatory reporting obligations.

3.3 What about other types of health care institutions?

If a health care institution does not fall within the definition of hospital in the proposed regulations, it is not required to report serious ADRs and MDIs to Health Canada. The rationale for limiting the scope of health care institutions to hospitals is that this is where treatment of serious adverse drug reactions and medical device incidents are most likely to occur, rather than where the event originated. However, health care institutions that are outside the scope of the definition of hospitals, such as nursing homes or private clinics, continue to be encouraged to report to Health Canada on a voluntary basis either directly and/or via the manufacturer/importer (who must report all serious ADRs and MDIs to Health Canada).

3.4 Other Situations

Regardless of whether the serious ADR or MDI originated outside of a hospital setting or if the patient is admitted to hospital or not, if the serious ADR or MDI is documented within the hospital, the hospital is required to report the serious ADR or MDI to Health Canada.

3.4.1 What if a serious ADR or MDI occurred in another health care institution that was not a hospital (e.g. nursing home) and led to the patient's hospitalization?

A nursing home is not a hospital and would not be required to report to Health Canada. Even though the serious ADR/MDI had occurred at the nursing home in this example, the hospital that the patient was admitted to as a result would be required to report the serious ADR or MDI.

A hospital is required to provide Health Canada with information about serious ADRs and MDIs that is 'in a hospital's control.' This means they would be required to submit to Health Canada serious ADR and MDI

reports documented by health care professionals within their facilities, but would not be required to further investigate the event with the institution where the ADR/MDI originated. However, the hospital would be encouraged to follow up with the other health care institution, the nursing home in this case, to obtain the required information in order to submit a more complete report.

3.4.2 What if a serious ADR or MDI occurred in the community and led to the patient's hospitalization?

If the serious ADR or MDI occurred in the community, led to the patient's hospitalization and was documented within the hospital, the hospital would be required to report the serious ADR or MDI to Health Canada.

3.4.3 What if a serious ADR or MDI occurred in the community and the patient was treated in the hospital's emergency room but not admitted as an in-patient?

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 forwarding this report 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.

3.4.4 What if the patient had a serious ADR or MDI at one hospital but is transferred to another hospital?

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.

4 Therapeutic products subject to mandatory reporting requirements

4.1 What therapeutic products do the mandatory reporting requirements apply to?

The proposed mandatory reporting requirements for hospitals apply to "therapeutic products" as defined by the *Food and Drugs Act*, including:

- Pharmaceuticals (which includes prescription and non-prescription pharmaceutical drugs),
- Biologic drugs (excluding vaccines administered under a routine immunization program of a province or territory),
- Radiopharmaceutical drugs as set out in Schedule C to the *Food and Drugs Act*,
- Disinfectants, and
- Medical Devices as defined in Section 1 of the *Medical Devices Regulations*.

4.2 Does mandatory reporting apply to adverse reactions to cells, tissues and organs, blood and blood components and semen?

While cells, tissues and organs, blood and blood components and semen are products that would be included in the definition of therapeutic product, they currently have separate reporting frameworks and as such, mandatory reporting for these products is required for certain types of health facilities through other federal regulations.

4.3 Are drugs and medical devices regulated under Clinical Trial (drugs)/ Investigational Testing (medical devices) and Special Access Program frameworks included in mandatory reporting?

Drugs and medical devices that are regulated under Clinical Trial/ Investigational Testing and Special Access Program (SAP) frameworks have separate reporting schemes in place. The authority for these reporting schemes[2] is found in the *Food and Drug Regulations* and *Medical Devices Regulations* and supporting guidance materials. As such, these categories of drugs and medical devices are proposed to be excluded from the new reporting requirements under Vanessa's Law.

4.4 Does mandatory reporting apply to vaccines that are administered under a routine immunization program of a province/territory?

Mandatory reporting does not apply to vaccines that are administered under a routine immunization program of a province or territory. Hospitals and health care professionals are encouraged to submit these reports to their local public health unit.

As part of provincial and territorial immunization programs, adverse events following immunization (AEFI) are reported to the local health units so that the Medical Officer of Health can monitor the local programs. These reports are also forwarded to provincial and territorial health authorities so that they can monitor their local immunization programs and to the Public Health Agency of Canada for national collation and analysis. The Public Health Agency of Canada then shares the data in these reports with Health Canada to enable regulatory action related to vaccines marketed in Canada. This is the current and preferred route for receiving AEFI reports given the considerable scrutiny vaccine safety receives.

[2] The authority for reporting schemes for Clinical Trial drugs and SAP drugs is found in C.05.014 and C.08.010 of the *Food and Drug Regulations* respectively. The authority for reporting schemes for Investigational Testing medical devices and SAP medical devices is found in sections 81(k) and 77 of the *Medical Device Regulations* respectively.

Given that there is an established AEFI network to monitor vaccine safety and that AEFI reporting is mandatory for health care professionals in most provincial and territorial jurisdictions, the proposed regulations state that vaccines administered under a routine provincial and territorial immunization program are to be exempted from the scope of the reporting requirements. The proposed regulations would still apply to all other types of vaccines that are used outside of routine immunization programs.

Requiring the mandatory reporting by hospitals for serious 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.

4.5 Are drugs for an urgent public health need, regulated under Part C, Division 10 of the *Food and Drug Regulations,* included in this mandatory reporting requirement?

Drugs regulated under Part C, Division 10 of the *Food and Drug Regulations* (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), currently have serious ADR reporting requirements that are similar, but not identical to, the requirements outlined in the proposed regulations for mandatory reporting. To avoid confusion and redundancy, Health Canada proposes to repeal the current ADR reporting requirements under Part C, Division 10 of the *Food and Drug Regulations* and include drugs regulated under Part C, Division 10 of the *Food and Drug Regulations* in the proposed mandatory reporting regulations of serious ADRs and MDIs for hospitals.

This would mean that hospitals would be required to report serious ADRs for drugs regulated by Part C, Division 10 of the *Food and Drug Regulations*. As part of a serious ADR report related to a drug for an urgent public health need, hospitals would need to provide some information that was previously not a requirement, such as: a patient's age and sex; the date on which the patient first used the drug; the date on which the serious ADR first occurred; any medical condition of the patient that directly relates to the serious ADR; any concomitant therapeutic products used by the patient; and the result of the serious ADR on the patient's health.

5 Serious ADRs and MDIs to be Reported by Hospitals

5.1 What is a serious adverse drug reaction?

A serious adverse drug reaction, as defined in 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. Health Canada requires hospitals to report serious ADRs.

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. 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.

5.1.1 Does a serious ADR need to be reported if the use was off-label?

All serious ADRs must be reported to Health Canada, even if they occur as a result of an off-label use. Off-label use refers to any intentional use of a drug 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 marketing authorization.

5.1.2 What are some examples of serious ADRs?

Some case examples are provided below as examples of serious ADRs that, if documented within the hospital, should be reported to Health Canada.

1. A 25 year old male patient with seizure disorder was admitted to the hospital after experiencing fever, chills and lymphadenopathy for 1 week duration. Additionally, a non-itchy, erythematous maculopapular rash involving the trunk and extremities was noticed for 2 weeks duration. He also started to have yellowish eye discoloration 7 days after the onset of fever. Laboratory data demonstrated marked elevation in eosinophils, serum creatinine and liver enzymes. The patient was taking phenytoin. Phenytoin-induced hypersensitivity syndrome was suspected.

2. A 67 year old female with abdominal pain, nausea and vomiting, jaundice, anorexia, sweating, and weakness for the previous 3 days was referred urgently to hospital. She has a history of hypertension, heart failure and type 2 diabetes mellitus for which she is taking digoxin, hydrochlorothiazide and a combination of rosiglitazone/metformin. On physical examination, the abdomen was distended. Laboratory data on admission revealed increased serum amylase levels and WBC, but all other laboratory examinations were normal. Abdominal ultrasonography ruled out intestinal obstruction and gallstones. Hydrochlorothaizide-induced pancreatitis was considered after the exclusion of other causes.

3. A 40 year old patient diagnosed with Hodgkin's lymphoma was started on a drug regimen of doxorubicin, bleomycin, vincristine, and dacarbazine. Following cycle 3, the patient was admitted with complaints of dry cough and shortness of breath on exertion. The patient was suspected to have bleomycin-induced pulmonary fibrosis.

5.1.3 Can a serious ADR report refer to more than one patient?

No, a serious ADR report 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.

5.2 What is a medical device incident (MDI)?

As defined in the proposed regulations, 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.

5.2.1 What types of medical devices should be included in MDI Reporting?

The term "medical devices", as defined in 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 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, 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.

5.2.2 What are some 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. Patient received under-infusion of needed fluids and required extra days in hospital to correct.

5.2.3 Are 'near incidents' included in the definition of medical device incidents?

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'. 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 harm if they were to recur are included in the definition of MDIs.

An example of a near incident is the following:

- A monitor suspension system, that was installed, maintained and used according to 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.

5.2.4 What kinds of incidents do not meet the definition of medical device incident and would not need to be reported under the mandatory reporting regulations?

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.

Incident caused by a patient's condition

When the reporter 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 reporter should have documented information available to conclude that the device performed as intended and did not cause, or contribute to, death or serious deterioration in health.

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

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.

Abnormal use incident

An abnormal use incident, which is the intentional use for a non-approved purpose (“off-label use”) or use that is not recommended in the labelling, need not be reported to Health Canada.

Examples:

Failure to conduct device checks prior to each use as defined by the manufacturer, as described in the labelling. The failure led to serious harm to the patient.

During the placement of a pacemaker lead, an inexperienced physician or other non-qualified individual perforates the heart. The labelling indicated that only qualified staff place the lead. This procedure led to serious harm to the patient.

In all the above cases, while it is not required, if a hospital believes that there would be a benefit in reporting an incident that is outside the scope of the definition of medical device incident, the hospital is strongly encouraged to report the event to Health Canada and manufacturers on a voluntary basis. The reports in the situations above should be directed to *(…. to be inserted in the final Guidance).*

5.3 In order for a serious ADR or MDI to be reported, does causality between the therapeutic product and an adverse drug reaction or incident need to be established?

Hospitals are not required to establish causality between a certain therapeutic product and an adverse reaction or incident. The information to be submitted by the hospital to Health Canada only needs to represent the suspicions of the documenting health care professional that a serious ADR or MDI has been observed. It is acknowledged that when the serious ADRs and MDIs are documented by health care professionals, there will be some professional judgement exercised in making this assessment. However, there would be no need to perform a causality assessment to determine whether a therapeutic product caused the serious ADR or MDI in order to send the report to Health Canada. This approach for establishing associations is in line with international best practices for ADR and MDI reporting.

5.4 What if a reporter is not sure which of a number of drugs or devices caused a serious ADR or MDI?

The information submitted only needs to represent the suspicions of the health care professional and there is no need to establish causality in order to send a serious ADR or MDI report to Health Canada.
If the serious ADR or MDI may be related to a single suspected drug/device, Health Canada would expect the serious ADR or MDI report to be provided for the suspected drug/device with the concomitant therapeutic products identified.

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

5.5 What are examples of serious ADR and MDI 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/ patient safety learning database, computerized prescription recording system.

6 Information requirements for serious ADR and MDI reports

6.1 What type of information about serious ADRs and MDIs needs to be reported to Health Canada?

Based on the proposed regulations, hospitals are required to report certain information about serious ADRs and MDIs if the information is in the control of the hospital. While the information requirements for serious ADRs and MDIs are different from one another, this is due to the differences in the required information for the monitoring of these two types of products.

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;
(d) the drug identification number 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 patient first used the drug and, if applicable, the date on which the patient stopped using the drug;
(h) 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 adverse drug reaction;
(i) any medical condition of the patient that directly relates to the serious adverse drug reaction;
(j) any concomitant therapeutic products used by the patient; and
(k) the result 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 of the device and its identifier;
(c) the name of the manufacturer of the device;
(d) a description of the medical device incident;
(e) the lot number of the device or its serial number;
(f) any contributing factors to the medical device incident, including any medical condition of the patient that directly relates to the medical device incident; and
(g) the result of the medical device incident on the patient's health.

If the hospital has more information than those listed above as required information for a serious ADR or MDI, Health Canada encourages the hospital to include this information in the serious ADR and MDI reports sent to Health Canada. Appendices 2 & 3, at the end of this document, include two draft comprehensive lists of data elements that could be captured for ADRs (Appendix 2) and MDIs (Appendix 3). While it is not mandatory to complete all the data elements in these Appendices, health professionals and hospitals are encouraged to complete as many data fields as possible in order to ensure the highest quality reports possible.

6.2 What does it mean for information to be '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/ 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 pieces of information by contacting sources outside the hospital (eg. a family physician's office or another health care institution).

6.3 What is the obligation on the hospital if it does not have all the information requirements for a serious ADR or MDI report?

For serious ADR reports, a hospital would be exempt from sending the report to Health Canada if the hospital does not have, in its control, all the information in the list below:

(a) the drug's brand name, proper name or common name;
(b) 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;
(c) the patient's age and sex; and
(d) a description of the serious adverse drug reaction.

For MDI reports, a hospital would be exempt from sending the report to Health Canada if the hospital does not have, in its control, all the information in the list below:

(a) the name of the device and its identifier;
(b) the name of the manufacturer of the device; and
(c) a description of the medical device incident.

The reason for exempting the hospital from having to report serious ADRs and MDIs if it does not have these key pieces of information is that these pieces of information are necessary for Health Canada to conduct a basic assessment of these reports.

7 When and how to submit serious ADR and MDI reports

7.1 When do serious ADRs and MDIs need to be reported?

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.

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.

Processes for submitting follow-up reports in development. More to follow in the coming year.

7.2 Will there be follow up done on the reports submitted to 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 the department. Thus, hospitals should consider implementing a tracking system for the reports that are submitted to Health Canada.

More information on follow up processes to be developed. More to follow in the coming year.

7.3 What is the process for submission of serious ADRs and MDIs to Health Canada?

This section is currently under development. More to follow in the coming year.

7.4 Form templates for serious ADR and MDI reports.

This section is currently under development. More to follow in the coming year.

8 Privacy

8.1 How will Health Canada manage potential privacy issues associated with patient information in serious ADR and MDI reports?

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).

9 Additional reporting mechanisms

9.1 Once the proposed regulations are in force, do hospitals need to report to both Health Canada and manufacturers/importers, or just to Health Canada?

The proposed regulations will require hospitals to report serious ADRs/ MDIs to Health Canada. Hospitals will not be required under the proposed regulations to report to the manufacturer. However, 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, in the case of MDIs) for patient safety reasons, as well as to Health Canada.

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/importer's assessment of the root cause of the incident and plan for the corrective actions taken in respect of the incident, as applicable.

9.2 Once the proposed regulations are in force, will the Canadian Medical Devices Sentinel Network (CMDSNet) continue?

CMDSNet uses a proactive approach to surveillance that encourages voluntary medical device incident reporting from all types of institutions so that Health Canada can more fully understand the circumstances in which medical devices are used. While there is some overlap between the two reporting programs, they are not exact duplicates and would complement each other. The CMDSNet will continue, even once the proposed regulations are in force.

Appendix 1 - Glossary: Regulatory definitions

Adverse Drug Reaction (*Food and Drug Regulations)*
Adverse drug reaction as defined in the *Food and Drug Regulations* is a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function.

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 Act.

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.

Medical Device Incident *(proposed for Medical Devices Regulations)*
As defined in the proposed Regulations, 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.

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.

Appendix 2 - Serious adverse drug reaction reporting data elements

Serious adverse drug reaction reporting data elements*

Category	Data Elements
Patient Information	Age
	Sex
	Height
	Weight
	Medical history and other related information (allergies, pregnancy, smoking/alcohol use, liver disease, etc.)
Reporter Information	Name of Hospital
	Contact Information for representative of the hospital: Telephone
	Email
	Address
	City
	Province/Territory
	Preferred language
	Select one that best describes person documenting serious ADR (Physician, Pharmacist, Other)
Adverse Drug Reaction	Adverse drug reaction start date
	Adverse drug reaction end date
	Describe the adverse drug reaction (timelines, treatment, etc.)
	Recovered after the adverse drug reaction (Yes, No, Unknown, Recovering)
	Seriousness of the adverse drug reaction (death, life-threatening, admitted to hospital, lengthened hospital stay, disability, birth defect, needed medical attention)
Health Product	Brand Name, Common name or Product Name
	Dosage (strength and quantity)
	How the product was taken (e.g. by mouth)
	What was the product prescribed/taken for?
	Manufacturer
	Lot #
	DIN #
	Identifying number or code
	Country of purchase (Canada, United States, other)
	How it was purchased/obtained (pharmacy, grocery store, internet, other)
	Product start date
	Product end date
	Frequency
	Did use of the product stop after the adverse drug reaction appeared?
	If the product was stopped, did the adverse drug reaction stop?
	Was the product restarted after the adverse drug reaction stopped?
	If the product was restarted, did the adverse drug reaction return?
	Likelihood that the product caused the adverse drug reaction (certain, probably/likely,

	possibly, not available/unable to assess, unlikely, unrelated)
	Other health products taken at the time of the adverse drug reaction, excluding treatment (length of use, timelines, etc.)
	Related test/laboratory results

*This is a draft list of comprehensive data elements that could be captured for serious ADRs. They may not all be applicable for the purposes of reporting by hospitals. Mandatory reporting is not required for all these data elements.

Appendix 3 - Medical device incident reporting data elements

Medical device incident reporting data elements

Category	Data Elements
Report Information	Report Type (new, update)
	Report Purpose (hospital mandatory)
	Reporter File Number
Reporter Information	Name of Hospital
	Contact Information for representative of the hospital: Telephone
	Email
	Address
	City
	Province/Territory
	Preferred Language of Hospital Representative
	Select one that best describes person documenting MDI (Physician, Pharmacist, Other)
Incident Information	Date of Incident
	Description of Incident
	Identify the type of environment where the incident occurred (hospital, home, nursing home/long term care, outpatient, unknown)
	Incident Contributing Factors (patient/environment)
	Device Contributing Factors
	Relationship of affected person to incident (patient, health care provider, other)
Affected Persons (for each person involved)	How was the affected person impacted by the incident? (death, serious injury, potential for death or serious injury, injury, unknown)
	Age (years)
	Gender (male, female, unknown)
	Weight (lbs or kg)
	Device Name (including model number if applicable)
Device Information (for each device involved)	Manufacturer's Catalog or Reference Number
	Software Version
	Serial Number
	Global Medical Device Nomenclature (GMDN) Number
	Unique Device Identifier
	Lot/Batch Number
	Was it a single-use device that was reprocessed and reused on a patient?
	Is the device available for evaluation?
	Organization Type (manufacturer, importer)
Manufacturer/Importer Information (for each	Business Name
	Name

device involved if different)	Title
	Address
	City
	Province/State
	Country
	Postal Code
	Telephone
	Email

*This is a draft list of comprehensive data elements that could be captured for MDIs. They may not all be applicable for the purposes of mandatory reporting by hospitals. Mandatory reporting is not required for all these data elements.