Health Canada Santé Canada

Protected “B” when completed

Serious adverse drug reaction reporting form for hospitals

Canada Vigilance - Adverse reaction reporting program

For best results, download and open this form in a PDF reader.

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance adverse reaction reporting program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

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

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

For more information: This personal information collection is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a26. Refer to the personal information bank HC PPU 417.

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

Submission methods

Electronic reporting
If you are interested in submitting reports electronically (e.g. secure file transfer protocol - sFTP) to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca

Fax
Download, complete and print the Serious adverse drug reaction reporting form for hospitals.
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
Toll-free telephone: 1-866-234-2345

Canada

* = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting)
** = required (hospital is exempt from mandatory reporting if this information is unavailable)
Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

A. General information

1. Type of report* ☐ Initial ☐ Follow-up	2. Health Canada reference no. (for follow-up reports only)	
3. Organization file no.	4. Date report submitted	5. Documentation date*

6. a. Organization contact first name* b. Last name*	7.a. Phone no.* ext. b. Email c. Fax

8. Organization name*

9. Source of report (profession)	10. Health Canada institutional ID (If ID provided, no need to provide address)		
11. Address	12. City	13.Province / Territory	14. Postal code

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

☐ (a) Death (yyyy-mm-dd) _____ ☐ (b) Life-threatening ☐ (c) Disability ☐ (d) Congenital malformation
☐ (e) Caused/prolonged in-patient hospitalization ☐ (f) Required medical intervention to avoid any of (a) to (e)

B. Patient information

1. Patient ID (e.g. initials, record no.)	2. Sex**	3. Age**	4. Height	5. Weight
			cm or ft in	kg or lbs oz

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

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

C. Serious adverse drug reaction(s)

1. Did the patient recover?* (please choose one of the following)	2. Reaction start date*	3. Reaction end date*
☐ Recovered ☐ Recovering ☐ Not recovered ☐ Died ☐ Unknown ☐ Recovered with sequelae		

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

D. Suspect product one

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*	2. Identifying code for urgent public health need drugs**
3. Brand name** (per product label)	4. Common/proper name** (active ingredient)
5. Strength (per unit)	6. Dose

7. Frequency

8. Dosage form (e.g. tablet, powder, liquid)

9. Route of administration	10. Product start date*	11. Product end date*

12. Indication

13. Lot no.	14. Expiry date

15. a. Manufacturer name b. Did you also report to the manufacturer?* ☐ Yes ☐ No c. Date reported d. Reference no.* (if known)	16. What action was taken? 17. Did the reaction stop if dose was reduced or removed? ☐ Yes ☐ No ☐ Unknown ☐ N/A 18. Did the reaction return with reintroduction of the product? ☐ Yes ☐ No ☐ Unknown ☐ N/A

D. Suspect product two

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*	2. Identifying code for urgent public health need drugs**
3. Brand name** (per product label)	4. Common/proper name** (active ingredient)
5. Strength (per unit)	6. Dose

7. Frequency

8. Dosage form (e.g. tablet, powder, liquid)

9. Route of administration	10. Product start date*	11. Product end date*

12. Indication

13. Lot no.	14. Expiry date

15. a. Manufacturer name

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

c. Date reported

d. Reference no.* (if known)

16. What action was taken?

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

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

E. Concomitant therapeutic product(s)

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

F. Additional information

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

Instructions on completing the serious adverse drug reaction (ADR) reporting form for hospitals

A. General information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Patient information

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

B2. **Sex****: Enter the patient's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

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

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

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

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

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

C. Serious adverse drug reaction(s)

C1. **Recovery status***: Indicate the outcome of the serious ADR.

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

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

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

D. Suspect product(s)

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

Reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect product. The drug identification number (DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their brand name. Generic drugs can be uniquely identified by providing both the generic name and the manufacturer name. Please also include the lot number, if known.

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

D2. **Identifying code for urgent public health need drugs****: If the drug was imported as part of the access to drugs in exceptional circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

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

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

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

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

D8. **Dosage form**: Indicate the dosage form of the product (e.g. tablet, powder, liquid)

D9. **Route of administration**: Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D10. **Product start date***: Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D11. **Product end date***: Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D12. **Indication**: Enter the therapeutic reason for use.

D13. **Lot no.**: If known, indicate the lot number(s) of the suspect product.

D14. **Expiry date**: If known, indicate the expiry date.

D15. **Manufacturer details***: Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D16. **Action taken:** Indicate what action was taken with the product.

D17. **Reaction stopped if dose was reduced or removed:** Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D18. **Reaction returned with reintroduction:** Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

E. Concomitant therapeutic product(s)

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

F. Additional information

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

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