Health Canada Santé Canada

Mandatory Adverse Reaction Reporting Form for Industry

Report of suspected adverse reaction to marketed health products* in Canada

CANADA VIGILANCE PROGRAM

How to Submit the Form

Completed forms should be

faxed to: 613-957-0335

or

mailed to: Canada Vigilance Program
Marketed Health Products Directorate
Health Canada
Postal Locator 1908C
Ottawa, Ontario K1A 0K9

Submission of a report does not constitute an admission that medical personnel or the health product caused or contributed to the adverse reaction.

For further information on adverse reaction reporting by Market Authorization Holders (MAHs) and source establishments, please refer to:

- **Drugs and Natural Health Products**:
  Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products
  (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-industry-reporting-adverse-reactions-marketed-health-products-health-canada-2011.html).
- **Cells, Tissues and Organs**:
  Guidance Document for Source Establishments – Reporting Adverse Reactions to Human Cells, Tissues and Organs
  (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/reporting-adverse-reactions-human-cells-tissues-organs.html).

* *Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including biotechnology products, fractionated blood products, and vaccines), natural health products, radiopharmaceuticals or human cells, tissues or organs.*

A program of MedEffect™ Canada

HC Pub.: 091086 (April 2018)

Canada

INSTRUCTIONS ON COMPLETING THE MANDATORY ADVERSE REACTION REPORTING FORM FOR INDUSTRY

A. REPORTER INFORMATION

This section must be completed by the market authorization holder (MAH), or the source establishment (for cells, tissues and organs).

A1. Report Source: Indicate the source of the report (from where the information originated). For literature sources, provide the full literature citation in box C6. Check "Not Available to MAH/Unknown" if the initial reporter did not specify the report source. Select "Other" to indicate that the report source is known, but does not fit into one of the categories provided.

A2. Reporter Qualification: Indicate the type of reporter who initially reported the adverse reaction (AR) to the MAH or source establishment.

A3. Reporter Also Sent Report to the Canada Vigilance Program: Indicate whether the initial reporter also reported the AR to the Canada Vigilance Program.

A4. MAH/Source Establishment Contact Office: Enter the full name, civic address, and telephone and facsimile numbers of the MAH or source establishment. Include a contact name. For source establishments, include the establishment registration number.

A5. MAH/Source Establishment Report No.: Indicate the MAH's or source establishment's identification number for the case. For follow-up reports, the report number should be the same as the number assigned to the initial report.

A6. Type of Report:

- Initial: Report has not previously been submitted by the MAH or source establishment.
- Follow-up: Report is a follow-up to a previously submitted case.

A7. Date of Most Recent Information Received by MAH/Source Establishment: Indicate the date when the MAH or source establishment received the information for this report.

A8. Date of this Report: Indicate the date that this form was completed by the MAH or source establishment.

B. PATIENT INFORMATION

B1. Unique Identifier: Provide a patient identifier in order to readily locate the case for follow-up purposes. Do not use the patient's name or initials.

B2. Age at Time of Reaction: Provide the patient's age at the time of reaction.

B3. Sex: Enter the patient's gender.

B4. Height: Enter the patient's height, in centimetres (cm).

B5. Weight: Enter the patient's weight, in kilograms (kg).

C. ADVERSE REACTION

C1. Country in which Reaction Occurred: Indicate the country where the reaction took place.

C2. Date of Reaction: Provide the date of onset of the adverse reaction.

C3. Serious Report: Indicate if the report is serious.

C4. Criteria for Report Seriousness: Check all boxes that apply to the definition of a serious adverse reaction per the *Food and Drug Regulations* (C.R.C., c.870), the *Natural Health Products Regulations* (SOR/2003-196), and the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (SOR/2007-118).

- For Drugs and Natural Health Products, a serious adverse reaction is a noxious and unintended response to a drug or natural health product that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.
- For Cells, Tissues and Organs, a serious adverse reaction means an undesirable response in the recipient to transplanted cells, tissues or organs, including the transmission of a disease or disease agent, that results in any of the following consequences in the recipient: their in-patient hospitalization or its prolongation; persistent or significant disability or incapacity; medical, dental or surgical intervention to preclude a persistent or significant disability or incapacity; a life-threatening condition; and death.

C5. Outcome: Indicate the outcome of the adverse reaction.

C6. Describe the Reaction: Provide a full description of the reaction(s) (e.g., body site and severity) and all relevant clinical information (medical status prior to the event, reported signs and/or symptoms, differential diagnosis for the event in question, clinical course, etc.).

C7. Relevant Tests/Laboratory Data: Provide all appropriate information, including relevant negative tests and laboratory findings.

C8. Other Relevant History, Including Pre-existing Medical Conditions: If available, provide information on the patient's history (e.g., race, allergies, pregnancy history, smoking and alcohol use, drug abuse) and other conditions known in the patient.

D. HEALTH PRODUCT(S)

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

D1, D2 Suspected Health Product Name: For each suspected product, provide the product name, check the box that applies to the type of health product, and provide the additional information below.

- Drugs: Provide the Drug Identification Number (DIN) if available. Otherwise, list all active ingredients. Also provide the strength and dosage form.
- Natural Health Products: Provide the label (preferably), or provide the Natural Product Number (NPN) or the Homeopathic Medicine Number (DIN-HM) if available. Otherwise, list all medicinal ingredients. Also provide the strength and dosage form.
- Cells, Tissues and Organs: Also provide the donor identification code and the common name, followed by "cell", "tissue" or "organ" in parenthesis [e.g., Cornea (Tissue)].

D.i) Dose, Frequency & Route Used: Describe how the product was used by the patient. For cells, tissues and organs, this box is only applicable to cells.

D.ii) Therapy Dates:

- Drugs and Natural Health Products: Provide the dates of therapy (start and stop dates of administration). If no dates are known, an estimated duration is acceptable.
- Cells, Tissues and Organs: Provide the date of transplant.

D.iii) Indication for Use of Suspected Health Product:

- Drugs and Natural Health Products: Provide the indication for which the health product was prescribed or used in this particular patient.
- Cells, Tissues and Organs: Provide the diagnostic reason or indication for the implantation, transplantation or infusion.

D.iv) Reaction Abated After Discontinuation or Dose Reduced:

- Drugs and Natural Health Products: Indicate if the adverse reaction abated after the suspected health product was discontinued, or the dose was reduced.
- Cells, Tissues and Organs: Check "Does not apply".

D.v) Reaction Reappeared after Reintroduction:

- Drugs and Natural Health Products: Indicate if the adverse reaction reappeared after the suspected health product was reintroduced.
- Cells, Tissues and Organs: Check "Does not apply".

D.vi) Lot #: If known, indicate the lot number(s) of the suspected health product.

D.vii) Expiry Date: If known, indicate the expiry date. For cells, tissues and organs, provide the date of expiration on the label, if any.

D3. Concomitant Health Products: List and provide therapy dates for any other health products (drugs, biologics, including cells, tissues and organs, radiopharmaceuticals, natural health products, etc.) that the patient was using at the time of the event. Do not include health products used to treat the event.

D4. Treatment of the Adverse Reaction: Describe the treatment of the adverse reaction, including other health products and/or therapies.

Health Canada / Santé Canada

Mandatory Adverse Reaction Reporting Form for Industry

CANADA VIGILANCE PROGRAM

PROTECTED B (when completed)**

Page ___ of ___

Mandatory fields are indicated by a *

A. REPORTER INFORMATION

(Must be completed by the Market Authorization Holder (MAH) or the Source Establishment)

1. Report Source*

◯ Spontaneous ◯ Study
◯ Not available to MAH/Unknown ◯ Other (specify): _____

2. Reporter Qualification

◯ Physician ◯ Lawyer
◯ Pharmacist ◯ Consumer
◯ Other health professional (specialization): _____ ◯ Other (specify): _____

3. Reporter Also Sent Report to the Canada Vigilance Program?*

◯ Yes ◯ No ◯ Unknown

4. MAH/Source Establishment Contact Office*

5. MAH/Source Establishment Report No.

6. Type of Report*

◯ Initial ◯ Follow-up: _____

7. Date of Most Recent Information Received by MAH/Source Establishment*

(YYYY-MM-DD)

8. Date of this Report

(YYYY-MM-DD)

B. PATIENT INFORMATION

1. Unique Identifier

2. Age at Time of Reaction

_____ ◯ Years ◯ Months ◯ Other (specify:)_____

3. Sex

◯ Male ◯ Female ◯ Unknown

4. Height

_____ cm

5. Weight

_____ kg

Privacy Notice Statement: For the purposes of the Canada Vigilance Adverse Reaction Monitoring Program, information related to the identity of the patient and/or reporter will be protected as personal information under the Privacy Act, including in cases of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; PIB# PPU 088 at: https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a25

C. ADVERSE REACTION

1. Country in which Reaction Occurred:*

2. Date of Reaction (YYYY-MM-DD)

3. Serious Report:* ☐ Yes ☐ No

4. Criteria for Report Seriousness (check all that apply)

☐ Death _____ (YYYY-MM-DD) ☐ Life-threatening
☐ Caused/Prolonged hospitalization ☐ Disabling/Incapacitating
☐ Congenital anomaly/Birth defect
☐ Other medically important condition (specify): _____

5. Outcome:*

◯ Recovered ◯ Not Recovered ◯ Recovering
◯ Fatal ◯ Recovered with Sequelae ◯ Unknown

6. Describe the Reaction* (If more space is required, attach additional sheets.)

7. Relevant Tests/Laboratory Data (including dates) (YYYY-MM-DD)

8. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction)

** *As per the Treasury Board of Canada Secretariat Government Security Policy*

A program of MedEffect™ Canada

HC Pub.: 091086 (April 2018)

Canada

D. HEALTH PRODUCT(S)

If more than two health products are suspected, attach additional sheets.

1. Suspected Health Product Name*

Provide name, strength and dosage form, and check the circle that applies.

- ◯ Drug – provide the DIN if available, otherwise list active ingredient(s)
- ◯ Natural Health Product – provide the label, NPN or DIN-HM if available, otherwise list medicinal ingredients
- ◯ Cells, Tissues and Organs – also provide the donor identification code and the common name followed by "cell", "tissue" or "organ" in parenthesis [e.g., Cornea (Tissue)]

i) Dose, Frequency & Route Used

ii) Therapy Dates (if unknown, give duration) _____

From _____ (YYYY-MM-DD) to _____ (YYYY-MM-DD)

iii) Indication for Use of Suspected Health Product

iv) Reaction Abated After Discontinuation or Dose Reduced

◯ Yes ◯ No ◯ Does not apply

v) Reaction Reappeared After Reintroduction

◯ Yes ◯ No ◯ Does not apply

vi) Lot # (if known)

vii) Expiry Date (if known)

2. Suspected Health Product Name

Provide name, strength and dosage form, and check the circle that applies.

- ◯ Drug – provide the DIN if available, otherwise list active ingredient(s)
- ◯ Natural Health Product – provide the label, NPN or DIN-HM if available, otherwise list medicinal ingredients
- ◯ Cells, Tissues and Organs – also provide the donor identification code and the common name followed by "cell", "tissue" or "organ" in parenthesis [e.g., Cornea (Tissue)]

i) Dose, Frequency & Route Used

ii) Therapy Dates (if unknown, give duration) _____

From _____ (YYYY-MM-DD) to _____ (YYYY-MM-DD)

iii) Indication for Use of Suspected Health Product

iv) Reaction Abated After Discontinuation or Dose Reduced

◯ Yes ◯ No ◯ Does not apply

v) Reaction Reappeared After Reintroduction

◯ Yes ◯ No ◯ Does not apply

vi) Lot # (if known)

vii) Expiry Date (if known)

3. Concomitant Health Products (exclude treatment of reaction)

Name	**Dose, Frequency & Route Used**	**Therapy Dates** (yyyy-mm-dd)

4. Treatment of Adverse Reaction (health products and/or other therapy)