Health Canada Santé Canada

# Canada Vigilance Adverse Reaction Reporting Form

Report of suspected adverse reactions to marketed health products in Canada

See instructions and information on adverse reaction reporting and confidentiality on Page 2.

Complete all mandatory items, marked by a *, and provide as much information as possible for the remaining items. PROTECTED WHEN COMPLETED – B**

## A. Patient Information

**1. Identifier**

| 2. Age | 3. Sex* | 4. Height | 5. Weight |
|---|---|---|---|
| ☐ Years | ☐ Male | _____ cm | _____ kg |
| _____ ☐ Months | ☐ Female | _____ feet | _____ lbs |

## B. Adverse Reaction

**1. Outcome attributed to adverse reaction** (Select all that apply)

- ☐ Death: (yyyy-mm-dd)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization – prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/impairment
- ☐ Other:

**2. Reaction date** (yyyy-mm-dd)

**3. Report date** (yyyy-mm-dd)

**4. Describe reaction or problem***

**5. Relevant tests/laboratory data** (including dates (yyyy-mm-dd))

**6. Relevant history and pre-existing medical conditions** (e.g. allergies, pregnancy, smoking/alcohol use, hepatic/renal dysfunction)

## C. Suspected Health Product(s)

**1. Name*, strength and manufacturer** (if known)

#1

#2

**2. Dose, frequency and route used**

| #1 | #2 |
|---|---|
| | |

**3. Therapy dates** (or duration)

| #1 From (yyyy-mm-dd) - To (yyyy-mm-dd) | #2 From (yyyy-mm-dd) - To (yyyy-mm-dd) |
|---|---|
| | |

**4. Indication for use**

| #1 | #2 |
|---|---|
| | |

**5. Reaction abated after use stopped or dose reduced**

| #1 | #2 |
|---|---|
| ☐Yes ☐No ☐Does not apply | ☐Yes ☐No ☐Does not apply |

| 6. Lot # | 7. Expiration |
|---|---|
| #1 | #1 (yyyy-mm-dd) |
| #2 | #2 (yyyy-mm-dd) |

**8. Reaction reappeared after reintroduction**

| #1 | #2 |
|---|---|
| ☐Yes ☐No ☐Does not apply | ☐Yes ☐No ☐Does not apply |

**9. Concomitant health products, excluding treatment of reaction** (name, dose, frequency, route used and therapy dates (yyyy-mm-dd))

**10. Treatment of reaction, including dates** (yyyy-mm-dd)

## D. Reporter Information

**1. Name*, occupation, address, telephone number***

| 2. Health professional? | 3. Reported to manufacturer? |
|---|---|
| ☐Yes ☐No | ☐Yes ☐No |

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

## Instructions to Complete the Canada Vigilance Adverse Reaction Reporting Form

- Use this form only to report adverse reactions to Canadian marketed health products, including prescription and non-prescription medications; natural health products; biologically derived products such as vaccines and fractionated blood products; cells, tissues and organs; radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.
- All sections of the form should be filled in as completely as possible. Use a separate form for each patient. Up to two suspected health products for a particular adverse reaction may be reported on one form. Attach an additional form if there are more than two suspected health products for the adverse reaction being reported. Additional pages may be attached if more space is required.
- For the "Identifier" box, provide some type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information; do not use the patient's name. See the Confidentiality disclaimer at the bottom of this page.
- Any follow-up information for an adverse reaction that has already been reported can be submitted using a new form, indicating that it consists of follow-up information, including, if known, the date of the original report and the Adverse Reaction Number provided in the acknowledgement letter.
- **Reports can be faxed** to 1-866-678-6789 (toll-free) **or mailed** to: Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Postal Locator 0701E, Ottawa, Ontario K1A 0K9. Postage paid labels are available at www.health.gc.ca/medeffect or by calling 1-866-234-2345 (toll-free). Do not send reports by e-mail.

## Information on Adverse Reaction Reporting

### What is an adverse reaction?

An adverse reaction is a harmful and unintended response to a health product. This includes any undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.

A serious adverse reaction is one 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. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

### Which adverse reactions should be reported?

All suspected adverse reactions should be reported, especially those that are:

- *unexpected*, regardless of their severity, i.e., not consistent with product information or labelling; or
- *serious*, whether expected or not; or
- reactions to *recently marketed health products* (on the market for less than five years), regardless of their nature or severity.

### Alternative ways to report

You can also report side effects to health products to the Canada Vigilance Program:

- By calling 1-866-234-2345 (toll-free)
- Online: www.health.gc.ca/medeffect

The Canada Vigilance Adverse Reaction Reporting Form is also available online at www.health.gc.ca/medeffect or at the back of the *Compendium of Pharmaceuticals and Specialties* (CPS).

### Other Information

- Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the adverse reaction.
- Adverse reaction reports are, for the most part, only suspected associations. A temporal or possible association is sufficient for a report to be made. Reporting of an adverse reaction does not imply a definitive causal link.
- Health professionals and consumers may also report adverse reactions to the market authorization holder (MAH). Indicate on your adverse reaction report sent to Health Canada if a case was also reported to the product's MAH.

**For additional information, contact a Canada Vigilance Regional Office by telephone at 1-866-234-2345 (toll-free) or:**

**Canada Vigilance Regional Office – British Columbia and Yukon**
400-4595 Canada Way, Burnaby, BC V5G 1J9
CanadaVigilance_BC@hc-sc.gc.ca

**Canada Vigilance Regional Office – Alberta and Northwest Territories**
Suite 730, 9700 Jasper Ave, Edmonton, AB T5J 4C3
CanadaVigilance_AB@hc-sc.gc.ca

**Canada Vigilance Regional Office – Saskatchewan**
101 - 22nd Street East, Saskatoon, SK S7K 0E1
CanadaVigilance_SK@hc-sc.gc.ca

**Canada Vigilance Regional Office – Manitoba**
510 Lagimodière Blvd, Winnipeg, MB R2J 3Y1
CanadaVigilance_MB@hc-sc.gc.ca

**Canada Vigilance Regional Office – Ontario and Nunavut**
2301 Midland Ave, Toronto, ON M1P 4R7
CanadaVigilance_ON@hc-sc.gc.ca

**Canada Vigilance Regional Office – Québec**
Suite 202-40, East Tower
200 René-Lévesque Blvd. West, Montréal, QC H2Z 1X4
CanadaVigilance_QC@hc-sc.gc.ca

**For New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador:**

**Canada Vigilance Regional Office – Atlantic**
Suite 1625, 1505 Barrington St., Halifax, NS B3J 3Y6
CanadaVigilance_ATL@hc-sc.gc.ca

### Confidentiality

Personal information collected, used or disclosed under the Canada Vigilance Program is confidential and protected. For the purposes of the Canada Vigilance Program, information related to the identity of a patient and/or reporter of the adverse reaction will be protected as personal information under the Privacy Act, and under the Access to Information Act, in the case of an access to information request. Provision of the information requested on this form is voluntary. Information from adverse reaction reports is maintained in a computerized database and used for the monitoring of marketed health products, which may contribute to the detection of potential product-related safety issues, as well as to the benefit-risk assessments of these products. For details about personal information collected under this program, visit the Government of Canada web site on Institution-Specific Personal Information Banks under Health Canada, Health Products and Food Branch, Branch Incident Reporting System, PIB # ppu 088 at: http://infosource.gc.ca/inst/shc/fed07-eng.asp (Health Products and Food Branch, Branch Incident Reporting System).