SIDE EFFECT REPORTING FORM

Reporting suspected side effects (also known as adverse reactions) to marketed health products in Canada may contribute to the identification of previously unrecognized rare or serious side effects, which may lead to changes in the product's safety information.

Instructions on how to complete and submit this form and information about confidentiality can be found on Page 2. Complete all mandatory fields, marked by a *, and provide as much detail as possible for the remaining fields.

FAX completed form to 1-866-678-6789
For more information call 1-866-234-2345

PROTECTED "B" WHEN COMPLETED**

A) About the person who had the side effect

Reference # (if applicable)

1. Age*	2. Sex*	3. Height	4. Weight
_____ Years _____ Months	☐ Male ☐ Female	_____ cm _____ ft _____ in	_____ kg _____ lbs _____ oz

5. Medical history and other related information (allergies, pregnancy, smoking/alcohol use, liver disease, etc.)

B) Reporter information

1. Name*	2. Telephone*	3. Province/Territory

4. Address

5. E-mail

6. Preferred language

☐ English
☐ French

7. Organization (if applicable)

8. Select one that best describes you

☐ Consumer or other non-health professional ☐ Physician ☐ Pharmacist

☐ Other health professional (specify) _____

9. Has this also been reported to the manufacturer?

☐ Yes ☐ No

C) Side Effect

1. Seriousness of the side effect

☐ Death (yyyy-mm-dd) _____
☐ Life-threatening
☐ Admitted to hospital
☐ Lengthened hospital stay
☐ Disability
☐ Birth defect
☐ Needed medical attention

2. Recovered after the side effect*

☐ Yes ☐ No ☐ Unknown

☐ Recovering (explain) _____

3. Side effect start date* (yyyy-mm-dd)

4. Side effect end date (yyyy-mm-dd)

5. Describe the side effect (timeliness, treatment, etc.)*

D) Suspected health product

1. Product name*	2. Strength	3. Manufacturer

4. Lot #	5. DIN #/NPN #

6. Country of purchase

☐ Canada
☐ United States
☐ Other (specify): _____

7. Where it was purchased/obtained

☐ Pharmacy
☐ Grocery store
☐ Internet
☐ Other (specify): _____

8. Product start date (yyyy-mm-dd)*	9. Product end date (yyyy-mm-dd)

At the time of the side effect, specify:

10. Dosage* (strength and quantity)	11. Frequency (e.g. twice daily)	12. How the product was taken* (e.g. by mouth)

13. What was the product prescribed/taken for?*

14. Did use of the product stop after the side effect appeared?

☐ Yes
☐ No

15. If the product was stopped did the side effect stop?

☐ Yes
☐ No
☐ Does not apply

16. Was the product restarted after the side effect stopped?

☐ Yes
☐ No
☐ Does not apply

17. If the product was restarted, did the side effect return?

☐ Yes
☐ No
☐ Does not apply

18. Likelihood that the product caused the side effect

☐ Certain
☐ Probably/Likely
☐ Possible
☐ Not available/Unable to assess
☐ Unlikely
☐ Unrelated

19. Other health products taken at the time of the side effect, excluding treatment (length of use, timelines, etc.)

20. Related test/laboratory results

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

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How to complete the Side Effect Reporting Form

- All sections of the form should be filled in as completely as possible. Use a separate form for each patient. Attach an additional form if there is more than one suspected health product. Additional pages may be attached if more space is required. Please provide the product label where possible.
- Follow-up information for a side effect 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 report number provided in the acknowledgement.

What is a side effect?

A side effect (also known as adverse reaction) is a harmful and unintended response to a health product. Health products include prescription and non-prescription medications; natural health products; biologics (includes biotechnology products, vaccines, fractionated blood products, human blood and blood components, as well as human cells, tissues and organs) radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims. This includes any undesirable patient effect suspected to be associated with health product use. An 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 side effects.

What is considered a serious side effect?

A serious side effect 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. Side effects that result in significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

What types of side effects should be reported?

All suspected side effects should be reported, especially those that are:

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

How to submit your completed form	Other ways to report a side effect
Fax: 1-866-678-6789 **Mail:** Canada Vigilance Program Marketed Health Products Directorate Health Canada Address locator 0701E Ottawa ON K1A 0K9	**Online:** www.health.gc.ca/medeffect **Telephone:** 1-866-234-2345 ***Do not send reports by e-mail.*** *Health Canada is not able to ensure secure transfer of information by e-mail.*

Other information

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

For more information about side effect reporting, call Health Canada at 1-866-234-2345 or contact a regional office directly:	
British Columbia CanadaVigilance_BC@hc-sc.gc.ca **Alberta, Northwest Territories and Yukon** CanadaVigilance_AB@hc-sc.gc.ca **Saskatchewan and Nunavut** CanadaVigilance_SK@hc-sc.gc.ca **Manitoba** CanadaVigilance_MB@hc-sc.gc.ca	**Ontario** CanadaVigilance_ON@hc-sc.gc.ca **Québec** CanadaVigilance_QC@hc-sc.gc.ca **New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador** CanadaVigilance_ATL@hc-sc.gc.ca

Confidentiality

In the context of Health Canada's side effect reporting program (the Canada Vigilance Program), personal information is collected pursuant to section 4 of the *Department of Health Act*, for the purpose of monitoring licensed products, detecting potential emerging safety issues and trends, mitigating the risks and improving the safe use and efficacy of the health products. Information related to the identity of the patient and/or reporter will be protected as personal information under the *Privacy Act*, and in the case of an access to information request, under the *Access to Information Act*. Suspected health product side effect-related information that is voluntarily submitted to Health Canada is maintained in a secure computerized database. The program endeavours to use and disclose only de-identified information but may use and disclose personal information that is not de-identified as permitted under the *Privacy Act*. For further details regarding the 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: **www.hc-sc.gc.ca/ahc-asc/activit/atip-aiprp/infosource/index-eng.php#a2**. Every Canadian individual has the right to access their own personal information and is entitled to request correction to ensure accuracy of their information. If you wish to exercise this right, contact the Treasury Board of Canada Secretariat (**www.tbs-sct.gc.ca/tbsf-fsct/350-58-eng.ASP**).