Health Canada Santé Canada

Adverse Reaction Reporting and Health Product Safety Information

Guide for Health Professionals

MedEffect™ Canada

Together we can improve health product safety

Canada

Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Published by authority of the
Minister of Health.

Adverse Reaction Reporting and Health Product Safety Information - Guide for Health Professionals is available on the Internet at the following address:
http://www.healthcanada.gc.ca/medeffect

This publication can be made available on request on diskette, large print, audio-cassette and braille.

HC Pub.: 4619
Cat.: H14-28/2008
ISBN: 978-0-662-05641-6

About MedEffect™ Canada

MedEffect™ Canada provides a simple and efficient means for health professionals to report an adverse reaction to the Canada Vigilance Program[1]. It also serves as a centralized point to access the latest health product safety information such as advisories, warnings and recalls.

Adverse reaction reports make a difference— ***take time to report!***

[1] The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada.

What is an adverse reaction?

Adverse reactions are noxious and unintended effects to health products. Health products include both prescription and non-prescription medications; natural health products; biologically derived products such as therapeutic or diagnostic vaccines and fractionated blood products; cells, tissues and organs; radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.

Reactions may occur under normal use conditions of the product. Reactions may be evident within minutes or years after exposure to the product and may range from minor reactions like a skin rash to serious and life-threatening events such as a heart attack or liver damage.

What to report?

You do not have to be certain that a health product caused the reaction in order to report it. Adverse reaction reports are, for the most part, only *suspected associations*.

Health Canada wants to know about *all* suspected adverse reactions, but especially if they are:

- unexpected (not consistent with product information or labelling) regardless of their severity;
- serious, whether expected or not; or
- related to a health product that has been on the market less than 5 years.

If in doubt, report!

Please do not hesitate to report *any suspected adverse reaction of clinical concern*, even if you are unable to supply all the details.

Adverse reaction reports require four information items in order to be properly assessed by the Canada Vigilance Program.

The minimum items needed are:

1. **patient information –** for reasons of confidentiality the patient name should not be used
2. **description of the reaction** the patient experienced
3. **name of the health product** you suspect caused the adverse reaction
4. **contact information** in case Health Canada requires additional information

Other useful information includes: patient characteristics (age, gender, height and weight); therapy dates (date the adverse reaction occurred and resolved if applicable; and date the health product was started and stopped); relevant tests/lab data; and concomitant health products.

When to report?

As soon as possible! **You should report an adverse reaction soon after the reaction occurred, even if you are not certain that a particular health product was the cause.**

Why report?

Every time you report an adverse reaction to Health Canada, you contribute to improving the safety of drugs and other health products used by Canadians. That's the impact you have when you report an adverse reaction through MedEffect™ Canada.

All marketed health products have benefits and risks. Although health products are carefully tested before they are licensed for sale in Canada, some adverse reactions may become evident only after a product is in use by the general population.

When you submit a suspected adverse reaction report, you contribute to the ongoing collection of information that occurs once health products are on the market.

Your report may contribute to:

- the identification of previously unrecognized rare, or serious adverse reactions;
- changes in product safety information, or other regulatory actions such as the withdrawal of a product from the Canadian market;
- international data regarding benefits, risks or effectiveness of drugs and health products; and
- increasing the safety of health products, which benefits all Canadians.

What are the benefits of reporting?

Adverse reaction reports are assessed to detect potential health product safety signals. A signal is considered to be the preliminary indication of a product-related issue. Signals must be carefully

evaluated in order to confirm or to disprove the potential association between the health product and the adverse reaction.

Patients, health professionals, manufacturers and health product regulatory authorities work together to monitor adverse reactions. Voluntary reporting by health professionals and consumers of suspected reactions is the most common way to monitor the safety and effectiveness of marketed health products. These individual reports may be the only source of information concerning previously undetected adverse reactions or changes in product safety and effectiveness profiles to marketed health products.

Some adverse reactions may take a long time to develop or occur infrequently. In addition, the controlled conditions under which patients use health products in clinical trials (e.g. under direct medical supervision without significant exposure to other products and/or underlying diseases) do not necessarily reflect the way the product will be used in real life conditions once it is marketed.

Information about the identity of the patient and the health care provider is kept confidential, as per the *Privacy Act*. Disclosure of data is only done in accordance with the provisions of the *Access to Information Act*.

How to submit a report?

There are three easy ways to report an adverse reaction to the Canada Vigilance Program:

- **By calling toll-free** at **1-866-234-2345**
- **Online at www.healthcanada.gc.ca/medeffect**
- **By completing a form** which you can send by:
  - **postage paid mail** or
  - **fax toll-free to 1-866-678-6789**

  The form and postage paid label are available at **www.healthcanada.gc.ca/medeffect** or by calling **1-866-234-2345**

The adverse reaction reporting form is also available at the back of the *Compendium of Pharmaceuticals and Specialties (CPS)*.

New safety information about health products

New or emerging information about the safety and effectiveness of marketed health products is accessible via the MedEffect™ Canada Web site. This information helps health professionals and consumers to make informed decisions concerning the appropriate use of marketed health products.

Advisories, warnings and recalls inform and educate health professionals and consumers about new health risks associated with the use of certain marketed health products.

The **Canadian Adverse Reaction Newsletter** (CARN) raises awareness and provides facts and safety information about marketed health products and reported adverse reactions that are suspected to be associated with specific health products. Topics discuss health products and specific adverse reactions. CARN is also distributed to physicians and pharmacists across Canada.

MedEffect™ e-Notice is a free email service that informs subscribers about health product advisories, warnings and recalls. Through MedEffect™ e-Notice, subscribers also receive the Canadian Adverse Reaction Newsletter.

Definition

A **serious adverse reaction** is defined in general terms as one which requires 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 outcomes are also considered to be serious.

Notes: