Adverse Reaction Reporting by Health Professionals and Consumers

Why report?

All marketed health products have benefits and risks. Although health products are carefully tested for safety and efficacy before they are licensed, some adverse reactions* may not become evident until the general population uses a health product under "real life" circumstances. By submitting a suspected adverse reaction report, you are contributing to the ongoing collection of safety and effectiveness information that occurs once health products are marketed.

Reported adverse reaction information **may contribute** to:

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

What to report?

Health Canada, through the Canadian Adverse Drug Reaction Monitoring Program, is responsible for collecting and assessing adverse reaction reports for the following health products marketed in Canada: pharmaceuticals, biologics (including fractionated blood products as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals.

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.

We want to know about all suspected adverse reactions, **but especially if they are**:

- **unexpected** adverse reactions, regardless of their severity (not consistent with product information or labelling);
- **serious** adverse reactions**, whether expected or not;
- adverse reactions **related to recently marketed** health products (on the market for less than 5 years).

When to report?

As soon as possible!

How to report?

Complete the adverse reaction reporting form which can be obtained:

- at **www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html;**
- by contacting your Regional Adverse Reaction Centre:
  Toll-free phone: 1-866-234-2345
  Toll-free fax: 1-866-678-6789
- in the CPS (Compendium of Pharmaceuticals and Specialties) publication.

Submit the report:

By toll-free fax: 1-866-678-6789
By toll-free phone: 1-866-234-2345
(calls are automatically directed to the National or a Regional Adverse Reaction Centre)

Keep Informed:

By subscribing to Health Canada's **MedEffect e-Notice** mailing list. You will automatically receive the most recent Canadian Adverse Reaction Newsletter and health product advisories free by e-mail. Go to **www.hc-sc.gc.ca/dhp-mps/medeff/subscribe-abonnement/index_e.html**.

* adverse reaction = side effect
** A serious adverse reaction is one which 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 outcomes are also considered to be serious.

Catalogue No.: H44-69/2004E-PDF
ISBN: 0-662-37052-X
Publication Number:4629

Health Canada Santé Canada

Canada