



Risk Communication: Protecting Canadians through Information

Communicating about risk is a key component of any risk management plan. At Health Canada, communicating risks about health products* involves developing and disseminating the most current information on potential or known health risks, to aid health professionals and patients in making better informed treatment decisions. Risk communications are not intended as medical advice.

A shared responsibility

In Canada, many different organizations and individuals play a role in communicating risks associated with health products, including:

- The manufacturer, or "Market Authorization Holder," which has a primary responsibility to monitor the continued safe use of its products and communicate new information on the safety of a product in an effective and timely manner.
- Health Canada, which is responsible for authorizing health products for sale in the Canadian market, as well as coordinating and monitoring the continued safety of health products on the market and communicating safety information.

- Provincial licensing authorities, which set the standards of practice for health professionals and provide a trusted source of safety information for members.
- Health professionals (physicians, pharmacists, nurses, naturopaths, etc.), who prescribe, dispense, and provide information about treatment to their patients, and look for and report adverse reactions.
- Patients, who, with guidance from their health professionals and other resources, can make informed decisions about treatment while watching for and reporting any adverse reactions they may have.

Health Canada considers many factors in the evaluation of an emerging health product safety concern (e.g., availability and reliability of data, seriousness of the event) and the urgency of the communication. The lead in issuing a risk communication may be Health Canada and/or the Market Authorization Holder. A risk communication may be targeted to various audiences, including the general public and/or health professionals and hospitals.

Lead for Issuance of Risk Communication Products

Health Canada

- Public Advisory
- Health Canada-issued Health Professional Communication: 'Dear Health Care Professional' Letter
- Health Canada-issued Health Professional Communication: 'Notice to Hospitals'
- Information Update
- Foreign Product Alert
- *Canadian Adverse Reaction Newsletter*
- *It's Your Health* Publication
- Fact Sheets and Backgrounders

Market Authorization Holders (i.e. Industry)

- Industry-issued Health Professional Communication: 'Dear Health Care Professional' Letter
- Industry-issued Health Professional Communication: 'Notice to Hospitals'
- Public Communication
- Health Product Recall Notice (refers to a Type I or Type II health hazard)

[Note: Type I health hazard refers to risk of serious adverse health consequences or death. Type II health hazard refers to risk of temporary adverse health consequences or remote risk of serious adverse effects.]

* Health products include prescription and non-prescription medications, biologics (including biotechnology products, fractionated blood products and vaccines), natural health products, medical devices, and radiopharmaceuticals.

The chart below outlines the urgency level of each communication product disseminated by Health Canada and/or industry for public and professional audiences.

Urgency of Communication and Target Audience

		TARGET AUDIENCE	
		HEALTH PROFESSIONALS AND HOSPITALS	PUBLIC
URGENCY OF COMMUNICATION	HIGH	Health Product Recall Notice (refers to a Type I health hazard)	Health Product Recall Notice (refers to a Type I health hazard) Health Canada Public Advisory
	MEDIUM	Health Professional Communication: 'Dear Health Care Professional' Letter Health Professional Communication: 'Notice to Hospitals' Health Product Recall Notice (refers to a Type II health hazard)	Industry-issued Public Communication Health Product Recall Notice (refers to a Type II health hazard) Health Canada Information Update Health Canada Foreign Product Alert
	LOW	<i>Canadian Adverse Reaction Newsletter</i>	<i>It's Your Health</i> Fact Sheets and Backgrounders

A collaborative approach

Industry has a responsibility for timely and effective communication regarding the safe use of its products. Health Canada works closely with industry early in the risk communication development process to provide a consistent approach to communicating the most accurate, relevant and complete safety information.

In addition to working with provincial and territorial ministries and organizations, Health Canada engages with health professionals, their associations, academia, industry members, and consumer and patient groups to enhance the collection and communication of information on health product benefits and risks.

Information on how to report an adverse reaction is available at

www.health.gc.ca/medeffect

Getting the word out

Different audiences have different preferences in how they receive health product risk information. Therefore, each of Health Canada's risk communications has a specific dissemination strategy. Dissemination methods depend on the targeted audience and may include:

- Posting on the Health Canada and MedEffect™ Canada Web sites;
- Electronic distribution via the *MedEffect™ e-Notice* mailing list and MedEffect™ Canada RSS Feeds;
- Targeted distribution to the health care community, including professional associations, health and consumer groups and other stakeholders to encourage further dissemination;
- Fax-outs and mail-outs to health professionals and hospitals; and
- Distribution to traditional news media and using social media tools such as Twitter.

To provide health product risk information to Canadians as quickly as possible, Health Canada posts risk communications on the MedEffect™ Canada Web site at www.health.gc.ca/medeffect. This central hub of health product safety information offers the most comprehensive coverage and access to both Health Canada-issued and industry-issued risk communication products.

More information about these and other risk communication products can be found in Health Canada's Guidance Document: **Description of Current Risk Communication Documents for Marketed Health Products for Human Use.**