MedEffect™ Canada Initiative — The Public Interface to Post-Market Surveillance Programs and Information

The MedEffect™ Canada Initiative was created in August 2005 to improve access to new safety information and adverse reaction reporting as well as to provide a single window approach to post-market surveillance activities and programs related to health products marketed in Canada. These products include prescription and non-prescription medications, biologics (including fractionated blood products and vaccines), natural health products, cells, tissues and organs, and radiopharmaceuticals.

Centralized, Simple, Visible and Collaborative

The MedEffect™ Canada Initiative brings together under one umbrella all communication and promotion activities for post-market surveillance that target or engage health professionals and consumers/patients.

The objectives of the MedEffect™ Canada Initiative are to:

- provide centralized access to new safety information about marketed health products in an easy-to-find, easy-to-remember location via the MedEffect™ Canada Web site;
- address the requirement to make it as simple and efficient as possible for consumers, patients and health professionals to report adverse reactions;
- increase awareness about the importance of reporting adverse reactions in the identification of potential risks associated with certain drugs or health products through advertising, presentations and participation in conferences and trade shows; and
- identify the needs of target audiences for post-market surveillance activities, by utilizing advisory committees and consultations on post-market surveillance guidance and regulations.

Public-focused Activities Undertaken through a Single Gateway

The MedEffect™ Canada Initiative is key to the involvement of the public in supporting an effective post-market surveillance program. The program involves the following process:

- collection and monitoring of adverse reaction and medication incident data;
- review and analysis of marketed health product safety data;
- undertaking benefit and risk assessments of marketed health products;
- communicating product-related risks to health professionals and the public;
- overseeing regulatory advertising activities;
- developing and implementing policies to effectively regulate marketed health products; and
- actively monitoring health product safety and therapeutic effectiveness.

Together We Can Improve Health ProductSafety

Post-market surveillance relies heavily on collaboration with external third parties and the pooling of data. These, in turn, depend upon Health Canada's solid stakeholder relations and strategic partnerships, as well as its capacity to communicate effectively to its target audiences.

MedEffect™ Canada helps maximize the safety of health products in the Canadian market by reaching out to key public audiences – consumers/patients, health professionals and industry by:

- **building awareness** about the importance of reporting adverse reactions and undertaking reporting;
- **facilitating access** to a centralized network (Web site, online tools, printed material, etc.) to stay informed on the latest health product safety information, obtain important safety notifications and report adverse reactions;
- **making access easier for Market Authorization Holders (manufacturers and distributors)** to guidance and consultative documents, legislation and Acts.

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The initiative works continuously to improve its accountability, communications and outreach activities, as well as stakeholder relations and public confidence, by:

- providing audience-friendly, clear and consistent messaging;
- seamlessly integrating its use of multiple mediums and platforms to deliver products, services and activities; and
- adapting new technologies and approaches to reflect changes in the ways target audiences choose to obtain information and communicate with government.

A Comprehensive Network of Programs, Services and Products

Under its umbrella, the MedEffect™ Canada Initiative offers consumers, health professionals and industry a variety of programs, services and products. The MedEffect™ Canada Web site provides a centralized access point for many elements of the post-market surveillance program.

1. The **Canada Vigilance Program**, which is responsible for collecting and assessing adverse reaction reports from the public, health professionals and industry.
2. **Advisories & Recalls** that give Canadians timely new safety information on health products as it becomes available.
3. The **Canada Vigilance Adverse Reaction Online Database** which permits Canadians to view adverse reaction reports submitted to Health Canada.
4. The ***Canadian Adverse Reaction Newsletter (CARN)***, featuring articles and data related to serious or unexpected adverse reactions that are suspected of being associated with marketed health products in Canada.
5. **MedEffect™ e-Notice**, an e-mail-based notification system the gives subscribers the latest health product alerts, which includes the Canadian Adverse Reaction Newsletter.
6. **MedEffect™ Canada RSS Feed** subscriptions to obtain links to new and updated information available online from MedEffect™ Canada.
7. **Online learning centre** of educational tools to simplify the process of adverse reaction reporting for health professionals, consumers and patients.
8. The **Expert Advisory Committee on the Vigilance of Health Products (EAC-VHP)**, a component of the post-market surveillance program, represents patients and consumers, health and industry sectors, researchers and academics and provides broad strategic policy advice on the safety and therapeutic effectiveness of marketed health products.
9. **Consultations** to gather varied input that will shape decisions about the safety, effectiveness and access to marketed health products available to Canadians.
10. **Regulatory guidelines**, such as mandatory adverse reaction reporting by industry, and associated guidance documents to help the industry familiarize itself with regulatory requirements.
11. **Reports and other publications** related to reporting adverse reactions, obtaining new safety information on marketed health products, and other information related to risk communications.