Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Planning for Our Future:

Highlights of the Federal Regulatory Post-Market Surveillance Strategy 2007-2012

Canada

Health Canada is the federal department responsible for helping the people of Canada 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.

Également disponible en français sous le titre *Planifier l'avenir : Points saillants de la Stratégie de réglementation fédérale pour la surveillance après la mise en marché 2007-2012*

This document is available on the Internet at the following addresses:
www.healthcanada.gc.ca/medeffect or
www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index_e.html

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Print: HC Pub: 1440
Cat#: H164-59/2007-1
ISBN: 978-0-662-05237

PDF: Cat#: H164-59/2007-1E-PDF
ISBN: 978-0-662-47232-2

Your Health and Safety…Our Priority

As Canada's federal authority responsible for regulating health products and food, the **Health Products and Food Branch** (HPFB) evaluates and monitors the safety, quality and effectiveness of the thousands of human and veterinary drugs, vaccines, medical devices, natural health products and other therapeutic products available to Canadians, as well as the safety and quality of their foods.

HPFB's role doesn't end when products are authorized for sale. Equally important in protecting the health of Canadians is the monitoring of the safety and quality of health products after they enter the marketplace. "Post-market surveillance," as this monitoring is known, is essential to detecting and addressing safety issues and ensuring that a balance is maintained between the health benefits and the risks posed by all health products (excluding foods). Within HPFB, post-market surveillance is the responsibility of the **Marketed Health Products Directorate** (MHPD) since its creation in 2002.

The Role of Post-Market Surveillance

With more than 22,000 pharmaceutical products, 42,000 natural health products and 50,000 medical devices on the market, MHPD's creation in 2002 was driven by:

- The need for independent monitoring of health product safety—a distinct function from the pre-market approval process;
- Patients wanting to take more responsibility for their health product decisions;
- The need for more rigorous monitoring of marketed health products as a result of regulatory developments, increased international standardization and cooperation, advances in access to information, and public expectations; and
- The increased potential for adverse reactions and interactions among drugs, health products and food products.

Working collaboratively with other HPFB directorates, MHPD coordinates the monitoring of health products on the market for prompt action when safety risks are identified. It investigates the link between adverse reactions and health products, and determines cause-and-effect relationships. Taking the risk tolerance of Canadians into account in its risk management decisions, it then takes appropriate action, ranging from informing the public and health care professionals of new product safety information, to recommending labelling changes or removal of a product from the market altogether.

MHPD also regulates the advertising of health products in Canada, and works closely with various self-attesting pre-clearance agencies.

Toward a Stronger Post-Market Surveillance Program

MHPD's Vision

MHPD's vision is to lead a post-market surveillance program that is at the forefront of regulatory science, promotes the safety and effectiveness of health products, and is recognized for its contributions to the health and safety of Canadians.

MHPD works collaboratively with many stakeholders who, together, endeavour to provide the best health care possible. In addition to Health Canada and provincial and territorial governments, these stakeholders include health care professionals, patient groups and consumers, the academic and research community, industry, foreign regulators, the general public, various associations and the Canadian Agency for Drugs and Technologies in Health.

To ensure meaningful stakeholder involvement, MHPD is setting up a new communication channel with the formation of the Expert Advisory Committee on the Vigilance of Health Products. Management will soon be able to consult regularly with the EAC-VHP for ongoing external advice and integrated public input.

Strategic Themes

A key success factor for improved surveillance and more effective risk management is a stronger scientific capacity for MHPD. This capacity is a critical element of its forward-looking agenda, which focuses on three strategic themes. An overview follows of principal projects that are planned for the next five years.

- Partnering—sharing information and work;
- Being proactive—working toward sustainable post-market surveillance; and
- Reaching out—strengthening HPFB's role as a credible, efficient and timely source of post-market safety information via the web and point-of-care.

Key Partnering Projects

Partnering projects focus on building and maintaining solid stakeholder relationships that capitalize on information, knowledge, and the work of other organizations in Canada and around the world.

- Enhance existing information sources
  - Now being implemented, a new monitoring system is augmenting MHPD's ability to assess adverse reaction data about marketed pharmaceuticals and biologics, vaccines and natural health products.
- Develop new sources of information
  Because the success of post-market surveillance depends on the quantity and quality of health product information, MHPD is investigating the use of new sources of information such as:
  - Data on the therapeutic effectiveness of health products;
  - Medication incident information;
  - Adverse reaction data collected in other countries;
  - Periodic safety update reports submitted by industry;
  - Plans submitted by industry when market approval is requested, which outline what it will do to identify and monitor safety risks once its health products are on the market; and
  - Health product and drug use data.
- Set up international collaboration agreements for work sharing with other regulatory agencies
- Establish an Expert Advisory Committee on the Vigilance of Health Products
  - For ongoing external advice from health care professionals, patients, academia, industry and others, and
  - For a channel through which the public can more easily voice its opinions.

Key Proactive Surveillance Projects

Proactive surveillance projects will enable MHPD to focus on early, preventive actions that make the most of limited resources. A strengthened method of prioritizing safety issues—according to level of risk to health associated with particular health products or issues—will be investigated.

- Establish new regulatory authorities to increase the responsibility of industry in the monitoring of marketed health product safety;
- Define a plan for managing a potential pandemic or other emergency; and
- Make management of post-market surveillance more transparent and understandable by sharing methodologies, programs, and their results with all stakeholders.

Key Outreach Projects

HPFB has planned a number of outreach projects to enhance its visibility and efficiency, as well as the engagement of its stakeholders.

- Develop mechanisms to encourage the participation of stakeholders in post-market surveillance activities;
- Expand educational and promotional programs for health professionals and the public to increase adverse reaction reporting;
- More effectively promote the safe use of marketed health products through improved communication with health professionals and the public about risks; and
- Promote the use of MedEffect Canada, Health Canada's web-based product safety/adverse reaction information centre for marketed health products.

Looking Ahead

Our primary goal is to better protect the health and safety of Canadians. By **partnering, being proactive** and **reaching out**, MHPD is addressing new challenges to the health and safety of Canadians and keeping pace in a rapidly changing environment.

As MHPD's post-market surveillance strategy is implemented, stakeholders can expect:

- To be consulted prior to the finalization of key post-market surveillance policies, regulatory changes, strategies and guidance documents;
- To be informed in a timely manner after safety risks have been identified, and decisions made, along with the rationale for the decisions;
- To have access to post-market surveillance strategic and business plans, as well as annual reports of activities; and
- To be able to communicate their questions and concerns to MHPD more easily.

In brief, the evolving post-market surveillance program will be characterized by:

- A more cost-effective, efficient, proactive and transparent system that is based on sound risk assessment and prioritization; and a surveillance program that follows a product through its entire life cycle;
- Better informed and engaged health professionals and public;
- Stronger regulations; and
- Greater public confidence in MHPD's post-market surveillance contribution to the health care system.

For updates on how we're doing, and to learn how you can help make health products safer and more effective, please visit the MedEffect Canada website at **www.healthcanada.gc.ca/medeffect**

Be sure to check our website this fall for the first-ever report on our activities. It will be a fact- and photo-filled retrospective of how far we've come in our first five years, as well as a sneak preview of early accomplishments in our strategy for the next five.

Together we can improve health product safety!