Working Together for a Better Post-Market Surveillance Program

The success of a well-managed post-market surveillance program relies on working with various stakeholders, both internal and external. Internal stakeholders of the Marketed Health Products Directorate (MHPD) include other directorates within the Health Products and Food Branch (HPFB) and from other branches of Health Canada. MHPD's external stakeholders are illustrated in the diagram below.

Post-market Surveillance Stakeholders

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MedEffect™ Canada
Together we can improve health product safety
MedEffet℠ Canada
Ensemble nous pouvons améliorer l'innocuité des produits de santé
Canada

Strategic Alliances

MHPD is one of many contributors sharing responsibility for the health and safety of Canadians. It works nationally with provinces, territories, health care providers, and consumer and patient groups, forming strategic relationships that help strengthen current post-market surveillance. Through committees, advisory boards, and working groups, MHPD strengthens its network and improves information sharing and collaboration.

To leverage an interconnected and global environment, MHPD works with international partners to share information, implement collaborative initiatives, and develop international standards through forums such as the Global Harmonization Task Force.

Health Professionals and Consumers

A cornerstone of adverse reaction (AR) reporting in Canada is the Canada Vigilance Program's voluntary reporting of ARs by consumers, patients, caregivers, and health practitioners such as physicians, pharmacists, nurses, naturopaths, and dentists.

The Canada Vigilance Program collects and assesses reports of suspected adverse reactions to health products marketed in Canada.

MHPD helps health professionals and consumers stay informed of new health product risks by providing them timely new health risk information.

Provincial/Territorial Governments

Provincial/territorial governments also play a role in building a comprehensive post-market surveillance system for Canada by collecting information on product utilization and, in some cases, outcomes of therapeutic treatments.

Industry

Industry plays an important role in providing consumers with information about their marketed health products. |Companies are required to submit serious adverse reaction reports to the Canada Vigilance Program when they become aware of an adverse reaction to a product. Mandatory reporting requirements for manufacturers of health products, which are known as Market Authorization Holders, are outlined in the *Canada Food and Drug Act and Regulations* and the *Natural Health Products Regulations*.

The reporting of medical device problems is also an essential element of the post-market surveillance system. While only manufacturers are required by the *Medical Devices Regulations* to report problems, Health Canada encourages anyone purchasing, using, or maintaining medical devices to report problems. The same is true for reporting adverse reactions to marketed health products.

Advertising Preclearance Agencies

MHPD is responsible for regulatory oversight of the advertising of marketed health products in Canada. It works closely with advertising pre-clearance agencies such as the Pharmaceutical Advertising Advisory Board, Advertising Standards Canada, and the Broadcast Clearance Advisory to make sure that advertising material that is disseminated to Canadians is in compliance with the applicable regulatory provisions.