Canada Vigilance Program—Collecting and Assessing Adverse Reaction Reports

The Canada Vigilance Program collects and assesses reports of suspected adverse reactions to marketed health products in Canada, including prescription and non-prescription medications; natural health products; biologically derived products such as vaccines and fractionated blood products; cells, tissues and organs; radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.

Adverse reaction reports are submitted voluntarily to Health Canada by Canadian health professionals and consumers. Market Authorization Holders (manufacturers and distributors) and source establishments are required to report adverse reactions as mandated by the *Food and Drugs Regulations*, the *Natural Health Product Regulations* and the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*. This information is one of the tools that enables Health Canada to monitor the safety profile of health products to determine if their benefits continue to outweigh their risks.

Health Canada has collected reports of suspected adverse reactions since 1965 and currently receives adverse reaction reports daily, including new reports and additional information for reports previously submitted.

Health professionals and consumers can report suspected adverse reactions online, by phone or by submitting a reporting form by fax or by mail.

Central to the Program, the **Canada Vigilance Database** improves Health Canada's capacity to analyse safety data and detect potential safety signals for marketed health products.

National Reach

Seven regional offices support the Canada Vigilance Program, providing local points of contact for health professionals and consumers. Adverse reaction reports are collected regionally and forwarded to the National Office for further analysis. Market Authorization Holders send reports directly to the National Office.

Detecting Signals from Adverse Reaction Reports

Adverse reaction reports are analysed for potential health product safety signals. A signal is considered the first indication of a product-related issue. A signal is not proof that an adverse reaction is a direct result from use of a certain health product; rather it triggers the need to further investigate to confirm or disprove the association between the product and the adverse reaction.

Signals may be detected through periodic analysis of the information contained in the Canada Vigilance Database. Systematic targeted monitoring strategies and statistical tools are used for the monitoring of health products. Health Canada uses the Database's statistical tools as well as those developed by the World Health Organization.

Processing and Managing Data

Each adverse reaction report relates to a single patient; however, more than one reaction may have been described and coded within a single report. Information is coded by key words, using reaction terms described in the report.

The **Initial Data Entry** of an adverse reaction report involves the registration and scanning of the report into the Canada Vigilance Database.

The **Screening** stage is a triage process for determining whether a report requires priority attention or re-direction to an adverse reaction reporting program for products outside the scope of the Canada Vigilance Program.

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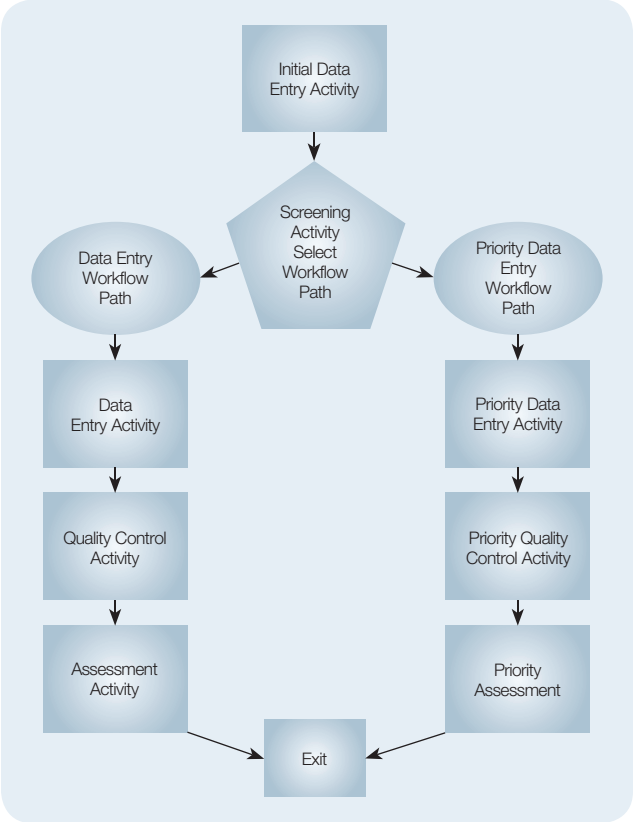
The subsequent **Data Entry** stage involves the detailed allocation of product therapy and patient information for both standard and priority entries.

The **Quality Control** stage corresponds to quality assurance processes for data entry and monitoring for consistent application of data entry procedures.

The **Assessment** stage involves the coding of reactions, indications and patient history, using the Medical Dictionary for Regulatory Activities (MedDRA), the internationally recognized, standardized dictionary of medical terminology. A review process then follows to assess seriousness and outcome, which may lead to further monitoring for potential signals.

Managing Adverse Reaction Reports



Adverse Reaction Report Data

The Canada Vigilance Database stores the following information for each reported adverse reaction:

- patient characteristics;
- nature of the adverse reaction;
- suspected health product;
- other health products taken at the same time;
- medical history and laboratory data;
- treatment of the adverse reaction;
- patient outcome; and
- information about the reporter.

All information related to patient and reporter identifiers is kept strictly confidential in accordance with the *Privacy Act*.

Public Access

Consumers, health professionals, Market Authorization Holders, and the general public can view the types of adverse reactions that have been reported to Health Canada via the **Canada Vigilance Adverse Reaction Online Database**, which contains over 225,000 suspected adverse reaction reports that have occurred in Canada since 1965. The Database is updated quarterly to reflect new information received by Health Canada.

Information contained in the Canada Vigilance Adverse Reaction Online Database uses generic terminology that excludes any identifiers relating to the patient and/or reporter.

Features of the Canada Vigilance Adverse Reaction Online Database include:

- search capacity by brand name, active ingredient name, adverse reaction term or system organ class;
- help documentation and background information; and
- capacity to print/save/export search results.