The Post-Market Surveillance Continuum—Maximizing Safety, Minimizing Risk

Post-market surveillance is an integrated set of activities for the monitoring, assessment (evaluation), and risk management of marketed health products. It is also a continuation of the regulated health product review process initiated in the pre-approval areas of the product development process.

The goals of post-market surveillance include:

- identifying, as early as possible, potential safety and effectiveness issues;
- refining and adding to information on suspected or known reactions and interactions between drugs; and
- communicating new safety information to health professionals and the public in order to improve therapeutic practice.

A positive benefit/risk balance is maintained by the continuous function of information gathering, monitoring and processing, signal detection and assessment, and risk management and intervention. Specific steps involved with these processes are described below.

Information Gathering, Monitoring and Processing

- Adverse reaction reports are received and assessed by Health Canada.
- Data is entered into a computer system using terminology from the Medical Dictionary for Regulatory Activities (MedDRA).
- Additional information is gathered from literature scans, other regulatory agencies, the World Health Organization, and health product manufacturers.
- New risks are detected with increased use of products in the marketplace.

Signal Detection and Assessment

- Many information sources may be combined to identify a signal—a preliminary indication of a product-related safety issue. Assessment consists of the scientific/medical review of multiple data sources to analyse risks and benefits, while determining the likelihood of the association between the reaction and the health product.

Risk Management and Intervention

- After risks have been identified, a risk management approach is defined that may include interventions such as communicating risk information to health care professionals and the public, labelling changes, regulatory advertising interventions or recommending the removal of a product from the market.
- Interventions are communicated broadly in the interests of transparency and facilitation of informed choices.

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