## Questions and Answers - Sentinel Event Communication and Reporting

### What is the Canada Vigilance Program?

- The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products including marketed blood products (plasma derivatives) and blood components that are used in Canada.
- Manufacturers and blood establishments are required to report adverse reactions to Health Canada as mandated by the *Food and Drug Regulations and Blood Regulations.*
    - There is a fifteen (15) day requirement for reporting serious and serious unexpected adverse reactions to blood products and blood components and a twenty-four (24) hour requirement for reporting fatalities associated with blood components.
- Canadian health professionals and consumers submit adverse reaction reports to blood products on a volunteer basis to Health Canada.

### What is the MedEffect™ Canada Initiative?

- The MedEffect™ Canada Initiative is Health Canada's public interface for post-market surveillance programs, services and information that includes:
    - The Canada Vigilance Program;
    - Advisories and Recalls;
    - The Canada Vigilance Adverse Reaction Online Database;
    - The Health Product InfoWatch publication;
    - e-Notices for Alerts;
    - Online Learning Centre;
    - The Expert Advisory Committee on the Vigilance of Health Products;
    - Consultations, Regulatory Guidelines and Reports/Publications.

### How does the Canada Vigilance Program collaborate with the Transfusion Transmitted Injury Surveillance System (TTISS)?

- The public health surveillance complements rather than replaces the regulatory pharmacovigilance program. There is information sharing between Health Canada's regulated product vigilance system and Public Health Agency of Canada's (PHAC) TTISS.
    - Under the new TTISS reporting algorithm, serious adverse reactions to blood products should be reported by health professionals to the manufacturer only. Some health professionals copy Health Canada as well. There is considerable variation in the TTISS reporting algorithm among jurisdictions with some jurisdictions reporting all adverse reactions (serious and non-serious).

### Are there any gaps in the current adverse event reporting systems?

- There are a number of gaps in the current adverse event reporting systems as noted in an editorial in the *Canadian Medical Association Journal* in May, 2015:
    - Current lack of documentation of adverse drug reactions by healthcare providers;
    - Current adverse reaction reporting systems are not widely used by clinicians;
    - It is estimated that less than 5% of all adverse reactions are reported by healthcare professionals;
    - Recommend reporting of adverse reactions must be improved, simplified and support clinical decisions at the point of care;
    - Recommend the reporting IT infrastructure is seamless and integrated with electronic medical record systems (EMRs) in Canada.

**What is Intravenous Immune Globulin (IVIG)?**

- IVIG is a biological product licensed for use by Health Canada.
- It is a fractionated blood product consisting primarily of concentrated immunoglobulin G derived from human plasma pools of 3,000 to 10,000-plus donors.

**Is IVIG safe to use?**

- Although IVIG products are considered as safe, it is important to be aware that the controlled clinical studies that support the licensure process have been of moderate size and have power to define the incidence of only the most common adverse reactions.
- There are risks and benefits associated with IVIG utilization.

**What are adverse reactions?**

- Adverse reactions are noxious and unintended responses to health products.
- Reactions may occur under normal use conditions of the product. Reactions may be evident within minutes or years after exposure to the product and range from minor reactions such as a skin rash to life-threatening events such as a heart attack or liver damage.

**What is a serious adverse drug reaction?**

- An unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of hospitalization, causes congenital malformations, results in persistent or significant disability, is life-threatening or results in death.

**What is a serious unexpected adverse reaction?**

- A serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out in the label of the drug.

**Are there product-specific differences in the rate of adverse reactions?**

- Yes, there are reports on product-specific differences in the rates of serious adverse reactions such as IVIG-associated hemolysis.

**Why is it important to report serious and serious unexpected adverse reactions?**

- Reporting an adverse reaction contributes to the following:
    - Identification of previously unrecognized rare or serious adverse reactions;
    - Changes in product safety information;
    - Regulatory actions such as withdrawal of a product from the market;
    - International data on the benefits and risks of health products;
    - Increasing the safety profiles of health products;
    - Risk-benefit evaluations of licensed products.

**What are Health Canada's future considerations for adverse reaction reporting systems?**

- The Health Product Vigilance Framework is an overarching model that captures Canada's current product vigilance system and conceptually describes the future integrated product vigilance system that is continuing to be developed over the next two years.
- There will be a step-wise introduction of new vigilance tools with a focus on clinical outcomes and will begin with higher-risk pharmaceuticals and biologic products.

- The new product vigilance system will shift emphasis from passive to more proactive, lifecycle approach to regulating all health products.
- The future regulatory system will transition from a point-in-time approach (e.g. licensing decisions that are supported by clinical trials prior to marketing) to a product lifecycle approach where what is known about the benefit-risk of a product is assessed and applied throughout the lifecycle starting at the clinical trial stage and continuing after market authorization.
- The future system includes the *Protecting Canadians from Unsafe Drugs Act* (*Vanessa's Law*) that amends the *Food and Drugs Act* and strengthens the regulation of health products and makes mandatory the reporting of serious adverse reactions by healthcare institutions (pending new regulations). The amendments apply to IVIG.
- The benefit-risk of a licensed product could be re-evaluated when a safety signal arises, after which the conditions of licensure could be changed, suspended or revoked by the federal Minister of Health.

Sources of Information:


1. Canada Vigilance Program- Collecting and Assessing Adverse Reaction Reports, website, Health Canada.
2. MedEffect™ Canada Initiative-The Public Interface to Post-Market Surveillance Programs and Information, website, Health Canada.
3. MedEffect™ Canada-Canada Vigilance Adverse Reaction Online Database, website, Health Canada.
4. Health Product Vigilance Framework, website, Health Canada.
5. Consultation: Draft Guidance Document for Developing a Post-Market Benefit-Risk Assessment, website, Health Canada.
6. Adverse Reaction Reporting and Health Product Safety Information, Guide for Health Professionals, website, Health Canada.
7. Guidelines on the Use of Intravenous Immune Globulin for Hematologic Conditions, Anderson et. al., Transfusion Medicine Reviews, vol 21, no. 2, Suppl 1, pp S9-S56, April, 2007.
8. Risks Associated with the Use of Intravenous Immunoglobulin, Pierce and Jain, Transfusion Medicine Reviews, 17:241-251, 2003.
9. Better documentation of adverse drug reactions needed for new Bill C-17 to improve drug safety, C. Hohl, Commentary, *Canadian Medical Association Journal*, May, 2015.