Key Messages- Sentinel Event Communication and Reporting

Purpose- The purpose of the key messages is to assist and encourage health care professionals in meeting the adverse reaction reporting requirements for blood and blood products to Health Canada.

- Currently, there are dual mechanisms for reporting adverse reactions:
  - The Canada Vigilance Adverse Reaction Database- This database is part of Canada's regulatory pharmacovigilance system. Reporting of adverse reactions is mandated by federal legislation and subject to regulatory actions by Health Canada.
    - **Required by Law:** Mandatory reporting of serious and/or serious unexpected adverse reactions to blood products (plasma derivatives) by the manufacturer and to blood components by the blood establishments within fifteen (15) days, and within twenty-four (24) hours for fatalities associated with blood components (*Food and Drug Regulations* and *Blood Regulations*).
    - **Encouraged/Desired:** Voluntary reporting of adverse reactions to blood products by health professionals and consumers to Health Canada.
  - Public Health Surveillance- Transfusion Transmitted Injury Surveillance System (TTISS)
    - **Encouraged/Desired:** Voluntary reporting of serious, moderate, and selected minor transfusion-related adverse reactions by hospitals. TTISS is retrospective, not real-time and provides annual trending and reports.
- The rate of adverse reactions to IVIG infusion is reported to be in the range of 3% to 15%. A significant number are serious affecting renal, cardiovascular, central nervous system, integumentary and hematologic systems. The risk and severity factors in adverse reactions include the patient age, co-morbidity, history (migraine, cardiovascular or renal), dose, concentration, rate of infusion, proprietary formulation and lot(s).
- The minimum reporting information for serious and serious unexpected adverse reactions include:
  - Case Identifiers (personal health information legislative considerations);
  - Description of the adverse reaction experienced, including treatment and outcome;
  - Name and lot number of the blood product or blood component suspected to cause the adverse reaction;
  - MAH/ Provider's contact information in case Health Canada needs further information.
- The adverse reaction reporting mechanisms to the Canada Vigilance Program include:
  - By completing a form which you can send preferably by fax (1-866-678-6789)
  - The adverse reaction form is available online at www.health.gc.ca/medeffect and at the back of the *Compendium of Pharmaceuticals and Specialties* (CPS).
  - By calling toll free at 1-866-234-2345
  - In addition, the Transfusion Medicine stakeholders can send a heads-up email to: MHPD.Blood@hc-sc.gc.ca about lot-associated issues, particularly potential clusters of serious and non-serious reactions.
- Safety signals can be identified by Health Canada using the Canada Vigilance Adverse Reaction Database. A signal is the first sign of a product-related adverse reaction triggering the need for further investigation.
  - Some adverse reactions may become evident only after a product is in use by the general population over time.