Questions and Answers Briefing - Bill C-17: Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

What is Vanessa's Law?

- Vanessa's Law amends the *Food and Drugs Act* to improve Health Canada's ability to:
  - Collect post-market safety information;
  - Take action when a serious risk to health is identified.

What do the amendments apply to?

- The amendments to the *Food and Drugs Act* apply to:
  - A drug (including blood products and blood components) and medical device or a combination thereof.

When will the amendments be effective?

- Some of the new powers are effective as of the date of Royal Assent on November 6, 2014. Other changes to the *Food and Drugs Act* cannot come into force until supporting regulations are published, which is ongoing.

Under Vanessa's Law, who will be required to report adverse reactions?

- Healthcare institutions will be mandated to report serious adverse reactions to the Canada Vigilance Program. Regulations are in progress. Note: The Blood Regulations already mandate blood establishments, including hospitals, to report to the Canada Vigilance Program.
  - Increased reporting by healthcare institutions will improve the quality and quantity of adverse event reporting.
  - Reporting by healthcare institutions will provide further evidence for Health Canada to assess the level of risk to patients, issue risk communications to the public and health professionals, and enact further action such as label changes, product reassessment, further testing and recalls.

What are the implications of these future reporting requirements for health care professionals?

- It is anticipated that *Vanessa's Law* will require extra effort from health care professionals to conduct additional reporting of adverse reactions to comply with the provincial and federal reporting requirements.

What are the key elements of the amendments to the *Food and Drugs Act*?

- Mandatory reporting of serious adverse reactions by healthcare institutions;
- Power to require manufacturers to compile information, conduct new tests and monitor experience for the purpose of reassessing the benefits and harms associated with licensed health products;
- Power to require a manufacturer to revise the label of a health product to include new safety information or to change the brand name or packaging to prevent injury to health;
- Power to order a withdrawal (recall) of a health product from the market when the products poses a serious risk to health;
- Tougher measures for those who do not comply with the Act or regulations;
  - Increases fines to a maximum of $5 million per day or two years in prison;
  - Statutory injunction power so a court can order a person to refrain from performing an offense under the Act;

- Ability to incorporate by reference technical and non-technical documents (e.g. technical standards, lists, guidelines, etc) relating to health products and does not require regulatory amendment.

What new regulations are in progress?

- The new legislation will be accompanied by supporting regulations that will include:
    - Ability to amend the terms and conditions on a market authorization or license;
    - Ability to require manufacturers to publicly report safety information from a clinical trial;
    - Ability to make regulations regarding what, how and by who adverse drug reactions and medical device incidents will be reported to Health Canada.
- There will be new transparency authorities related to clinical trial registration, regulatory decisions and disclosure of confidential business information.
    - Obligation of Market Authorization Holders (e.g. manufacturers) to make public any clinical trial information in a timely manner including adverse reactions. Regulations are in progress.
    - Obligation on the Minister to make orders for label changes, recalls, further testing and reassessment publicly available; Positive and negative regulatory decisions on issuance, reassessment, suspension and recall to be publicly available.
    - New authority to disclose confidential business information about a health product if the Minister believes it is necessary to determine whether a health product poses a serious risk to human health.

Will there be a user-friendly reference for these amendments?

- Health Canada is developing a Guide for the implementation of new authorities under Vanessa's Law.

What is the position of the Canadian Medical Association on these changes to reporting adverse events?

- A review on the new legislation was published in an editorial entitled 'Better Documentation of Adverse Drug Reactions Needed for New Bill C-17 to Improve Drug Safety' in the *Canadian Medical Association Journal* in May, 2015. Highlights of the article included:
    - There is a 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;
    - The authors recommend reporting of adverse reactions must be improved, simplified and support clinical decisions at the point of care;
    - Vanessa's Law can strengthen Canada's drug safety environment but only if implementation of reporting infrastructure is seamless and integrated with electronic medical record systems (EMRs) in Canada.

<u>Sources of Information</u>:

1. Amendments to Food and Drugs Act: Overview of Vanessa's Law, Webinar, Government of Canada, May, 2015.
2. Protecting Canadians from Unsafe Drugs Act (Vanessa's law) Amendments to the Food and Drugs Act (Bill C-17), Legislation and Guidelines, Questions/Answers, Overview of Vanessa's Law, Implementation of Vanessa's Law, Health Canada, website.
3. 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.