SafeMedicationUse.ca
SUPPORTED BY HEALTH CANADA

BROUGHT TO YOU BY ismp CANADA

A COMPONENT OF THE CMIRPS Canadian Medication Incident Reporting and Prevention System SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

SafeMedicationUse.ca Newsletter

Volume 10 • Issue 8 • August 21, 2019

Protecting Canadians from Unsafe Drugs Act
What It Means for You

The *Protecting Canadians from Unsafe Drugs Act* is also known as Vanessa's Law. Vanessa's Law regulations will require hospitals to report serious adverse drug reactions and medical device incidents to Health Canada. This mandatory reporting will give Health Canada more information about the safety of drugs and medical devices.

Serious adverse drug reactions are harms from a drug that are severe enough to result in hospital admission, birth defects, long-lasting disability or incapacity, a life-threatening medical situation, or death.

Medical device incidents are problems with any type of medical product or equipment (such as infusion pumps, blood glucose meters, pacemakers, and breast implants) that led to or could have led to a serious health concern.

Educational materials have been developed to support mandatory reporting of serious adverse drug reactions and medical device incidents.

Who was Vanessa?

- Vanessa Young died at the age of 15, in 2000. She experienced a cardiac problem after taking cisapride (Prepulsid®) as prescribed.
- A campaign for increased regulation of drugs and devices was created.
- **Vanessa's Law** was enacted in 2014 and the mandatory reporting requirements come into effect December 16th, 2019.

Patients for Patient Safety Canada has developed a customized presentation for patients and families. The above image shows an example slide from this presentation.

Canadians will benefit from Vanessa's Law in many ways. Health Canada will be better able to:

- require manufacturers to make changes to health product labelling or packaging to make safety information more available to everyone;
- take action when a serious risk to health is identified (for example, by removing unsafe drugs and medical devices from the Canadian market); and
- improve product safety for all Canadians.

SafeMedicationUse.ca has the following tips for consumers:

- For each of your medications, ask your health care provider what side effects you should watch for. This information can help you notice health changes that might be due to your medication. Use the 5 Questions to Ask to start a conversation with your health care provider.
- For each medical device that you use, ask your health care provider what potential concerns you should watch for.
- When you go to a hospital, talk to a health care provider about your medications and medical devices. Having a complete list of your medications and devices can help health care providers to identify if an adverse drug reaction or medical device incident may have occurred.
- You can report adverse drug reactions to the Canada Vigilance Program. You can report medical device incidents to Health Canada by completing a Health Product Complaint Form. You can also ask your health care provider to report the reaction or incident.

Resource Links

- Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): Questions/Answers (https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/questions-answers-regarding-law-protecting-canadians-unsafe-drugs-act-vanessa-law.html)
- Educational Support for Mandatory Reporting of Serious ADRs and MDIs by Hospitals (https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx)
- Patients for Patient Safety Canada: Customized Presentation (https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/Public-Vanessas-Law.aspx)
- 5 Questions to Ask about Your Medications (https://safemedicationuse.ca/tools_resources/5questions.html)
- Canada Vigilance Program to Report an Adverse Drug Reaction (https://hpr-rps.hres.ca/static/content/form-formule.php?lang=en)
- Health Product Complaint Form to Report a Medical Device Incident (http://health.canada.ca/en/health-canada/services/drugs-health-products/compliance- enforcement/problem-reporting/health-product-complaint-form-0317.html)

Medication safety bulletins contribute to Global Patient Safety Alerts.

This newsletter was developed in collaboration with Best Medicines Coalition and Patients for Patient Safety Canada.

Recommendations are shared with healthcare providers, through the ISMP Canada Safety Bulletin, so that changes can be made together.

This newsletter shares information about safe medication practices, is noncommercial, and is therefore exempt from Canadian anti-spam legislation.