Vanessa's Law
Fact sheet

Vanessa's Law

- Vanessa's Law is the Protecting Canadians from Unsafe Drugs Act, which received royal assent in 2014.
- Vanessa's Law introduces amendments to the Food and Drugs Act that give Health Canada the power to require mandatory reporting of serious adverse drug reactions (ADRs) and medical device incidents (MDIs), order recalls, impose tougher penalties for unsafe products, and compel drug companies to revise labels or do further testing on products.
- The intention of Vanessa's Law is to improve the quality and increase the quantity of serious ADR and MDI reports to Health Canada in order to optimize detection of health product safety issues and allow Health Canada to act quickly in the interest of public safety.
- Mandatory reporting requirements became effective December 16, 2019.

Mandatory Reporting of serious ADRs and MDIs

- Hospitals are required to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada within 30 days of the event being documented within the hospital.
- A serious ADR is defined as a noxious, unintended response to a drug at any dose that:
    - required inpatient hospitalization or prolongation of existing hospitalization
    - caused congenital malformation
    - resulted in persistent or significant disability or incapacity
    - was life-threatening or resulted in death
    - led to other important medical events (use professional judgement)
- An MDI is defined as an incident related to the failure of a medical device, deterioration in its effectiveness, or inadequacy in its labeling or directions that led to the death or serious deterioration in health of a patient, user, or other person OR could do so were it to recur.

Reporting ADRs and MDIs in PSLS

- BC Patient Safety Learning System (BCPSLS) has had ADR reporting through to Health Canada in place since 2014 and has long facilitated MDI identification.
- When an ADR or MDI is reported in PSLS, Central Office staff will ensure the report is reviewed, de-identified, and submitted to Health Canada within the 30-day deadline.
- To report an ADR, access PSLS and select the ADR report form from the PSLS landing page.
- To report an MDI, access PSLS and select the MDI report form from the PSLS landing page OR select the appropriate patient safety event report form (e.g. Fall, Medication, Hazard) and choose "Yes" for the question "Was equipment involved?", then enter details about the device and how you suspect it contributed to the incident.

For more information

- Complete the *Vanessa's Law: Advancing Mandatory Reporting* eLearning module on LearningHub (provincial) or iLearn (Interior Health).
- Visit www.bcpslscentral.ca/vanessas-law for more information and downloadable resources.
- Review the Mandatory Reporting Guidance Document.
- Contact Health Canada's BC coordinator for mandatory reporting: thanh.vu@canada.ca.
- Contact your health authority PSLS Coordinator.
- Contact BCPSLS Central Office at bcpslscentral@phsa.ca.

Vanessa's Law
Frequently Asked Questions (FAQs)

What is Vanessa's Law?

Vanessa's Law is the Protecting Canadians from Unsafe Drugs Act, which received royal assent in 2014. Vanessa's law introduces amendments to the Food and Drugs Act that give Health Canada more power to protect Canadians from unsafe products. These amendments include the requirement for hospitals to report all serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada within 30 days of the event being documented within the hospital.

What does Vanessa's Law enable Health Canada to enforce?

In addition to mandatory reporting of serious adverse drug reactions (ADRs) and medical device incidents (MDIs), Vanessa's Law empowers Health Canada to order recalls, impose tougher penalties for unsafe products, and compel drug companies to revise labels or do further testing on products.

Why is it called "Vanessa's Law"?

The law is named after Vanessa Young, who died of cardiac arrhythmia at the age of fifteen after being prescribed Prepulsid (cisapride) for a stomach disorder. At that time, the United States Food & Drug Administration (US FDA) had advised against prescribing the medication to patients that had conditions similar to Vanessa's and Health Canada was in the process of reviewing the drug but had few adverse reaction reports compared with the US FDA. After Vanessa died, a campaign for increased regulation of therapeutic products led to greater powers for Health Canada to request safety data about drugs and medical devices from hospitals and industry.

When did mandatory reporting come into effect?

Mandatory reporting requirements have been effective since December 16, 2019.

Why is Health Canada requiring reporting of serious adverse drug reactions (ADRs) and medical device incidents (MDIs)?

Mandatory reporting is intended to improve the quality and increase the quantity of serious ADRs and MDIs reported to Health Canada in order to optimize detection of health product safety issues. Many ADRs and MDIs are only detected after market approval. The more reports Health Canada receives, the more information it will have to identify emerging safety issues and act quickly in the interest of public health and safety.

Who do mandatory reporting regulations apply to?

The regulations mandate **hospitals** to report. Targeting hospitals is anticipated to capture serious adverse drug reactions (ADRs) and medical device incidents (MDIs) that occur in other settings, such as long-term care facilities, resulting in patient transfers to hospital and emergency room visits. Hospitals rely on health care professionals to report, including physicians and other prescribers, nurses, technicians, and pharmacists.

Should I report ADRs and MDIs to Health Canada or PSLS?

In BC, serious adverse drug reactions (ADRs) and medical device incidents (MDIs) should be reported in PSLS. This will ensure that reports are reviewed and investigated locally in addition to being forwarded to Health Canada by BCPSLS Central Office within the 30-day deadline. PSLS has long facilitated MDI identification and ADR reporting through to Health Canada has been in place since 2014. Reporting in PSLS means that you don't have to report twice.

What happens to my report after it's submitted in PSLS?

BCPSLS Central Office staff will review your report, de-identify it if needed, and forward it to Health Canada within the 30-day deadline. Central Office staff may contact you for more information or to share any relevant information about the safety of the drug or device.

Who should report ADRs and MDIs in PSLS?

All health care professionals should report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) in PSLS, including physicians and other prescribers, nurses, technicians, and pharmacists. If you are the first person to discover an ADR or MDI, you are the one who should report it in PSLS. The person who discovers the ADR or MDI is best positioned to give the most accurate account of what happened. As the reporter, you may be contacted by BCPSLS Central Office for more information or to receive feedback about the drug or device involved.

What is a serious adverse drug reaction (ADR)?

A serious adverse drug reaction (ADR) is defined as a noxious, unintended response to a drug at any dose that required inpatient hospitalization or prolongation of existing hospitalization; caused congenital malformation; resulted in persistent or significant disability or incapacity; was life-threatening, or resulted in death; or led to other important medical event (use professional judgement). Example: Kidney damage from a diuretic (water pill) that required dialysis.

What types of drugs does Vanessa's Law apply to?

Mandatory reporting of serious adverse drug reactions (ADRs) applies to pharmaceuticals (prescribed, over-the-counter, and contrast media); radiopharmaceuticals (e.g. Technetium-99m); disinfectants (hard surface, non-topical, with DIN); biologic drugs; and natural health products.

Do I have to report adverse reactions to vaccines in PSLS?

No. Adverse reactions to vaccines should continue to be reported via current methods (e.g. to BCCDC), not in PSLS. For more information, review the BC Centre for Disease Control's Immunization Manual or review surveillance forms on the BCCDC website.

How is an adverse drug reaction (ADR) different from a medication incident?

ADRs are not errors in care! They occur even if processes and procedures are followed correctly. Medication safety incidents, or events, are often preventable and should be reported via the medication incident report form in PSLS.

What is a medical device incident (MDI)?

A medical device incident (MDI) is defined as an incident related to the failure of a medical device, deterioration in its effectiveness, or inadequacy in its labeling or directions that led to the death or serious deterioration in health of a patient, user, or other person OR could do so were it to recur. Example: An infusion pump stopped due to a malfunction but failed to give an alarm and the patient received an under-infusion of antibiotics, resulting in septic shock that prolonged the patient's stay in hospital.

What types of medical devices does Vanessa's Law apply to?

"Device" includes invasive, non-invasive, active, and biomedical devices, electronic and non-electronic equipment, implants, products, supplies, disposables, and general items used in all aspects of patient care. Mandatory reporting of medical device incidents (MDIs) applies to all classes of medical devices: Class I (e.g. hospital beds, wheelchairs); Class II (e.g. infusion sets, urethral catheters); Class III (e.g. infusion pumps, intrauterine devices); Class IV (e.g. pacemakers, defibrillators, bone grafts).

Should I report only *serious* ADRs and MDIs?

Health care providers should report **all** adverse drug reactions and medical device problems in PSLS. While it's only mandatory to report serious ADRs and MDIs to Health Canada, all reports are helpful to protect Canadians from unsafe drugs and devices. When in doubt, report!

What if I'm not sure if the drug or device caused the problem?

When in doubt, report! All adverse drug reactions (ADRs) and medical device incidents (MDIs) should be reported in PSLS even if the incident's association with a drug and/or medical device is only suspected, causality is not confirmed, all the details are not known, or it may not be serious.

What information should I provide about the drug or device when I report in PSLS?

It's important to provide enough information about the drug or device to uniquely identify it. In PSLS, the quickest and easiest way to identify a drug is to type in the DIN. If you don't have the DIN, you can search by brand name or generic name. If the drug is generic, be sure to include the manufacturer in PSLS as well. For devices, include the device type and any identifying numbers.

When I report an ADR or MDI, will I hear anything back?

Health care professionals who report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) may receive feedback and information from Health Canada about the safety of therapeutic products they prescribe or administer. In addition, BCPSLS Central Office may forward reporters any relevant information they've received about the drug or device.

Where can I go for more information?

- Complete the *Vanessa's Law: Advancing Mandatory Reporting* eLearning module on LearningHub (provincial) or iLearn (Interior Health)
- Visit www.bcpslscentral.ca/vanessas-law for more information and downloadable resources
- Review the Mandatory Reporting Guidance Document
- Contact Health Canada's BC coordinator for mandatory reporting: thanh.vu@canada.ca
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