



Clinical Pharmacology & Toxicology Pearl of the Week

~ Pharmacovigilance ~

Background:

- ✓ **Pharmacovigilance** is ‘the science and activities related to the detection, assessment, understanding and prevention of adverse events or any other drug-related problem.’
- ✓ In 2014, Canada passed C-17, the **Protecting Canadians from Unsafe Drugs Act**, also referred to as **Vanessa’s Law**. Vanessa, the daughter of former MP Terrence Young, died in 2000 of complications from a drug prescribed for a gastrointestinal condition (Cisapride).
- ✓ This law empowers Health Canada to develop regulations governing mandatory reporting of Severe Adverse Drug Reactions and Medical Device Incidents.

Who reports?

- ✓ Regulations governing mandatory reporting **apply specifically to hospitals**, and not to healthcare workers working outside of an institution. A ‘hospital’ is any facility designated as such by a province, or a federal facility that provides care to inpatients.

What events are reportable?

- ✓ **Severe Adverse Drug Reactions** - “a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.”
- ✓ **Medical Device Incidents** - “an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur”.

What products are subject to mandatory reporting?

- ✓ **Nearly all drugs or medical devices** except vaccines, natural health products, clinical trial drugs, drugs authorized on an emergency basis.

What is the timeline for reporting?

- ✓ 30 days

References:

[Protecting Canadians from Unsafe Drugs Act \(Vanessa’s Law\)](#)

[Protecting Canadians from Unsafe Drugs Act \(Vanessa's Law\): Questions/Answers - Canada.ca](#)

The Clinical Pharmacology (CP) physician consultation service is available Mon-Fri, 8am-5pm. The on-call physician is listed in ROCA on the AHS Insite page. CP consultations are also available through Netcare e-referral and Specialist Link. You can also find us in the [Alberta Referral Directory](#) (ARD) by searching “Pharmacology” from the ARD home page. Click [HERE](#) for more details about the service.

The Poison and Drug Information Service (PADIS) is available 24/7 for questions related to poisonings. Please call 1-800-332-1414 (AB and NWT) or 1-866-454-1212 (SK). Information about our outpatient Medical Toxicology Clinic can be found in [Alberta Referral Directory](#) (ARD) by searching “Toxicology” from the ARD home page.

More CPT Pearls of the Week can be found [HERE](#).

Created: January 31, 2023

Reviewed: March 12, 2025