



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



The Calgary Clinical Pharmacology physician consultation service is available Mon-Fri, 8am-5pm. The on-call physician is listed in ROCA. Clinical Pharmacology consultations are also available through the Netcare e-referral process and through Calgary Zone Specialist Link. Click [HERE](#) for more details.



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).