FAQ – Mandatory reporting of serious Adverse Drug Reactions (ADR)and Medical Device Incidents (MDI) to Health Canada (Vanessa's Law)

How did the law originate?

- **Vanessa Young died in 2000, at the age of 15, of a cardiac arrhythmia after taking cisapride (Prepulsid®) as prescribed.**
- **A campaign for increased regulation of therapeutic products subsequently led to greater powers for Health Canada to request safety data from hospitals and industry about drugs and medical devices.**

What is a serious ADR?

A *serious adverse drug reaction (serious ADR)* is 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.**

What is a MDI?

A *medical device incident (MDI)* is 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 is the effective date of reporting?

- **Vanessa's Law** was enacted by Health Canada in 2014 and the mandatory reporting requirements come into effect December 16th, 2019.

Who is required to report?

- The regulations apply to **all hospitals (acute care).**

When must hospitals report?

- The regulations require hospitals to report serious ADRs and MDIs in writing to Health Canada **within 30 calendar days of first documentation** of the serious ADR or MDI within the hospital.

Should a known reaction be reported?

- The regulation requires hospitals to report serious ADRs, regardless of whether the reaction is expected or unexpected.

Where can I find more information?

- http://publications.gc.ca/collections/collection_2019/sc-hc/H164-280-2019-eng.pdf
- https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx

Who is Responsible to report?

- If healthcare providers deem an ADR or MDI to be serious using their clinical expertise/expertise then it would be considered reportable under the requirements.
- There should be a collaborative approach between health care providers to determine if the event is reportable.

Types of Medical Devices Included

- Medical devices are classified into **Class I** (lowest risk) to **Class IV** (highest risk). Examples are:
    - Class I – hospital beds, wheelchairs, leg prostheses
    - Class II – infusion sets, syringes, tracheostomy tubes, urethral catheters
    - Class III – infusion pumps, anesthesia gas machines, intrauterine devices
    - Class IV – pacemakers, defibrillators, breast implants, bone grafts
- **All classes of medical devices are included in mandatory reporting by hospitals.**

Note: Hospitals are not required to establish causality; the information to be submitted by the hospital to Health Canada only needs to represent the suspicions of a health care professional that a serious ADR or MDI has been observed.