Health PEI
One Island Health System

Vanessa's Law
Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Hospitals

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

Amendments to the *Food and Drugs Act* include

- Power to require information, tests or studies
- Power to require a label change/package modification
- Power to recall unsafe therapeutic products
- Ability to disclose information in certain circumstances
- Tougher measures for those that do not comply
- **Mandatory reporting of serious adverse drug reactions and medical device incidents by health care institutions**

Who Is Required to Report?

The regulations apply to **all hospitals.**

The regulations define a **hospital** as a facility that:

- is licensed, approved or designated as a hospital by a province or territory, in accordance with the laws of the province or territory, to provide care or treatment to persons suffering from any form of disease or illness; or
- is operated by the Government of Canada and provides health services to in-patients

What are the Definitions of a Serious ADR and MDI?

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.

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 Products Are In Scope of these Regulations?

The mandatory reporting requirements for hospitals apply to therapeutic products, including:

- Pharmaceuticals (prescription and non-prescription drugs)
- Biologic drugs (biotechnology products, fractionated blood products, plasma proteins, and vaccines [excluding vaccines administered under a routine immunization program of a province or territory])
- Radiopharmaceutical drugs
- Disinfectants
- Medical devices
- Drugs for an urgent public health need

When in doubt, Health Canada encourages hospitals to report

When Must Hospitals Report?

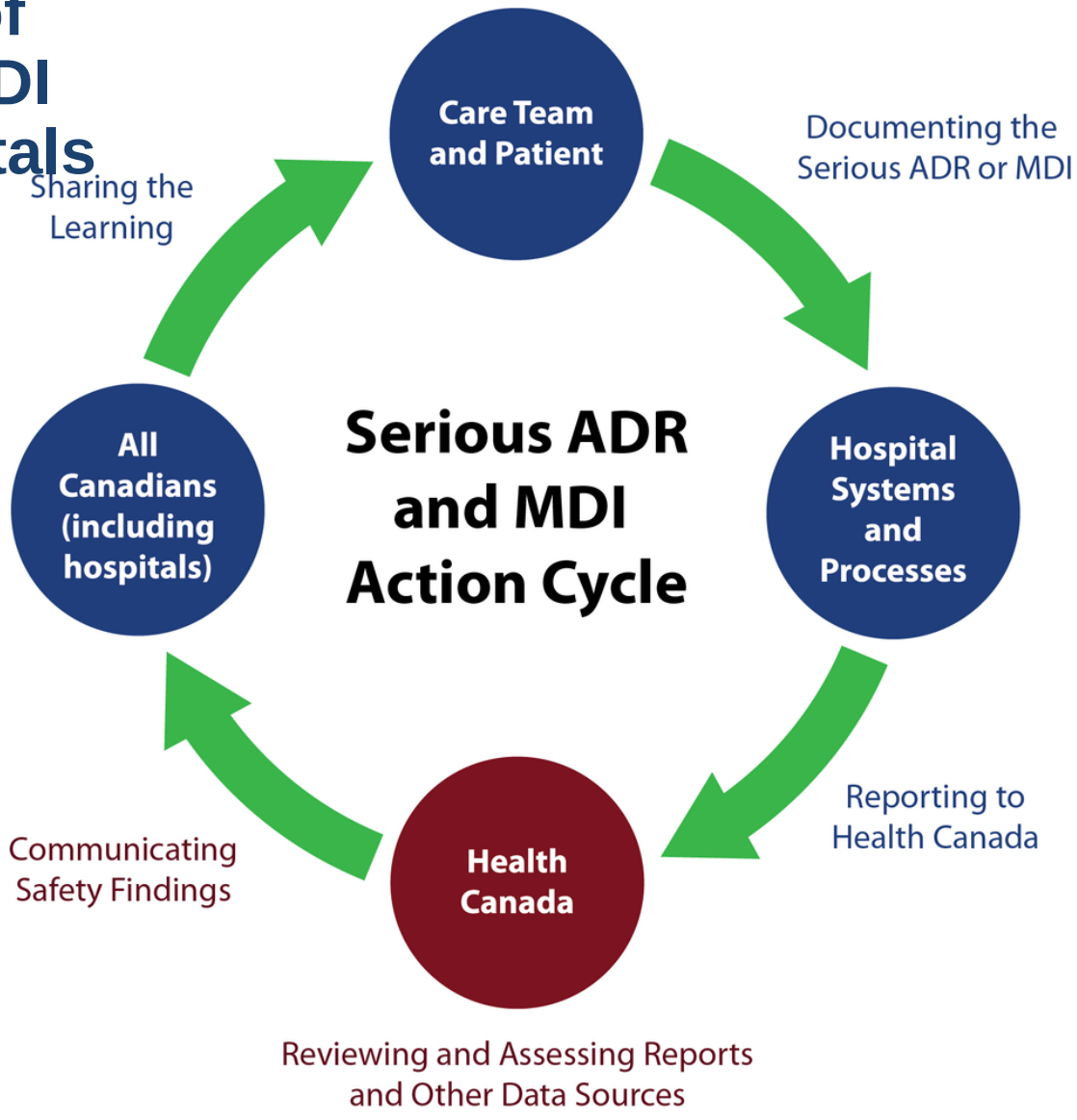
- The regulations require hospitals to report serious ADRs or MDIs in writing to Health Canada **within 30 calendar days of first documentation** of the serious ADR or MDI within the hospital.

Information “Within the Control of the Hospital”

The regulations require hospitals to report all documented serious ADRs and all documented MDIs, where the required information is **within the control of the hospital**.

- Information that is within the control of the hospital is information that would be reasonably accessible within the hospital.
- While it is encouraged for hospitals to take all reasonable steps to retrieve the required information to complete as thorough a report as possible, there is no requirement to do further investigation in order to obtain the pieces of information.

Conceptual Model of Serious ADR and MDI Reporting by Hospitals



Source: Serious ADR and MDI Action Cycle. ISMP Canada, HSO, CPSI; 2019.