Introduction

1.1. Purpose

BACKGROUND:

The Protecting Canadians from Unsafe Drugs Act (also referred to as Vanessa’s Law) and its regulations require hospitals to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada as of December 16, 2019. The intention of this legislation is to increase patient safety in Canada by increasing the post-marketing reporting of adverse drug reactions and help to inform Health Canada regarding the safety of drugs and whether further actions are required (e.g., changes in monitoring, restrictions or warnings regarding use, etc.).

DEFINITION:

Health Canada defines a serious adverse drug reaction as:

- a noxious and unintended response to a drug that occurs at any dose and that resulted in or caused any of the following:
  - in-patient hospitalization or prolongation of existing hospitalization
  - congenital malformation
  - persistent or significant disability or incapacity
  - was life-threatening, or resulted in death

Adverse drug reactions that require significant medical intervention to prevent one of these outcomes are also considered to be serious.¹

1.2. Scope

This Policy applies to all Health Care Providers, BC Children’s and BC Women’s Hospital.

Policy

2.1 All health care professionals are required to report adverse drug reactions (ADRs) to health products marketed in Canada within 30 days of the reaction being documented within the hospital.

2.2 All suspected adverse reactions shall be documented in the patient’s health record and in the Patient Safety & Learning System (PSLS) using the Serious ADR report form.²

2.3 The Clinical Coordinator of Pharmacy (or their delegate) shall be the handler for all serious ADR reports in PSLS for BC Children’s and BC Women’s Hospitals and responsible for overseeing collection, assessment, and trending of adverse reactions submitted.

2.4 In Scope (reporting of serious ADR is mandatory):

- Pharmaceuticals (prescription and non-prescription drugs)
- Biologic drugs (biotechnology products, fractionated blood products, plasma proteins, non-routine vaccinations)
- Radiopharmaceutical drugs
- Disinfectants with a drug identification number (DIN)
- Drugs for an urgent public health need
2.5 Out of Scope (reporting of adverse reactions is not mandatory but is strongly recommended or has different requirements for mandatory reporting or adverse reactions are reported through a different process (e.g., clinical trials or vaccines, respectively):

- Natural health products
- Known and anticipated reactions to drugs, if the reaction was not serious or the mitigation strategy was effective
- Unexpected adverse reactions, regardless of their severity (not consistent with product information or labelling);
- Adverse reactions, regardless of severity, related to recently marketed health products (on the market for less than 5 years)
- Vaccines administered as routine immunization program of a province or territory (voluntary reporting recommended: use the Adverse Event Following Immunization (AEFI) Report Form)
- Blood and blood components
- Drugs acquired through Health Canada’s Special Access Programme
- Investigational products or drugs administered as part of a clinical trial

Responsibilities

3.1 Health Care Professional

- Identifies suspected adverse reactions and determines whether the adverse reaction meets the criteria set forth in the definition provided by Health Canada (see definition above).
- Identifies member of the care team responsible for investigating, reporting and documenting the adverse reaction.
- For reportable adverse reactions, completes the PSLS Serious Adverse Reaction Report
- Documents adverse reactions in the patient’s health record.

3.2 Clinical Coordinator, Children’s & Women’s Pharmacy

- Reviews PSLS Report (as Handler), ensures complete, and approves the ADR Report.

3.3 PSLS Administrator

- De-identifies, submits to Health Canada

References


4. Provincial Health Services Authority Serious Adverse Drug Reactions: Reporting to Health Canada Policy #C-99-11-20536
Developed By
Pharmacy

Version History

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<td>12-Nov-2019</td>
<td>C-0506-12-60416  PTN.07.002 Mandatory Adverse Drug Reaction Reporting Policy</td>
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