REPORTING ADVERSE REACTIONS to Vaccines and Medications

As healthcare professionals, pharmacists and pharmacy technicians are required by law to make certain reports when they become aware of adverse reactions to vaccines. The Standards of Practice also require that pharmacists, when providing patient care, report the occurrence of adverse reactions involving medication or health products.

RESOURCES RELATED TO VACCINE REPORTING FROM PUBLIC HEALTH ONTARIO

- Fact sheet: Adverse Event Following Immunization Reporting for Health Providers
- Adverse Events Following Immunization Reporting Form

An adverse reaction is defined as a harmful and unintended effect from use of a health products.[1] Pharmacy professionals are not required to be certain that a particular health product caused a reaction in order to report it – only suspect that it had an effect.

It is extremely important to report adverse reactions as reports can help with the identification of potentially severe reactions, result in changes to the information provided with the product, and assist in improving the health and safety of all Canadians.

ADVERSE EVENTS FOLLOWING IMMUNIZATION

An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that occurs after someone receives a vaccine.[2] Pharmacy

professionals do not need to be certain that the effect was caused by the vaccine itself.

Reports on AEFIs can be made using the Ontario AEFI Reporting Form and the completed form should be sent to the local Public Health unit. This is in addition to any other reporting that may take place, such as to a designated manager, institution, MedEffect Canada or the manufacturer.

Aside from mandatory reporting to Public Health, pharmacy professionals should document circumstances relating to any adverse reaction experienced by the patient and treatment recommended or administered as a result. Refer to the College's Administering Injections Guideline and the Administering Injections practice tool.

ADVERSE REACTIONS TO MEDICATION OR OTHER HEALTH PRODUCTS

MedEffect Canada is Health Canada's program for reporting of adverse reactions to health products, including medications (both prescription and non-prescription), natural health products, and vaccines. Health professionals are asked to report all suspected adverse reactions, particularly if they are:

HEALTH CANADA'S DEFINITION OF A SERIOUS ADVERSE REACTION

Requires hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these outcomes are also considered to be serious.[1]

- Unexpected i.e. not consistent with patient information or labelling;
- Serious; or
- Related to a health product that has been on the market less than five years.[1]

Be prepared to provide patient information (e.g. age, weight and other non-identifying information), a description of the reaction, the name of the health product and contact information. Reports can be made online, by mail or by phone at 1-866-234-2345.

Pharmacy professionals can stay informed on new or emerging information about health product safety and effectiveness by subscribing with MedEffect Canada or regularly visiting their Advisories, Warnings and Recalls page.

REFERENCES

1. Health Canada. Adverse Reaction Reporting and Health Product Safety Information – Guide for Health Professionals (2011). Cited 2017 June 9. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/adverse-reaction-reporting-health-product-safety-information-guide-health-professionals-health-canada-2011.html

2. Public Health Ontario. Vaccine Safety (2017). Cited June 9, 20-17. Available from: http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Vaccine-Safety.aspx?_cldee=dGFyYS5oYXJyaXNAb2FocHAuY2E%3d&recipientid=contact-09f77f1fb-2c2e41191f10050569e0009-347c2740fdb84ffeac2b3a9e1dd63727&esid=54d2d5dc-8c35-e711-89df-0050569e0009

HEALTH CANADA CONSULTATION ON MANDATORY REPORTING OF SERIOUS ADVERSE DRUG REACTIONS AND MEDICAL DEVICE INCIDENTS

Health Canada is currently seeking feedback from health professionals and healthcare institutions on proposed changes to the Food and Drug Regulations and Medical Devices Regulations, which would make it mandatory for healthcare institutions to report serious adverse drug reactions and medical device incidents. These changes are part of the implementation of the *Protecting Canadians from Unsafe Drugs Act* (or Vanessa's Law). Learn more and provide your feedback on the Health Canada website.