College of Physicians and Surgeons of British Columbia

Professional Standards and Guidelines

Reporting Adverse Drug Reactions

Preamble

This document is a standard of the Board of the College of Physicians and Surgeons of British Columbia.

It is important for physicians to keep up-to-date on identified adverse reactions (ARs) to prescribed or over-the-counter (OTC) medications. By submitting a suspected adverse reaction report, physicians contribute to the ongoing collection of safety and effectiveness information that occurs once health products are on the Canadian market.

Canadian Adverse Drug Reaction Monitoring Program

Health Canada, through the Canadian Adverse Drug Reaction Monitoring Program (CADRMP), is responsible for collecting and assessing adverse reaction reports for the following health products marketed in Canada: pharmaceuticals, biologics (including fractionated blood products, and therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals. Adverse reaction reports are assessed for any signs or trends (signals), which may be preliminary indicators of product-related issues. The identification of a signal is not by itself proof of the association of an adverse reaction to a health product; however, it triggers the need to further investigate a potential association.

Which Adverse Reactions Should be Reported?

Adverse reaction reports are, for the most part, only suspected associations. Proof that a health product has actually caused an adverse reaction is NOT a requirement for reporting. If an adverse reaction is suspected of being drug-related, particularly if the event is unusual in context of the illness, it should be reported. Practitioners should report all clinically significant suspected adverse reactions, especially if they are:

1. unexpected adverse reactions, regardless of their severity (i.e. not consistent with product information or labelling)
2. serious adverse reactions (reactions requiring in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening, requires significant medical intervention, or results in death), whether expected or not

3. adverse reactions related to recently marketed health products (i.e. on the market for less than five years)

Keep Informed

The Health Canada website is a valuable source of adverse reaction information. To download a copy of the adverse reaction reporting form, to report online, or to join Health Canada's MedEffect e-Notice mailing list and receive the *Canadian Adverse Reaction Newsletter (CARN)* and health product advisories free by email, go to: http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html

The *CARN* is a reputable source of adverse reaction information recognized by health professionals and individuals interested in the area of post-market surveillance of drugs. It is published in January, April, July and October of each year. The electronic subscription to the *CARN* and advisories will allow practitioners to obtain time-sensitive information about Canadian marketed health products quickly and, in turn, to join the efforts of CADRMP to augment the dissemination of drug safety information in order to enhance the safe care of the Canadian public.

How to Report

There are multiple ways to report an adverse reaction to Health Canada.

To report an AR go to http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html

- Complete and submit your report online, or
- Download and print a paper copy of the reporting form. (The reporting form is also available in the back of the CPS.) Submit the form:
    - by mail (addresses can be found on the back of the form or on the Health Canada website)
    - by toll-free fax at 1-866-678-6789
- You can also report an AR by toll-free phone at 1-866-234-2345 (phone calls and faxes are automatically directed to the appropriate Regional AR Monitoring Office).

Contact Information

For more information on CADRMP, to request copies of AR reporting forms or to report an AR, practitioners are invited to contact the BC Adverse Reaction Monitoring Office:

Canadian Adverse Reaction Monitoring – BC
400–4595 Canada Way
Burnaby BC V5G 1J9

Tel: 604-666-1407
Fax: 604-666-1474
Email: British_Columbia_AR@hc-sc.gc.ca

Toll free telephone: 1-866-234-2345
Toll free fax: 1-866-678-6789

Updated September 2009