Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

CANADIAN ADVERSE DRUG REACTION MONITORING PROGRAM (CADRMP) GUIDELINES FOR THE VOLUNTARY REPORTING OF SUSPECTED ADVERSE REACTIONS TO HEALTH PRODUCTS BY HEALTH PROFESSIONALS AND CONSUMERS

Marketed Health Products Directorate

http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html

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Canada

Canadian Adverse Drug Reaction Monitoring Program (CADRMP) Guidelines for the Voluntary Reporting of Suspected Adverse Reactions to Health Products by Health Professionals and Consumers

What to report?
Adverse reactions (ARs) to Canadian marketed health products including prescription, non-prescription, biologic (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health and radiopharmaceutical products are collected by the Canadian Adverse Drug Reaction Monitoring Program (CADRMP). An adverse reaction (AR) is a harmful and unintended response to a health product. This includes **any** undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable ARs.

AR reports are, for the most part, only suspected associations. A temporal or possible association is sufficient for a report to be made. Reporting of an AR does not imply a definitive causal link.

All suspected adverse reactions should be reported, especially those that are:

- **unexpected**, regardless of their severity, i.e., not consistent with product information or labelling; or
- **serious**, whether expected or not; or
- reactions to **recently marketed health products** (on the market for less than five years), regardless of their nature or severity.

What is a serious adverse reaction?
A serious AR is one 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. ARs that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

How to report?
To report a suspected AR for health products [pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals] marketed in Canada, health professionals or consumers (preferably in conjunction with their health professional, so that information about medical history can be included in order to make the reports more complete and scientifically valid) should complete a copy of the AR Reporting Form [Report of Suspected Adverse Reaction Due to Health Products Marketed in Canada (HC/SC 4016)]. This form may be obtained from the Internet at **http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html**, from your Regional AR Monitoring Office (see contact information below), and is also available in the appendices of the *Compendium of Pharmaceuticals and Specialities (CPS).*

All applicable sections of the AR reporting form should be filled in as completely as possible. Use a separate form for each patient. Up to two suspected health products for a particular AR may be reported on one form. Attach an additional form if there are more than two suspected health products for the AR being reported. Additional pages may be attached if more space is required. The success of the program depends on the quality and accuracy of the information provided by the reporter.

To report an Adverse Event Following an Immunization (AEFI) for a vaccine used in the prevention of infectious disease, the same criteria as stated in these guidelines are used. Health professionals should complete a copy of an *Adverse Event Following Immunization Reporting Form*. This form is available on the internet at **http://www.phac-aspc.gc.ca/im/aefi-form_e.html** or in the appendices of the CPS. Forms also exist as customized provincial/territorial adverse event forms which can be obtained either from local public health departments or from the provincial/territorial health authorities.

Is AR information considered confidential?
Any information related to the identity of the patient and/or the reporter of the AR will be protected as per the *Access to Information Act* and the *Privacy Act*.

How to deal with follow-up information for an AR that has already been reported?
Any follow-up information for an AR that has already been reported can be submitted using a new AR reporting form. It can be communicated by telephone, fax or e-mail to the appropriate regional AR monitoring office (see contact information below). In order that this information can be matched with the original report, indicate that it is follow-up information, the date of the original report, if known, and the case report tracking number provided in the acknowledgement letter. It is very important that follow-up reports are identified and linked to the original report.

What about reporting ARs to the Market Authorization Holder (manufacturer)?
Health professionals and consumers may also report ARs to the market authorization holder (MAH). Please indicate on your AR report sent to Health Canada if a case was also reported to the suspected product's MAH.

Where to send the report or obtain more information?
Adverse reactions for Canadian marketed health products [pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals] are monitored by the CADRMP of Health Canada's Marketed Health Products Directorate. Forward AR reports to your appropriate regional AR monitoring office, as listed below.

Adverse reactions to preventative vaccines are monitored by the Canadian Public Health Agency. For vaccines, the preferred route for reporting is to the local public health department; however, completed forms can be sent by mail or fax to the address on the *Adverse Event Following Immunization Reporting Form*. For more information on the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), please contact The Vaccine Safety Unit, Centre for Infectious Disease Prevention and Control, Building #6, AL:K0602C, Ottawa ON K1A 0K9, tel: (613) 954-5590, fax: (613) 946-0244, e-mail: CAEFI@phac-aspc.gc.ca

For more information on CADRMP, additional copies of AR reporting forms or to report an AR, health professionals and consumers are invited to contact the AR Monitoring Office listed below for their region.

The following toll-free numbers may be used by health professionals and consumers. Calls will automatically be routed to the appropriate regional AR monitoring office based on the area code from which the call originates.

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

BC and Yukon
Canadian Adverse Reaction Monitoring - BC and Yukon
400 - 4595 Canada Way,
Burnaby, British Columbia V5G 1J9
British_Columbia_AR@hc-sc.gc.ca

Alberta and Northwest Territories
Canadian Adverse Reaction Monitoring - Alberta and Northwest Territories
Suite 730, 9700 Jasper Avenue
Edmonton, Alberta T5J 4C3
Alberta_AR@hc-sc.gc.ca

Saskatchewan
Canadian Adverse Reaction Monitoring - Saskatchewan
4th floor, Room 412
101 - 22nd Street East
Saskatoon, Saskatchewan S7K 0E1
Saskatchewan_AR@hc-sc.gc.ca

Manitoba
Canadian Adverse Reaction Monitoring - Manitoba
510 Lagimodière Blvd
Winnipeg, Manitoba R2J 3Y1
Manitoba_AR@hc-sc.gc.ca

Ontario and Nunavut
Canadian Adverse Reaction Monitoring - Ontario and Nunavut
2301 Midland Avenue
Toronto, Ontario M1P 4R7
Ontario_AR@hc-sc.gc.ca

Québec
Canadian Adverse Reaction Monitoring - Québec
1001 Saint-Laurent Street West
Longueuil, Québec J4K 1C7
Quebec_AR@hc-sc.gc.ca

Atlantic
Canadian Adverse Reaction Monitoring - Atlantic
1505 Barrington St., Maritime Centre
Suite 1625, 16th floor
Halifax, Nova Scotia B3J 3Y6
Atlantic_AR@hc-sc.gc.ca