Health Canada Santé Canada

PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

CANADIAN ADVERSE DRUG REACTION MONITORING PROGRAM GUIDELINES FOR THE VOLUNTARY REPORTING OF ADVERSE DRUG REACTIONS BY HEALTH PROFESSIONALS

Therapeutic Products Programme Website

www.hc-sc.gc.ca/hpb-dgps/therapeut

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What to report

An adverse drug reaction (ADR) is a noxious and unintended response to a drug which occurs with use or testing for the diagnosis, treatment or prevention of a disease or the modification of an organic function. This includes **any** undesirable patient effect suspected to be associated with drug use. ADRs as a result of prescription, non-prescription, biological (including blood products), complementary medicines (including herbals) and radiopharmaceutical drug products are monitored. Drug abuse, drug overdoses, drug interactions and unusual lack of therapeutic efficacy are also considered to be reportable as ADRs.

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

ADRs that should be reported include all suspected adverse drug reactions which are:
- **unexpected,** regardless of their severity i.e. not consistent with product information or labeling; or
- **serious,** whether expected or not; or
- reactions to **recently marketed drugs** (on the market for less than five years) regardless of their nature or severity.

What is a serious reaction?

The Canadian Regulations pertaining to reporting ADRs for marketed drug products define a serious adverse drug reaction as " a noxious and unintended response to a drug, which occurs at any dose and 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". ADRs that require significant medical intervention to prevent one of the other outcomes listed above are considered to be serious.

How to report

To report a suspected ADR for drug products marketed in Canada, Health Professionals should complete a copy of the **ADR Reporting Form (Report of suspected adverse reaction due to drug products marketed in Canada (Vaccines excluded)** (HC 4016 (12-98))**.** This form may be obtained from your regional centre or from the national ADR centre (see addresses below), and is included in the Compendium of Pharmaceuticals and Specialities (CPS). http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/forms/adverse_e.pdf

To report an ADR for a vaccine, Health Professionals should complete a copy of the Vaccine-Associated Adverse Event Form. This form is also included in the CPS.

Fill in the sections that apply to the report as completely as possible, using a separate form for each patient. Additional pages may be attached if additional space is required. The success of the program depends on the quality and accuracy of the information sent in by the reporter.

Is ADR information considered confidential?

Any information related to the reporter and patient identifiers is kept strictly confidential.

How to deal with follow-up information for an ADR that has already been reported

Any follow-up information for an ADR that has already been reported can be sent on another ADR form, or it can be communicated by telephone, fax or e-mail if convenient to the appropriate address for your region (see addresses below). So that this information can be matched with the original report, indicate that it is follow-up information, the date of the original report and the report case number if known. It is very important that follow-up reports are identified and linked to the original report.

What about reporting ADRs to the Manufacturer?

Health Professionals may also report ADRs to the manufacturer. Indicate on your ADR report sent to Health Canada if a case was also

reported to the manufacturer.

Where to send the report or to obtain more information.

Adverse reactions for drug products that are marketed in Canada are monitored by the Canadian Adverse Drug Reaction Monitoring Program (CADRMP). Adverse reactions to vaccines are monitored by the Laboratory Centre for Disease Control. Send these reports to the address listed on the Vaccine-Associated Adverse Event Form.

For more information on the ADR monitoring program, additional copies of ADR reporting forms or to report an ADR, physicians, pharmacists and other Health Professionals are invited to contact the addresses listed for your region.

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