Health Canada Santé Canada

Guidance on releasing information from adverse reaction and medical device incident reports to the public

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Lignes directrices sur la divulgation au public de renseignements tirés des déclarations d'effets indésirables et d'incidents liés aux instruments médicaux

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Forward

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of other applicable guidance documents.

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Overview

Purpose

This document increases government transparency by providing:

- the Health Products and Food Branch (HPFB) procedures for releasing information from adverse reaction (AR) and medical device incident (MDI) reports to the public
- the Regulatory Operations and Enforcement Branch (ROEB) procedures for releasing information on reports or complaints about medical devices

It outlines:

- a consistent and uniform application of government laws, policies and guidelines governing the public's right of access to information held by government
- Health Canada's duty to protect personal and confidential third-party information in accordance with applicable laws, including the:
    - *Privacy Act*
    - *Access to Information Act*

The report relates to:

- medical devices
- adverse reactions to health products such as:
    - biologics
    - pharmaceuticals
    - natural health products
    - blood and blood components (B/BCs)
    - human cells, tissues and organs (CTOs)
    - sperm and ova for the purpose of assisted human reproduction (AHR)

This document outlines the procedures for providing this information to members of the public including:

- media
- industry
- academia
- consumers
- research communities
- health care professionals

Background

We have collected reports of adverse reactions to health products in Canada since 1965. For marketed health products, these reports are known as adverse reaction or medical device incident reports.

The associated regulations of the *Food and Drugs Act* and *Assisted Human Reproduction Act* require important safety information from:

- licensees
- hospitals
- blood establishments
- source establishments
- primary establishments
- medical device licence holders
- market authorization holders (MAH)

They must provide Health Canada with safety information, including adverse reaction and medical device incident reports, about the products they are responsible for in Canada.

Health professionals such as physicians, pharmacists, nurses, dentists, veterinarians and veterinary technicians as well as consumers are encouraged to report adverse reactions and medical device incidents on a voluntary basis.

The type of information collected in adverse reaction or medical device incident reports includes:

- high-level information about the patient or device user
- details of the reaction(s) suspected with the health product(s)
- general findings and the treatment and final outcome(s) of the adverse reaction or medical device incident

Adverse reaction reports and medical device incidents provide information on events suspected to be related to a health product. Each report represents the suspicion, opinion, or observation of the individual making the report. They don't represent all known or possible safety information concerning the suspected product.

Find more information about the adverse reaction and medical device incident reporting programs.

Scope

This procedure applies only to adverse reaction and medical device incident reports from organizations within the:

- Health Products and Food Branch (HPFB)
- Regulatory Operations and Enforcement Branch (ROEB)

From the Health Products and Food Branch, this includes the:

- Biologic and Radiopharmaceutical Drugs Directorate (BRDD), which collects reports on:
    - adverse transfusion reaction/event, clinical trial adverse reaction reports for biological drugs and radiopharmaceuticals and related Special Access Program products
- Marketed Health Products Directorate (MHPD), Canada Vigilance Program, which collects reports on:
    - post-market side effect reports for pharmaceutical drugs, biologics, radiopharmaceuticals, CTOs, B/BCs (donor), AHR, natural health products and medical devices approved for use in humans
    - medical device incident reports for Special Access Program and investigational testing
- Pharmaceuticals Drug Directorate (PPD), which collects reports on:
    - clinical trial adverse reaction reports for pharmaceuticals and natural health products and Special Access Program adverse reaction reports for pharmaceuticals
- Veterinary Drugs Directorate (VDD), which collects reports on:
    - post-market adverse reaction reports for veterinary drugs approved for use in animals

From the ROEB, this includes the:

- Medical Devices and Clinical Compliance Directorate (MDCCD), which collects reports on:
    - medical device problem reports originating from consumers as well as trade and advertising complaints

Learn more about the responsibilities of these organizations.

Procedure for releasing information

The Health Products and Food Branch (HPFB) and Regulatory Operations and Enforcement Branch (ROEB) have different procedures for providing adverse reaction (AR) and medical device incident (MDI) data.

Information available on the Health Canada website

You can access a subset of the information from post-market domestic adverse reaction reports for health products approved for use in humans through the Canada Vigilance Adverse Reaction Online Database. The MHPD updates this database monthly to include data from 1965 up to that received 3 months prior to the update.

You can access medical device incident reports available to the public through the Medical Device Incidents database.

Information from post-market adverse reaction reporting programs in standard summary formats

The programs will only provide adverse reaction information from post-market domestic adverse reaction and medical device incident reports. You can request information from:

- post-market domestic adverse reaction reports from the Canada Vigilance Program and Veterinary Drugs Pharmacovigilance Programs
    - The programs will provide the adverse reaction data in a standard summary or line-listing format.
- medical device incident reports from the Canada Vigilance Program for medical device incidents submitted by industry, hospitals, and Canadian Medical Devices Sentinel Network(CMDSNet) or ROEB (for voluntary medical device incidents submitted by community health care practitioners/facilities and the general public)

Requests for information should include:

- your name, address, telephone number and email address (if available)
- information to help determine the identity of the health product(s) of interest (brand name or generic name/active ingredient, or tradename), manufacturer name(s), device identifier(s) or other pertinent information
- the time period of the search (time period when reports were received)
- any specific criteria or search limitations (specific reaction terms, gender, age range)

You can make requests for standard summary formats of adverse reaction data in writing (letter, fax or email) to the:

Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Postal Locator 1908C
Ottawa, Ontario K1A 0K9
Telephone: 1-866-234-2345
Fax: 1-866-678-6789
Email: canada.vigilance@hc-sc.gc.ca

Medical Devices Compliance Program
Medical Devices and Clinical Compliance Directorate
Regulatory Operations and Enforcement Branch
Health Canada
Email:meddev-matmed@hc-sc.gc.ca
Website: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/medical-devices-program.html

Pharmacovigilance Program
Clinical Evaluation Division
Veterinary Drugs Directorate
Health Canada
Postal Locator 3106D
Ottawa, Ontario K1A 0K9
Telephone: 1-877-838-7322
Fax: 613-946-1125
Email: pv-vet@hc-sc.gc.ca

Non-standard information

You can request information other than what is publicly available or represented in standard summary format reports. This includes:

- copies of adverse reaction or medical device incident reports
- information from
    - clinical trial adverse reaction reports
    - medical device incident reports
    - health products obtained through one of Health Canada's Special Access Programs

You may request this information under the *Access to Information Act* (ATIA) and pay the applicable fee using the online request system:

ATIP online request

Be sure to include the adverse reaction report number or medical device incident number for copies of reports.

Information from foreign regulatory agencies

You can request data received from foreign regulatory agencies from the responsible regulatory agency.

Protected information

Protected information includes both personal information and confidential third-party information.

Personal information

Personal information is defined in the *Privacy Act* (the Act) as "information about an identifiable individual that is recorded in any form (section 3). The Act protects personal information related to an identifiable patient, device user, animal/owner and/or reporter of the adverse reaction or medical device incident. The *Canadian Charter of Rights and Freedoms* (the Charter) and other applicable laws may also protect this information.

We will not provide information in standard summary format for requests where the search criteria selected include patient or reporter identifiers such as:

- addresses, including names of cities, towns, provinces and postal codes
- names of institutions, clinics or other organizations with whom patients, device users, animal/owners or reporters may be affiliated

These identifiers increase the risk of re-identification of the patient or reporter.

Confidential third-party information

For the purposes of this procedure, "third-party" means any person, group of persons or organization other than the person requesting the information or a government institution listed in Schedule 1 of the *Access to Information Act* (ATIA).

Health Canada holds confidential third-party information for various purposes. Having received such information in confidence, it has a duty to uphold its confidentiality in accordance with the applicable laws. The Charter also protects third-party information for which there is a reasonable expectation of privacy.

In circumstances where third-party information is requested pursuant to the ATIA, some types are, or can be, protected against release. This includes:

- information that may be a trade secret
- confidential financial, commercial, scientific or technical information supplied by the third party
- information which could reasonably be expected to result in material loss or gain to, or could prejudice, the third party's competitive position
- information that, when disclosed, could reasonably be expected to interfere with contractual or other negotiations

Limitations and interpretation of information

There are limitations to both the adverse reaction reports and the medical device incidents.

Adverse reaction reports

You should take the limitations of information from adverse reaction reports, described here, into consideration when interpreting adverse reaction data.

This summary is based on raw data from information provided on adverse reaction reports submitted to Health Canada:

- directly by health professionals and laypersons or
- via market authorization holders, licensees, blood establishments, source establishments or primary establishments

Each report represents the suspicion, opinion or observation of the individual reporter and does not necessarily mean the suspected health product(s) caused the reaction. The information is based on a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data have been collected by a spontaneous surveillance system in which adverse reactions to health products are reported to Health Canada either:

- on a voluntary basis or
- by regulated parties who are mandated to report according to the *Food and Drug Regulations* or *Assisted Human Reproduction Act*

Under-reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. You should not use accumulated case reports to determine the incidence of a reaction or to estimate risk for a particular product because we don’t know the:

- total number of reactions occurring
- number of patients exposed to the health product

Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include:

- regulatory actions
- publicity about an adverse reaction
- the length of time a drug is marketed
- the market share, size and sophistication of the sales force

In some cases, the reported clinical data is incomplete and there is no certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. We provide this information with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Medical device incidents

The information in the Medical Devices Incidents database is based on raw data provided on medical device incident reports submitted by manufacturers or importers directly to Health Canada. Each report represents the suspicion, opinion or observation of the individual reporter and does not necessarily mean the suspected health product(s) caused the incident. The data have been collected by a spontaneous surveillance system in which medical device incidents are reported to Health Canada:

- on a voluntary basis
- by regulated parties who are mandated to report according to the *Food and Drug Regulations*

Not all medical device incidents are reported to manufacturers or importers. Reporting may be influenced by multiple factors, including:

- the medical device incident
- the device(s) involved
- the level of media coverage

For these reasons, accumulated case reports should not be used as a basis to estimate risk nor do they represent all know safety information concerning the device(s) and should not be known on their own to make decisions about the use of these devices. We provide this information with the understanding that the data will be appropriately referenced and used with this caveat statement.

How you can use the information from adverse reaction reporting programs in Health Products and Food Branch or Regulatory Operations and Enforcement Branch

You may use the adverse reaction or medical device incident data provided by reporting programs of the HPFB in other documents, including publications. We ask that you:

- acknowledge the source of the data and the limitations of the data from spontaneous reporting systems
- provide a copy of the document or publication to the adverse reaction reporting program prior to its publication

Requests by the media

Representatives from the media who wish to request information or specific issues relating to an adverse reaction or a medical device incident should contact the Health Canada-Media Relations Unit:

Health Canada - Media Relations Unit
Communications and Public Affairs Branch Health Canada
Postal Locator 0912C
Ottawa, Ontario K1A 0K9
Telephone: 613-957-2983
Fax: 613-952-7747
Email: cpab.media.relations-relations.avec.les.media.sdgcap@hc-sc.gc.ca

Health Canada responsibilities

Health Canada: Access to Information and Privacy Operations Division

Health Canada: Access to Information and Privacy Operations Division (AIPOD) processes requests by:

- Canadian citizens, permanent residents or any persons or corporations residing in Canada for access to government records held under the control of Health Canada in accordance with the *Access to Information Act*
- any persons for access to their personal information held under the control of Health Canada in accordance with the *Privacy Act*

Health Canada: Media Relations Unit

Health Canada: Media Relations Unit (MRU) acts as a first point of contact for members of the media seeking information about Health Canada activities and programs. The unit's role is to:

- provide consistent, open and transparent information to members of the media
- to support the Minister, Deputy Minister and departmental spokespersons in their media relations activities

Health Products and Food Branch organizations

The Health Products and Food Branch (HPFB) is composed of many directorates whose roles with respect to adverse reaction (AR) and medical device incident (MDI) reporting are summarized here.

Biologic and Radiopharmaceutical Drugs Directorate

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) regulates biological drugs (products made from living sources) and radiopharmaceuticals (drugs that have radioactivity) for human use in Canada.

The BRDD collects and assesses serious and unexpected clinical trial and Special Access Program adverse reaction report information for these products. The BRDD also regulates certain products to comply with specific regulations, including:

- blood and blood components (B/BCs) for transfusion and further manufacture into a drug for human use through the *Blood Regulations*
    - blood products are regulated under the *Food and Drug Regulations*
- cells, tissues and organs (CTOs) for transplantation through the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*
- sperm and ova for assisted human reproduction (AHR) through the *Assisted Human Reproduction Act*

Marketed Health Products Directorate

The Marketed Health Products Directorate (MHPD) maintains and improves the Canada Vigilance Program. This program collects, processes and assesses adverse reaction and medical device information for post-market surveillance, assessment and risk communication activities of the HPFB. Adverse reactions collected by the Canada Vigilance Program include those from:

- pharmaceutical drugs
- biologics including:
    - biotechnology products
    - B/BCs
    - human CTOs
    - sperm and ova for the purpose of AHR
    - vaccines (therapeutic and diagnostic vaccines since 1965, immunization vaccines since January 1, 2011)
- radiopharmaceuticals
- natural health products

MHPD releases a sub-set of the information (without personal identifiers) from MHPD's post-market domestic adverse reactions to the World Health Organization's (WHO) International Drug Monitoring Program on a quarterly basis.

Natural and Non-prescription Health Products Directorate

The Natural and Non-prescription Health Products Directorate (NNHPD) regulates natural health products and non-prescription drugs for sale in Canada.

Pharmaceutical Drugs Directorate

The Pharmaceutical Drugs Directorate (PDD) oversees the regulation of pharmaceutical drugs. It collects and assesses serious and unexpected clinical trial adverse drug reactions reports from both domestic and international sources. It also collects and assesses adverse reaction reports for drugs obtained through the Special Access Program.

Veterinary Drugs Directorate

The Veterinary Drugs Directorate (VDD) regulates drugs approved for use in animals and evaluates post-market adverse reaction reports and assesses signals and safety trends concerning veterinary drugs. The VDD also oversees Veterinary Health Products (VHPs) for use in food and companion animals.

Regulatory Operations and Enforcement Branch

Medical Devices and Clinical Compliance Directorate

The Medical Devices Compliance Program (MDCP) is responsible for compliance and enforcement actions related to medical devices that violate or potentially violate the *Food and Drugs Act* (FDA) and the *Medical Devices Regulations* (MDR). This includes:

- Sentinel reports
- trade complaints
- voluntary problem reports
- any establishment licence (EL) non responders
- no device licence (DL) and no establishment licence incidents
- compliance verification aspect of any mandatory problem report (MPR)

Standard summary formats for adverse reaction data

We will provide adverse reaction (AR) data from the Health Products and Food Branch (HPFB) adverse reaction reporting programs as line-listing summaries, either as paper copies or electronically, as PDF or Excel files. The format of the line listing may vary depending on the period searched, and the database used during that period.

Marketed Health Products Directorate, Canada Vigilance Program

A Canada Vigilance line listing of adverse reaction information includes standard information:

- Adverse Event Report (AER) number: report number assigned by Health Canada
- Adverse Event Report version number: report version number assigned by Health Canada where version 0 is the initial report received and subsequent version numbers refer to follow-up reports
- initial received date: date the Marketed Health Products Directorate (MHPD) received the initial report, version 0
- latest received date: date the MHPD received the last follow-up report
- report source: indicates the location through which the reporter sent the report
- Market Authorization Holder (MAH) number: MAH report number for reports received from a MAH or manufacturer
- source country: country from which the report originated
- type of report: spontaneous, study, solicited, published, registry
- reporter type: indicates who reported the adverse reaction and their relationship to the patient
- record type: indicates if the report is a duplicate or is linked to another report
- Link Adverse Event Report number: the identification number(s) of the related report(s)
- seriousness of report: defined as yes or no
- reason for seriousness of report: death, disability, congenital anomaly, life threatening, hospitalization, other medically important condition
- patient information: age, gender, height, weight
- report outcome: represents the outcome of the reported case as described by the reporter at the time of reporting and does not infer a causal relationship
    - report outcome is not based on a scientific evaluation by Health Canada
- product information: product description (name of product), product role (the characterization of the role of each product as provided by the original reporter: for example, suspect, concomitant), dosage form, route of administration, dosing and dosing frequency, therapy duration
- reaction information: Medical Dictionary for Regulatory Activities (MedDRA) preferred term (reaction term(s) selected to describe the reactions in the report, using internationally accepted adverse reaction terminology), MedDRA version (version of MedDRA terminology in use when information was extracted from the database)
- duration: the length of time the patient experienced the adverse reaction
- report criteria: report runtime (date information was extracted from the database), health product (product specified in search criteria), initial date of receipt (time period for which the database was searched according to initial date a report was received), total number of reports

Please note that the detail of the line listing is limited to the amount of information provided in each report. That is, if the reporter did not include the product dosing or frequency, then the boxes for these values would be empty.

Veterinary Drugs Directorate, Pharmacovigilance Program

A line listing of adverse reaction information includes standard information:

- report identification number
- date report was received by Veterinary Drugs Directorate (VDD)
- indication if the report is serious, defined as yes or no
- animal age
- animal gender
- production type/breed or species
- dosage form of the health product
- route of administration for each health product
- frequency of the dose for each health product, for example once daily, twice daily
- duration of use for each health product;
- reaction term(s) selected to describe the reactions in the report, using internationally accepted adverse reaction terminology (Veterinary Dictionary for Drug Related Affairs, or VeDDRA)
- outcome at time of report
    - report outcome represents the outcome of the reported case as described by the reporter at the time of reporting and does not infer a causal relationship
    - report outcome is not based on a scientific evaluation by Health Canada
- total number of reports (shown at the end of the line listing)
- date the information was extracted from the database
- time period for which the database was searched

Please note that the detail of the line listing is limited to the amount of information provided in each case report.

Definitions

For the purpose of this procedure:

Adverse reaction (AR): a noxious and unintended response and includes "adverse drug reaction" as defined in the *Food and Drug Regulations* and "adverse reaction" as defined in the *Natural Health Product Regulations.*

"Adverse drug reaction" as defined in the *Food and Drug Regulations* means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function.

"Adverse reaction" as defined in the *Natural Health Products Regulations* means a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

Domestic adverse reaction: an adverse reaction occurring in Canada.

Domestic medical device incident: an incident that occurred inside Canada involving a medical device marketed in Canada.

Foreign adverse reaction: an adverse reaction occurring outside Canada to a product that is marketed in Canada.

Foreign medical device incident: an incident that occurred outside Canada to a medical device marketed in Canada.

Health product: includes drugs, medical devices, natural health products, blood and blood components, cells, tissues and organs, and sperm and ova for the purpose of assisted human reproduction. Drugs include both prescription and non-prescription pharmaceuticals; biotechnology products, biologically derived products such as vaccines, serums and blood derived products; disinfectants; radiopharmaceuticals; and medical devices.

Line listing: a summary of a subset of the data from individual adverse reaction reports provided in a table format.

Market authorization holder (MAH): the legal entity that holds the Notice of Compliance, the Drug Identification Number (DIN), the medical device licence for class II, III and IV devices, the Natural Product Number (NPN), the Homeopathic Medicine Number (DIN-HM), the product licence number or that has received approval to initiate clinical/field trials in Canada. Market authorization holder can also be referred to as the sponsor or manufacturer.

Medical Device Incident (MDI): as described in section 59(1) of the *Medical Devices Regulations,* any incident involving a medical device that is sold in Canada when the incident occurs either within or outside Canada; relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use (section 59 (1) (a)); and has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur (section 59 (1) (b)).

Medication incident: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Serious adverse reaction: a noxious and unintended response to a marketed health product covered by this document that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death and includes "serious adverse drug reaction" as defined in the *Food and Drug Regulations* and "serious adverse reaction" as defined in the *Natural Health Products Regulations*.

"Serious adverse drug reaction" as defined in C.01.001(1) of the *Food and Drug Regulations* is a noxious and unintended response to a drug that occurs at any dose and 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. For veterinary drugs, in the case of large animals this would include cases that required veterinary attention on-site.

"Serious adverse reaction" as defined in Section 1(1) of the *Natural Health Products Regulations* is a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization that causes congenital malformation, that results in persistent or significant disability or incapacity that is life threatening or that results in death.

Spontaneous adverse reaction: an unsolicited communication by health care professional or consumer/animal owner to a company, regulatory authority or other organization (for example, World Health Organization, regional centres, Poison Control Centre) that describes 1 or more adverse reactions or medical device incidents in a patient who was given 1 or more medicinal products and that does not derive from a study or any organized data collection scheme.