Procedure – The Release to the Public of Information Obtained from Adverse Reaction and Medical Device Incident Reports

Health Products and Food Branch

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Canada

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1.0 Introduction

1.1 Purpose

The purpose of this document is to increase government transparency by providing the Health Products and Food Branch (HPFB) procedures for the consistent and uniform application of government policies and guidelines associated with the *Access to Information Act* and *Privacy Act* when releasing to the public information from adverse reaction (AR) and medical device incident reports. The reports relate to adverse reactions to substances such as drugs, biologics, natural health products, human cells, tissues and organs (CTOs) and medical device incidents that are regulated by the Health Products and Food Branch (HPFB) of Health Canada.

Transparency will be achieved through the use of common procedures, that when applied, should result in a consistent and uniform application of government laws, policies and guidelines governing the public's right of access to information that is held by government and Health Canada's duty to protect personal and confidential third party information in accordance with its applicable laws.

This document outlines the procedures for providing this information to members of the public requesting AR and medical device incident data from the Health Products and Food Branch which may include health care professionals, consumers, media, industry, academia and research communities.

1.2 Background

A program to collect adverse reaction reports has existed in Canada since 1965. For marketed health products, these reports are known as spontaneous adverse reaction reports since they result from unsolicited communications that describe adverse reactions and are not derived from a study or any organized data collection scheme.

Today, market authorization holders (MAH) and medical device licence holders are mandated by the associated regulations of the *Food and Drugs Act* to provide Health Canada with important safety information, including adverse reaction and medical device incident reports, about the products they sell in Canada. Health professionals (such as physicians, pharmacists, nurses, dentists, veterinarians, veterinary technicians) and consumers are encouraged to report adverse reaction and medical device incidents on a voluntary basis.

The type of information collected in adverse reaction or medical device incident reports includes 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. The information received in adverse reaction reports or medical device incident reports does not represent all known or possible safety information concerning the suspected product.

Further information about the adverse reaction and medical device incident reporting programs is available at www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/reaction-eng.php#.

1.3 Scope

This procedure applies only to the release to the public of information obtained from adverse reaction and medical device incident reports from organizations within the Health Products and Food Branch which are listed in the table below. A description of the responsibilities of these organizations is found in Section 3 of this document.

Health Products and Food Branch (HPFB) Organizations	**Adverse Reaction Reports and Medical Device Incident Reports Collected.**
Biologics and Genetic Therapies Directorate (BGTD)	Adverse transfusion reaction/event, clinical trial adverse reaction reports for biological drugs and radiopharmaceuticals.
Health Products and Food Branch Inspectorate (HPFBI)	Incident reports for marketed medical devices.
Marketed Health Products Directorate (MHPD), Canada Vigilance Program	Post-market adverse reaction reports for pharmaceutical drugs, biologics, radiopharmaceuticals, cells, tissues and organs and natural health products approved for use in humans.
Natural Health Products Directorate (NHPD)	Clinical trial adverse reaction reports for natural health products.
Therapeutic Products Directorate (TPD)	Clinical trial adverse reaction reports for pharmaceuticals, medical device incident reports of investigational testing. Special Access Programs ARs (drugs) and medical device incidents reports.
Veterinary Drugs Directorate (VDD)	Post-market adverse reaction reports for pharmaceutical drugs approved for use in animals.

2.0 Procedure

The following information describes the Health Products and Food Branch (HPFB) procedure for providing adverse reaction and medical device incident data.

Information Available in Standard Summary Formats from Post-Market Adverse Reaction Reporting Programs

Only the adverse reaction information from post-market domestic AR reports will be provided by HPFB's adverse reaction and medical device incident programs. The public can request information for post-market domestic AR reports from the Canada Vigilance and Veterinary Drugs Pharmacovigilance Programs. The programs will provide the AR data in a standard summary or line-listing format (Appendix 1).

The following information should be included in the request to the responsible AR reporting program:

- the name and address, telephone number and e-mail address (if available) of the requester;
- the names of the health product(s) of interest (brand name or generic name/active ingredient); and
- the time period of the search (time period when reports were received), any specific criteria or search limitations (specific reaction terms).

Information Available on the Health Canada Web site

Information from the Canada Vigilance Program is also available to the public through the Health Canada website. A subset of the information from post-market domestic AR reports for health products approved for use in humans is made available through Marketed Health Products Directorate's (MHPD) Canada Vigilance Adverse Reaction Online Database (www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php) which is updated quarterly. Each new quarterly update contains information that is one quarter behind the actual release date.

Information not Available in Standard Summary Format or on the Web site

Requests for information, other than that which is publicly available or represented in standard summary format reports should be made through the Access to Information and Privacy Division of Health Canada (For contact information, see section 2.5 of this document).

Information from Clinical Trial Adverse Reaction Reports

Request for clinical trial adverse reaction data should be made through the Access to Information and Privacy Division of Health Canada.

Information from Medical Device Incident Reports

Request for medical device incident data should be made through the Access to Information and Privacy Division of Health Canada.

Information from Foreign Regulatory Agencies

Requests for data received from foreign regulatory agencies should be made to that responsible regulatory agency.

2.1 Protected Information

2.1.1 Personal Information

Personal information is defined in the *Privacy Act*, (R.S.C., 1985, c. P-21) as meaning information about an identifiable individual that is recorded in any form (Section 3). The *Privacy Act* (PA) governs the collection, correction, use, disclosure, retention and disposal of personal information. Personal information is also protected under the *Access to Information Act*, (R.S.C., 1985, c.A-1) and other applicable laws. In addition, the right to privacy is protected by s. 8 of the *Canadian Charter of Rights and Freedoms* (Charter). One aspect of this right includes the protection of information for which a person has a reasonable expectation of privacy.

Any information related to an identifiable patient, device user, animal/owner and/or reporter of the AR or medical device incident is protected in accordance with the PA. It may also be protected by the Charter and other applicable laws. Information will not be provided in standard summary format for requests where the search criteria selected include patient or reporter identifiers. Identifiers may include, but are not limited to addresses, including names of cities, towns, provinces and postal codes, names of institutions, clinics or other organizations that patients, device users, animal/owners or reporters may be affiliated with.

2.1.2 Confidential Third Party Information

For the purposes of this Procedure, the expression "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 and having received such information in confidence, it has a duty to uphold its confidentiality in accordance with the applicable laws. Section 8 of the Charter would also protect 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. For example, the information may be a trade secret; financial, commercial, scientific or technical confidential 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.

2.2 Statements Describing the Limitations and Interpretation of Information

The limitations of information from AR reports, as described in the caveat below that is included in the standard summary format for provision of adverse reaction data, should be taken into consideration when interpreting AR data.

This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. 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 primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis.

Underreporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. 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 the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. 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. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

2.3 Use of the Adverse Reaction (AR) or Medical Device Incident Information Provided from Adverse Reaction Reporting Programs in the Health Products and Food Branch (HPFB)

The adverse reaction or medical device incident data provided by AR or medical device incident reporting programs of the Health Products and Food Branch may be used in other documents, including publications. It is requested that the author acknowledges the source of the data, the limitations of the data from spontaneous reporting systems and provides a copy of the document or publication to the AR reporting program prior to publication.

2.4 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:

Media Relations Unit
Public Affairs - Consultations and Communication Branch
Health Canada
Postal Locator 0912C
Ottawa, Ontario K1A 0K9

Telephone: 613-957-2983
Fax: 613-952-7747

2.5 Requests for Data not Provided in Standard Formats or not Available Through Searchable Internet Tools Available to the Public

Requests for additional information not provided in standard formats (see Appendix 1) may be made through Access to Information and require payment of the applicable fee:

Director/Coordinator
Access to Information and Privacy Division
Health Canada
Postal Locator 2301D
Ottawa, Ontario K1A 0K9

Telephone: 613-954-9165
Fax: 613-941-4541
E-mail: atip-aiprp@hc-sc.gc.ca

The Access to Information Request Form is available on the Treasury Board of Canada Secretariat Web site at www.tbs-sct.gc.ca/tbsf-fsct/350-57_e.asp.

The information can also be requested via the Health Canada Web site at www.hc-sc.gc.ca/contact/ahc-asc/csb-dgsg/atip-aiprp-eng.php.

3.0 Responsibilities

3.1 Health Canada – Access to Information and Privacy Division

Health Canada – Access to Information and Privacy Division coordinates the receipt of and response to requests made by Canadians under the *Access to Information Act* and *Privacy Act* for Health Canada records.

3.2 Health Canada – Media Relations Unit

Health Canada – Media Relations Unit acts as a first point of contact for members of the media seeking information about Health Canada activities and programs. Their role is to provide consistent, open and transparent information to members of the media, and to support the Minister, Deputy Minister and departmental spokespersons in their media relations activities.

3.3 Health Products and Food Branch Organizations Responsible for Adverse Reaction or Medical Device Incident Reports

3.3.1 Biologics and Genetic Therapies Directorate (BGTD)

The Biologics and Genetic Therapies Directorate (BGTD) is responsible for overseeing the regulation of biological drugs (products derived from living sources) and radiopharmaceuticals for human use. It is responsible for the collection and assessment of clinical trial adverse reaction report information for these products. BGTD is also responsible for the collection and assessment of adverse transfusion reaction/events.

3.3.2 Health Products and Food Branch Inspectorate (HPFBI)

The Medical Devices Compliance Unit of the Health Products and Food Branch Inspectorate is responsible for receiving and evaluating medical device incident reports.

3.3.3 Marketed Health Products Directorate (MHPD)

The Marketed Health Products Directorate is responsible for the maintenance and enhancement of a National Program (Canada Vigilance Program) for collection, processing and assessment of adverse reaction information to contribute to post-market surveillance, assessment and risk communication activities of the HPFB. ARs collected by the Canada Vigilance Program include pharmaceutical drugs, biologics (which include biotechnology products, vaccines [therapeutic & diagnostic vaccines since 1965, immunization vaccines since January 1, 2011], fractionated blood products and human cell, tissues and organs), radiopharmaceuticals and natural health products. It is the responsibility of MHPD to release a sub-set (without personal identifiers) of the information from MHPD's post-market domestic ARs to the WHO International Drug Monitoring Program on a quarterly basis.

3.3.4 Natural Health Products Directorate (NHPD)

The Natural Health Products Directorate (NHPD) is responsible for overseeing the regulation of natural health products for sale in Canada. It is responsible for the collection and assessment of clinical trial adverse reaction report information for these products.

3.3.5 Therapeutic Products Directorate (TPD)

The Therapeutic Products Directorate (TPD) is responsible for overseeing the regulation of pharmaceutical drugs and medical devices for human use. It is responsible for the collection and assessment of serious and unexpected clinical trial and spontaneous adverse drug reactions reports related to investigational products from both domestic and international sources. The Directorate is also responsible for the collection of medical device incidents associated with investigational testing and the special access program for drugs and medical devices.

3.3.6 Veterinary Drugs Directorate (VDD)

The Veterinary Drugs Directorate is responsible for the coordination of the receipt and evaluation of post-market adverse reaction reports and assessment of signals and safety trends concerning drugs approved for use in animals.

Appendix 1: Standard Summary Formats for Provision of Adverse Reaction Data

The AR data from HPFB adverse reaction reporting programs will be provided as line-listing summaries, either as paper copies or, electronically, as PDF files. The format of the line-listing may vary depending on the time period searched, and the database used during that period. Line-listing summaries will not be provided for requests where the search criteria selected include patient, device user, animal/owner or reporter identifiers. Identifiers may include, but are not limited to addresses, including names of cities, towns, provinces and postal codes, names of institutions, clinics or other organizations that may be affiliated.

Marketed Health Products Directorate, Canada Vigilance Program

The following standard information is provided on a Canada Vigilance line-listing of adverse reaction information:

- **Adverse Event Report (AER) Number:** report number assigned by Health Canada
- **Adverse Event Report (AER) Version No:** 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 initial report, version 0, was received by Health Canada's Marketed Health Products Directorate
- **Latest Received Date:** date that the last follow-up report was received by Health Canada's Marketed Health Products Directorate
- **Report Source:** indicates the location through which the reporter sent the report
- **Market Authorization Holder (MAH) Number:** Market Authorization Holder report number for reports received from a MAH or manufacturer
- **Report Feature:** Scope of report, e.g., Adverse Reaction, Accidental exposure, Drug Abuse, Medication error, etc.
- **Type of Report:** e.g., Spontaneous, Study, Solicited, Published, Registry, etc.
- **Reporter Type:** indicates who reported the adverse reaction and their relationship to the patient
- **Record Type:** indicates if report is a duplicate or is linked to another report
- **Link Adverse Event Report (AER) 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. The 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: e.g., suspect, concomitant, etc.), 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)

- **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.

Veterinary Drugs Directorate, Pharmacovigilance Program

The following standard information is provided on a line-listing of adverse reaction information:

- Report identification number (number assigned by Health Canada);
- Date report was received by Veterinary Drugs Directorate (VDD);
- Indication if the report is serious, yes/no (Y/N) (See Appendix 4 for definition of a serious adverse reaction);
- Animal age;
- Animal gender;
- Production type/breed or species;
- Dosage form of each health product;
- Route of administration for each health product;
- Frequency of the dose for each health product (e.g., 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 (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. The 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 that 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.

Appendix 2: Program Contact Information for Requests for Standard Summary Formats of Adverse Reaction Data

Marketed Health Products Directorate, Canada Vigilance Program

Requests for standard summary formats of adverse reaction data should be made in writing (letter, fax or e-mail) to the:

Canada Vigilance Program
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Telephone: 613-957-0337
Fax: 613-957-0335
E-mail: CanadaVigilance@hc-sc.gc.ca

Veterinary Drugs Directorate, Pharmacovigilance Program

Requests for standard summary formats of adverse reaction data should be made in writing (letter, fax or e-mail) to the:

Pharmacovigilance Program
Clinical Evaluation Division
Veterinary Drugs Directorate
Health Canada
Postal Locator 3000A
Ottawa, Ontario
K1A 0K9

Fax: 613-946-1125
E-mail: pharmacovigilance-vet@hc-sc.gc.ca

Appendix 3: Abbreviations

AE: Adverse Event

AER: Adverse Event Report

AR: Adverse Reaction

ATIA: *Access to Information Act*

BGTD: Biologics and Genetic Therapies Directorate

Charter: *Canadian Charter of Rights and Freedoms*

CTO: Human Cells, Tissues and Organs

HPFB: Health Products and Food Branch

HPFBI: Health Products and Food Branch Inspectorate

MAH: Market Authorization Holder

MedDRA: Medical Dictionary for Regulatory Activities

MHPD: Marketed Health Products Directorate

NHPD: Natural Health Products Directorate

PA: *Privacy Act*

TPD: Therapeutic Products Directorate

VDD: Veterinary Drugs Directorate

WHO: World Health Organization

VedDRA: Veterinary Dictionary for Drug Related Affairs

Appendix 4: Definitions

For the purpose of this Procedure:

Adverse Reaction (AR): means 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 AR: 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, cells, tissues and organs. Drugs include both prescription and non-prescription pharmaceuticals; biotechnology products, biologically-derived products such as vaccines, serums, and blood derived products; disinfectants; and radiopharmaceuticals.

Line-Listing: a summary of a subset of the data from individual AR reports provided in a table format.

Market Authorization Holder (MAH): for the purpose of this procedure means the legal entity that holds the Notice of Compliance, the Drug Identification Number (DIN), the medical device license 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: "Incident" as described in section 59(1) of the *Medical Devices Regulations* means 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: means 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 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 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 healthcare professional or consumer/animal owner to a company, regulatory authority or other organization (e.g., World Health Organization, Regional Centres, Poison Control Centre), that describes one or more adverse reactions or medical device incidents in a patient who was given one or more medicinal products and that does not derive from a study or any organized data collection scheme.