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# Recall Policy for health products



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August 15, 2019

Canada 

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**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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#### **Disclaimer**

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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# 1. Purpose

The purpose of this policy is to outline what is expected of all responsible parties who are planning for and conducting recalls of health products in Canada, in accordance with the requirements of the:

- Act
  - *Food and Drugs Act* (Act)
- Regulations
  - Food and Drug Regulations (FDR)
  - Medical Devices Regulations (MDR)
  - Natural Health Products Regulations (NHPR)
  - Blood Regulations
  - Safety of Human Cells, Tissues and Organs for Transplantation Regulations
  - Processing and Distribution of Semen for Assisted Conception Regulations

# 2. Scope

This policy applies to all recalls of drugs, medical devices, natural health products, blood and blood components, cells, tissues, organs and semen for assisted conception.

This policy does not apply to:

- Biological products for veterinary use licensed with the Canadian Food Inspection Agency, and
- Devices for veterinary use.

The following actions, conducted by establishments, are not considered recalls and are therefore not subject to this policy:

- Stock recovery of products which have not left the direct control of a responsible party,
- Product withdrawal when there are no health and safety risks or contravention of applicable legislation, and
- Issuing of a product communication to reinforce labelling information.

This policy does not address investigation or other obligations outside of the recall context, including any obligations in respect of adverse reactions.

### 3. Policy Statement

Health Canada expects responsible parties to voluntarily recall a health product when:

- It contravenes the Act or the Regulations, **or**
- It presents a risk to the health of Canadians.

Responsible parties are expected to conduct a recall in a timely and effective manner and to have measures in place to correct non-compliance and prevent reoccurrence.

Health Canada, through the Regulatory Operations and Enforcement Branch (ROEB), may request a responsible party to conduct a voluntary recall if non-compliance or a risk to health is identified.

If Health Canada believes that a therapeutic product presents a serious or imminent risk to the health of Canadians, and the responsible party does not agree to a voluntary recall, Health Canada has the power to **order** a recall pursuant to section 21.3(1)(a) of the Act.

Whether undertaken at the initiative of a responsible party, in response to a request to voluntarily recall or an order to recall under the Act, responsible parties must take full responsibility for conducting recalls, which includes taking the mandatory actions outlined in Appendix A – Mandatory actions.

ROEB verifies that recalls are conducted in a timely and effective manner and in accordance with the Act and Regulations. Should a responsible party fail to effectively conduct a recall, ROEB may take compliance and enforcement actions in accordance with the *Compliance and enforcement policy for health products* (POL-0001).

ROEB expects that an effective recall will result in the following outcomes:

- Health Canada was notified of the risk to health and the recall within the **timelines specified in section 4.1.1 of this policy**, and was provided with information about the results of recalls and the actions taken to prevent reoccurrence of non-compliance.
- Non-compliant or potentially harmful health products have been removed from distribution or measures have been taken to correct the non-compliance in an effective and timely manner.
- Canadians have been informed of the affected products and associated health risks as necessary.

## 4. Roles & Responsibilities

### 4.1 Responsible Parties

The responsible party is accountable for the quality of every product they manufacture, distribute or sell in Canada. ROEB expects that responsible parties will take full responsibility for product recalls, which includes assessing the risk to health (i.e., Type I, II or III) by conducting a thorough health risk assessment, and taking timely and effective actions to mitigate that risk.

As required under the Act and Regulations, responsible parties must:

- For drugs, medical devices and natural health products: notify Health Canada when they commence a recall (refer to section 4.1.1 for specific timelines for notification to Health Canada);
- For blood or cells, tissues and organs: provide to Health Canada a preliminary report after they have started the conduct of an investigation into a suspected error or accident (refer to section 4.1.1 for specific timelines for submitting reports to Health Canada);
- For semen: provide to Health Canada a preliminary report after they have started the conduct of an investigation, to determine if semen is contaminated by an infectious agent (refer to section 4.1.1 for specific timelines for submitting reports to Health Canada);
- Maintain necessary distribution records and systems of product control, as required under the Regulations, to enable a rapid and complete recall;
- Have documented procedures that enable them to carry out effective and timely investigation of reported problems and recalls;
- Undertake recalls when ordered by Health Canada and comply with **all terms and conditions** set out in the Order.

It is also expected that responsible parties will:

- Undertake recalls as requested by Health Canada,
- Provide progress reports when requested by Health Canada, and
- Conduct recall effectiveness checks.

#### 4.1.1 Notification to Health Canada

The Regulations require that responsible parties have a documented recall system in place, which can be implemented, to ensure that Health Canada is notified of recalls in a timely manner, as follows:

## For drugs

The responsible party should notify Health Canada if there is a potential need to recall a distributed product at **the time a risk to health** is identified. Section C.01.051 of the Food and Drug Regulations requires a manufacturer or importer who commences a recall to submit information to Health Canada "**forthwith**". This is interpreted to mean that the responsible party who is recalling a drug must submit the information specified in section C.01.051 to Health Canada **within 24 hours of having made the decision to recall**. This initial notification may be made verbally or in writing. This notification should be followed **within 72 hours** by a written report (e.g. Health risk assessment) containing sufficient information to enable Health Canada to assess the risk to health of the implicated drug.

## For medical devices

- Section 64 of the Medical Devices Regulations requires the manufacturer and importer of a medical device to provide Health Canada with information concerning a recall "**on or before undertaking a recall**". This is interpreted to mean that the manufacturer and importer must submit to Health Canada as much recall information as is known **within 24 hours of having made the decision to recall**. This initial notification may be made verbally or in writing. This must be followed by a written report containing full information as required by section 64 **within three business days of starting the recall**. As per section 65 of the Medical Devices Regulations, a report on the results of the recall and the action taken to prevent a recurrence of the problem must be submitted **as soon as possible after the completion of a recall**.

## For natural health products

- The responsible party should notify Health Canada if there is a potential need to recall a distributed product at **the time a risk to health** is identified. Sections 25 and 62 of the Natural Health Products Regulations require every product licence holder, manufacturer, importer or distributor who commences a recall of a natural health product to provide the information referred to in section 62 to Health Canada **within three days after the day on which the recall is commenced**.

## For blood

- Section 107 of the Blood Regulations requires that a blood establishment conducting an investigation into a suspected error or accident, that is thought to have occurred during an activity it conducted, that is identified after the blood is distributed or transfused, and where there is a reasonable probability that the error or accident could lead to a serious adverse

reaction, must provide to Health Canada a preliminary report **within 24 hours after the start of the investigation** that includes all relevant information available. The blood establishment must provide a written update **within 15 days after the start of the investigation** on any new information about the suspected error or accident, on the progress of the investigation, and on the steps taken to mitigate further risks. The blood establishment must provide further written updates **on Health Canada's request at any time** after the preliminary report. The blood establishment must also file a final report containing (a) the results of the investigation; (b) the final disposition of the blood that was the subject of the investigation and the reasons for that disposition; and (c) any corrective actions taken and any other changes that are recommended to be made to relevant processes, **on completion of the investigation**.

### For cells, tissues and organs

- Section 51 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations requires that a source establishment conducting an investigation of a suspected error or accident, that is identified after distribution, and could lead to a serious adverse reaction involving the transmission of an infectious disease or disease agent, must provide to Health Canada a preliminary report **within 24 hours after the start of the investigation** that includes all relevant information available at that time. The source establishment must provide an update **every 15 days** on the progress of the investigation and on the steps taken to mitigate further risks until the final report is provided. Per section 54 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations, the source establishment must submit a detailed final report containing (a) the results of the investigation; (b) the final disposition of the cells, tissues and organs that were the subject of the investigation and the reasons for that disposition; and (c) any corrective actions taken, **on completion of the investigation**.

### For semen

- Subsection 15(3) of the Processing and Distribution of Semen for Assisted Conception Regulations requires that every processor conducting an investigation to determine if semen is contaminated by an infectious agent must provide to Health Canada the information specified in that section **within three days after the start of an investigation**, and must provide an update **every 30 days after the start of the investigation** on the progress of the investigation, until the final report is provided. Per section 18 of the Processing and Distribution of Semen for Assisted Conception Regulations, the processor must submit a detailed final report setting out the results of the investigation, including, where the semen is required to be collected, destroyed or reserved for special access distribution, the disposition of all containers of that semen, **on completion of the investigation**.



Notifications and other communications to Health Canada should be made by contacting the Regulatory Operations and Enforcement Branch (see Appendix C).

#### 4.1.2 Record keeping and standard operating procedures

The Regulations require responsible parties to maintain necessary records and develop a system of control for product recalls that can be put into effect when needed. In accordance with these requirements, it is expected that responsible parties will:

- Take actions to recall a product that is suspected or known to be defective in a manner that is prompt and in accordance with a predetermined plan.
- Have recall procedures in place that:
  - are in writing and known to all responsible staff,
  - describe how the responsible party notifies Health Canada, notifies product distributors and users, conducts a recall and carries out any follow-up activities,
  - can be put into operation at any time, during and outside normal working hours, and,
  - clearly identify the persons responsible for initiating and coordinating all recall activities.
- Notify all Canadian and foreign establishments involved in the fabrication, distribution or importation of the recalled product.
- Maintain distribution records that enable tracing and accounting for all products including those in transit, on loan, samples removed by the quality control department and any professional samples distributed.
- Identify all recalled products and, when appropriate, place those recalled products in quarantine until disposition is determined.
- Assess and record the progress and efficacy of the recall at intervals and issue a final report including a final reconciliation of implicated products. The final report should also indicate the actions taken to prevent a recurrence of the problem.
- For clinical trial drugs, the sponsor has a system for retrieving clinical trial drugs and documenting this retrieval of deficient product.

## 4.2 Regulatory Operations and Enforcement Branch

The Regulatory Operations and Enforcement Branch (ROEB) monitors recalls and assesses the effectiveness of a responsible party's actions, with a focus on protecting the health and safety of Canadians. These actions include:

- Engaging with regulated parties on their plans and progress in assessing root cause;
- Ensuring that the health risk classification (i.e., Type I, II, or III) assigned to the recall by the responsible party is appropriate based on the risk posed by the product;
- Requesting a formal health risk assessment or risk confirmation from Health Canada program directorates when identified risk is unclear or questionable;
- Issuing risk communications to alert the public when it believes there is a serious risk to health associated with the recalled product;
- Reviewing how the responsible party disposed of or intends to dispose of the recovered products;
- Verifying that the responsible party has implemented corrective measures to prevent reoccurrence of non-compliance or risks to health.

Note that all health product recalls are published on Health Canada's [Recalls and Safety Alerts Database](#).

### Health Canada's International Responsibilities

International partners are notified of recalls, by Health Canada, in accordance with voluntary or mandatory commitments and agreements negotiated with those partners.

For drugs, ROEB's responsibilities under existing Mutual Recognition Agreements (MRAs) are stipulated in those agreements, and include an alert notification to partner authorities of recalls, as appropriate, to the level of risk of the product recalled.

Several voluntary agreements for international exchange of information on recalls also exist.

These include:

- For medical devices, information on high risk recalls disclosed under the International Medical Device Regulators Forum (IMDRF) National Competent Authority Report (NCAR) exchange program.

- Courtesy copies to individual countries as appropriate for Type I and II health risk classifications (e.g. **Pharmaceutical Inspection Cooperation Scheme (PIC/S)** members).

Where no such agreements are in place, ROEB will make efforts to inform foreign authorities of the status of any exported products posing a serious health risk.

# Appendix A – Mandatory Actions

Table 1: Drugs

Person	Applicable Legislation	Requirements
Sellers (includes persons distributing without consideration)	Section 21.3(1) and 31.2 of the <a href="#">Food and Drugs Act</a>	Order to recall, send the product to a specified place, or take corrective action, where Health Canada believes that a drug (other than a natural health product) or a device presents a serious or imminent risk of injury to health. The recipient of an Order has a legal obligation to comply with it. A person who contravenes an Order made under s.21.3(1) commits an offence under s.31.2 of the Act.
Manufacturers, Importers	C.01.051 of the <a href="#">Food and Drug Regulations</a>	Notification of recall to Health Canada.
Fabricators, Packagers/Labellers, Distributors as referred to in section C.01A.003, Importers, Wholesalers	C.02.012(1)(a) of the <a href="#">Food and Drug Regulations</a>	Maintenance of a product control system to enable a complete and rapid recall of a drug that is on the market.
Wholesalers, Distributors as referred to in section C.01A.003, Importers	C.02.022 of the <a href="#">Food and Drug Regulations</a>	Records of all sales are retained or kept readily accessible, for a period of at least one year after the expiration date of that lot or batch (or in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed), in a manner that will permit a complete and rapid recall of any lot or batch of a drug. This requirement need not necessarily involve tracking by lot number.

Table 1: Drugs

Person	Applicable Legislation	Requirements
Sponsors	C.05.010(j) of the <a href="#">Food and Drug Regulations</a> for clinical trials authorized under C.05.006(1)	C.02.012 and C.02.022 of the Food and Drug Regulations apply. Per <a href="#">GUI-0036: Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials</a> , procedures for retrieving clinical trial drugs, including comparators, and documenting this retrieval should be established by the sponsor, in collaboration with the manufacturer or importer where different. The qualified investigators need to understand their obligations under the retrieval procedure.

Table 2: Medical Devices

Person	Applicable Legislation	Requirements
Sellers (incl. persons distributing not for consideration)	Section 21.3(1) and 31.2 of the <a href="#">Food and Drugs Act</a>	Order to recall, send the product to a specified place, or take corrective action, where Health Canada believes that a drug (other than a natural health product) or a device presents a serious or imminent risk of injury to health. The recipient of an Order has a legal obligation to comply with it. A person who contravenes an Order made under s.21.3(1) commits an offence under s.31.2 of the Act.
Manufacturers, Importers	Sections 52 to 58, and 63 to 65 of the <a href="#">Medical Devices Regulations</a> , and, section 88 of the Medical Devices Regulations for Medical Devices for Investigational Testing Involving Human Subjects	Maintaining distribution records, complaint handling, implementation of investigation and recall procedures, notification of a recall to Health Canada, and report of completion of a recall and corrective action taken.
Distributors	Sections 52 to 58 of the <a href="#">Medical Devices Regulations</a>	Maintaining distribution records, complaint handling, and implementation of investigation and recall procedures.

**Table 3: Natural Health Products**

Person	Applicable Legislation	Requirements
Product Licence Holder	Sections 25 and 62 of the <a href="#">Natural Health Products Regulations</a>	Notification of a recall to Health Canada.
Manufacturers, Importers and Distributors	Sections 25, 50, 51, 53, 56, 57 and 62 of the <a href="#">Natural Health Products Regulations</a>	Investigation of complaints, corrective actions, system of control and record-keeping to enable a recall, and notification of a recall to Health Canada.
Packagers	Sections 50, 51, and 54 of the <a href="#">Natural Health Products Regulations</a>	Investigation of complaints, corrective actions, system of control and record-keeping to enable a recall.
Labellers	Sections 50, 51 and 55 of the <a href="#">Natural Health Products Regulations</a>	Investigation of complaints, corrective actions, system of control and record-keeping to enable a recall.

**Table 4: Blood**

Person	Applicable Legislation	Requirements
Sellers (incl. persons distributing not for consideration)	Section 21.3(1) and 31.2 of the <a href="#">Food and Drugs Act</a>	Order to recall, to send the product to a specified place, or take corrective action, where Health Canada believes that a drug (other than a natural health product) or a device presents a serious or imminent risk of injury to health. The recipient of an Order has a legal obligation to comply with it. A person who contravenes an Order made under s.21.3(1) commits an offence under s.31.2 of the Act.
All blood establishments required to be licensed or registered	Section 93 and 94 of the <a href="#">Blood Regulations</a>	Quality management system including a system for identification and investigation of post-donation information, errors, accidents and adverse reactions, and the conduct of recalls.
All blood establishments	Section 95 of the <a href="#">Blood Regulations</a>	Operating procedures for activities with respect to human safety and the safety of blood.
All blood establishments	Section 103 to 108 of the <a href="#">Blood Regulations</a>	Quarantine; notification of suspected compromise of blood to other establishments; investigation if error or accident during activity conducted by establishment may have compromised safety of blood; notification of investigation to other establishments; information-sharing with other establishments; and provision of preliminary, progress and final reports on investigation (including corrective actions) to Health Canada.



Table 4: Blood

Person	Applicable Legislation	Requirements
All blood establishments	Section 117 of the <a href="#">Blood Regulations</a>	Records must be accurate, complete, legible, indelible and readily retrievable. This will enable establishments to quickly and efficiently retrieve blood traceability information to enable prompt recalls of blood.

Table 5: Human Cells, Tissues and Organs for Transplantation

Person	Applicable Legislation	Requirements
Sellers (incl. persons distributing not for consideration)	Section 21.3(1) and 31.2 of the <a href="#">Food and Drugs Act</a>	Order to recall, to send the product to a specified place, or take corrective action, where Health Canada believes that a drug (other than a natural health product) or a device presents a serious or imminent risk of injury to health. The recipient of an Order has a legal obligation to comply with it. A person who contravenes an Order made under s.21.3(1) commits an offence under s.31.2 of the Act.
All establishments	Section 55 to 63, 71 to 76 of the <a href="#">Safety of Human Cells, Tissues and Organs for Transplantation Regulations</a>	Record-keeping, quality assurance system and standard operating procedures to enable compliance with regulations.
Source establishments	Sections 44, 51, 53 and 54 of the <a href="#">Safety of Human Cells, Tissues and Organs for Transplantation Regulations</a>	Quarantine; investigation; notification of error or accident investigation to Health Canada and other establishments; provision of preliminary, progress and final reports on the investigation (including corrective actions) to Health Canada; and summary of final report to other establishments.
Establishments other than source establishments	Sections 43, 46 and 50 of the <a href="#">Safety of Human Cells, Tissues and Organs for Transplantation Regulations</a>	Quarantine; notification to the source establishment and other establishments; and information-sharing with the source establishment and other establishments.

Table 6: Semen for Assisted Conception

Person	Applicable Legislation	Requirements
Sellers (incl. persons distributing not for consideration)	Section 21.3(1) and 31.2 of the <a href="#">Food and Drugs Act</a>	Order to recall, to send the product to a specified place, or take corrective action, where Health Canada believes that a drug (other than a natural health product) or a device presents a serious or imminent risk of injury to health. The recipient of an Order has a legal obligation to comply with it. A person who contravenes an Order made under s.21.3(1) commits an offence under s.31.2 of the Act.
Processors	Sections 12, 15, 16 and 18 of the <a href="#">Processing and Distribution of Semen for Assisted Conception Regulations</a>	Procedures and record-keeping to trace semen; quarantine; investigation; notification of investigation to Health Canada and others; collection and destruction of contaminated semen; provision of reports to Health Canada; and summary of investigation results to others.
Distributors	Sections 13, 14 and 17 of the <a href="#">Processing and Distribution of Semen for Assisted Conception Regulations</a>	Record-keeping to trace semen; stop-distribution and notification to processor of suspected transmission of infections agent; quarantine or destruction of contaminated semen; and report on actions.

# Appendix B – Glossary

## Acronyms

FDR:	Food and Drug Regulations
IMDRF:	International Medical Device Regulators Forum
MDR:	Medical Device Regulations
MRA:	Mutual Recognition Agreement
NCAR:	National Competent Authority Report
NHPR:	Natural Health Products Regulations
PIC/S:	Pharmaceutical Inspection Cooperation Scheme
ROEB:	Regulatory Operations and Enforcement Branch

## Terms



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or associated regulations, the definition in the Act or regulations prevails.

**Accident (for blood)** – An unexpected event that is not attributable to a deviation from the operating procedures or applicable laws and that could compromise human safety or the safety of blood.

**Accident (for cells, tissues and organs)** – An unexpected event that is not attributable to a deviation from the standard operating procedures or applicable laws and that could adversely affect the safety of a transplant recipient or the safety, efficacy or quality of cells, tissues or organs.

**Blood Establishment** – A person that conducts importation, processing, distribution, transformation or transfusion in respect of blood (see section 1 of the Blood Regulations).

**Consignee** – Anyone who has received, purchased, or used the product being recalled.

**Correction** – Repair, modification, adjustment, relabelling, or inspection (including patient monitoring) of a product without its physical removal to some other location.

**Distributor** – See manufacturer (drugs). Divisions 1A and 2 to 4 of the Food and Drug Regulations apply to the following distributors:

- a) a distributor of an active ingredient; and
- b) a distributor of a drug for which the distributor holds the drug identification number (section C.01A.003).

**Distributor (for natural health products)** – A person who sells a natural health product to another person for the purpose of further sale by that other person (Section 1 of the Natural Health Products Regulations).

**Distributor (for medical devices, for the purpose of this policy)** – A person other than a manufacturer, importer or retailer who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

**Distributor/Distribute (for health products other than drugs, medical devices and natural health products)** – each has its common meaning, except:

- In the case of blood, distribute does not include to transfuse (Section 1 of the Blood Regulations)
- In the case of cells, tissues and organs, distribute does not include to transplant (Section 1 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations).

**Effectiveness Check** – Includes a survey of those affected by a recall (including consignees, in the case of medical devices) to verify they have received the recall information and are aware of any appropriate action to be taken and may include verification of the action taken.

**Error (for blood)** – A deviation from the operating procedures or applicable laws that could compromise human safety or the safety of blood.

**Error (for cells, tissues and organs)** – A deviation from the operating procedures or applicable laws that could adversely affect the safety of a transplant recipient or the safety, efficacy or quality of cells, tissues or organs.

**Establishment (for cells, tissues and organs)** – A person, a partnership or an unincorporated entity, or a part of any of them, that carries out any of the following activities in respect of cells, tissues or organs: importation; processing; distribution; and transplantation (See section 1 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations).

**Health Product** – Includes any product under the mandate of Health Canada (the Regulatory Operations and Enforcement Branch) and regulated under the *Food and Drugs Act*, such as pharmaceutical, biological and radiopharmaceutical drugs for human use; veterinary drugs; medical devices; natural health products; blood; cells, tissues and organs for transplantation; and, semen for assisted conception.

**Health Risk Assessment** – The scientific characterization of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process consists of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Health Risk Classification** – A numerical designation that may be assigned by Health Canada to a particular product to indicate the relative degree of risk to human health presented by the product, as follows:

**Type I** – A situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.

**Type II** – A situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

**Type III** – A situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences.



Types I and II include situations where a product which does not have generally recognized or scientifically supported therapeutic value is promoted in such a way that avoidance of recognized therapy may occur and where such avoidance could lead to injury or death.

**International Medical Device Regulators Forum** – A voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices and aims to accelerate international medical device regulatory harmonization and convergence.

**Manufacturer or distributor (for drugs)** – A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a drug (A.01.010 of the Food and Drug Regulations).

**Manufacturer (for medical devices)** – A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the

person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf (Section 1 of the Medical Devices Regulations).

**Manufacturer (for natural health products)** – A person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient (Section 1 of the Natural Health Products Regulations).

**Mutual Recognition Agreement** – An international agreement that provides for the mutual recognition of compliance certification for Good Manufacturing Practices for drugs (C.01A.001 of the Food and Drug Regulations).

**Pharmaceutical Inspection Cooperation Scheme** – The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a worldwide organization and co-operative arrangement between 52 participating international pharmaceutical Regulatory Authorities and leads the international development, implementation and maintenance of harmonized Good Manufacturing Practices (GMP) standards and quality systems of inspectorates in the field of medicinal products.

**Processor** – A person or establishment that collects, tests, prepares, preserves, labels, and stores semen for use in assisted conception (see section 1 of the Processing and Distribution of Semen for Assisted Conception Regulations).

**Product Withdrawal** – The removal from further sale or use or correction of a distributed product where there is no health and safety risk and no contravention of the legislation or regulations. It is not considered to be a recall.

**Recall (for health products other than medical devices)** – A responsible party's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates the Act or the Regulations.

**Recall (for medical devices)** – In respect of a medical device that has been sold, any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: a) may be hazardous to health; b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or c) may not meet the requirements of the Act or the Medical Devices Regulations (Section 1 of the Medical Devices Regulations).

**Responsible Party** – The person responsible for initiating and conducting a recall. Without limiting the generality of the foregoing, responsible parties may include manufacturers,

distributors, importers, persons in Canada responsible for the sale of the product and wholesalers for drugs; sponsors of clinical trials; manufacturers, importers and distributors for medical devices; manufacturers, importers, distributors, and product licence holders for natural health products; blood establishments for blood; source establishments for cells, tissues and organs; and processors for semen.

**Sell** – Includes offer to sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration (Section 2 of the *Food and Drugs Act*).

**Source Establishment (for cells, tissues and organs)** – as defined in section 1 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations.

**Sponsor** – An individual, corporate body, institution or organization that conducts a drug clinical trial (C.05.001 of the Food and Drug Regulations).

**Stock Recovery (drugs and natural health products)** – The removal or correction of a product that has not been distributed or that has not left the direct control of the party ordering the removal or correction. It is not considered to be a recall.

**Stock recovery (medical devices)** – A manufacturer, importer or distributor's removal or correction of a device that has not been distributed or that has not left the direct control of the company. A stock recovery is not considered to be a recall. However, if the product leaves the control of a manufacturer but has not left the control of subsequent importers or distributors, the action is considered a recall at the manufacturer's level and a stock recovery at the importer/distributor's level. If permitted by the manufacturer (per section 65.1 of the MDR), the importer may prepare and submit recall information and documents on the manufacturer's behalf.

**Therapeutic Product** – A drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the [Natural Health Products Regulations](#) (Section 2 of the *Food and Drugs Act*).

**Two-Way Alert (or Rapid Alert)** – A system implemented amongst MRA partners to rapidly notify each other of any situations that is known or may be expected to negatively affect the quality of a medicinal product/drug covered under the scope of the MRA. It may include but is not limited to:

- confirmed problem reports, corrective actions, or recalls
- the cancellation or suspension of a manufacturing authorization or an establishment licence related to quality deficiencies, in whole or in part, by a regulatory authority listed in the agreement
- counterfeiting and tampering



**Wholesaler (for drugs)** – A person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale:

- (a) a drug in dosage form that is listed in Schedule C or D to the Act, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001(1) of the FDR;
- (b) an active ingredient; or
- (c) a narcotic as defined in the [Narcotic Control Regulations](#); or
- (d) a drug containing cannabis as defined in subsection 2(1) of the [Cannabis Act](#).

# Appendix C – Contact information

## **Contact Health Canada:**

For blood, cells, tissues, organs and semen: [hc.bpcp-pcpb.sc@canada.ca](mailto:hc.bpcp-pcpb.sc@canada.ca)

For drugs and natural health products: [hc.hpce-cpsal.sc@canada.ca](mailto:hc.hpce-cpsal.sc@canada.ca)

For medical devices: [hc.mdcu-ucim.sc@canada.ca](mailto:hc.mdcu-ucim.sc@canada.ca)

Toll free number (Regulatory Operations and Enforcement Branch): 1-800-267-9675

# Appendix D – References

## Blood Regulations

<http://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/page-1.html>

## Compliance and enforcement policy for health products (POL-0001)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>

## Food and Drugs Act

<http://laws-lois.justice.gc.ca/eng/acts/f-27/>

## Food and Drug Regulations

[http://laws.justice.gc.ca/eng/regulations/c.r.c.,\\_c.\\_870/index.html](http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html)

## GUI-0036: Annex 13 to the Current Edition of the Good Manufacturing Practices Guidelines Drugs Used in Clinical Trials

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/annex-13-good-manufacturing-practices-guidelines-drugs-clinical-trials-0036.html>

## Medical Device Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html>

## Natural Health Products Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/index.html>

## Safety of Human Cells, Tissues and Organs for Transplantation Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-118/index.html>

## Processing and Distribution of Semen for Assisted Conception Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-96-254/index.html>