



Health
Canada Santé
Canada

Our Mandate:

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

Guidance Document on the Import Requirements for Health Products under the *Food and Drugs Act* and its *Regulations*

GUI-0084

Supersedes:

GUI-0084 and POL-0060 supersedes POL-0019

Date issued:

June 1, 2010

Date of implementation:

June 1, 2010

Disclaimer

This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that 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. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Table of Contents

1.0 Purpose	Page 3
2.0 Scope	Page 3
3.0 Definitions and Acronyms	Page 3
4.0 Admissibility Determinations and Actions that may be taken at the Border	Page 6
5.0 Commercial Importation	Page 6
6.0 Human Drugs	Page 7
7.0 Natural Health Products (NHP)	Page 10
8.0 Medical Devices	Page 11
9.0 Veterinary Drugs	Page 12
10.0 Blood and Blood Components for Transfusion	Page 15
11.0 Human Cells, Tissues and Organs for Transplantation	Page 16
12.0 Semen for Assisted Conception	Page 16
13.0 Contact Information	Page 17
14.0 Legislation	Page 18

1.0 Purpose

The purpose of this guidance document is to outline the requirements related to the importation of all health products as defined by the *Food and Drugs Act* and its *Regulations*. This guidance document also provides the differentiation between a commercial and personal use importation.

2.0 Scope

This guidance document applies to all health products as defined by the *Food and Drugs Act* and its *Regulations*. This includes Human Drugs; Natural Health Products; Medical Devices; Veterinary Drugs; Blood and Blood Components for Transfusion; Human Cells, Tissues and Organs for Transplantation; and Semen for Assisted Conception.

This guidance document only addresses the requirements under the *Food and Drugs Act* and its *Regulations* for health products. Some health products may also have additional restrictions placed on them by other Acts and Legislation, such as the *Controlled Drugs and Substances Act* and its *Regulations*. Where two different restrictions/requirements exist, such as the quantity allowed for importation, the most restrictive or prescriptive will take precedence.

3.0 Definitions and Acronyms

For the purpose of this guidance document the following acronyms and definitions are used:

Active Pharmaceutical Ingredient (API): Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure and the function of the body.

Agricultural Implant: A product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency. For the purpose of C.01.045 (2) and C.01.046 of the *Food and Drugs Regulations*, an agricultural implant is considered to be a dosage form not suitable for human use.

Device: Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

- (a) The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
- (b) Restoring, correcting or modifying a body function or the body structure of a human being or animals;
- (c) The diagnosis of pregnancy in human beings or animals; or
- (d) The care of human beings or animals during pregnancy and at and after birth of offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.

Donor Semen Special Access Program (DSSAP): A special access program, via Part 2 of the *Processing and Distribution of Semen for Assisted Conception Regulations*, that provides access, in exceptional circumstances, to donor semen that has not been processed in accordance with the Regulations. If authorization is granted, Health Canada will provide a Letter of Authorization (LOA) to the exporter, which must accompany the shipment.

Dosage Form: The final physical form of the drug product which may be used by the consumer without requiring any further manufacturing.

Drug: Under the *Food and Drugs Act* this includes any substance or mixture of substances manufactured, sold, or represented for use in:

- (a) The diagnosis, treatment, mitigation, or prevention of disease, disorder, or abnormal physical state, or symptoms in human beings or animals;
- (b) Restoring, correcting, or modifying organic functions in human beings or animals; and
- (c) Disinfection of premises in which food is manufactured, prepared, or kept.

Drug Identification Number (DIN): An eight (8) digit numerical code assigned to each drug product marketed under or in accordance with the *Food and Drugs Act* and its *Regulations*.

Emergency Drug Release (EDR) for Veterinary Drugs Not Available in Canada:

Emergency Drug Release (EDR), via exemptions set out in C.08.010 and C.08.011 of the *Food and Drugs Act*, allows practitioners, ie those who are registered and entitled under the laws of a province to practice the profession of veterinary medicine, to access veterinary drugs that have not been granted a market authorization in Canada. If authorization is granted, Health Canada will provide an “Emergency Drug Release Authorization” to the practitioner. A copy of this authorization should be sent with the shipment to allow timely entry of the drug into Canada.

Establishment Registration Number (for CTO): A six (6) digit numerical code beginning in a one (1) assigned to an approved establishment under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*

Good Manufacturing Practices (GMP): In this document refers to the requirements of Part C, Division 2 (Good Manufacturing Practices) of the *Food and Drugs Regulations* and the interpretive guidelines on the subject published by Health Canada.

Homeopathic Medicine Number (DIN-HM): Is an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the *Natural Health Products Regulations*.

Marketing authorization: A legal document issued by Health Canada authorizing the sale of a drug or a device based on the health and safety requirements of the *Food and Drugs Act* and its *Regulations*. The marketing authorization may be in the form of a Drug Identification Number (DIN), a device licence for classes II, III and IV medical devices, or a natural health product licence (NPN or DIN-HM).

Medical device: Any device (see definition of device above) within the meaning of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals.

Natural Health Product (NHP): A substance listed in Schedule 1 of the *Natural Health Products Regulations* or a combination of substances in which all the medicinal ingredients are substances listed in Schedule 1, ie a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- (a) The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) Restoring or correcting organic functions in humans; or
- (c) Modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

NHPs include traditional medicines, vitamins, minerals, and bulk raw materials manufactured, sold or represented for use as NHPs

However, a Natural Health Product does not include a substance listed in Schedule 2 of the *Natural Health Product Regulations*, any combination of substances that includes a substance listed in Schedule 2, or a medicine (homeopathic or traditional) that is or includes a substance listed in Schedule 2.

Please refer to the Schedule 1 and 2 of the *Natural Health Products Regulations* (<http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/index.html>)

Natural Product Number (NPN): Is an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the *Natural Health Products Regulations*.

Personal Use Importation: Refers to importation by an individual for their own use, or for a person/animal under that individual's care or guardianship, and not for further sale. It does not apply to a practitioner (Doctor, Veterinarian etc) importing drugs for patients/animals under their care.

Prescription Drugs: Any drug containing a substance listed in Schedule F of the *Food and Drug Regulations* with the exception of substances listed in Part II of the Schedule which are not considered prescription drugs if they are labelled for veterinary use only or are in a form not suitable for humans use. Please consult the current list of Schedule F substances (http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)

Sell: As per the *Food and Drugs Act* includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

Special Access Program (SAP) for Drugs and Medical Devices not Available in Canada: The Special Access Programme (SAP), via exemptions set out in C.08.010 and C.08.011 of the *Food and Drugs Act* and Part 2 Section 69-78 of the *Medical Devices Regulations*, allows physicians and dentists to gain access to health products for human use that have not been granted market authorization in Canada. Decisions to authorize this access are based on the circumstances and details of each situation. If authorization is granted, Health Canada provides a Letter of Authorization (LOA) to the manufacturer of the drug or device authorizing its sale to the requesting practitioner. A copy of this letter is sent to the practitioner. A copy of this letter must be sent with the shipment to allow timely entry of the drug/medical device into Canada.

Source Establishment (for CTO): Under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* this includes:

- (a) subject to paragraph (b), in the case of an organ from a deceased donor, the relevant organ donation organization;
- (b) in the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank;
- (c) in the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the relevant transplant establishment;
- (d) in the case of tissues or banked lymphohematopoietic cells, the relevant cell or tissue bank; and
- (e) in the case of islet cells, the establishment that prepares the cells for use in transplantation.

4.0 Admissibility Determinations and Actions that may be taken at the Border

Health Canada in partnership with the Canadian Border Services Agency (CBSA), will take actions at the border to prevent products that pose an identified unacceptable risk to the health and safety of Canadians from entering Canada.

The detention of goods is described in section 101 of the *Customs Act*, which provides Border Service Officers with the power to detain goods in accordance with the Act of Parliament which is contravened by such goods, in this case, the *Food and Drugs Act* and its *Regulations*. The *Food and Drugs Act* provides Health Canada with the power to seize and detain any health product that is believed to be in contravention of the Act and its Regulations. Health Canada also has the power under Section 27 of the *Food and Drugs Act* to dispose of goods that are in violation of the *Act* and its *Regulations*.

Importers are responsible for ensuring that any product not destined for their own personal consumption are compliant with the requirements of the *Food and Drugs Act* and its *Regulations* prior to importation into Canada, or in the case of market authorized drugs, as defined in the Act (Human, Veterinary, Natural Health Products etc), that they can come into compliance within an agreed upon time as per section A.01.044 of the *Food and Drug Regulations*. For products that do not meet these requirements the Importer may be required to immediately return the products to the country of origin, dispose of them in consultation with and under the direction of Health Canada, or forfeit them to Health Canada in accordance with subsection 27(1) of the *Food and Drugs Act* for disposal.

Health Canada will take actions to prevent the personal importation of health products that contain Schedule F substances or product for which Health Canada has identified a risk and taken domestic actions (recalls, stop sales, import alerts, etc).

All importations, either personal or commercial, of suspected counterfeit health products will be refused entry and seized as they pose an unacceptable risk to health and safety.

5.0 Commercial Importation

All health products commercially imported into Canada must meet all applicable requirements of the *Food and Drugs Act* and its *Regulations*, including, but not limited to:

- Labelling

- Marketing authorization requirements and Establishment Licence, Site Licence or Establishment Registration requirements; or authorization to conduct a clinical trial; and
- GMP requirements.

Health Canada considers that commercial importation activities include, but are not limited to, the following importations:

1. A shipment destined for a retailer, distributor, or other commercial establishment. This would include shipments being sent to independent sales contractors/distributors, or to a practitioner for use in their practice.
2. A shipment from a single foreign supplier consisting of individually addressed parcels, and the importer of record as indicated on a separate invoice for each parcel is not unique for each parcel.
3. A shipment that contains more than a 90-day supply of a drug, based on its directions for use or reasonable intake.
4. A shipment that is part of a pattern of repeat personal importations of the same drug to the same individual at the same address within a 90-day period and the total quantity imported in all shipments totals more than a 90 day supply based on its directions for use or reasonable intake.
5. A shipment that is accompanied by or associated with materials to be used for advertising or promotion.
6. A shipment destined for export.
7. A shipment of health product destined to a practitioner or qualified investigator of a clinical trial that is to be given to or used to treat a patient or a subject in a clinical trial. In the case of an animal practitioner this includes importation and administration to animals they do not own.

Drug in the above list being defined in the *Food and Drugs Act*, e.g. Human, Veterinary, Natural Health Products etc.

6.0 Human Drugs

Human Drugs are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Food and Drug Regulations*.

Human Drugs fall under a number of different Schedules of the *Food and Drugs Act* and the *Food and Drug Regulations*.

- List of Schedule D drugs
(http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)
- List of Schedule F drugs
(http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)

Importation requirements differ according to which Schedule the drug falls under and are as follows:

Commercial Importations

Figure 1. Commercial Importation Requirements for Human Drugs

Commercial Importations	Health Canada Requirements
Schedule C (Radiopharmaceuticals excluding radionuclides)	<ul style="list-style-type: none"> • No Drug Identification Number (DIN) required. • Importer must hold an Establishment Licence (EL). • The foreign manufacturing site must be listed on the Importer's EL.

Commercial Importations	Health Canada Requirements
Schedule D drugs (Drugs derived from Human, Animal or microbial sources, such as insulin and blood based products)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL). • The foreign manufacturing site must be listed on the Importer's EL.
Prescription Drugs (Schedule F)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL) and also must be a practitioner, a drug manufacturer, a wholesale druggist or a registered pharmacist. • The foreign manufacturing site must be listed on the Importer's EL.
Over the counter drugs (OTC)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL). • The foreign manufacturing site must be listed on the Importer's EL.
Products imported under the Special Access Programme (SAP)	<ul style="list-style-type: none"> • A Letter of Authorization (LOA) issued by the Special Access Programme (SAP) of Health Canada authorizing the sale/use of a pharmaceutical product for each instance. A copy of this authorization must be provided at the port of entry.
Human Drugs imported for use in a clinical trial (Other than phase IV)	<ul style="list-style-type: none"> • A No Objection Letter (NOL) issued by the Therapeutic Products Directorate (TPD) or the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada authorizing the use of the drug in a clinical trial for each drug/trial. A copy of this authorization must be provided at the port of entry.

Personal Use Importations

Figure 2. Personal Use Importation Requirements for Human Drugs

Personal use Importations	Health Canada Requirements
Prescription Drugs (Schedule F)	<p>Under Section C.01.045 of the <i>Food and Drug Regulations</i> importation of Schedule F drugs is restricted to a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist, or a resident of a foreign country while a visitor in Canada. Note that drugs imported by practitioners for treating patients are not considered to be personal importations but rather commercial importation for sale as per Section 5.0.</p> <p>Visitors to Canada: Visitors to Canada may bring into Canada, on their person a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug.</p> <p>The drug must be for the individual's own personal use, for the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.

Personal use Importations	Health Canada Requirements
	<p>A Visitor may import an additional single unit, single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug. When a prescription drug is mailed to a Visitor, the drug should be accompanied by some form of documentation indicating that the drug is destined to a Visitor and/or the Visitor should be prepared to provide documentation/written evidence (stamped passport, student/work visa, letter from an employer/university etc) that they are a Visitor to Canada when requested.</p> <p>Canadian Resident: Importations of prescription drugs by Canadian residents are not permitted by mail or courier.</p> <p>So as not to interrupt a course of treatment, Health Canada may use enforcement discretion to permit a Canadians returning from abroad to bring with them on their person a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug.</p> <p>The drug must be for the individual's own personal use or the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The drug must be in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.
Over the Counter Drugs (OTC)	<p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an Over the Counter Drug.</p> <p>The drug must be for the individual's own personal use or for the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.
<p>Drugs used in a clinical trial which is not sponsored in any manner in Canada and used strictly by the patient</p> <p>(Applies to Canadian patients enrolled in foreign clinical trials where drugs are required to be imported)</p>	<p>Documentation may be required to prove that the patient is enrolled in a foreign (i.e. outside Canada) clinical trial.</p> <p>In order to not interrupt a course of medical treatment, Health Canada may use enforcement discretion to permit the importation of clinical trial drugs not otherwise permitted, however, restrictions similar to personal importations would be followed, ie maximum 90 day supply.</p>

Personal use Importations	Health Canada Requirements
<p>Schedule D drugs (drugs derived from Human, Animal or microbial sources, such as insulin and blood based products)</p>	<p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an Over the Counter Drug.</p> <p>The drug must be for the individual’s own personal use or for the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.

7.0 Natural Health Products (NHP)

Natural Health Products are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Natural Health Product Regulations*.

Commercial Importations

Figure 3. Commercial Importation Requirements for Natural Health Products

Commercial Importations	Health Canada Requirements
NHP	<ul style="list-style-type: none"> • A product licence (NPN or DIN-HM) for each product. • The importer must hold a Site Licence (SL) • The foreign manufacturing site must be listed on the Importer’s SL.
NHP imported for use in a clinical trial	<ul style="list-style-type: none"> • A Notice of Authorization (NOA) authorizing the use of the product in a clinical trial is issued by the Natural Health Products Directorate (NHPD) of Health Canada. A copy of this authorization must be provided at the port of entry.

Personal Use Importations

Figure 4. Personal Use Importation Requirements for Natural Health Products

Personal Use Importations	Health Canada Requirements
NHP	<p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an NHP.</p> <p>The NHP must be for the individual’s own personal use or for the use of a person for whom they are responsible and with whom they are travelling.</p> <p>The NHP must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.

8.0 Medical Devices

Medical Devices are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Medical Devices Regulations*.

(<http://laws.justice.gc.ca/en/showtdm/cr/SOR-98-282>)

Medical Devices are grouped into four classes with Class I devices presenting the lowest potential risk (i.e.: a bandage) and Class IV devices presenting the greatest potential risk (i.e.: pacemakers). Refer to the Medical Devices Active Licences (<http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php>) for an up-to-date listing of Class II, III and IV devices in compliance for sale in Canada.

Commercial Importations

Figure 5. Commercial Importation Requirements for Medical Devices

Commercial Importations	Health Canada Requirements
Class I devices. (examples: bandage, wheelchairs, bed scales, hospital beds/stretchers and crutches)	<ul style="list-style-type: none"> • Device Licence not required. • Importer must have an Establishment Licence (EL); see list below table for those entities that are exempt from needing an EL (*).
Class II, III and IV devices. (examples: gauze pads, electronic stethoscopes, electrodes, hearing aids, medical examination gloves, scalpels, electrocardiographs, blood pressure cuffs, latex condoms, pregnancy tests, defibrillators, infusion pumps, bacteria and drug test kits, hyperbaric oxygen therapy chambers, implants, insulin pumps and cardiac pacemakers, glucose testing systems, embolectomy and occlusion catheters, balloon thermodilution catheters, blood catheters, central venous catheter kits, aneurysm clips, excimer laser and intraocular lens)	<ul style="list-style-type: none"> • Device Licence required for each Device. • Importers must have an Establishment Licence (EL); see list below table for those entities that are exempt from needing an EL (*).
Investigational testing devices to be used on human subjects	<p>Require identification as "Investigational Device" on the label of the device.</p> <p>Letter of Authorization (LOA) issued by the Medical Device Bureau (MDB) must accompany Class II, III and IV devices under Investigational Testing status.</p>
Special Access and Custom-made devices.	<p>Label must specify that the device is custom-made or for Special Access.</p> <p>Letter of Authorization (LOA) issued by the Medical Device Bureau (MDB) must accompany all classes of Special Access devices; and class III and IV custom-made devices.</p>

(*)The following entities are exempt from the requirement of having an Establishment Licence (EL) to import medical devices:

1. A Retailer;
2. A Health Care Facility;
3. Manufacturers of Class I devices if the manufacturer imports or distributes through a person who holds an Establishment Licence;

4. A person who only imports a medical device for their own personal use;
5. Establishments only importing or selling veterinary products;
6. Dispensers; and
7. Establishments that only import or sell custom-made devices, medical devices for Special Access, or devices for Investigational Testing involving human subjects.

Personal Importations for Medical Devices:

There are no requirements for Medical Devices imported for personal use as the *Medical Devices Regulations* do not apply to these devices.

Veterinary Medical Devices:

There are no requirements for Medical Devices imported for use in/on animals as the *Medical Devices Regulations* do not apply to these devices.

9.0 Veterinary Drugs

Veterinary Drugs are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Food and Drug Regulations*.

Veterinary Drugs fall under a number of different Schedules of the *Food and Drugs Act* and the *Food and Drug Regulations*.

- List of Schedule D drugs
(http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)
- List of Schedule F drugs
(http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html)

Veterinary biologics are regulated by the Canadian Food Inspection Agency (CFIA) under the authority of the *Health of Animals Act* (<http://laws-lois.justice.gc.ca/eng/acts/H-3.3/index.html>) and its *Regulations* (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._296/index.html). Please consult CFIA for more details on veterinary biologics and their importation requirements.

Commercial Importations

Figure 6. Commercial Importation Requirements for Veterinary Drugs

Commercial Importations	Health Canada Requirements
Agricultural implants that contain controlled drugs (Anabolic steroids or zeranol)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL). • The foreign manufacturing site must be listed on the Importer’s EL. <p>The Office of Controlled Substances within the Healthy Environments and Consumer Safety Branch (HECSB) should also be consulted with respect to additional restrictions under the <i>Controlled Drug and Substances Act</i>.</p>

Commercial Importations	Health Canada Requirements
Prescription Drugs (Schedule F)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL) and also must be a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist, for Schedule F, Part I and, unless conditions below are met, for Schedule F, Part II drugs as well: <ul style="list-style-type: none"> (a) the drug is in a form not suitable for human use; or (b) the principal display panel of both the inner label and the outer label carries, in both official languages, the statement "Pour usage vétérinaire/For Veterinary Use Only" or "Usage vétérinaire seulement/ Veterinary Use Only", immediately following or preceding the brand name, proper name or common name, in type size not less than one-half as large as the largest type on the label. • The foreign manufacturing site must be listed on the Importer's EL.
Over the Counter Drugs (OTC)	<ul style="list-style-type: none"> • A Drug Identification Number (DIN) for each product. • Importer must hold an Establishment Licence (EL). • The foreign manufacturing site must be listed on the Importer's EL.
Products imported under the Emergency Drug Release Program (EDR)	A copy of the "Emergency Drug Release Authorization" issued by the EDR Officer of Health Canada authorizing the sale of a pharmaceutical product for each instance. A copy of this authorization must be provided at the port of entry.
Products imported under an Experimental Study Certificate (ESC) for use in an experimental study	An Experimental Study Certificate (ESC) issued by the Veterinary Drugs Directorate (VDD) of Health Canada for each drug. A copy of this authorization must be provided at the port of entry.
Products imported for use in a clinical trial	A No Objection Letter (NOL) issued by the Veterinary Drugs Directorate (VDD) of Health Canada authorizing the use of the drug in a clinical trial. A copy of this authorization must be provided at the port of entry.
Drugs prohibited for food producing animals (i.e., Chloramphenicol or its salts or derivatives; a 5-nitrofurantoin compound; clenbuterol or its salts or derivatives; a 5-nitroimidazole compound; or diethylstilbestrol or other stilbene compounds.)	Import is not permitted if the drug is destined to be sold for administration to food producing animals.
Drug containing substances with oestrogenic activity (Estrogen/oestrogen or estrogen derivatives)	Import is not permitted if the drug is destined to be sold for administration to poultry that may be consumed as food.
Import of Active Pharmaceutical Ingredients (APIs)	<p>Bulk active pharmaceutical ingredients (APIs) or raw materials are considered to be drugs in final dosage form when they are intended for direct administration to animals (e.g., topically, in water, in feed) without further compounding (by a pharmacist or veterinary practitioner) or manufacturing.</p> <p>For more information on the importation of APIs for veterinary use, please refer to Health Canada's Policy 18 entitled <i>Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use</i> (www.hc-sc.gc.ca/dhp-mpps/alt_formats/hpfb-dgpsa/pdf/compli-conform/pol_18_e.pdf)</p>

Personal Use Importations

Figure 7. Personal Use Importation Requirements for Veterinary Drugs

Personal Use Importations	Health Canada Requirements
<p>Prescription Drugs (Schedule F, Part I)</p>	<p>Under Section C.01.045 of the <i>Food and Drug Regulations</i> importation of Schedule F drugs is restricted to a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist, or a resident of a foreign country while a visitor in Canada. Note that drugs imported by practitioners for treating an animal other than their own are not considered to be personal importations but rather commercial importation for sale as per Section 5.0.</p> <p>Visitors to Canada: Visitors to Canada, travelling with an animal, may bring into Canada, on their person a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug.</p> <p>The drug must be for use on an animal for which the individual is responsible and with whom they are travelling.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains. <p>A Visitor may import an additional single unit, single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug. When a prescription drug is mailed to a Visitor, the drug should be accompanied by some form of documentation indicating that the drug is destined to a Visitor and/or the Visitor should be prepared to provide documentation/written evidence (stamped passport, student/work visa, letter from an employer/university etc) that they are a Visitor to Canada when requested.</p> <p>Canadian Resident: Importations of prescription drugs by Canadian residents are not permitted by mail or courier.</p> <p>So as not to interrupt a course of treatment, Health Canada may use enforcement discretion to permit a Canadians returning from abroad to bring with them on their person a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a prescription drug.</p> <p>The drug must be for use on an animal for which the individual is responsible and with whom they are travelling.</p> <p>The drug must be in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.

Personal Use Importations	Health Canada Requirements
<p>Over the Counter Drugs and Schedule F, Part II Drugs (Packaged and labelled for use in animals only)</p>	<p>Any individual may import a Schedule F Part II drug for veterinary use if:</p> <p>(a) the drug is in a form not suitable for human use; or</p> <p>(b) the principal display panel of both the inner label and the outer label carries, in both official languages, the statement "Pour usage vétérinaire seulement/For Veterinary Use Only " or "Usage vétérinaire seulement/Veterinary Use Only ", immediately following or preceding the brand name, proper name or common name, in type size not less than one-half as large as the largest type on the label.</p> <p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less, of an Over the Counter Drug or Schedule F Part II Drug.</p> <p>The drug must be for use on an animal for which the individual is responsible.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains.
<p>Agricultural implants that contain controlled drugs (Anabolic steroids or zeranol)</p>	<p>Individuals are permitted to import a single course of treatment or a 90-day supply based on the directions for use, whichever is less.</p> <p>The drug must be for use on an animal for which the individual is responsible.</p> <p>The drug must be shipped/carried in one of the following:</p> <ul style="list-style-type: none"> • Hospital or pharmacy dispensed packaging; • Original retail packaging; or • have the original label affixed to it which clearly indicates what the health product is and what it contains. <p>The Office of Controlled Substances within the Healthy Environments and Consumer Safety Branch (HECSB) should also be consulted with respect to additional restrictions under the <i>Controlled Drug and Substances Act</i>.</p>

10.0 Blood and Blood Components for Transfusion

Blood and Blood Components for Transfusion are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Food and Drug Regulations*. Refer to Schedule D under Human Drugs (Section 6.0) for the requirements for blood based products.

Blood samples imported for testing or research do not fall under Health Canada’s jurisdiction, but may require import permits from either the Public Health Agency of Canada (PHAC) or the Canadian Food Inspection Agency (CFIA) as cultures, diagnostic specimens or research tissue may be a potential carriers of a human or animal pathogen. Please consult these organizations for more details.

Figure 8. Importation Requirements for Blood and Blood Components for Transfusion

Product	Health Canada Requirements
Blood and Blood Components for transfusion	<ul style="list-style-type: none"> • Blood and blood components for transfusion do not require a Drug Identification Number (DIN), but must have been produced to GMP standards. • Importer must hold an Establishment Licence (EL). <p>If blood and blood components for transfusion are being imported pursuant to a prescription the above requirements are waived. Proof of the prescription must be provided at the port of entry.</p>

11.0 Human Cells, Tissues and Organs for Transplantation

Human Cell Tissues and Organs for Transplantation are regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.

Figure 9. Importation Requirements for Human Cell Tissues and Organs for Transplantation

Product	Health Canada Requirements
Lymphohematopoietic cells (stem cells) and Organs	Due to the lifesaving nature and circumstances surrounding these products there is no need for the product or exporters to be registered with Health Canada. Importers are required to be registered with Health Canada.
Islet Cells and Tissues	There are no requirements for the product. Importers must have a Health Canada Establishment Registration Number unless they are the end user of the products. Exporters that are Source Establishments must hold a Establishment Registration Number. The name and Establishment Registration Number of the Source Establishment and where appropriate the importer should be clearly displayed on the exterior of the package.

12.0 Semen for Assisted Conception

Semen for Assisted Conception is regulated by Health Canada under the authority of the *Food and Drugs Act* and the *Processing and Distribution of Semen for Assisted Conception Regulations*.

Figure 10. Importation Requirements for Semen for Assisted Conception

Product	Health Canada Requirements
Semen for Assisted Conception	<p>Semen imported for distribution must meet the requirements of the <i>Semen Regulations</i>. Importers must notify Health Canada 10 days in advance of commencing importation.</p> <p>The shipment must have the name and business address of the foreign processor on the outer shipping container as well as a signed declaration certifying that the semen has been processed in accordance with the <i>Processing and Distribution of Semen for Assisted Conception Regulations</i> and quarantined for a minimum of six months.</p>
Donor Semen Special Access Program (DSSAP)	<p>A Letter of Authorization (LOA) issued by the Biologics and Genetics Therapies Directorate (BGTD) of Health Canada, must accompany the shipment.</p> <p>In addition, the outer shipping container must clearly display the name and business address of the foreign processor, as well as an indication that the semen may only be distributed in accordance with the authorization.</p>

13.0 Contact Information

- For more information regarding requirements for importation of the products addressed in this document, please visit the Inspectorate's Compliance and Enforcement (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html)
- During local regular business hours, you may contact your local regional Health Canada office by calling toll free 1-800-267-9675 or directly at:

Figure 11. Contact Information for Local Regional Health Canada Offices

<p>Atlantic (NFL, NB, PEI, NS) 1505 Barrington Street. Suite 1625 Halifax, Nova Scotia. B3J 3Y6 Tel: 902-426-4775 or 902-426-5350 Fax: 902-426-6676</p>	<p>Quebec 1001 rue St-Laurent Ouest Longueuil, Québec. J4K 1C7 Tel: 450-646-1353 Fax: 450-928-4455</p>
<p>Ontario 2301 Midland Avenue Scarborough, Ontario. M1P 4R7 Tel: 416-973-1600 Fax: 416-954-4581</p>	<p>Manitoba and Saskatchewan 510 Lagimodière Blvd. Winnipeg, Manitoba. R2J 3YI Tel: 204-984-1341 Fax: 204-984-2155</p>
<p>Western (AB, BC, YK and NWT) 400 - 4595 Canada Way Burnaby, British Columbia. V5G 1J9 Tel: 604-666-3350 Fax: 604-666-3149</p>	

3. You may also contact Health Canada after hours emergency pager at 1-888-238-3858
 - Monday to Friday 4-11pm EST
 - Saturday, Sundays and Holidays 7am-11pm EST
4. Contact the Border Integrity Unit (BIU_UIF@hc-sc.gc.ca) in Ottawa with general questions by e-mail.

14.0 Legislation

Customs Act

<http://laws.justice.gc.ca/en/showtdm/cs/C-52.6>

Food and Drugs Act

<http://laws.justice.gc.ca/en/F-27/index.html>

Food and Drug Regulations

<http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html>

Medical Devices Regulations

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

Natural Health Products Regulations

<http://laws.justice.gc.ca/en/F-27/SOR-2003-196/index.html>

Processing and Distribution of Semen for Assisted Conception Regulations

<http://laws.justice.gc.ca/en/F-27/SOR-96-254/index.html>

Safety of Human Cells, Tissues and Organs for Transplantation Regulations

<http://laws.justice.gc.ca/en/showtdm/cr/SOR-2007-118>