Health Canada Santé Canada

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Importing and exporting health products for commercial use

GUI-0117

December 21, 2020

Canada

Date issued:	December 21, 2020
Date implemented:	December 21, 2020
Replaces:	*GUI-0117 version 1, Guidance Document on the Importation Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084), Import and Export Policy for Health products under the Food and Drugs Act and its Regulations (POL-0060), Border Integrity Approach (POL-0059) and Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use (POL-0018).*

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.

Également disponible en français sous le titre :
Importer et exporter des produits de santé à des fins commerciales

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Publication date: December 21, 2020

Cat.: H139-3/2019E-PDF
ISBN: 978-0-660-31235-4
Pub.: 190105

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.

Table of Contents

The following table shows the two types of icons used in this document, and the way they are intended to be used:

	**Important:** Key or cautionary information for people to know.
	**Information:** Supplementary information like quotes and legal references.

Purpose

This guidance document provides information about how to ensure that the health products you bring into Canada for commercial use meet the regulatory requirements of the *Food and Drugs Act* (Act) and its associated Regulations at the time of import. The guidance also provides information about exporting health products from Canada for commercial use. Health products include active pharmaceutical ingredients; human drugs; veterinary drugs; medical devices; natural health products; blood and blood components for transfusion; and human cells, tissues and organs for transplantation.

This guidance:

- defines commercial use and
- outlines the requirements for importing and exporting health products into and out of Canada for commercial use.

Scope

This guidance document applies to any person, which includes an individual or an organization, that imports or exports health products for commercial purposes such as:

- retailers, distributors or other commercial establishments that sell, manufacture, package, label and test health products;
- independent sales contractors or direct sellers;
- health care professionals or investigators of clinical trials; or
- individuals importing quantities that are not for personal use (as explained in *GUI-0116: Bringing Health Products into Canada for Personal Use*) based on the directions for use or reasonable intake.

This guidance document only addresses the requirements under the Act and its associated Regulations for health products. Some health products may also have additional restrictions placed on them by other Acts/Regulations/Conventions, such as the *Controlled Drugs and Substances Act*, the Narcotic Control Regulations and the *Convention on International Trade in Endangered Species of Wild Fauna and Flora*. You are responsible for making sure that you meet all Government of Canada requirements.

Previously, donor semen for assisted conception was classified as a drug under the Act and the Processing and Distribution of Semen for Assisted Conception Regulations (Semen Regulations). As of February 4, 2020 the Semen Regulations are repealed and replaced with the new Safety of Sperm and Ova Regulations (Safety Regulations) made under the authority of the *Assisted Human Reproduction Act*.

For more information on importing sperm and ova for commercial use, refer to the *Guidance Document - Safety of Sperm and Ova Regulations*.

If you are importing health products for personal use, please refer to *GUI-0116: Bringing Health Products into Canada for Personal Use*.

Importer's Role

Importers are responsible for ensuring that health products imported for sale are compliant with the requirements of the Act and its Regulations at the time of import. Before importing health products into Canada, importers must ensure that the health products they are bringing in are market authorized in Canada, where applicable, and are being imported by appropriately licensed persons. The products must be manufactured, packaged, labelled and tested at compliant foreign sites and contain the Canadian authorized labeling.

Ensure that shipments of health products are accompanied at the time of import by all information that demonstrates compliance with Canadian laws. Health Canada inspectors make determinations on a shipment's compliance based on the information available at the time of import. For example, a copy of the Establishment/Site Licence with evidence of authorized exporter/importer is important to identify Good Manufacturing Practices (GMP) compliant facilities as well as any specific letters of authorization (e.g. No Objection Letter for clinical trials).

Government of Canada's Role

Health Canada is responsible for compliance monitoring and enforcement activities related to health products in order to verify that regulatory requirements are being applied appropriately.

Health Canada works in partnership with the Canada Border Services Agency (CBSA) to assess the compliance of referred health products at the border against the Act and its Regulations to help ensure that imported health products are safe, effective and of high quality.

CBSA customs officers may detain any health product they suspect does not comply with the Act and its Regulations using their powers as described under section 101 of the *Customs Act*.

> **Import** - Any action that causes a product to cross the Canadian border from outside Canada regardless if under Customs bond.
>
> **Export** - The sending or transporting of a health product abroad, the sale or advertising over the Internet of a health product to a foreign jurisdiction.

The CBSA may then contact Health Canada to confirm whether the product is compliant with the importation requirements found in the Act and its Regulations. Health Products found to be non-compliant during the Health Canada inspection will be refused entry or seized. To verify whether the product meets the requirements, Health Canada will assess the product and make an admissibility determination. The assessment may include taking samples of the product for laboratory analysis to confirm the product's composition and that it is not adulterated with an unspecified ingredient (e.g. prescription drug in a health supplement). Health Canada may also contact you for copies of relevant records or documents. To avoid potential delays at the border, Health Canada recommends that all pertinent information about the product and persons authorized to import (or export) the product be included with the shipment at the time of import.

The Act provides Health Canada with the authority to seize and detain any health product that is believed to be in contravention of the Act or its Regulations. Health Canada also has the authority to order unlawful imported goods to be removed from Canada, or where removal is not possible, to order the goods to be destroyed.

Health Canada will notify you and the CBSA in writing of the outcome of the inspection should your product(s) be deemed inadmissible into Canada including any notice of seizure (if applicable) and disposition options, where applicable.

Note: Under section 30.7 (1) of the Act, Health Canada may recover expenses associated with the storage, transport or disposal of seized goods or the removal or destruction of unlawfully imported goods from the owner or importer or the person having possession, care or control of the goods at the time of the inspection. Furthermore, Health Canada is not responsible for any consequences including financial loss as a result of an admissibility determination made in accordance with its authority under the Act.

Importing for Commercial Use:

Health product shipments may be considered commercial imports when destined to a:

- Retailer, distributor or other commercial establishment, including independent sales contractors or distributors.
- Health care professional to use in their practice.
- Health care professional or a qualified investigator to use in a clinical trial or experimental study.
- Health care professional under the Special Access Program (allows foreign manufacturers to sell drugs or medical devices not approved for sale in Canada to healthcare professionals for treating serious life-threatening conditions of individual patients for emergency use where conventional therapies have failed, are unsuitable or unavailable).
- Health care professional under the Emergency Drug Release Program (allows foreign manufacturers to sell new drugs not approved in Canada to veterinarians).
- A drug establishment licence holder through the Access to Drugs in Exceptional Circumstances regulatory pathway (also known as Drugs for an Urgent Public Health Need).
- Person whose shipment is accompanied by materials to be used for advertising or promotion.
- Person whose shipment contains a health product whose unsubstantiated personal use quantity exceeds a 90-day supply based on the product's directions for use or prescribed dosage.
- Person whose shipment is part of repeat shipments of the same health product, received within a 90-day period, whose combined quantity exceeds a 90-day supply based on the product's directions for use or prescribed dosage.
- Retailer, distributor or other commercial establishment, health care professional, or person who intends to export the health products (not including health products transhipped under section 38 of the Act - see Goods In Transit).
- Person who solicits and transmits orders to a foreign supplier, intends to sell, or give away any quantity of a health product (excludes consolidated shipments as defined below).

Note: This list is not exhaustive and other factors may be taken into consideration during the admissibility determination process.

A consolidated shipment means a number of separate shipments grouped together by a consolidator or freight forwarder and shipped to an agent or a freight forwarder as one shipment under one bill of lading and reported to Customs on one cargo control document. Deconsolidation is a process whereby a consolidated shipment is divided into individual shipments consigned to various consignees.

An exporter outside Canada who wishes to combine multiple personal shipments as a consolidated shipment and ship via a courier or transporter into Canada may do so, provided that each personal shipment is for a different individual. The personal shipments must be individually packaged and accompanied with individual invoices so that the contents can be readily assessed by Health Canada to determine if commercial licensing requirements apply. Other factors will also be considered by Health Canada when assessing consolidated shipments, such as who is arranging the importation, order taking, and distribution in order to determine whether or not it is a commercial shipment or a consolidation of personal shipments.

Commercial Importation Requirements

To facilitate admissibility, it is important to work with brokers/couriers to ensure sufficient documentation accompanies your shipment for Health Canada to make its admissibility determination. Supporting documents and product information may include:

- appropriate labelling with market authorization number (e.g. Drug Identification Number (DIN), Natural Product Number (NPN))
- invoices/customs documents to show authorized or licensed suppliers/importers

Importers should ensure that references to the appropriate product licence numbers, establishment licence numbers or other import documents issued by Health Canada are either referenced in the shipment, or a copy is provided with the shipment, to ensure that CBSA and Health Canada have the necessary information to make a timely admissibility determination. The tables that follow (1 through 8) outline the product licensing, establishment licensing or other commercial importation requirements for health products regulated under the Act and its Regulations.

Active Pharmaceutical Ingredients (APIs) for Human Use

Active ingredients are the substances in drugs that are responsible for the beneficial health effects experienced by consumers. The active ingredient in a pharmaceutical drug is called an active pharmaceutical ingredient (API). An example of an API is the acetaminophen contained in a pain relief tablet. APIs are regulated by Health Canada under the Act and Food and Drug Regulations (FDR). Importation requirements for APIs are found in Table 1.

Table 1. Importation Requirements for APIs for Human Use

	Product Licence	Establishment Licence	Other Importation Requirements
Active Pharmaceutical Ingredients (APIs)	Not Applicable	• Importer must have an Establishment Licence (EL) for the activity of import for the category of API. • The foreign manufacturing site must be listed on the importer's EL (Table A).	Controlled substances (as listed in the schedules of the *Controlled Drugs and Substances Act* (CDSA)) have additional restrictions under the CDSA e.g. dealers licence/permit. Consult Health Canada's Office of Controlled Substances for information about other possible restrictions that may apply.
Active Pharmaceutical Ingredients used in the manufacture of a finished dosage form drug in a clinical trial	Not Applicable	Not Applicable	A No Objection Letter (NOL) for the finished dosage form drug issued by Health Canada's Therapeutic Products Directorate or Biologic and Radiopharmaceutical Drugs Directorate as applicable. A copy of the NOL should be included in the shipment.

Human Drugs

Drugs are regulated by Health Canada under the Act and its Regulations. Drugs include both prescription and non-prescription drugs; biologically derived products such as vaccines, blood derived products, and products produced through biotechnology; disinfectants; and radiopharmaceuticals. Although Natural Health Products (NHPs) are also drugs, they have different import requirements and are described separately in this document.

Human drugs must have an eight (8) digit number called a Drug Identification Number (DIN) assigned by Health Canada to each drug product prior to being marketed in Canada.

Human drugs without a DIN may be imported under the following circumstances:

- Where authorized under a clinical trial occurring in Canada and a no objection letter (NOL) is issued.
- Through a request by a practitioner to the Special Access Program (SAP) via exemptions set out in C.08.010 and C.08.011 of the FDR. The SAP considers requests for access to drugs that are unavailable for sale in Canada from physicians and dentists treating

patients with serious or life-threatening conditions when conventional treatments have failed, are unsuitable or unavailable. 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 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 into Canada.

- Through the regulatory pathway for Access to Drugs in Exceptional Circumstances (also known as Drugs for an Urgent Public Health Need) which enables access to drugs which have been authorized for sale in certain foreign jurisdictions, but are not available in Canada, to address urgent public health needs. Importation requirements are outlined in Table 2, and additional information regarding this regulatory pathway can be found in the document Questions and Answers – Access to Drugs in Exceptional Circumstances.

Table 2. Importation Requirements for Human Drugs

	Product Licence	Establishment Licence	Other Importation Requirements
Biologics (Schedule D of the FDR)	Drug Identification Number	• Importer must have an Establishment Licence (EL) for the activity of import for the category of Schedule D. • The foreign manufacturing site must be listed on the importer's EL.	Not Applicable
Clinical Trials (Other than Phase IV)	Not Applicable	Not Applicable	A No Objection Letter (NOL) issued by Health Canada's Therapeutic Products Directorate or Biologic and Radiopharmaceutical Drugs Directorate as applicable. A copy of the NOL should be included in the shipment showing the valid control number on the NOL.

	Product Licence	Establishment Licence	Other Importation Requirements
Phase IV Clinical Trials	Drug Identification Number	• Importer must have an EL for the activity of import for the appropriate drug category (section C.01A.008 FDR, Table II). • The foreign manufacturing site must be listed on the importer's EL.	Not Applicable
Over-the-Counter drugs	Drug Identification Number	• Importer must have an EL for the activity of import for the appropriate drug category (section C.01A.008 FDR, Table II). • The foreign manufacturing site must be listed on the importer's EL.	Not Applicable
Prescription drugs	Drug Identification Number	• Importer must have an EL for the activity of import for the appropriate drug category (section C.01A.008 FDR, Table II). • The foreign manufacturing site must be listed on the importer's EL.	Importer must be a practitioner, drug manufacturer, wholesale druggist, or pharmacist. Drugs containing controlled substances have additional restrictions under the *Controlled Drugs and Substances Act*. Consult Health Canada's Office of Controlled Substances for information about other possible restrictions that may apply.
Radiopharmaceuticals (Schedule C of the FDR)	Drug Identification Number	• Importer must have an EL for the activity of import for the appropriate drug category of Schedule C (section C.01A.008 FDR, Table II). • The foreign manufacturing site must be listed on the importer's EL.	Not Applicable

	Product Licence	Establishment Licence	Other Importation Requirements
Special Access Program	Not Applicable	Not Applicable	Letter of Authorization (LOA) issued by Health Canada's Special Access Program. A copy of the LOA should accompany the shipment.
Drugs for an Urgent Public Health Need	Not Applicable	• Importer must have an EL for the activity of import for the appropriate drug category.	The drug must meet the prescribed criteria on the List for an Urgent Public Health Need.

Natural Health Products

Natural health products (NHPs) are regulated by Health Canada under the authority of the Act and the Natural Health Products Regulations (NHPR) and must be licensed prior to marketing in Canada. Licensed NHPs are assigned an eight (8) digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM). To be classified as an NHP all of the medicinal ingredients in the product must be in Schedule 1 of the NHPR, not include any substances listed in Schedule 2 of the NHPR and marketed for health reasons. Table 3 specifies the importation requirements for NHPs.

NHPs include traditional medicines; health supplements/vitamins; minerals; and bulk raw materials manufactured, sold or represented for use as NHPs. Cosmetics containing NHP ingredients and that meet both the function and substance components of the NHP definition are regulated as NHPs. Cosmetic products that do not fall within the NHP definition (see Appendix A) are regulated under the Cosmetics Regulations of the Act and are the responsibility of Health Canada's Cosmetics Program.

Table 3. Importation Requirements for Natural Health Products (NHPs)

	Product Licence	Site Licence	Other Importation Requirements
NHPs	NPN or DIN-HM	• Importer must have a Site Licence (SL) for the activity of import. • The foreign manufacturing site must be listed on the Importer's SL.	Not Applicable
NHP imported for use in a clinical trial	Not Applicable	Not Applicable	A Notice of Authorization (NoA) authorizing the use of the product in a clinical trial issued by Health Canada's Natural and Non-prescription Health Products Directorate. A copy of the NoA should be included with the shipment.

APIs for Veterinary Use

As of May 17, 2018, new regulatory requirements apply to importers of APIs for veterinary use, whereby they must now hold an Establishment Licence (EL) for this activity.

Examples of APIs for veterinary use are ingredients such as corticosteroids or antibiotics found in ear drops to treat infection.

The new EL requirements also apply to healthcare professionals, such as veterinarians and pharmacists, who import APIs listed on Health Canada's List A: List of certain antimicrobial active pharmaceutical ingredients for compounding veterinary drugs. List A names certain antimicrobial APIs that are important in human medicine for which additional restrictions have been put in place to limit the development of resistance to these important antimicrobials.

Importation requirements for APIs for veterinary use are found in Table 4.

Table 4. Importation Requirements for APIs for Veterinary Use

	Product Licence	Establishment Licence	Other Importation Requirements
Veterinary APIs	Not Applicable	• Importer must have an Establishment Licence (EL) for the activity of import for the category of API. • The foreign manufacturing site must be listed on the importer's EL (Table A).	Not Applicable
Veterinary APIs on List A	Not Applicable	• Importer must have an EL for the activity of import for the category of APIs set out in List A that are for veterinary use. • The foreign manufacturing site must be listed on the importer's EL (Table A).	Not Applicable
Veterinary APIs imported and intended for direct administration to animals (not including VHP substances)	Drug Identification Number	• Importer must have an EL for the activity of import. • The foreign manufacturing site must be listed on the importer's EL.	Bulk 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 veterinarian or manufacturing.

Veterinary Drugs & Veterinary Health Products

Veterinary drugs, including veterinary health products (VHPs) are regulated by Health Canada under the authority of the Act and FDR. Licensed veterinary drugs are assigned an eight (8) digit Drug Identification Number (DIN) similar to human drugs. Veterinary health products are low risk ready to use drugs for supporting the health and welfare of animals produced in accordance with List C: Veterinary Health Products and are provided an alpha-numeric Notification Number upon notification to and authorization by, the Veterinary Drugs Directorate. Applicable establishment and product licensing needed to import a veterinary drug is found in Table 5.

Veterinary drugs without a DIN may be imported under the following circumstances:

- Through the Emergency Drug Release (EDR) program. The EDR, via exemptions set out in C.08.010 and C.08.011 of the FDR, allows practitioners (i.e. 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 to treat their client's animals. In such cases, practitioners must seek an EDR Authorization from Health Canada. A copy of this authorization must accompany the shipment to allow timely entry of the drug into Canada.
- Under an Experimental Studies Certificate (ESC) issued by Health Canada to researchers for use in an experimental study on animals. A copy of this authorization must accompany the shipment to allow timely entry of the drug into Canada.
- Through a No Objection Letter (NOL) issued by Health Canada to investigators for use in an investigational new drug study on animals. A copy of the NOL must accompany the shipment to allow timely entry of the drug into Canada.

An unlicensed drug intended for use in food-producing animals or animals intended to be consumed as food (including horses) can only be imported by personal importation if it is on List B: List of Certain Veterinary Drugs Which May Be Imported But Not Sold. "Personal Importation" of veterinary drugs means that you are bringing a health product into Canada for an animal that is under your care. Refer to the admissibility criteria for List B. For information on personal importation of health products please see *GUI-0116 - Bringing health products into Canada for personal use*.

Products found on List B cannot be:

•imported for sale or given to someone else, even when the distribution is for free

•imported in quantities that are more than a 90-day supply based on the directions for use and the number of animals under your care

Details on the requirements for importation of veterinary drugs and health products are available in Table 5.

Table 5. Importation Requirements of Veterinary drugs and Veterinary Health Products

	Product Licence	Establishment Licence	Other Importation Requirements
Agricultural implants that contain controlled drugs (anabolic steroids or zeranol)	Drug Identification Number	• Importer must have an Establishment Licence (EL) for the activity of import. • The foreign manufacturing site must be listed on the Importer's EL.	Not Applicable
Veterinary Health Products	Notification	Not Applicable	VHPs need to be notified at the time of importation and labelled as per the requirements of the FDR.
Over-the-Counter drugs	Drug Identification Number	• Importer must have an EL for the activity of import. • The foreign manufacturing site must be listed on the Importer's EL.	Not Applicable
Prescription drugs	Drug Identification Number	• Importer must have an EL for the activity of import. • The foreign manufacturing site must be listed on the importer's EL.	Importer must be a practitioner, drug manufacturer, wholesale druggist, or pharmacist.
Products imported for use in a clinical trial (called investigational new drug)	Not Applicable	Not Applicable	A No Objection Letter (NOL) issued by Health Canada's Veterinary Drugs Directorate for each shipment.
Products imported under an Experimental Studies Certificate (ESC) for use in an experimental study	Not Applicable	Not Applicable	An ESC issued by Health Canada's Veterinary Drugs Directorate for each drug. A copy of this authorization must be provided at the port of entry.
Products imported under the Emergency Drug Release Program	Not Applicable	Not Applicable	An Emergency Drug Release Authorization issued by Health Canada's Veterinary Drugs Directorate for each shipment.

	Product Licence	Establishment Licence	Other Importation Requirements
Drugs 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.		
Drugs prohibited for food producing animal (i.e., chloramphenicol or its salts or derivatives; a 5-nitrofuran 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.		

In Canada, veterinary biologics are regulated by the Canadian Food Inspection Agency (CFIA) under the legislative authority of the *Health of Animals Act* and Health of Animals Regulations. The veterinary biologics regulatory program is administered by the Canadian Centre for Veterinary Biologics in collaboration with the CFIA's Veterinary Biologics Operations. For information on the importation of veterinary biologics, please see Importation of Veterinary Biologics – Overview.

Medical Devices

Medical devices are regulated by Health Canada under the authority of the Act and the Medical Devices Regulations (MDR). Medical devices are categorized into four classes (I, II, III or IV) based on the level of risk related to their use. Class I devices present the lowest potential risk (e.g. thermometers). Class IV devices present the highest potential risk (e.g. pacemakers).

Health Canada issues two types of medical device licences in Canada.

(1) **Medical Device Establishment Licence (MDEL)**: a licence issued to an establishment that imports or sells medical devices in Canada. This includes manufacturers of Class I medical devices as well as importers and distributors of all classes of medical devices.

An MDEL is issued by Health Canada's Medical Devices and Clinical Compliance Directorate (MDCCD).

Health Canada's *Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees*, GUI-0016, provides guidance on all aspects of an MDEL, and includes definitions of a manufacturer, importer and distributor.

(2) Medical Device Licence (MDL): a licence issued to a manufacturer authorizing the sale of a Class II, III or IV device in Canada. Class I devices do not require an MDL.

MDLs are issued to manufacturers of Class II, III, or IV devices by the Medical Devices Directorate (MDD), Health Canada based on scientific evidence for quality, safety and efficacy.

For more information on how to obtain an MDL, please see the *Guidance Document: How to Complete the Application for a New Medical Device Licence*.

An imported medical device must have an MDL if it is a Class II, III or IV device. Furthermore, importers of any Class of medical device that offer a medical device for sale require an MDEL unless they are a:

- retailer;
- health care facility;
- class I device manufacturer who imports or distributes only class I devices through someone else who has an MDEL;
- class II, III or IV device manufacturer that only sells medical devices for which they hold a valid licence;
- person who only imports or sells veterinary devices;
- dispenser; or
- person who only imports or sells custom-made devices, medical devices for Special Access, or devices for Investigational Testing involving human subjects.

Medical devices without a medical device licence may be imported through a request by a health care professional to the Special Access Program (SAP), via exemptions set out in Part 2, Section 69-78 of the MDR. The SAP considers requests from health care professionals for access to unlicensed medical devices for emergency use where conventional therapies have failed, are unavailable or are unsuitable. Additionally, the SAP grants authorizations for custom-made medical devices required for unique patient circumstances. Decisions to authorize this access are based on the circumstances and details of each situation. If authorization is granted, Health Canada provides an LOA to the manufacturer of the medical 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 medical device into Canada. Table 6 identifies Health Canada's importation requirements for medical devices.

Table 6. Importation Requirements for Medical Devices

	Device Licence	Establishment Licence	Other Importation Requirements
Class I	Not Applicable	Importer must have a Medical Device Establishment Licence (MDEL) for the activity of import unless exempted. Class I device manufacturer must have an MDEL to import, unless the manufacturer imports or distributes solely through someone else who has an MDEL	Not Applicable
Class II, III or IV	Device Licence	Importer must have an MDEL for the activity of import unless exempted.	Not Applicable
Investigational testing on human subjects	Not Applicable	Not Applicable	Letter of Authorization (LOA) issued by Health Canada's Medical Devices Directorate should accompany Class II, III or IV devices under Investigational Testing status. Require Identification as "Investigational Device" and "To Be Used by Qualified Investigators Only" on the label of the device.
Special Access and Custom-made devices	Not Applicable	Not Applicable	LOA issued by Health Canada's Medical Devices Directorate should accompany all classes of Special Access devices; and class III or IV custom-made devices. Device label must specify that the device is custom-made or for Special Access.

Blood and Blood Components for Transfusion

Blood and Blood Components for Transfusion are regulated by Health Canada under the authority of the Act and the Blood Regulations (see Table 7 for import requirements).

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 or the CFIA as cultures, diagnostic specimens or research tissue may be potential carriers of human or animal pathogens. Please consult these organizations for more details.

Table 7. Importation Requirements for Blood and Blood Components for Transfusion

	Product Licence	Establishment Licence	Other Importation Requirements
Blood and Blood Components for Transfusion	Not Applicable	• Importer must have a Blood Establishment Licence (BEL) for the activity of import. • Foreign Establishment must be on the importer's BEL.	Blood and Blood Components must meet the requirements of the Blood Regulations. If blood and blood components for transfusion are being imported pursuant to a prescription, the requirements in the Blood Regulations are waived. Proof of the prescription should be provided at the port of entry.

Cells, Tissues and Organs (CTOs) for Transplantation

The Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations) contain safety requirements with respect to importation as well as processing, storage, distribution, record keeping, etc. The CTO Regulations apply only to human CTOs that are to be used in transplantation. CTOs donated for different purposes, such as for education or non-clinical research, are not within the scope of the CTO Regulations. For CTO importation requirements, see Table 8.

Table 8. Importation Requirements for Human Cells, Tissues and Organs for Transplantation

	Product Licence	Establishment Licence	Other Importation Requirements
Islet Cells and Tissues	Not applicable	Not applicable	Importing establishment requires a CTO registration number unless it is the end user. Exporting Source Establishment requires a CTO registration number. Name and Registration Number of the Establishment(s) should be displayed on the exterior of the package
Lymphohematopoetic cells (stem cells) and Organs	Not applicable	Not applicable	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.

An Establishment Registration Number is a six (6) digit numerical code beginning in a one (1) assigned to an approved establishment under the CTO Regulations.

As defined in section 1 of the Safety of Human Cells, Tissues and Organs for Transplantation Regulations, a Source Establishment means:

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.

Sperm and Ova for Assisted Human Reproduction

Donor sperm and ova for assisted human reproduction are regulated under the Safety of Sperm and Ova Regulations under the *Assisted Human Reproduction Act*. For more information regarding the importation requirements for donor sperm and ova, please refer to Health Canada's *Guidance Document – Safety of Sperm and Ova Regulations*.

Advanced Notice of Importation of Non-compliant Drugs (section A.01.044 of FDR)

The importation for sale of non-compliant drugs, including natural health products, is prohibited under section A.01.040 of the FDR. However, section A.01.044 of the FDR allows for the importation of non-compliant drugs provided two specific conditions are met:

1. The importer provides advanced notice to a Health Canada inspector of the proposed importation (notice cannot be provided at the border as is already considered imported at that point).

   And

2. The product is relabelled or modified as required to enable its sale to be lawful in Canada.

This process does not provide time for products to seek market authorization in Canada as the modifications are to be completed within a three month period. For more information on section A.01.044, please refer to the Important Information to Stakeholders - Implementation of Advance Notice of Importation Process Pilot for Cosmetics and Drugs.

Advanced Notice of Importation of Medical Devices with non-compliant labelling (section 21.1 of MDR)

The importation for sale of a medical device with labelling that does not meet the requirements of Section 21(1) of the MDR is prohibited. However, Section 21.1 of the MDR allows for the importation of a medical device that is not labelled in accordance with the Regulations provided:

(a) if that person holds an establishment licence to import the medical device, that they send prior notice of the proposed importation to Health Canada or, if they do not hold such a licence, that the manufacturer of the medical device sends the prior notice; and

(b) before selling the medical device, that the manufacturer of the medical device has relabelled it in accordance with these Regulations within three months after the date of its importation.

In addition, any person who imports for sale a medical device that is not labelled in accordance with these Regulations shall ensure that the manufacturer of the medical device notifies Health Canada in writing of the name of the person who will relabel it in Canada if it is to be relabelled on the manufacturer's behalf.

The Advance Notice of Importation Process for Medical Devices assists manufacturers and importers in meeting the requirement to send prior notice of the proposed importation of non-compliant labelled medical devices to the Minister. All other licensing requirements continue to apply, including that the medical device be: licensed for sale in Canada; imported from a foreign manufacturer or distributor that holds a valid MDEL; or, imported and sold through a party in Canada that holds a valid MDEL, unless exempted under S.44(2) of the MDR. For more information on section 21.1 and the Advance Notice of Importation Process for Medical Devices, please refer to the Important Information to Stakeholders - Implementation of Advance Notice of Importation Process for Medical Devices.

Importing Foreign Drugs for Packaging and Labelling in Canada

If you provide packaging and labelling services to foreign drug manufacturers, you may import drugs in dosage form that have not been approved for sale in Canada under the following conditions (all to be met):

- You have a drug establishment licence for packaging/labelling activities.
- You only carry out packaging/labelling of the product.
- You export the packaged and labelled drugs back to the originating country.
- The unapproved drugs are not sold in Canada.
- You do not sell the drugs in other countries.
- The foreign manufacturer or supplier retains ownership of the drugs during the import, packaging/labelling and export periods. Where product is not going to be returned directly to the owner, proof of ownership must be provided, otherwise the export may be considered distribution and Canadian licensing requirements would apply.

See *Conditions for Provision of Packaging/Labelling Services for Drugs under Foreign Ownership (GUI-0067)* for the requirements you must fulfill.

Exporting Health Products

The following describes the conditions and requirements under which health products may be exported from Canada. You must ensure that you export only those health products which do not pose a risk to health and safety, and which are effective and of high quality. As a responsible member of the global community, Health Canada must maintain the integrity of agreements and commitments made to our international partners such as Mutual Recognition Agreements (MRAs). For more information please refer to Health Canada's website: Mutual Recognition Agreements.

Exporting Licensed Health Products

You may export a health product licensed by Health Canada commercially as long as the sale of the product complies with the Act and its Regulations. At a minimum, this means that the product must **not** be:

- adulterated
- manufactured in unsanitary conditions
- manufactured, sold or advertised in a way that is false, misleading or deceptive
- injurious to the health of the users

For a drug, this means that the product has to be manufactured according to the Good Manufacturing Practices (GMP) requirements found in the FDR and the site must hold an EL.

If requested, Health Canada may issue licensed health products:

- a Certificate of Pharmaceutical Product (CPP) for drugs, or
- a Manufacturer's Certificate to Export (MCE) for medical devices

Health Canada issues these certificates to manufacturers to facilitate the export process as a service to the Canadian medical device and drug industry. Consult the following guides on Health Canada website to request a CPP or an MCE:

- *Guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024)*

- *Guidance to apply for a Manufacturer's Certificate to Export licenced medical devices from Canada (GUI-0097)*

Exporting Unlicensed Health Products

Products Manufactured in Canada for Export

If you manufacture or prepare a health product in Canada, including an active pharmaceutical ingredient, intended for export only, you must comply with the Act and its Regulations.

If products are being shipped to an MRA partner, and they are within the scope of the MRA, then the products must continue to be manufactured in accordance with the Act and its Regulations.

For drugs and active pharmaceutical ingredients to comply with the Act and its Regulations the following must be met:

- products are manufactured according to the GMP requirements
- site holds an establishment licence
- the manufacturer should attest that the product is not known to contravene any laws of the importing country

If you require an exemption from the requirements of any of the Act and its Regulations in order to meet the laws or requirements of the country to which products are being shipped, you may invoke section 37 of the Act.

According to section 37, exports are exempt from the Act under the following conditions:

- The health product must be manufactured or prepared in Canada.
- The health product must be for export only and must not be manufactured, prepared or sold for consumption or use in Canada.
- You have an Export Certificate that is notarized and attests that the package and contents do not contravene any known requirement of the law of the importing country (see Appendix III of the FDR or Schedule 3 of the Medical Devices Regulations).
- Drug products manufactured in Canada for export cannot be adulterated, or made in unsanitary conditions, or be packaged or labelled in a way which is misleading or deceptive (section 37(1.1)(b) of the Act).
- Medical Devices which are manufactured in Canada for export cannot cause injury to the health of the purchaser/user when used according to directions or customary use, or be packaged or labelled in a way which is misleading or deceptive (section 37(1.1)(d) of the Act).

Note that a Certificate of a Pharmaceutical Product or a Manufacturer's Certificate for a medical device will not be issued by Health Canada for a health product that seeks exemption from the Act under section 37.

You should notify Health Canada of your intention to use section 37 using the form titled *Export Certificate for Drugs Exported Under Section 37 of the Food and Drugs Act (FRM-0038)*. If you use section 37:

- product lots that are for export only and for which the packaging is not yet complete are to be clearly identified as such, for example by written indication on the manufacturing order or bulk containers
- you must keep manufacturing records and copies of export certificates at your premises and provide them to Health Canada inspectors **before or during** inspection.

If you choose to use section 37 and you have an export certificate, health products are not subject to inspection. Health Canada will identify to foreign regulatory authorities, those products for which you have notified Health Canada of your intent to use section 37.

Section 37 cannot be used for products within the scope of a mutual recognition agreement (MRA) that are being shipped to an MRA partner. If you use section 37, those health products are excluded from any MRAs; this means you cannot benefit from the arrangements under any MRA.

Exemptions under section 37 do not apply to products being imported. If you import products into Canada for the purpose of manufacturing a product for export, the product you import must comply with the Act at the time of import and the importer must hold the appropriate licence.

Goods In Transit

Transhipments of health products are exempt under section 38 of the Act when the products meet the following conditions:

1. Manufactured or prepared outside of Canada.
2. Imported solely for the purpose of export and are not sold for consumption or use in Canada.

   And

3. Meets the requirements prescribed by section 38(c) of the Act.

Section 38 of the Act does not apply to health products that are imported for further manufacturing, labelling or packaging (i.e. not solely for export) regardless of whether the products are intended for export or enter Canada under bond. Products that enter Canada as transhipments are to be under bond with CBSA and remain under bond until exported from Canada.

The following examples are included to help clarify the application of section 38 of the Act:

Example 1:

A company wants to have a shipment of health products pass through Canada from country A on its way to country B. The shipment needs to tranship through Canada for logistical reasons. The importation may be permitted if:

- The shipment contains health products that are fully compliant with the Canadian regulatory requirements (e.g. DIN, bilingual labelling, importer licence) in place.

Or

- The shipment contains health products that are non-compliant with the Canadian regulatory requirements, but are merely transiting through Canada to complete a journey beginning and ending beyond the borders of Canada. Furthermore, the products are not undergoing licensable activities such as fabrication, packaging/labelling, distribution, wholesaling or testing in Canada without the proper EL.

Example 2:

A company wants to have a shipment of unlicensed health products imported for delivery to a warehouse. The products will not be sold to Canadians. Upon receiving orders from foreign clients, the company would fulfill the orders and export the unlicensed health products to foreign clients.

This importation is not considered a transhipment as there is sale involved in Canada. In this scenario, the products cannot be imported without meeting the Canadian regulatory requirements (e.g. EL, product licence, appropriate labelling).

Appendices

Appendix A – Glossary

Acronyms

API: Active Pharmaceutical Ingredient

BEL: Blood Establishment Licence

CBSA: Canada Border Services Agency

CDSA: *Controlled Drugs and Substances Act*

CFIA: Canadian Food Inspection Agency

CPP: Certificate of Pharmaceutical Product

CTO: Cells, Tissues, Organs

DELU: Drug Establishment Licence Unit

DIN: Drug Identification Number

DIN-HM: Homeopathic Medicine Number

EDR: Emergency Drug Release

EL: Establishment Licence

ESC: Experimental Study Certificate

FDR: Food and Drug Regulations

GMP: Good Manufacturing Practices

LOA: Letter of Authorization

MCE: Manufacturer's Certificate to Export

MDCCD: Medical Devices and Clinical Compliance Directorate

MDD: Medical Devices Directorate

MDEL: Medical Devices Establishment Licence

MDL: Medical Device Licence

MDR: Medical Devices Regulations

MRA: Mutual Recognition Agreement

NHP: Natural Health Products

NHPR: Natural Health Products Regulations

NoA: Notice of Authorization

NOL: No Objection Letter

NPN: Natural Health Product Number

SAP: Special Access Program

TPD: Therapeutic Products Directorate

VHP: Veterinary Health Products

Terms

These definitions explain how terms are used in this document. If there is a conflict with the definitions below, the definition in the Act/Regulations prevails.

Active ingredient: means a drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect (Division 1A, Part C, Food and Drug Regulations).

Active pharmaceutical ingredient (API): means an active ingredient that is used in the fabrication of a pharmaceutical (Division 1A, Part C, Food and Drug Regulations).

Advertise: Includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.

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 Drug Regulations, an agricultural implant is considered to be a dosage form not suitable for human use.

Commercial importation: includes but is not limited to a shipment destined for a retailer, distributor, or other commercial establishment. This includes shipments being sent to independent sales contractors/distributors, or to a practitioner for use in their practice.

Device: Means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(c) diagnosing pregnancy in human beings or animals,

(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(e) preventing conception in human beings or animals;

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal (Section 2 of the Act).

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

Drug: Includes any substance or mixture of substances 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 organic functions in human beings or animals, or

(c) disinfection in premises in which food is manufactured, prepared or kept (Section 2 of the Act).

Drug Identification Number (DIN): A drug identification number (DIN) is an eight (8)-digit numerical code assigned by Health Canada to each drug product marketed under the *Food and Drugs Act* and Regulations. A DIN uniquely identifies the following product characteristics: manufacturer,

brand name, medicinal ingredient(s), strength of medicinal ingredients(s), pharmaceutical form, route of administration.

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 (i.e. those who are registered and entitled under the laws of a province or territory 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 Cells, Tissues and Organs (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.

Export: For the purposes of this guide, "export" includes, in addition to the sending or transporting of a health product abroad, the sale or advertising over the Internet of a health product to a foreign jurisdiction.

Good Manufacturing Practices (GMP): the requirements of Part C, Division 2 (Good Manufacturing Practices) of the Food and Drug Regulations and the interpretive guidelines on the subject published by Health Canada.

Health care facility: A facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities (Section 1, Medical Devices Regulations).

Healthcare Professionals: This group includes physicians, dentists, pharmacists, veterinarians and other professionals in the healthcare field as well as those at healthcare facilities and hospitals. Members of this group are generally regulated by their professional bodies and/or under provincial/territorial law, although they may also have obligations under the *Food and Drugs Act* and its associated Regulations.

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.

Import: For the purposes of this guide, "import" is any action that causes a product to cross the Canadian border from outside Canada regardless if under Customs bond.

Market 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 associated Regulations. The marketing authorization may be in the form of a Notice of Compliance (NOC),

Drug Identification Number (DIN), a device licence for classes II, III or IV medical devices, or a natural product number (NPN) or homeopathic DIN (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 set out 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, i.e. 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.
>
> However, a Natural Health Product does not include a substance listed in Schedule 2 of the Natural Health Products 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.
>
> Also, in accordance with subsection 2(2) of the NHPR, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the Food and Drug Regulations (FDR), is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of the FDR.

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 and is generally less than a 90-day supply. It does not apply to a practitioner (Doctor, Veterinarian etc.) importing drugs for patients/animals under their care, which is considered commercial importation.

Phase IV Clinical Trial: All studies performed within the approved indication after the drug has been approved by the regulator for the market. These studies are often important for optimizing the drug's use. They may be of any type but must have valid scientific objectives. Commonly conducted studies include safety studies and studies designed to support use under the approved indication (e.g., mortality and morbidity studies, or epidemiological studies). (*Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications*)

Prescription Drug: A drug that is set out in the Prescription Drug List, as amended from time to time, or a drug that is part of a class of drugs that is set out in it.

Prescription Drug List: The list established by the Minister under section 29.1 of the Act.

Sell: includes

(a) offer for sale, expose for sale or have in possession for sale — or distribute to one or more persons, whether or not the distribution is made for consideration, and

(b) lease, offer for lease, expose for lease or have in possession for lease (section 2 of the Act).

Shipment: A load of goods from one shipper destined to an importer irrespective of the quantity or number of containers, package or pieces.

Special Access Program (SAP) for Drugs and Medical Devices not available in Canada: The Special Access Program (SAP), via exemptions set out in C.08.010 and C.08.011 of the Food and Drug Regulations 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 these exemptions 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.

Veterinary Health Product (VHP): low risk drugs in dosage (ready to use) form. They are used to maintain or promote the health and welfare of companion and food-producing animals. They are not for use to treat, prevent or cure disease. VHPs must be made using permitted substances according to conditions outlined on List C: Veterinary Health Products.

Appendix B - Contact us

1) For help in applying these guidelines, contact the Health Products Border Compliance Program:
   Email: hc.hpbcp-pcpsf.sc@canada.ca
   Telephone: 1-800-267-9675

2) For questions about controlled substances, contact the Office of Controlled Substances at https://www.canada.ca/en/health-canada/corporate/contact-us/office-controlled-substances.html.

3) For information on how to obtain a Drug Identification Number (DIN), contact the Therapeutic Products Directorate (TPD):
   E-mail: hc.osip-bppi.sc@canada.ca
   Telephone: 613-941-0827

4) For information on how to apply for a Drug Establishment Licence, contact the Drug Establishment Licence Unit (DELU):
   E-mail: hc.del.questions-leppp.sc@canada.ca
   Telephone: 613-618-4529
   Teletypewriter: 1-800-465-7735 (Service Canada)

5) For information on how to obtain an NPN, DIN-HM and/or an SL, contact the Natural and Non-prescription Health Products Directorate:
   Email: hc.nnhpd-dpsnso.sc@canada.ca
   Telephone: 613-960-8827
   For classification of your product, contact hc.ingredient.support.sc@canada.ca.

6) For information on how to apply for a Medical Device Establishment Licence, contact the Medical Devices Compliance and Licensing Unit, Medical Devices and Clinical Compliance Directorate:
   E-mail: hc.mdel.questions.leim.sc@canada.ca
   Telephone: (613) 954-6790

7) For information on how to apply for a Medical Device Licence or for classification of your product, contact the Medical Devices Directorate (MDD):
   E-mail: hc.devicelicensing-homologationinstruments.sc@canada.ca
   Telephone: (613) 957-7285

8) For information regarding special access to drugs and health products, contact the Special Access Program:
   Email: hc.sapd-pasm.sc@canada.ca
   Telephone: 613-941-2108

9) For information regarding veterinary drugs and/or veterinary health products, contact the Veterinary Drugs Directorate:
Email: hc.vdd.vetdrugs-medsvet.dmv.sc@canada.ca
Telephone: 613-954-5687

10) For questions regarding blood, sperm and ova, and cells, tissues and organs, contact the Biological Product Compliance Program: Email: hc.bpcp-pcpb.sc@canada.ca
Teletypewriter: 1-800-465-7735

For information regarding establishment registration of cells, tissues and organs, contact hc.rorb.cto-dgorr.sc@canada.ca.

Appendix C — References

Laws

Assisted Human Reproduction Act
https://laws-lois.justice.gc.ca/eng/acts/a-13.4/

Controlled Drugs and Substances Act
laws-lois.justice.gc.ca/eng/acts/C-38.8/index.html

Customs Act
http://laws-lois.justice.gc.ca/eng/acts/C-52.6/

Food and Drugs Act
laws-lois.justice.gc.ca/eng/acts/f-27/

Health of Animals Act
https://laws-lois.justice.gc.ca/eng/acts/h-3.3/

Blood Regulations
laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/page-1.html

Food and Drug Regulations
laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

Health of Animals Regulations
https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._296/

Medical Devices Regulations
laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/

Narcotic Control Regulations
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/

Natural Health Products Regulations
laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/

Safety of Sperm and Ova Regulations
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-192/index.html

Safety of Human Cells, Tissues and Organs for Transplantation Regulations
http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-118/

Policies and Guidance documents

Bringing health products into Canada for personal use (GUI-0116)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/personal-use-health-products-guidance/document.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

Conditions for Provision of Packaging/Labelling Services for Drugs under Foreign Ownership (GUI-0067)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/conditions-provision-packaging-labelling-services-drugs-foreign-ownership-guide-0067.html

Good manufacturing practices guide for drug products (GUI-0001)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html

Guidance Document on Classification of Veterinary Drugs and Livestock Feeds
https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/legislation-guidelines/guidance-documents/guidance-document-classification-veterinary-drugs-livestock-feeds.html

Guidance Document – How to Complete the Application for a New Medical Device Licence
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-complete-application-new-medical-device-licence.html

Guidance Document: How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-complete-application-new-medical-device-licence-amendment-private-label.html

Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (GUI-0100)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html

Guidance on Drug Establishment Licences (GUI-0002)
www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html

Guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-application-certificate-pharmaceutical-product-0024.html

Guidance on Medical Device Establishment Licensing (GUI-0016)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-medical-device-establishment-licensing-0016.html

Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidance-evidence-demonstrate-drug-compliance-foreign-sites-0080.html

Guidance Document – Safety of Sperm and Ova Regulations
canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html

Site Licensing Guidance Document
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/site-licensing-guidance-document.html

Application forms

Application for an Experimental Study Certificate for a Veterinary Drug
https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/applications-submissions/experimental-studies-certificate-application-form-for-a-veterinary-drug.pdf

Blood Establishment Licensing Application Form and Instructions (FRM-0354)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/blood-establishment-licensing-application-form-instructions-0354.html

Drug establishment licence application: forms and instructions (FRM-0033)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html

Human Cells, Tissues and Organs (CTO) for Transplantation Establishment Registration Application Form (FRM-0171)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/human-cells-tissues-organs-transplantation-registration-application-form-0171.html

Export Certificate for Drugs Exported Under Section 37 of the Food and Drugs Act (FRM-0038)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/intention-invoke-section-37-canada-food-drugs-act-products-being-exported.html

Guidance to apply for a Manufacturer's Certificate to Export licenced medical devices from Canada (GUI-0097)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/application-manufacturer-certificate-cover-export-medical-devices-0097.html

Product Licence Application Form
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing/forms-templates/product-licence-application-natural-health-products-health-canada.html

Other

Convention on International Trade in Endangered Species of Wild Fauna and Flora
www.cites.org/

Drugs - Special Access Program
https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html

Emergency Drug Release program
https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/emergency-drug-release-veterinary-drugs.html

Important Information to Stakeholders - Implementation of Advance Notice of Importation Process Pilot for Cosmetics and Drugs
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/implementation-advance-notice-importation-process-pilot-cosmetics-drugs.html#wb-cont

Important Information to Stakeholders - Implementation of Advance Notice of Importation Process for Medical Devices
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-guidance-notification-importation.html

Importation of Veterinary Biologics – Overview
http://www.inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/3-25f/eng/1328639619579/1328640363370

List A: List of certain antimicrobial active pharmaceutical ingredients
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-antimicrobial-sales-reporting/list-a.html

List B: List of Certain Veterinary Drugs Which May Be Imported But Not Sold
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/personal-importation-certain-drugs-food-producing-animals/list-b.html

List C: Veterinary Health Products
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products/list-c.html

List of Drugs for an Urgent Public Health Need
https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html

Medical Devices Special Access Program
https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/medical-devices.html

Prescription Drug List
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html

Product Licensing
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/product-licensing.html

Questions and Answers – Access to Drugs in Exceptional Circumstances
https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/questions-answers.html