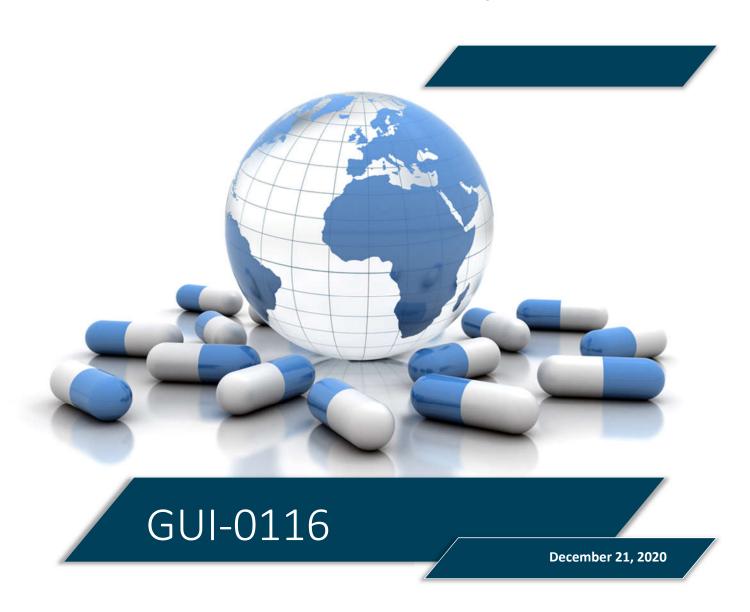
## Bringing health products into Canada for personal use





Date issued: December 21, 2020
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Replaces: Guidance Document on the Import Requirements for Health Products under

the Food and Drugs Act and its Regulations (GUI-0084), Border Integrity Approach (POL-0059), Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations (POL-0060), 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 : Apporter des produits de santé au Canada pour usage personnel

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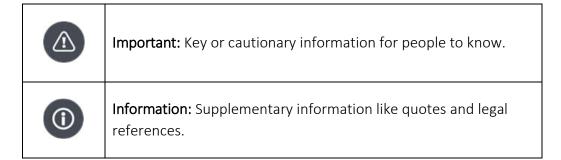
#### Disclaimer

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

## Table of contents

Purpose		6
Scope		6
Role of Indiv	ridual	7
Governmen	t of Canada's role	7
What types	of health products are regulated under the Food and Drugs Act?	8
Guidelines f	or importing health products for personal use	9
	What is meant by personal use?	9
	Who can import a health product for personal use?	11
	Can I bring medical devices into Canada?	12
	Can I bring prescription drugs into Canada?	12
	Are there shipping or packaging requirements?	14
	Can I bring drugs for food producing animals or animals intended for food	
	(including all horses) into Canada?	14
	Can my doctor/veterinarian access health products for me that are not	
	available in Canada?	15
	Can I bring/mail health products to a foreign country?	15
Appendices		17
Appendix A	- Glossary	17
	Acronyms	
	Terms	18
Appendix B	- Contact us	22
Appendix C - References		23
	Laws	23
	Policies and Guidance documents	23
	Other	24

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



## Purpose

This guidance document describes the rules for bringing health products into Canada for personal human and veterinary use. Health products include prescription drugs; over-the-counter (OTC) medications; natural health products (NHPs); veterinary health products (VHPs); medical devices; blood for transfusion; human cells, tissues and organs for transplantation.

The guidance document:

- describes what health products you can and cannot bring into Canada
- defines personal importation and
- explains the difference between a personal versus commercial import

By following the information in this guidance, you will better understand what is considered a personal use import, the restrictions in place for the importation of prescription drugs and the commercial licensing implications that apply when a shipment is considered to fall outside the conditions of a personal use import.



Shipments that are imported for the purpose of sale in Canada are considered commercial imports and must meet the applicable regulatory requirements as outlined in *Importing and Exporting Health Products for Commercial Use (GUI-0117)*. Non-compliant shipments may be seized or refused entry into Canada. Please refer to the *Compliance and Enforcement Policy for Health Products (POL-0001)* which describes how the Regulatory Operations and Enforcement Branch (ROEB) of Health Canada delivers its national border compliance and enforcement program.

## Scope

These guidelines apply to you if you:

- live in Canada (resident of Canada)
- are returning to Canada from abroad
- are a visitor to Canada such as a tourist or a visitor with a study or work permit

This guidance document addresses the requirements under the <u>Food and Drugs Act (Act)</u> and its regulations for health products. Some health products may also have additional restrictions placed on them by other Acts, such as the <u>Controlled Drugs and Substances Act</u> (CDSA) and its

regulations and the <u>Convention on International Trade in Endangered Species of Wild Fauna and Flora</u>. Where multiple restrictions/requirements exist, the most restrictive conditions will apply.

### Role of Individual

Canadians are encouraged to buy licensed health products in Canada that have been assessed to be safe and effective if used according to their directions for use.

If health products are purchased outside the country, individuals need to be aware of the potential health and financial risks (loss of product, purchase/shipping costs) associated with this activity, particularly when buying <u>drugs</u>, <u>natural health products</u> or <u>medical devices</u> online. Health products sold online may be cheaper and easily purchased but riskier because they may be counterfeit (i.e. "fake"), contain the wrong level of an active ingredient, contain toxic substances, or even be past their expiry date.



It can be difficult for Canadians to determine if an internet store is located in Canada, as some sites may appear to be operating in Canada, when in fact they are not. For example, internet stores may have Canada in their name or include a symbol such as a maple leaf that could lead one to assume it is a site operating within Canada. Avoid buying health products from questionable websites. If you have questions about whether an Internet pharmacy is legitimate, contact the licensing body in your province or territory.

Individuals are responsible for knowing if the products being imported contain a <u>prescription</u> drug or a controlled substance as they have distinct import restrictions.

### 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, regardless of whether the products are entering by mail/courier or on your person.

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*.

The CBSA may then contact Health Canada to confirm if the product is compliant with the importation requirements found in the Act and its Regulations. Health products found to be noncompliant 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, 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 it 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.

# What types of health products are regulated under the *Food and Drugs Act?*

Health products are generally associated with the treatment or diagnosis of a disease, sickness or human/animal condition. They are separate from cosmetics which are regulated under the Act, but not as a drug or a medical device. Cosmetics do not have a therapeutic purpose and are typically used for cleansing, improving or altering the complexion of the skin, hair or teeth, including, deodorants and perfumes. The addition of health claims can make a product that would otherwise appear to be a cosmetic, a health product. The following types of health products are regulated under the Act and its associated Regulations in Canada:

- Prescription drugs for human and animal use (e.g. antibiotics, heartworm medication containing medicinal ingredients on the Prescription Drug List (PDL)
- Over-the-counter drugs for human and animal use (e.g. pain relief tablets and cough medications, oral deworming medication which includes medicinal ingredients not found on the PDL or schedules of the CDSA)
- Natural health products for human use (e.g. vitamins and minerals, herbal remedies, homeopathic medicines)
- Veterinary health products (e.g. veterinary health products for joint support in animals containing active, homeopathic or traditional medicine substances found in <u>List C</u>)
- Medical devices for human use (e.g. thermometers, contact lenses, blood pressure monitors, diabetes test strips, condoms)
- Blood and blood components for human transfusion\*
- Human cells, tissues and organs for transplantation \*
- Active pharmaceutical ingredients intended for human and animal use

\*Only blood, human cells, tissues and organs for the uses noted above are regulated under the Act. Sperm and ova for the purpose of assisted human reproduction are regulated under the <u>Assisted Human Reproduction Act</u> and the <u>Safety of Sperm and Ova Regulations</u>, and therefore are out of scope of this document. Any use falling outside of this scope may still require permits from either the Public Health Agency of Canada or the Canadian Food Inspection Agency due to their potential to carry human or animal pathogens (see <u>Appendix B - Contact Us</u>). For more information on the requirements for donor sperm and ova, please refer to the <u>Guidance</u> <u>Document - Safety of Sperm and Ova Regulations</u>.

# Guidelines for importing health products for personal use

This section describes what you need to know to bring health products into Canada for your personal use.

#### What is meant by personal use?

Personal use means that you are bringing a health product into Canada and the product is:

- for your own use,
- for the use of a person or animal who is under your care, or
- for the use of a person or animal with whom you are travelling

Health Canada takes the following factors into consideration in determining whether the import is for a personal use (list is not exhaustive).

- quantity (health products)
  - o no more than a 90-day supply or a single course of treatment, whichever is less, based on the product's directions for use
- medical device usage
  - o the medical device does not require direct oversight or administration by a trained operator for its use

"Directions for use" refers to:

- the dosage information included on the health product's label or packaging
- the insert or product monograph included with the health product, or
- an official prescription, hospital/pharmacy dispensing instructions, or a doctor's order included with the health product

If the health product does not include directions for use or if the directions for use are in a foreign language or unclear, Health Canada may look at dosage instructions from similar products or recognized sources.



You are a commercial importer if you bring a health product into Canada to:

- sell or give it to someone else that is not under your care
- treat a patient as part of a practitioner/patient relationship
- treat an animal that is not your own
- advertise its sale
- export it out of the country

Each of these activities is considered a sale of a health product, regardless of whether there is an exchange of money. As such, both the individual (<u>establishment licence</u> or <u>Natural health product site licence</u>) as well as the product requires licensing.

See guidelines for <u>Importing or Exporting Health Products for Commercial Use</u> (<u>GUI-0117</u>) for a description of the rules commercial importers must follow.



Importation of health products exceeding the personal importation limit of 90-days may be considered a commercial import. For animals, the quantity is based on the number of animals being treated. For medical devices, the quantity of units imported may be taken into consideration.

If you bring the same health products into Canada in multiple shipments and the total amount exceeds a 90-day supply over a 90-day period, you may be considered a commercial importer.

#### Who can import a health product for personal use?

Residents of Canada and visitors are permitted to bring into Canada a personal use quantity (a 90-day supply or single course of treatment) of an OTC medication, NHP, VHP or a medical device for personal use without requiring specific licences for the import.

There are no import restrictions for medical devices for personal use. However, it must be clear that the device can be used directly by the individual without the need for assistance or oversight by a professional. If the device needs the assistance or oversight of a professional, it would be classified as a commercial device.

Specific import restrictions exist for drugs to be used on food producing animals or animals intended for food (including all horses). These drugs must either be market authorized in Canada, be on the list of <u>notified VHP</u>, or a product found on <u>List B: List of Certain Veterinary Drugs Which May Be Imported But Not Sold</u> and be specifically authorized for use on the animal species in question.

Prescription drugs also have specific import requirements and are only permitted to be imported by a practitioner, a drug manufacturer, a wholesale druggist, a registered pharmacist, or a resident of a foreign country while a visitor in Canada. Canadian residents are generally not permitted to import prescription drugs by mail or courier. In certain cases, exemptions exist for Canadian residents to import prescription drugs (see <u>Can I bring prescription drugs into</u> Canada?).



Be aware that a medication that does not need a prescription in another country could need a prescription in Canada. Check Health Canada's <u>Prescription Drug List</u> (PDL) to see if the health product needs a prescription in Canada.

The PDL is comprised of human drugs in the first part of the list and veterinary drugs in the second part of the list.

#### Can I bring medical devices into Canada?



Medical devices imported for personal use are not subject to restrictions under the Act or the Medical Devices Regulations; however, it must be clear that the use of such a device would not require the direct oversight of, or administration by, a trained operator, otherwise it would be considered a commercial import. Health Canada maintains a listing of all active licences online. Information accompanying medical devices including the manufacturer's instructions or operator's manual will be used to determine intended uses. The quantity of medical devices imported may also be taken into consideration.

#### Can I bring prescription drugs into Canada?



Some health products, particularly prescription drugs, may also contain controlled substances. A health product that is a controlled drug or substance in Canada has its own regulations and rules, including specific import requirements. You are responsible for making sure you meet any rules or conditions that apply to your situation. Please consult the <u>Office of Controlled Substances</u> for information about other possible restrictions that may apply.

#### Residents of Canada

Generally, residents of Canada are **not** allowed to bring prescription drugs into Canada for people or animals. This includes whether you carry them across the border or have them delivered by mail or courier. Health Canada may permit you to import a personal quantity (a 90-day supply or a single course of treatment) of a prescription drug in the following situations:

- Canadian residents returning to Canada with prescription drugs that were prescribed and filled in Canada for their use or for use on a person/animal for whom they are responsible.
- Canadian residents returning to Canada with prescription drugs for themselves or for an individual or animal under their care and with whom they are travelling, who are continuing a medical treatment that was required to be initiated while abroad.
- Canadian residents and visitors to Canada that belong to a foreign-sponsored clinical trial.
- Recently landed immigrants or refugees seeking continued treatment.

Canadian residents requiring ongoing treatment with a prescription medication that was started abroad should speak with their doctor about accessing a licensed product in Canada. Where a licensed product is not available, the individual may wish to speak with their doctor about Health Canada's Special Access Programs (SAP), or to their veterinarian about the Emergency Drug Release program as applicable. For details, see "Can my doctor/veterinarian access health products for me that are not available in Canada?" Prescriptions that are issued abroad may not be filled in Canada; likewise, drugs prescribed in Canada should only be filled in Canada.

Health Canada recognizes the need for continued treatment without interruption of medical conditions that began outside of Canada. If you are a Canadian resident under the long-term care of a doctor from another country, you should contact a Canadian medical practitioner to get the medication within Canada.

#### Visitors to Canada

Visitors entering Canada may bring a personal quantity of a prescription drug for their own use or for the use of a person or animal under their care and with whom they are travelling.

Visitors staying in Canada for more than three months may bring into Canada an additional 90-day supply of a health product every three months for their own personal use by mail or courier.

Visitors to Canada must be ready to provide evidence of their visitor status. Evidence includes documents such as:

- a copy of your passport
- student or work visa, or
- letter from an employer or university

As a visitor, if the drug is mailed to you, you are encouraged to include a copy of any of the above documentation in the package and indicate on the outside of the shipping package that it is destined to a visitor in Canada.

#### Are there shipping or packaging requirements?

Health products you bring into Canada for personal use must either:

- be in the package dispensed by the hospital or pharmacy
- be in the original retail package, or
- have the original label attached to it (the label must clearly say what the health product is and what it contains)



When deciding whether a health product meets the amount allowed for personal use, Health Canada will look at the directions for use. It is important that products have proper labelling information.

## Can I bring drugs for food producing animals or animals intended for food (including all horses) into Canada?

No person can import a drug for use in/on food-producing animals or animals intended to be consumed as food (including all horses) unless the product has been authorized by Health Canada for such use. This means that the drug must either be market authorized for sale in Canada, be on <u>List B: List of Certain Veterinary Drugs Which May Be Imported But Not Sold</u> or be a notified VHP.

Drugs imported corresponding to List B products must:

- match the criteria on List B including brand name, manufacturer, country in which product has been authorized for sale, dosage form and strength
- be brought in to treat the appropriate species as detailed on List B and
- not exceed a personal quantity based on the number of animals to be treated under your care and the drug's directions for use

If you want to import a drug that is not already on List B, a request must be submitted to Health Canada for the product to be added to List B. See <u>Appendix B - Contact us</u> for information about how to request a drug to be added to List B.

## Can my doctor/veterinarian access health products for me that are not available in Canada?

You may be able to gain access to drugs and medical devices that are not available in Canada through a Canadian doctor using the Special Access Programs (SAP).

The SAP is available to Canadian doctors to obtain drugs for their patients under the following circumstances:

- the drug is not available for sale in Canada
- you have a serious life-threatening condition and conventional therapies:
  - have been considered and ruled out
  - have failed
  - o are unsuitable
  - o are unavailable

You may be able to gain access to veterinary drugs that are not available in Canada through a Canadian veterinarian using the <u>Emergency Drug Release</u> (EDR) program.

The EDR program considers requests for access to drugs for veterinary use that are:

- unavailable for sale in Canada; and
- submitted by veterinarians for the purpose of diagnosing or treating a medical emergency in a patient (or group of animals) under their care

#### Can I bring/mail health products to a foreign country?

Some health products that are legal in Canada may be illegal in other countries. You are subject to the laws of the country you are entering, so it is up to you to learn about that country's rules and restrictions before you leave Canada. You can do this by contacting the embassy, consulate or mission of the country you will be entering. Health Canada also recommends you carry a copy of your prescription with you when travelling.

Exportation for "personal use" is exportation for an individual's own personal use, the use of a person for whom they are responsible or for use on an animal for which they are responsible.

Larger volumes shipments, multiple repeat shipments of the same product within short periods of time (<3 months), shipments accompanied by or associated with materials to be used for advertising or promotion, and/or shipments that indicate a Canadian business is involved in the

transaction, will be considered commercial shipments. rules commercial exporters must follow.	See <u>GUI-0117</u> for a description of the

## **Appendices**

## Appendix A - Glossary

#### Acronyms

CBSA: Canada Border Services Agency

CDSA: Controlled Drugs and Substances Act

CFIA: Canadian Food Inspection Agency

DIN: Drug Identification Number

DIN-HM: Homeopathic Medicine Number

EDR: Emergency Drug Release

FDR: Food and Drug Regulations

LOA: Letter of Authorization

NHP: Natural Health Products

NOC: Notice of Compliance

NPN: Natural Health Product Number

OLS: Office of Laboratory Security

OTC: Over-the-counter

PDL: Prescription Drug List

PHAC: Public Health Agency of Canada

ROEB: Regulatory Operations and Enforcement Branch

SAP: Special Access Programs

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.

**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.

**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 (See GUI-0117 for specific examples of commercial importation).

**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).

**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).

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.

**Export:** For the purposes of this guidance document, "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.

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

**List B:** means the document, as per the Food and Drug Regulations, entitled <u>List of Certain Veterinary Drugs Which May be Imported But Not Sold</u>, as amended from time to time (C.01.001(1) of the FDR).

**List C:** means the document, entitled <u>Veterinary Health Products</u>, that is published by the Government of Canada on its website, as amended from time to time (C.01.001(1) of the FDR)

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 and 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 set-out in Schedule 1, 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 set-out in Schedule 2 of the *Natural Health Products Regulations (NHPR)*, any combination of substances that includes a substance set-out in Schedule 2, or a homeopathic medicine or a traditional medicine that is or includes a substance set-out 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.

**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.

**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 *Food and Drugs 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 Programs (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.

**Veterinary practitioner:** means a person who is registered and entitled under the laws of a province to practice the profession of veterinary medicine.

**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.

**Visitor**: a person who is not a Canadian resident. It is a person that is not living in Canada and who is in Canada for visiting, studying or for work under a work visa. Residential address will be used to determine if an individual with dual citizenship is a visitor or not.

## Appendix B - Contact us

1) For questions about importing health products, contact the Health Products Border Compliance Program:

Email: <a href="mailto:hc.hpbcp-pcpsf.sc@canada.ca">hc.hpbcp-pcpsf.sc@canada.ca</a>

Phone: 1-800-267-9675

- 2) For questions about controlled substances, contact the <u>Office of Controlled Substances</u> https://www.canada.ca/en/health-canada/corporate/contact-us/office-controlled-substances.html
- 3) For questions about the import of cultures, diagnostic specimens or research tissues that may be carriers of human or animal pathogens contact the Public Health Agency of Canada (PHAC) or the Canadian Food Inspection Agency (CFIA) as applicable:
  - PHAC's Office of Laboratory Security (OLS)

Email: biosecurite@phac-aspc.gc.ca

Phone: 613-957-1779

• CFIA National Import Service Centre

https://www.inspection.gc.ca/importing-food-plants-or-animals/food-imports/nisc/eng/1364059150360/1364059265637

Phone: 1-800-835-4486 (Canada or U.S.A.)

289-247-4099 (local calls and all other countries)

Facsimile: 613-773-9999

- 4) To submit a request to add a drug to List B we recommend that you contact:
  - your food producer association to make a request on your behalf or
  - Health Canada to get a copy of the Request Form to add a drug to List B:

o telephone: 613-954-5687

o email: listb-vdd.listeb-dmv@hc-sc.gc.ca

Please see information on the criteria and how to add a drug to List B.

5) For questions regarding blood, sperm and ova, and cells, tissues and organs, contact the Biological Product Compliance Program: Email: <a href="https://hc.bpcp-pcpb.sc@canada.ca">hc.bpcp-pcpb.sc@canada.ca</a> Teletypewriter: 1-800-465-7735

## Appendix C - References

#### Laws

#### Assisted Human Reproduction Act

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/

#### Food and Drug Regulations

laws.justice.gc.ca/eng/regulations/c.r.c., c. 870/index.html

#### Medical Devices Regulations

http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/

#### Natural Health Products Regulations

laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/

#### Safety of Sperm and Ova Regulations

laws-lois.justice.gc.ca/eng/regulations/SOR-2019-192/index.html

#### Policies and Guidance documents

#### 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

#### Guidance Document – Safety of Sperm and Ova Regulations

www.canada.ca/en/health-canada/programs/consultation-safety-sperm-ova-regulations/document.html

#### Importing or exporting health products for commercial use (GUI-0117)

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/commercial-use-health-products-guidance/document.html

#### Other

#### Buying drugs over the internet

www.canada.ca/en/health-canada/services/buying-drugs-over-internet.html

#### Buying Medical Devices from the Internet

https://www.canada.ca/en/health-canada/services/healthy-living/your-health/medical-information/buying-medical-devices-over-internet.html

## <u>Convention on International Trade in Endangered Species of Wild Fauna and Flora</u> 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

www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/emergency-drug-release-veterinary-drugs.html

#### Establishment Licences

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences.html

#### Information on the criteria and how to add a drug to List B

https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/personal-importation-certain-drugs-food-producing-animals.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

#### <u>List C: Veterinary Health Products</u>

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

#### List of Notified Products

https://health-products.canada.ca/vhp-psa/en/product-list

#### Medical Devices Special Access Program

https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/medical-devices.html

#### Natural health product site licence

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

#### Office of Controlled Substances

http://www.hc-sc.gc.ca/contact/dhp-mps/hecs-dgsesc/ocs-bsc-eng.php

#### Online Pharmacies (National Association of Pharmacy Regulatory Authorities)

https://napra.ca/online-pharmacies

#### Prescription Drug List

www. canada. ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html

#### Recalls and safety alerts database

healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3

#### Risks of buying natural health products online

https://www.canada.ca/en/health-canada/services/natural-health-products/risks-buying-natural-health-products-online.html