HEALTH CANADA

Program: Veterinary Drugs

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PGA: Health Canada

Program: Veterinary Drugs

Veterinary Drugs are regulated by Health Canada (HC) under the authority of the Food and Drugs Act and the Food and Drug Regulations. These products fall under several different Schedules of the Food and Drugs Act and the Food and Drug Regulations. Veterinary biologics are not covered in this document. Biologics are regulated by CFIA (see CFIA guidance document for SWI for imports of biologics).

CBSA works with Health Canada to ensure that veterinary drugs are properly identified, documented, tracked and controlled at the time of import to ensure that importers are licensed to import these controlled substances within authorized quantities.

Implementation of the CBSA Single Window Initiative (SWI)

The CBSA assists Health Canada in administering the following legislation at the border: the Canada Consumer Product Safety Act, the Controlled Drugs and Substances Act, the Food and Drugs Act, the Hazardous Products Act, the Radiation Emitting Devices Act, the Pest Control Products Act, as well as regulations made thereunder.

These activities apply to all drugs and devices as defined by the Food and Drug Act, including veterinary drugs.

Under SWI, release requests will be submitted utilizing a new LPCO requirements.

Import Requirements:
For imports of veterinary drugs, the following information must be provided:

- An importer contact name and information must be provided to meet HC Requirements.
- The intended end-use of the commodity
  - Depending on the intended end-use code, additional details may be required
- The brand name of the commodity being imported.
  - If a commercial brand name is not available (e.g. drugs for clinical study purposes), provide the product name, or active ingredient or chemical name of the commodity as indicated by the manufacturer.
- A Canadian Product Category must be provided depending on the Intended End-Use
- Although not mandatory, the date on which the commodity was manufactured may be provided.
  It is also recommended to provide an image of the following documents:
  - Experimental Studies Certificate
  - Emergency Drug Release Authorization
  - Veterinary No Objection Letter (NOL)

For further clarification, where reference is made to a veterinarian, it means the name and address of the person who practices veterinary medicine.

Additional data elements are conditional depending on the intended use and risk of the drug.

Note: Under SWI, information requirements will remain the same. There are no additional data requirements for the import process.

Harmonized System (HS) Codes

The most common headings for veterinary drugs include goods of headings: 3001, 3002, 3003, 3004, 3005, 3006. A list of HS codes applicable to goods that may be regulated by Health Canada (Veterinary Drugs) is found at: **https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/hc-sc-eng.html**

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements under the Single Window Initiative

Importer Contact Name	PGAs to contact the importer for IID clarification.
Importer Contact Telephone Number	PGAs to contact the importer for IID clarification.
Importer Contact Email Address	PGAs to contact the importer for IID clarification.
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.).
File	Optional but allows for clearer identification of the product and may ease need for referral.
GTIN Number	Optional but allows for clearer identification of the product and may ease need for referral.
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Brand Name	Brand name is required to be on the product label.
Batch/Lot Number	Batch/lot number is optional as of 7/26/18 for the product label. This information will allow for timely recall postings by having knowledge of the batches/lots imported into Canada.
Commodity Type	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Manufacture Date	Manufacture date may be provided on the product label. This information will allow for timely recall of goods imported into Canada.
LPCO Type / Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.
LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.).

Intended use and Program conditions for Veterinary Drugs

Commodities regulated by Health Canada's Veterinary Drugs Program are subject to HS classification control and specific intended use provisions, the following are the applicable intended use conditions:

Intended use	Description
HC07	HC - Generic – Research & Development
HC10	HC - Generic - Veterinary Therapeutic Use
HC11	HC - Veterinary Drugs - Veterinary Experimental Study
HC12	HC - Veterinary Drugs - Veterinary Clinical Study
HC14	HC - Veterinary Drugs - Veterinary Emergency Drug Release (EDR)
HC29	HC – Generic – Other

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements for HC Declarations. The data elements are: Mandatory (M), Conditional (C) or Optional (O).

Data element name	PGA element definition	Data element status	Data element rules and conditions
Contact Identification	Importer Contact Name	M	For Health Canada, an importer contact name must be provided for this declaration.
Contact Method	Importer Contact Telephone Number	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Contact Method	Importer Contact Email Address	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ Authorization Type	C	The coded identifier of applicable document types being provided at the declaration level must be provided in this field. Document types provided here must be applicable to all commodities on this declaration. If not applicable to all commodities, please provide the document types at the commodity line level (SG121). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A for Intended uses and Canadian Product categories.

Document Reference Number	LPCO Number	C	For each document provided at the declaration level, the associated reference number related to that document must be provided. Refer to Appendix B for Document types and Reference numbers.
Document Source Description	File	O	It is strongly recommended to provide an image of the following documents that can be accessed by qualified CBSA and Health Canada employees: • Experimental Studies Certificate • Emergency Drug Release Authorization • Veterinary No Objection Letter (NOL) Providing an image may improve communication in case of a referral.
Product Identifier	GTIN Number	O	Veterinary Drugs can be identified through their GTIN GS1 Asset Identifier. Although not required, this information would allow a clearer identification of the product and facilitate communication in case of referrals. The qualifier for GS1 Global Trade Identification Number (GTIN) must be provided in the 7402, 2 field.
Intended End Use	Intended Use	M	The intended end-use of the commodity must be provided. Depending on the intended end-use code, additional details are required as follows: Refer to Appendix A for Intended uses and Canadian Product categories.
Commodity Brand Name	Brand Name	M	The brand name of the commodity being imported must be provided. For commodities where a commercial brand name may not be available (e.g. drugs destined for clinical study purposes), please use this field to provide the product name, or active ingredient or chemical name of the commodity as indicated by the manufacturer.
Commodity Lot Number	Batch/Lot Number	O	The lot number that the manufacturer assigned to the product may be provided.
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP as follows: The qualifier for field 5389 should be the code for HC – Veterinary Drugs Refer to Appendix C for Intended uses and Canadian product categories.
Production/ Expiry Date	Manufacture Date	O	The date on which the commodity was manufactured may be provided. If a format without time zone information is provided the time must be in CBSA Headquarters time (EST, e.g., GTM -5)

Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ Authorization Type	C	The coded identifier of any applicable document must be provided in this field if applicable to a specific commodity line entry. If applicable to all commodities, please provide the documents at the declaration level (SG9). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A for Intended uses and Canadian Product categories.
Document Reference Number	LPCO Number	C	For each document type provided at the commodity level, an associated reference number related to that document must be provided. Refer to Appendix B for Document types and Reference numbers.
Document Source Description	File	O	It is strongly recommended to provide an image of the following documents that can be accessed by qualified CBSA and Health Canada employees: Experimental Studies Certificate Emergency Drug Release Authorization Veterinary No Objection Letter (NOL). Providing an image may improve communication in case of a referral.

Additional resources

Reference Code Tables

Legislation:

For more information on the importation of active pharmaceutical ingredients for veterinary use, refer to Health Canada's Policy 18 entitled **Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use.**

A **Guidance Document on the Import Requirements for Health Products** under the Food and Drugs Act and its Regulations contains additional information on Veterinary Medical Drugs in Section 9. It states that Veterinary Drugs are regulated by Health Canada under the authority of the Food and Drugs Act and the Food and Drug Regulations.

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

- **List of Schedule D drugs**
- **List of Schedule F drugs**

Customs Memoranda:

Requirements concerning the administration of Health Canada Acts and regulations relating to certain controlled, prohibited or regulated goods are found in **D19-9-1.**

Appendix A: Intended uses and Canadian Product categories

Intended Use	Canadian Product Category	Document Type(s)
Veterinary Therapeutic Use	Veterinary Drug	Establishment Licence (EL) AND -Drug Identification (DI)
	Veterinary Drug – Veterinary Health Product	Veterinary Notification
Veterinary Experimental Study	Veterinary Drug	Experimental Studies Certificate
Veterinary Emergency Drug Release (EDR)		Emergency Drug Release Authorization
Veterinary Clinical Study		Veterinary No Objection Letter (NOL)
Research & Development		None required
Other		None required

Appendix B: Document types and Reference numbers

Document Type	Reference Number
Establishment Licence (EL)	Establishment Licence Number
Drug Identification (DI)	Drug Identification Number (DIN)
Veterinary Notification	Veterinary Notification Number (NN)
Experimental Studies Certificate	Experimental Studies Certificate Number
Emergency Drug Release Authorization	Emergency Drug Release Authorization Number
Veterinary No Objection Letter (NOL	Veterinary No Objection Letter (NOL)

Appendix C: Intended uses and Canadian product categories	
Intended Use (SG117 APP)	**Canadian Product Category**
Veterinary Therapeutic Use	Veterinary Drug
Veterinary Experimental Study	Veterinary Drug – Low Risk
Veterinary Emergency Drug Release (EDR)	Veterinary Drug
Veterinary Clinical Study	
Research & Development	
Other	

Contact Livingston

Have questions or need help with your SWI imports?
Contact your Livingston client services representative.
Write to us at: **clientserviceCanada@livingstonintl.com** or give us a call at **1-855-225-5544**.