HEALTH CANADA

Program: Human Drugs

LIVINGSTON
Simplify Trade

PGA: Health Canada

Program: Human Drugs

Implementation of the CBSA Single Window Initiative (SWI)

The Canada Border Services Agency (CBSA) assists Health Canada in administering the following legislation at the border:

- Canada Consumer Product Safety Act
- Controlled Drugs and Substances Act
- Food and Drugs Act
- Hazardous Products Act
- Radiation Emitting Devices Act
- Pest Control Products Ac

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

Previous to Single Window, shipments were already being transmitted to CBSA electronically. They will continue to be submitted electronically under SWI .

Under the Single Window Initiative, release requests will be submitted via the Integrated Import Declaration (IID), which allows customs brokers to submit and obtain electronic release for goods also regulated by participating government departments and agencies.

Release requests for Human Drugs products may be provided to the CBSA electronically by submitting an IID. The IID must include the following information:

a. LPCO Type/Authorization Type
b. LPCO Number
c. Brand Name
d. Intended Use
e. Commodity Type
f. Manufacture Date

Note: The information required under the SWI remains the same as what is currently required for the importation of Human Drug products. There are no additional requirements due to SWI.

Harmonized System (HS) Codes

List of HS codes applicable to goods/substances that may be regulated by Health Canada:
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 required 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.
Brand Name	Brand name is required to be on the product label.
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Commodity Type	The Canadian Product Category, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number required.
Manufacture Date	Manufacture date is required to be on the product label. This information will allow for timely recall postings for goods imported into Canada.
Batch/Lot Number	Batch/lot number is recommended to be on the product label. This information will allow for timely recall postings by having knowledge of the batches/lots imported into Canada.

Intended use and Program conditions for Human Drugs:

Intended use	Description
HC02, HC07	HC02 – Generic – Special Access HC07 – Generic – Research & Development
HC05	HC05 – Generic – Human Clinical Trial Use
HC31	HC31 – Urgent Public Health Need
HC01, HC29	HC01 – Generic – Human Therapeutic Use HC29 – 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 email address must be provided must be provided.

Document Type (License, Permit, Certificate, Other)	LPCO 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. See Appendix A for details.
Document Reference Number	Authorization Type	C	For each document provided at the declaration level, the associated reference number related to that document must be provided, as outlined in Appendix B.
Document Source Description	LPCO Number	O	It is strongly recommended to provide an image of the following documents that can be accessed by qualified CBSA and Health Canada employees: • Letter of Authorization (LOA) • Clinical Trial No Objection Letter (NOL)
Product Identifier	File	O	Human Drugs can be identified through their GTIN GS1 Asset Identifier. Although not required, this information would allow a clearer identification of the product and expedite communication in case of referrals. The qualifier for GS1 Global Trade Identification Number (GTIN) must be provided in the 7402, 2 field.
Commodity Characteristic (Brand Name)	GTIN Number	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 trial purposes), please use this field to provide the product name, or active ingredient or chemical name of the commodity as indicated by the manufacturer.
Intended End Use	End Use	M	The intended end-use of the commodity must be provided. Depending on the intended end-use code, additional details are required. See Appendix A for details.
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP. For a list of Intended Use Codes and corresponding Canadian Product Categories, see appendix C.
Production / Expiry Date	Manufacture Date	M	The date on which the commodity was manufactured is required. If a format without time zone information is provided the time must be in CBSA Headquarters time (EST, e.g., GTM -5)
Commodity Lot Number	Batch/Lot Number	M	The batch/lot number that the manufacturer assigned to the product must be provided

Additional resources

Regulated Commodities:
Reference Code Tables

Legislative References:
The Food and Drugs Act
Food and Drug Regulations

Custom Memoranda:
The Administration of Health Canada Acts and Regulations Relating to Certain Controlled, Prohibited or Regulated Goods
Importation and Exportation of Controlled Substances and Precursors

Appendix A: Acceptable document types

Intended Use Code	Canadian Product Category	Document Type(s)
Human Therapeutic Use	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical	• Establishment Licence (EL) and Drug Identification (DI) • Establishment Licence (EL)
Special Access	• Human Drug other than Radiopharmaceutical	• Letter of Authorization (LOA)
Human Clinical Trial Use	• Phase I Clinical Trial Drug • Phase II Clinical Trial Drug • Phase III Clinical Trial Drug • Phase IV Clinical Trial Drug	• Clinical Trial No Objection Letter (CT NOL) • Clinical Trial No Objection Letter (CT NOL) • Clinical Trial No Objection Letter (CT NOL) • Drug Identification (DI)
Research and Development	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical	• None required • None required
Other	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical	• None required • None required

Appendix B: Document reference number

Document Type(s)	Reference Number
Establishment Licence (EL)	Establishment Licence Number
Drug Identification (DI)	Drug Identification Number (DIN)
Letter of Authorization (LOA)	LOA Number
Clinical Trial No Objection Letter (CT NOL)	CT NOL Number

Appendix C: Intended Use Codes and corresponding Canadian Product Categories	
Intended Use Code	**Canadian Product Category**
Human Therapeutic Use	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical
Special Access	• Human Drug other than Radiopharmaceutical
Human Clinical Trial Use	• Phase I Clinical Trial Drug • Phase II Clinical Trial Drug • Phase III Clinical Trial Drug • Phase IV Clinical Trial Drug
Research and Development	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical
Other	• Human Drug other than Radiopharmaceutical • Radiopharmaceutical

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**.