

HEALTH CANADA

Program: Human Drugs

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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 Act

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

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 can be provided 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 |
| 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: <ul style="list-style-type: none"> • 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 | 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) |
| Commodity Lot Number | Batch/Lot Number | O | The batch/lot number that the manufacturer assigned to the product may 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 | <ul style="list-style-type: none">Human Drug other than RadiopharmaceuticalRadiopharmaceutical | <ul style="list-style-type: none">Establishment Licence (EL) and Drug Identification (DI)Establishment Licence (EL) |
| Special Access | <ul style="list-style-type: none">Human Drug other than Radiopharmaceutical | <ul style="list-style-type: none">Letter of Authorization (LOA) |
| Human Clinical Trial Use | <ul style="list-style-type: none">Phase I Clinical Trial DrugPhase II Clinical Trial DrugPhase III Clinical Trial DrugPhase IV Clinical Trial Drug | <ul style="list-style-type: none">Clinical Trial No Objection Letter (CT NOL)Clinical Trial No Objection Letter (CT NOL)Clinical Trial No Objection Letter (CT NOL)Drug Identification (DI) |
| Urgent Public Health | <ul style="list-style-type: none">Human Drug other than RadiopharmaceuticalRadiopharmaceutical | <ul style="list-style-type: none">Establishment Licence (EL)Establishment Licence (EL) |
| Need | <ul style="list-style-type: none">Human Drug other than RadiopharmaceuticalRadiopharmaceutical | <ul style="list-style-type: none">None requiredNone required |
| Other | <ul style="list-style-type: none">Human Drug other than RadiopharmaceuticalRadiopharmaceutical | <ul style="list-style-type: none">None requiredNone 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 | <ul style="list-style-type: none">• Human Drug other than Radiopharmaceutical• Radiopharmaceutical |
| Special Access | <ul style="list-style-type: none">• Human Drug other than Radiopharmaceutical |
| Human Clinical Trial Use | <ul style="list-style-type: none">• Phase I Clinical Trial Drug• Phase II Clinical Trial Drug• Phase III Clinical Trial Drug• Phase IV Clinical Trial Drug |
| Urgent Public Health Need | <ul style="list-style-type: none">• Human Drug other than Radiopharmaceutical• Radiopharmaceutical |
| Research and Development | <ul style="list-style-type: none">• Human Drug other than Radiopharmaceutical• Radiopharmaceutical |
| Other | <ul style="list-style-type: none">• 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**.