# HEALTH CANADA

## Program: Blood & Blood Components

LIVINGSTON
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PGA: Health Canada

# Program: Blood & Blood Components

The Blood Regulations define “blood” as meaning human blood that is collected either for transfusion or for use in the manufacture of a drug for human use, and includes whole blood and blood components. Examples of blood components include red blood cells, plasma, platelets, and granulocytes. Blood components do not include products manufactured from plasma for further manufacture.

Blood and blood components are regulated by Health Canada (HC) under the authority of the Food and Drugs Act, Food and Drug Regulations and the Blood Regulations.

Health Canada meets regularly with the Expert Advisory Committee on Blood Regulation to provide the medical, scientific, and ethical advice required to assist the regulatory decision-making process for blood. Throughout the regulatory development process, Health Canada has consulted with industry stakeholders, Provincial and Territorial governments, the Public Health Agency of Canada (PHAC), and the blood establishments to blood components are regulated to ensure Canadians’ access to safe blood.

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 (PHAC) or the Canadian Food Inspection Agency (CFIA) as cultures, diagnostic specimens or research tissue may be a potential carrier of a human or animal pathogen. Please consult these organizations for more details.

## Implementation of the CBSA Single Window Initiative (SWI)

The CBSA assists Health Canada in administering the Food and Drugs Act and regulations made thereunder. These activities apply to all drugs and devices as defined by the Food and Drug Act, including blood and blood components for transfusion Under SWI, release requests will be submitted utilizing a new LPCO requirements.

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

## Harmonized System (HS) Codes

The HS Classification numbers for blood and blood components include those listed under heading 3002.

A complete list of HS codes and ranges applicable to goods regulated by Health Canada (including blood and blood components) 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 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. |
| Intended Use | The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number. |
| Commodity Type | The Commodity type, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number. |
| Expiry Date | ID's any concern with its use. |

## Intended use and Program conditions for Blood and Blood Components:

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

| Intended use | Description |
|---|---|
| HC01 | HC - Generic - Human Therapeutic Use. |

## Electronic Commerce Client Requirements Document (ECCRD)

**The following table provides the specific rules and conditions associated to each of the data elements. 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 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.<br><br>Refer to Appendix A for Intended use, Canadian product category and Document type. |

| | | | |
|---|---|---|---|
| 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.<br><br>Refer to Appendix B for Document type and Reference number. |
| Document Source Description | File | O | It is strongly recommended to provide an image of the Proof of Prescription as this will facilitate communication in case of a referral. |
| Product Identifier | GTIN Number | O | Blood and Blood Components can be identified through their GTIN GS1 Asset Identifiers.<br><br>Although not required, this information would allow a clearer identification of the product and facilitate communication in case of referrals.<br><br>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 as below. Depending on the intended end-use code, additional details are required.<br><br>Refer to Appendix A for Intended use, Canadian product category and Document type. |
| Canadian Product Category | Commodity Type | M | A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP.<br><br>Refer to Appendix C for Intended use and Canadian product category.<br><br>The qualifier for field 5389 should be the code for HC – Blood and Blood Components. |
| Production/ Expiry Date | Expiry Date | O | It is strongly recommended to provide the date on which the commodity will expire.<br><br>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 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.<br><br>Refer to Appendix A for Intended use, Canadian product category and Document type. |

| | | | |
|---|---|---|---|
| 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.<br><br>Refer to Appendix B for Document type and Reference number. |
| Document Source Description | File | O | It is strongly recommended to provide an image of the Proof of Prescription as this will facilitate communication in case of a referral. |

## Additional resources

### Reference Code Tables

**Legislation:**
For more information on the importation of blood and blood components, refer to Health Canada's **Guidance Document on Blood Regulations.**

**Additional Links and Guidance Documents** are available on the Health Canada Website.

A **Guidance Document on the Import Requirements for Health Products** under the Food and Drugs Act and its Regulations contains additional information on blood and blood components.

**Appendix A: Intended use, Canadian product category and Document type**

| Intended Use | Canadian Product Category | Document Type(s) |
|---|---|---|
| Human Therapeutic Use | Blood and Blood Components | Establishment Licence (EL) OR Proof of Prescription |

**Appendix B: Document type and Reference number**

| Document Type(s) | Reference Number |
|---|---|
| Establishment Licence (EL) | Establishment Licence Number |

**Appendix C: Intended use and Canadian product category**

| Intended Use | Canadian Product Category |
|---|---|
| Human Therapeutic Use | Blood and Blood Components |

## 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**.

**www.livingstonintl.com**

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