Import and Export Policy for Health Products under the *Food and Drugs Act* and its *Regulations* (POL-0060)

Disclaimer

This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that 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. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

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1.0 Purpose

This policy outlines the Inspectorate's position with respect to the importation to Canada and the exportation from Canada of health products.

2.0 Background

The Health Products and Food Inspectorate (Inspectorate) is the organization within Health Canada that has the primary responsibility of administering the *Food and Drugs Act* and its *Regulations*. This is achieved through compliance monitoring and enforcement activities such as inspections, compliance verification and investigations, and admissibility determinations at the border.

The Inspectorate administers its legislative and regulatory frameworks using an integrated approach which incorporates risk management and scientific evidence to manage the health-related risks and benefits of health products. This approach aims to minimize the health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products. In addition, the approach promotes conditions that enable Canadians to make healthy choices and provides them with information so that they can make informed decisions about their health.

A number of regulatory measures are available to Health Canada through the Inspectorate to achieve compliance. Please see the Inspectorate's Compliance and Enforcement Policy (POL-0001) for more details.

The majority of health products used and consumed within Canada are imported. The globalization of manufacturing and world trade has resulted in the increased importation of health products from countries with regulatory frameworks and enforcement policies that may differ from those in Canada. This globalization, combined with increasing movement of people and goods within the global community, make for more complex supply chains and, in turn, may pose an increased risk to the health and safety of Canadians.

Canada not only imports health products, but also exports a number of health products to other countries. As a responsible member of the global community, Canada must take all possible steps to export only those products which do not pose a risk to health and safety, and which are effective and of high quality. Moreover, as a member of the global community, Canada must maintain the integrity of agreements and commitments made to our international partners such as Mutual Recognition Agreements (MRAs).

The Inspectorate has entered into a number of MRAs with other regulatory authorities. An MRA consists of a mutual recognition by two regulatory authorities of the equivalency of their respective Good Manufacturing Practices (GMP) Compliance Programmes for medicinal products/drugs. The agreements result from a thorough evaluation of each party against a mutually agreed upon confidence building equivalence exercises and are entered into when equivalency is recognized by both parties. The requirements for the importation and exportation of those product covered by an MRA are officially confirmed by the regulatory authorities through the process of exchanging a certificate of compliance (CoC). For more details please refer to the MRA website.

It should be noted that Canadian law may classify and regulate various health products differently than other countries. These differences may result in either more or less stringent requirements. This should be taken into consideration before importing and exporting health products. This policy only addresses Canada's *Food and Drugs Act* and its *Regulations*.

This policy has been developed in cooperation with the Health Canada - Legal Services (Department of Justice) to help outline the conditions and requirements under which health products may be imported and exported from Canada. The Inspectorate will review this document periodically.

3.0 Scope

This policy applies to all health products as defined by the *Food and Drugs Act* and its *Regulations*. This includes Human Drugs; Natural Health Products; Medical Devices; Veterinary Drugs; Blood and Blood Components for Transfusion; Human Cells, Tissues and Organs for Transplantation; and Semen for Assisted Conception.

This policy only addresses the requirements under the *Food and Drugs Act* and its *Regulations* for health products. Some health products may also have additional restrictions placed on them by other Acts and Legislation, such as the *Controlled Drugs and Substances Act* and its *Regulations*. Where two different restrictions/requirements exist, such as the quantity allowed for importation, the most restrictive or prescriptive will take precedence.

4.0 Definitions

Export: For the purposes of this policy, “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 policy, “import” is the action of receiving or transporting health products across the Canadian border from outside Canada.

Sale: As per the *Food and Drugs Act*, “sale” includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

5.0 Policy Statement

5.1 Commercial Importation

All health products imported for sale in Canada must meet the requirements of the *Food and Drugs Act* and its *Regulations* at the time of importation or, in the case of market authorized drugs, they must be able to come into compliance within the time period specified in *A.01.044* of *Part A* of the *Food and Drug Regulations*.

All health products imported for use in a clinical trial in Canada must meet the requirements of the *Food and Drugs Act* and its *Regulations* at the time of importation.

5.2 Importation for Personal Use

Health Canada will take actions to prevent the importation of health products that are known to pose a risk to health or for which enforcement actions have been taken domestically.

For the purposes of this section the term “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.

The label or monograph of the Canadian Reference Product, ie the equivalent Canadian marketed health product, will be used if:

- None of the above items are present;
- No specific dosing information is provided;
- They are illegible or can not be read (foreign language); or
- The information is unreliable/contradictory.

In the event that there is no Canadian Reference Product the Inspectorate will exercise discretion and base a decision on information, preferably from other health authorities or recognized sources, available at the time of decision.

All importers of cells, tissues and organs including lymphohematopoietic cells for their own personal use are required to be registered with Health Canada as per the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*. All imported cells and tissues excluding lymphohematopoietic cells and organs are required to be processed by an establishment registered with Health Canada as per the same regulations.

Medical devices when imported by an individual for their own personal use are not regulated under the *Food and Drugs Act* or the *Medical Devices Regulations*.

5.2.1 Canadians returning from abroad

So as not to interrupt a course of treatment, Health Canada may use enforcement discretion to permit Canadians returning from abroad to bring with them on their person:

- A single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a health product.

The health product must be for the individual’s own personal use, the use of a person for whom they are responsible and with whom they are travelling, or for use on an animal for which they are responsible and with whom they are travelling.

The health product must be in one of the following:

- Hospital or pharmacy dispensed packaging;
- Original retail packaging; or
- have the original label affixed to it which clearly indicates what the health product is and what it contains.

5.2.2 Canadians importing by means other than on their person (via mail, courier, etc.)

Consumers are encouraged to buy health products which have received market authorization from Health Canada. Market authorization indicates that a product has been reviewed by Health Canada for safety and efficacy and found to have an acceptable risk/benefit profile for the conditions for which it was approved. Health Canada also conducts post-market activities for these products, including the monitoring of adverse reactions and complaints regarding quality. Consumers are also encouraged to obtain their health products only from reputable or known suppliers/retailers.

A Canadian who chooses to obtain a health product from outside Canada which may or may not have been reviewed and market authorized by Health Canada is allowed to import:

- A single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a health product as long as the product does not contain a substance listed in Schedule F of the *Food and Drug Regulations*.

The health product must be for their own personal use, the use of a person for whom they are responsible or for use on an animal for which they are responsible.

The health products must be in one of the following:

- Hospital or pharmacy dispensed packaging;
- Original retail packaging; or
- have the original label affixed to it which clearly indicates what the health product is and what it contains.

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 and the relevant requirements will apply (see section 5.1).

5.2.3 Visitors to Canada

Visitors to Canada may bring into Canada, on their person:

- A single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a health product.

The health product must be for the individual's own personal use, for the use of a person for whom they are responsible and with whom they are travelling, or for use on an animal for which they are responsible and with whom they are travelling.

The health product must be shipped/carried in one of the following:

- Hospital or pharmacy dispensed packaging;
- Original retail packaging; or
- have the original label affixed to it which clearly indicates what the health product is and what it contains.

Should a Visitor's stay in Canada exceeds the supply of medication imported at the time of their arrival to Canada, the Visitor may import an additional single unit, single course of treatment or a 90-day supply based on the directions for use, whichever is less, of a health product. When a health product is mailed to a Visitor, the health product should be accompanied by some form of documentation indicating that the health product

is destined to a Visitor and/or the Visitor should be prepared to provide documentation/written evidence (stamped passport, student/work visa, letter from an employer/university etc) that they are a Visitor to Canada when requested.

Visitors are advised that the exporting country may also have additional restrictions on what may be exported to Canada. Visitors are advised to check with their local authorities before leaving and to plan accordingly.

Visitors are responsible for ensuring that any remaining health products they imported into Canada but have not consumed during their stay are either safely disposed of or exported from Canada by them when they leave the country.

5.3 Commercial Exportation

5.3.0 General Policy

Health products exported from Canada must meet the relevant requirements of the *Food and Drugs Act* and its *Regulations*. Such requirements include, among others, ensuring that products exported are not adulterated, manufactured in unsanitary conditions or manufactured, sold or advertised in a manner that is false or misleading.

5.3.1 Health products fabricated to a Canadian market authorized formulation/design by a Canadian licence holder

A health product may be exported from Canada that has been fabricated by a Canadian licence holder (Establishment, Site, Medical Device Establishment etc) to a Canadian market authorized formulation/design (Drug Identification number (DIN), Natural Product Number (NPN), Medical Device Number etc).

If the health product is fabricated in Canada for the sole purpose of export and is therefore not sold for consumption in Canada the product is not required to be labeled with the Canadian approved product labeling. However the labeling should indicate the product is for export only. The manufacturer should also attest that the product is not known to contravene any laws of the importing country.

If requested Health Canada may issue for these products a certificate (Certificate of Pharmaceutical Products (CPP), Manufacturer's Certificates etc).

5.3.2 Health products fabricated for use in clinical trials involving human subjects

A health product fabricated for use in a clinical trial involving human subjects may be exported if it meets the applicable requirements of the *Food and Drugs Act* and its *Regulations* for a clinical trial conducted in Canada.

In the absence of meeting such requirements, a health product must comply with section 5.3.1 or 5.3.3 of this policy, as appropriate, in order to be exported from Canada.

5.3.3 Section 37(1)

Section 37(1) of the *Food and Drugs Act* may be invoked to exempt health products not fabricated for consumption or sale in Canada – ie health products fabricated in Canada for export only – from the application of the *Act* and *Regulations*:

> *37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.*

Thus, pursuant to *Section 37(1)*, an establishment in Canada that fabricates a health product in Canada for export only is not subject to the requirements of the *Act* and *Regulations* in relation to that product, provided the product:

> (i) has been fabricated in Canada solely for export;
> (ii) complies with the labeling requirements of *Section 37(1)*; and
> (iii) *in the case of a drug* – is the subject of an Export Certificate in the form prescribed in Appendix III of the *Food and Drug Regulations* that has been attested to under oath by the exporter of the drug; or
> (iv) *in the case of a medical device*, is the subject of an Export Certificate in the form prescribed in *Schedule 3* of the *Medical Devices Regulations* that has been attested to under oath by the exporter of the medical device.

In requiring the issuance of an Export Certificate which states that the package and its contents do not contravene any law or requirement of the receiving country, *Section 37(1)* allows products fabricated for export only to exempt themselves from requirements that may be uniquely Canadian and not applicable in other countries (e.g. bilingual labeling requirements), all the while subjecting them to the health and safety requirements of other regulatory authorities.

Below are further points of clarification regarding *Section 37(1)*:

- Health products with respect to which the fabricator in Canada has notified the Inspectorate of its intention to invoke *Section 37(1)*, but which are not properly packaged in accordance with *Section 37(1)* (i.e., marked "Export" or "Exportation" on the package), are subject to inspection. Production lots/serials of health products that are for export only and for which the packaging is not yet complete should be clearly identified as such by written indication on the manufacturing order, packaging order, and on the bulk containers.

- Unless *Section 37(1)* is invoked and an Export Certificate is available, health products are subject to inspection and the other requirements of the *Act* and its *Regulations*.

- Exemptions under *Section 37(1)* do not apply to health products imported into Canada for commercial purposes; rather, they are limited to health products fabricated in Canada.

- The Inspectorate will not issue, for a health product that has been exempted under *Section 37(1)* or with respect to which a manufacturer has notified the Inspectorate of its intention to invoke *Section 37(1)*:

    a. A Certificate of a Pharmaceutical Product (CPP) for a drug; or
    b. A Manufacturer's Certificate for a medical device;

- Health products with respect to which the fabricator in Canada has invoked *Section 37(1)* are excluded from any MRAs and therefore cannot benefit from them. The Inspectorate will identify to foreign regulatory authorities, those products which the fabricator has notified the Inspectorate of its intent to invoke *Section 37(1)*.

- Evidence of compliance with the applicable legislative and/or regulatory requirements will be required if a company decides to rescind its request for exemption with respect to *Section 37(1)*.

- Companies availing themselves of the *Section 37(1)* exemption should voluntarily keep records with respect to their intention to invoke for a given health product(s), including: site, product, lot, serial number, date of export and destination of export.

- Companies intending to invoke *Section 37(1)* should notify Health Canada of such intention. The form entitled "*Intention to Invoke Section 37 of the Canada Food and Drugs Act for Products Being Exported*" should be used.

5.4 Exportation for Personal Use

Be aware that some drugs that are legal in Canada may be illegal in other countries. Travellers are subject to the judicial system of the country they are entering, and are advised to contact the embassy/consulate/mission of the country they will be entering before departure to enquire about health product admissibility.

When visiting a foreign country, travellers should carry proof of need/use (prescription, etc.). Moreover, the product should always be packaged in hospital or pharmacy dispensed packaging, original packaging or have the original label affixed to it which clearly indicate what the health product is and what it contains.

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 and the relevant requirements will apply (see 5.3.0).

5.5 Import for Export

5.5.0 General Policy

Health products and/or their components that are imported into Canada for export only must meet the relevant requirements of the *Food and Drugs Act* and its *Regulations* at the time of importation.

Some exceptions may apply (e.g. Inspectorate’s GUI-0067, “*Conditions for Provision of Packaging/Labelling Services for Drugs under Foreign Ownership”)*. Please see the relevant guidance for details.

5.5.1 Import for Export and Section 37(1)

As stated above (see section 5.3.1), *Section 37(1)* may not be invoked in cases where health products are commercially imported into Canada for the purpose of export only. Use of *Section 37(1)* as outlined in 5.3.1 of this policy is limited solely to health products that, although fabricated in Canada, are not intended for consumption or sale in Canada.

5.6 Refused Exports

All health products, including those exported under *Section 37(1)*, that are refused by another country and returned to Canada for sale are subject to the requirements of the *Food and Drugs Act* and its *Regulations* upon return to Canada.

5.7 Internet Pharmacy and Sales

Any Internet sale or advertising of a health product to a foreign jurisdiction that does not comply with the *Food and Drugs Act* and/or its *Regulations* is prohibited.

6.0 Responsibilities

It is the Inspectorate's responsibility to apply this policy.

The maintenance and enhancement of health and safety is a responsibility that is shared among government, industry, consumers, and healthcare professionals and their respective associations.

Regulated parties that market health products have the primary responsibility for the safety of any product they sell, advertise, manufacture, import or distribute to the Canadian public. These regulated parties must comply with all Canadian legislative and regulatory requirements.

Consumers have a responsibility for the maintenance of their health and the safe use of marketed health products. Consumers should use manufactured products according to the manufacturer's instructions. In addition, consumers are asked to inform the Health Products and Food Branch (HPFB) of any problems that they encounter (hazards, adverse reactions, malfunctions, and non-compliance) through the use of drugs and medical devices. They should also ensure that the health products they buy have been authorized for sale in Canada.

Healthcare professionals are encouraged to inform the HPFB of any problems they encounter (hazards, adverse reactions, malfunctions, and non-compliance) that may be related to these drugs and medical devices. The primary responsibility for safety of patients lies with the hospital and the treating physician. Physicians have professional standards and obligations and it is the responsibility of professional regulatory bodies (such as Colleges of Physicians and Surgeons) to ensure that these professional standards are met.

7.0 Effective Date

This Policy becomes effective June 15, 2017.