Ottawa, August 20, 2014

Memorandum D19-9-1

Importation of Human Drugs, Natural Health Products, and Medical Devices Regulated by the *Food and Drugs Act*

In Brief

1. This memorandum has been updated to reflect the Canada Border Services Agency's (CBSA) role in assisting Health Canada with the administration of the *Food and Drugs Act* as it relates to the importation of human drugs, natural health products, and medical devices.
2. Terminology has been updated to reflect changes in the CBSA's organizational structure.
3. Relevant provisions of the *Customs Act* and *Food and Drugs Act* are listed in the "Legislation" section.

The Canada Border Services Agency (CBSA) assists Health Canada with the administration of the *Food and Drugs Act* and its Regulations at the border. In accordance with the *Food and Drugs Act* and its Regulations, the importation, distribution and sale in Canada of human drugs, natural health products, and medical devices are regulated by Health Canada. This departmental memorandum outlines the policy and customs procedures related to the importation of human drugs, natural health products, and medical devices, as defined by the *Food and Drugs Act* and its Regulations.

This memorandum does not include policy and customs procedures related to the importation requirements for blood and blood components for transfusion; cells tissues and organs for transplantation; semen for assisted conception, or veterinary drugs. However, the importation, distribution and sale in Canada of the aforementioned products are regulated by the *Food and Drugs Act* and its Regulations administered by Health Canada. For more information on these products, please see Health Canada's *Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations (GUI-0084)*. This document is updated on a regular basis.

For information regarding the importation requirements of the *Controlled Drugs and Substances Act* please refer to Memorandum D19-9-2, *Importation and Exportation of Controlled Substances and Procedures*.

Legislation

Customs Act – Sections 101 and 107.(5)

Food and Drugs Act – Sections 2, 23.(1), 25, 27(1) to (3)

Regulations

Food and Drug Regulations – A.01.026, A.01.040, A.01.041, A.01.043, A.01.044.(1) and (2), C.01A.004.(1) to (3), C.01.014.(1) and (2), C.01.045

Natural Health Products Regulations – Sections 1.(1), 4.(1) to (3), 27.(1) and (2), 100.

Medical Devices Regulations – Sections 2, 26, 44.(1) and (2)

Guidelines and General Information

Definitions

1. For the purpose of this departmental memorandum, the following definitions are used:

"Drug Identification Number (DIN)" – An eight (8) digit numerical code assigned to each drug marketed under or in accordance with the *Food and Drugs Act* and its Regulations.

"Health product" – For the purposes of this memorandum, a health product is defined as a human drug, a natural health product, or a medical device.

"Human drugs" – means drugs as defined in the *Food and Drugs Act* (except for natural health products) and regulated under the *Food and Drug Regulations*. They include non-prescription and prescription drugs. **Note:** Drugs regulated under the *Controlled Drugs and Substances Act* are not included in the definition of "Human drugs." Controlled substances and precursors are covered in the Memorandum D19-9-2, *Importation and Exportation of Controlled Substances and Procedures*.

"Medical device" – means a device within the meaning of s.2 of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals. Medical devices are classified as Class I, II, III, or IV, depending on their risk level.

"Natural health products" – include traditional medicines, vitamins, minerals, and homeopathic medicines, manufactured, sold or represented for use as natural health products. For a complete definition, please refer to the *Natural Health Products Regulations*.

"Natural Product Number (NPN or DIN-HM)" – Eight (8) digit numerical code assigned to each natural health product approved or homeopathic medicine to be marketed under the *Natural Health Products Regulations*.

"Non-prescription drugs" – Any human drug that is not a prescription drug.

"Prescription drugs" – Any drug containing a substance listed on the Prescription Drug List found on the Health Canada Web site.

Role of the Canada Border Services Agency

2. The CBSA assists Health Canada in administering the import requirements of the *Food and Drugs Act* as it relates to health products.

3. Border officers are not required to verify, validate, stamp, or return any permits or licenses for health products on behalf of Health Canada.

4. The CBSA may detain health products under the authority of the *Customs Act* and refer them to Health Canada for an admissibility recommendation, either as a result of specific information or when border services officers find suspected contraventions of Health Canada's legislation.

5. The CBSA's enforcement role beyond the initial detention is limited to *Customs Act* contraventions. In such cases, the CBSA may seize the goods under the *Customs Act*.

Role of Health Canada

6. Health Canada is responsible for the administration and enforcement of the *Food and Drugs Act* and its Regulations.

7. Health Canada will identify to the CBSA certain health products that pose an increased risk to Canadians and request the interdiction and detention of these types of health products at time of importation.

8. The *Food and Drugs Act* authorizes Health Canada inspectors to exercise inspection powers in accordance with s.23(1)*(a)-(c)*, including opening and examining packages, taking samples and, making copies of any record or document.

9. Health Canada inspectors may also seize and detain any health product where the inspector has reasonable grounds to believe any provision of this Act or its Regulations have been contravened, in accordance with s.23(1)*(d)*.

10. Health Canada will provide a recommendation to the CBSA regarding the admissibility of seized and detained imported health products suspected to be in contravention of the *Food and Drugs Act* and its Regulations.

11. Health Canada will assist the CBSA by providing advice, guidance and direction as to the disposition of health products.

Role of Importers

12. Importers are responsible for ensuring that every Health Product imported is compliant with the requirements of the *Food and Drugs Act* and its Regulations prior to importation into Canada. Importers must also obtain or possess required licenses, permits or documents as required by the *Food and Drugs Act* and Regulations. In some circumstances these documents should accompany the shipment to facilitate the importation. For example, a copy of the establishment license, a copy of the site licenses, a No Objection Letter for clinical trial drugs, or a Letter of Authorization under the Special Access Program.

13. Importers, transporters, manufacturers or retailers may obtain more information about Health Canada requirements by visiting Health Canada's Web site.

Commercial Importations

14. Health Canada generally considers the following to be examples of commercial importations:

(a) An import shipment destined for a retailer, distributor, or other commercial establishment. This would include shipments being sent to independent sales contractors/distributors; to a practitioner for use in their practice; or to a qualified investigator of a clinical trial that is to be given to or used to treat a patient or subject in a clinical trial.

(b) An import shipment from a single foreign supplier consisting of individually addressed parcels, and the importer of record as indicated on a separate invoice for each parcel is not unique for each parcel.

(c) An import shipment that contains more than a 90-day supply of human drugs and natural health products, based on its directions for use or reasonable intake.

(d) An import shipment that is part of a pattern of repeat personal importations of the same human drug and natural health product to the same individual at the same address within a 90-day period and the total quantity imported in all shipments totals more than a 90-day supply based on its directions for use or reasonable intake.

(e) An import shipment that is accompanied by or associated with materials to be used for advertising or promotion.

(f) An import shipment destined for export sale.

(g) An import shipment of health product destined to a practitioner or qualified investigator of a clinical trial that is to be given to or used to treat a patient or a subject in a clinical trial.

Commercial Importation of Human Drugs and Natural Health Products

15. The *Food and Drugs Act* and its Regulations require that all human drugs be labelled with a Drug Identification Number (DIN) and that all natural health products be labelled with a Natural Product Number (NPN) or Homeopathic Medicines Number (DIN-HM).

16. Shipments of human drugs and natural health products not available in Canada may be authorized for importation through the Special Access Program or the clinical trial provisions of the *Food and Drug Regulations* or the *Natural Health Products Regulations*. These shipments may not be labelled with a DIN/NPN/DIN-HM but will be accompanied by a Health Canada authorization letter (No Objection Letter, Notice of Authorization, Letter of Authorization).

17. Commercial shipments of prescription drugs may only be imported by practitioners, drug manufacturers, wholesale druggists or registered pharmacists.

18. The CBSA may detain and refer human drugs and natural health products to Health Canada for an admissibility recommendation when these requirements are not met.

19. Importers of commercial shipments must hold an establishment licence (EL) or site license (SL) for the activity of importation. The foreign manufacturing site must be listed on the Importer's EL, EL/SL are not required to be presented to the CBSA and border officers are not required to verify these licences, however if it is suspected that an importer does not have an EL/SL, border officers should detain and refer to Health Canada.

Commercial Importation of Medical Devices

20. The *Medical Devices Regulations* require that Class II, III and IV medical devices have a device licence for each device.

21. Importers of commercial shipments of medical devices must hold an establishment licence (MDEL). However, the following are exempt from the requirement of having an MDEL to import medical devices:

(a) a retailer;

(b) a healthcare facility;

(c) manufacturers of Class I devices if the manufacturer imports or distributes through a person who holds an establishment licence;

(d) a person who only imports a medical device for their own personal use;

(e) establishments only importing or selling veterinary products;

(f) dispensers; and

(g) establishments that only import or sell custom-made devices, medical devices for Special Access, or devices for Investigational Testing involving human subjects.

22. Medical device licences and establishment licences are not required to be presented to CBSA, and border officers are not required to verify these licences, however if it is suspected that an importer does not have a medical device establishment licence or that the device is not licenced, border officers should detain and refer to Health Canada.

23. Shipments of medical devices not available in Canada may be authorized for importation through the Special Access Program or the investigational testing provisions of the *Medical Devices Regulations*. These shipments of medical devices may not have a medical device licence but will be accompanied by a Health Canada authorization letter (Investigational Testing Authorization or Letter of Authorization).

Personal Importations

24. Health Canada defines a personal importation as an importation by an individual for their own use or for the use of a person under their care or guardianship and which does not meet the definition of a commercial importation as defined in paragraph 14 of this memorandum.

Personal Importation of Prescription Drugs

25. Under C.01.045 of the *Food and Drug Regulations*, importation of prescription drugs is restricted to practitioners, drug manufacturers, wholesale druggists or registered pharmacists, or a resident of a foreign country while a visitor in Canada. Note that drugs imported by practitioners for treating patients are not considered to be personal importations but rather commercial importation for sale.

Canadian Residents

26. Health Canada may exercise enforcement discretion to permit a Canadian 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 prescription drug. This discretion is generally reserved for, but not limited to, Canadian residents

returning to Canada with prescription drugs which were dispensed for a treatment prior to leaving Canada, or drugs obtained through a filled prescription to treat an illness while abroad.

27. Prescription drugs imported in this fashion must be for the individual's own personal use or the use of a person for whom they are responsible and with whom they are travelling. Additionally, all personal importations of prescription drugs must be packaged in the hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains.

28. The CBSA may detain and refer prescription drugs to Health Canada when these conditions are not met.

29. Canadian residents may not import prescription drugs by mail or courier.

Non-residents of Canada

30. Visitors to Canada and non-residents arriving from abroad are permitted to import a single course of treatment or a 90-day supply of a prescription drug hand-carried for their personal use or the use of a person under their care and with whom they are travelling. Visitors and non-residents are allowed to import a single course of treatment or a 90 day supply of a prescription drug by mail or courier.

31. All personal importations of prescription drug must be packaged in the hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains.

32. The CBSA may detain and refer prescription drugs to Health Canada when these conditions are not met.

Personal Importation of Natural Health Products and Non-prescription Drugs

33. Residents, non-residents and visitors to Canada can import for their own use or for a person under that individual's care a single course of treatment or a 90-day supply of natural health products and non-prescription drugs. The drug must be packaged in the hospital, pharmacy dispensing or retail packaging, or have the original label affixed to it clearly indicating what the product is and what it contains.

34. The CBSA may detain and refer natural health products and non-prescription drugs to Health Canada when these requirements are not met.

Personal Importation of Medical Devices

35. Personal use generally does not include medical devices that require the intervention of a healthcare professional. The *Medical Devices Regulations* do not apply to importation of medical devices for personal use.

Detention

36. Imported health products that the CBSA suspects may be in contravention of the Health Canada legislation may be detained and the nearest Health Canada Border Centre contacted in order to obtain a response regarding import requirements.

37. In some cases, recommendation of admissibility into Canada of goods cannot be made until further analysis has been completed by Health Canada.

38. Upon receipt of a referral from the CBSA, Health Canada commits to respond within two business days. Health Canada's response may include requesting additional information or begin discussion with CBSA regarding options to resolve the issue.

39. In cases where Health Canada does not respond to a referral from the CBSA within two business days, the CBSA may release the goods in the normal manner. If the CBSA releases good pursuant to this clause, the CBSA will provide the appropriate Health Canada Regional Border Centre with the following customs information: importer name and address, product description, quantity and date of release. Health Canada will initiate follow-up action with the importer directly.

Health Canada Admissibility Recommendation

40. The *Food and Drugs Act* provides Health Canada with the power to seize and detain health products in accordance with paragraph 23(1)*(d)* of the *Food and Drugs Act*.

41. Once the admissibility recommendation of the product has been completed, Health Canada will advise CBSA of the appropriate course of action with respect to the goods. In the event of a Health Canada notice of seizure, Health Canada will be responsible for costs associated with this action, and CBSA regional offices should contact the appropriate Health Canada Regional Office to make arrangements for payment of any costs.

42. Importers should contact their regional Health Canada office, to obtain additional information about Health Canada's decision with respect to their goods.

Penalties

43. Penalties may apply for failure to comply with the *Food and Drugs Act* or the *Customs Act*. The penalties are outlined in the respective legislation.

Additional Information

44. You may contact your local regional Health Canada office by calling toll free **1-800-267-9675** during local regular business hours for additional information regarding administration of the *Food and Drugs Act*.

45. For more information, within Canada call the Border Information Service at **1-800-461-9999**. From outside Canada call 204-983-3500 or 506-636-5064. Long distance charges will apply. Agents are available Monday to Friday (08:00 – 16:00 local time/except holidays). TTY is also available within Canada: **1-866-335-3237**.

46. For more information regarding the CBSA's administration of the *Food and Drugs Act* as it relates to health products you may contact:

Other Government Department Programs Unit
Commercial Program Directorate
Programs Branch
150 Isabella Street, 5th Floor
Ottawa ON K1A 0L8

Telephone: 613-946-0240
Fax: 613-946-1520

References	
Issuing Office	Program and Policy Management Division Commercial Program Directorate Programs Branch
Headquarters File	
Legislative References	*Customs Act* *Food and Drugs Act* *Controlled Drugs and Substances Act* *Food and Drug Regulations* *Natural Health Products Regulations* *Medical Devices Regulations*
Other References	D19-9-2
Superseded Memorandum D	D19-9-1 dated March 24, 1999