Importation and Exportation Questions and Answers

This Importation and Exportation questions and answers (Q&A) list will be updated on a regular basis. Note that the date at the end of each Q&A represents the date on which the Q&A was added to the list.

IMPORTATION

Q.1 What type of information should I submit to demonstrate the GMP compliance of a foreign drug establishment?

A.1 Please consult the Health Products and Food Branch Inspectorate policy document entitled “Guidance on Evidence to Demonstrate Drug Compliance of Foreign Sites (GUI-0080)". (July 1, 2003)

Q.2 An On-Site Evaluation was performed for a specific product. Is the On-Site Evaluation Report sufficient to demonstrate GMP compliance of the foreign drug establishment?

A.2 No. An On-Site Evaluation (OSE) is a product-specific evaluation of the manufacture of a drug conducted on-site by a Qualified Authority to assess the conformity with the drug submission. An OSE does not cover all the sections of GMP requirements and when submitted alone is not considered sufficient to demonstrate GMP compliance of the foreign drug establishment. For further information, please consult the Health Products and Food Branch Inspectorate policy document “Guidance on Evidence to Demonstrate Drug Compliance of Foreign Sites (GUI-0080)". (July 1, 2003)

Q.3 If I want to import a drug, for additional packaging steps in Canada and, then re-export it, what do I have to do?

A.3 A drug importer is required to hold an Establishment Licence and meet the GMP requirements. The foreign site must be GMP compliant and be listed on the importer’s Establishment Licence.

If the drug product is being imported from a foreign site and exported back to the **same** foreign site, which retains ownership of the drug product throughout the process, the establishment is required to hold an Establishment Licence for packaging. The document entitled "Conditions for Provision of Packaging/Labelling Services for Drugs under Foreign Ownership (GUI-0067)" should be consulted for further guidance and additional requirements.

If the drug product is being imported from a foreign site and exported to **another** foreign site, you cannot be exempted from the requirements of the *Food and Drugs Act & Regulations*, and you cannot use the exemption provided under Section 37 . This is considered a commercial importation. All commercial

importation of drugs in dosage form must meet all the requirements of the *Food and Drug Regulations*, including Division 1 "Drugs", Division 1A "Establishment Licensing", Division 2 "Good Manufacturing Practices", and any other applicable requirements depending on the drug product. The site where the imported drug is fabricated must be listed on the importer's Establishment Licence and its compliance to the GMP requirements must be demonstrated. See Q&A #1 above. (July 1, 2003)

EXPORTATION

Q.1 What is the difference between an Export Certificate issued under Section 37 of the *Food and Drugs Act* and a CPP?

A.1 An Export Certificate issued under Section 37 of the *Food and Drugs Act* is a certificate signed by the fabricator and a Commissioner for Taking Oaths to attest that the drug for which the certificate is prepared is not manufactured, or sold, for consumption in Canada and that its package and the contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned.

A Certificate of a Pharmaceutical Product (CPP) is a certificate issued by the Health Products and Food Branch Inspectorate establishing the regulatory status of the pharmaceutical, biological or radiopharmaceutical product listed and the GMP status of the applicant. This certificate is in the format recommended by the World Health Organization (WHO). (July 1, 2003)

Q.2 If I'm exporting products, do I need to invoke Section 37?

A.2 No, it is the establishment's choice whether or not to invoke Section 37.

Section 37(1) of the *Food and Drugs Act* states: "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."

Guidance is available in the document entitled "Guidance Document on the Commercial Importation and Exportation of Drugs in Dosage Forms Under the *Food and Drugs Act* (GUI-0057)". (July 1, 2003)

Q.3 If I have invoked Section 37 for a product, is it still possible to receive a Certificate of Pharmaceutical Product (CPP) for this product?

A.3 No. If a Canadian fabricator chooses to invoke Section 37, the Health Products and Food Branch Inspectorate will not issue a CPP for these drugs. If a Certificate of Compliance is requested for an establishment, a list of drugs for which the fabricator has invoked Section 37 will also be provided to the foreign Regulatory Authority. (July 1, 2003)

Q.4 When and how do I notify the Health Products and Food Branch Inspectorate of my intention to invoke Section 37?

A.4 Establishments should notify the Health Products and Food Branch Inspectorate of their intention to invoke Section 37 of the *Food and Drugs Act* upon renewal of the Establishment Licence each year. The Establishment Licence renewal package includes a form entitled "Intention to invoke Section 37 of the Canada *Food and Drugs Act* for products being exported". This form requires establishments to declare the list of drug products for which they intend to invoke the exemption under Section 37. You must fill out this form and return it along with your Establishment Licence renewal to the Health Products and Food Branch Inspectorate. If a decision is made at another time during the year to invoke Section 37, the same form should be used and the information sent to the Health Products and Food Branch Inspectorate. Copies of Export Certificates must be provided.