Guidance for Application for Import and Export Licences for Pharmaceutical Products and Medicines

1. Under the Import and Export Ordinance (the I & E Ordinance), Chapter 60 of the Laws of Hong Kong, all imports and exports of pharmaceutical products and medicines must be covered by import and export licences issued by the Trade and Industry Department.

2. "Pharmaceutical product" —

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product.

Application Procedures

3. Applications for import and export licenses are lodged via the online Pharmaceuticals Licence Application and Movement Monitoring System ("PLAMMS"). Information on PLAMMS can be referred to the following website: https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html. If there are any queries related to the technical details of the system, you may contact the PLAMMS Service Team of the Department of Health at Tel No. 3974 4159.

4. The applicant should be a registered user of PLAMMS and holder of relevant trader license e.g., Antibiotics Permit, Wholesale Dealer Licence, Licence for Manufacturer of Pharmaceutical Products, Wholesale Dealer's Licence to Supply Dangerous Drugs or Licence to Manufacture Preparations of Dangerous Drugs.

5. If the applicant is not the holder of a registration certificate of the product to be imported, the application must be supported by authorization from the relevant product registration certificate holder.

6. For applications involving clinical trials on human beings or medicinal tests on animals, the application must be supported by a valid certificate for clinical trial/medicinal test. If the applicant is not the holder of the certificate, the application must also be supported by authorization from the relevant holder of certificate for clinical trial/medicinal test.

7. For each successful application, the system will generate a new licence number and the approved licence can be printed via PLAMMS.

8. In the case of an import licence application, the importer must present the original import licence which enables the licensee to take delivery of the goods from the carrier (shipping company, airline or transportation company). Please note that under Section 8 of the I & E Ordinance, the original must be presented to the carrier within 7 days after importation of the goods, irrespective of whether delivery of the goods is taken. The duplicate is for the licensee's retention.

9. In the case of an export licence application, the exporter must present the original export licence which should be surrendered to the carrier, without which the carrier is forbidden under Section 10 of the I & E Ordinance from accepting the goods for export.

10. The importer/exporter must comply with the conditions of issue specified on the licence.

Controlled Chemicals

11. The following 5 pharmaceutical raw materials (active pharmaceutical ingredients), namely ephedrine, ergotamine, ergometrine, pseudoephedrine, norephedrine (phenylpropanolamine) and their salts are controlled chemicals subject to the additional licensing control and requirement of import or export authorization under the Control of Chemicals Ordinance, Chapter 145 of the Laws of Hong Kong, administered by the Customs and Excise Department. Combined import licence Form 3/export licence Form 6 together with the corresponding application for import/export authorization covering these substances should be lodged through the Trade Single Window system available at https://www2.tradesinglewindow.hk/portal/en/index.html. For further information on the application for authorization to import and export controlled chemicals, please contact the Controlled Chemical Group of Customs and Excise Department at Tel No. 2541 4383.

Fees

12. Applications for import licence Form 3, export licence Form 6 covering pharmaceutical products and medicines, import and export authorizations covering controlled chemicals are free of charge.

Warning

13. Under Sections 6C(1) and 6D(1) of the I & E Ordinance, no person shall import or export pharmaceutical products and medicines except under and in accordance with a licence issued by the Director-General of Trade and Industry. Sections 6C(2) and 6D(3) of the I & E Ordinance stipulate that any person who contravenes Sections 6C(1) and 6D(1) shall be guilty of an offence and shall be liable on conviction to a fine of $500,000 and to imprisonment for two years.

14. As regards the pharmaceutical raw materials (controlled chemicals) listed in paragraph 11 above, any person who fails to observe the licensing requirements under Section 3 of the Control of Chemicals Ordinance commits a criminal offence and is liable on conviction to a fine of $1,000,000 and to imprisonment for 15 years.

Enquiries

15. Please contact the Drug Information and Import/Export Control Division, Department of Health on Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong, or at Tel No. 3974 4180 for general import/export licence application information.

Drug Information and Import/Export Control Division
Department of Health
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