

How to Apply for Import and Export Licences for Pharmaceutical Products and Medicines

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 Form

3. The relevant licence application forms are Import Licence Form 3 [TRA 187] and Export Licence Form 6 [TRA 394]. These forms are available for sale at the following locations:

Trade and Industry Department Room 1309, 13/F Trade and Industry Tower 3 Concorde Road, Kowloon City Kowloon, Hong Kong Tel No. : 2398 5325
Shroff Office Drug Evaluation and Import/Export Control Division Department of Health Suites 2002-05, 20/F AIA Kowloon Tower, Landmark East 100 How Ming Street, Kwun Tong Kowloon, Hong Kong Tel No. : 3974 4178

How to Complete the Application Forms

4. Detailed guidelines on how to complete these licence applications are set out in Annex 1. Specimen copies of completed import and export licence applications are at Annexes 2 and 3 respectively.

Application Procedures

(I) For application related to import and export of registered pharmaceutical products:-

5. Except for the pharmaceutical products mentioned in paragraph 8 below, the import licence application for pharmaceutical products & medicines, completed in quadruplicate or the export licence application completed in triplicate, should be lodged to the following address:

Drug Evaluation and Import/Export Control Division
Department of Health
Suites 2002-05, 20/F
AIA Kowloon Tower, Landmark East
100 How Ming Street, Kwun Tong
Kowloon, Hong Kong
Tel No. : 3974 4180

A numbered receipt will be issued to the applicant. The applicants shall collect the processed applications after one working day at the Drug Import/Export Control Unit with the receipt.

6. In the case of an import licence application, the applicant will be given the original and duplicate of licence. The original is to enable 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.

7. In the case of an export licence application, the licensee will be given only the original, 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.

(II) For the application related to import and export of unregistered pharmaceutical products:-

8. Applicant can apply import and export licences of unregistered pharmaceutical products, which are not for re-export purpose, through the procedures listed out in paragraphs 5 to 7. With effect from 1 July 2016, application for import and export licences for unregistered pharmaceutical products for re-export purpose can only be made through the electronic system, namely Pharmaceuticals Licence Application and Movement Monitoring System ("PLAMMS"). Please refer to Guidance Notes (Annex 4) and User Guide (Annex 5) for more information on how to use PLAMMS. 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 during office hours.

Controlled Chemicals

9. 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. To save traders' time in lodging relevant applications to two departments for approval, completed import licence Form 3/export licence Form 6 together with the corresponding application for import/export authorization covering these substances should be lodged to the Licensing Unit of the Controlled Chemicals Group, Customs and Excise Department, at 3/F Customs Headquarters Building, 222 Java Road, North Point, Hong Kong. Both the licence and authorization shall be available for collection at the Licensing Unit after processing. 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 (Tel No. : 2541 1016).

Fees

10. 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

11. 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.

12. As regards the pharmaceutical raw materials (controlled chemicals) listed in paragraph 8 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

13. Please contact the Drug Evaluation 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 Evaluation and Import/Export Control Division
Department of Health
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