

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 products and medicines" mean any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in :
- (a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;
 - (b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof;
 - (c) altering, modifying, correcting or restoring any organic function, in human beings or in animals.

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 :

Location	Price	
	Form 3	Form 6
Collection Office Room 104, 1/F Trade and Industry Department Trade and Industry Department Tower 700 Nathan Road Kowloon Tel No. : 2398 5325	\$26 per pad of 20 sets \$3 per set	\$16 per pad of 20 sets \$3 per set
Shroff Office Pharmaceutical Registration & Import/Export Control Section 3/F Public Health Laboratory Centre 382 Nam Cheong Street Kowloon Tel No. : 2319 8461	\$26 per pad of 20 sets	\$16 per pad of 20 sets

How to Complete the Application Forms

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

Application Procedures

5. Except for the pharmaceuticals 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 :

Pharmaceuticals Registration and Import/Export Control Section
Department of Health
3/F, Public Health Laboratory Centre
382 Nam Cheong Street
Kowloon
Tel No. : 2319 8460

A numbered receipt will be issued to the applicant. The applicants shall collect the processed applications after one working day at the Pharmaceuticals Registration and Import/Export Control Section 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.

Controlled Chemicals

8. 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 Room 631, 6/F, North Point Government Offices, 333 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 4383).

Fees

9. 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

10. 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.

11. 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

12. If you require further information, please contact the Pharmaceutical Registration and Import/Export Control Section, Department of Health on 3/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, or at Tel No. 2319 8460.

Pharmaceutical Registration and
Import/Export Control Section
Department of Health
June 2007