

Pharmaceutical Service, Department of Health

Import and Export of Dangerous Drugs

Guidance Notes for Applicants

1. **How to apply for import of dangerous drugs?**

Application for an Import Certificate

An importer who wishes to import a consignment of dangerous drug should first apply for an *import certificate* (in grey) at the Pharmaceuticals Import/Export Control Unit.

However, for some dangerous drugs, an application for import quota must first be made. Examples of these dangerous drugs are:

Alfentanil	Fentanyl
Cocaine	Methadone
Codeine	Morphine
Dextropropoxyphene	Normethadone
Diphenoxylate	Opium Preparations
Dipipanone	Pethidine
Ethylmorphine	Pholcodine

Application for import quota should be made using Form D1. On approval, a Form D2 will be issued to the applicant. The applicant should then apply for an *import certificate* using Form D3.

For most of the other dangerous drugs (such as the benzodiazepines), application for import quota is not required. The importer should directly apply for an *import certificate* using Form D3.

An application for *import certificate* must be accompanied by a copy of the following:

- (i) registration certificate of the drug (except if the drug is imported for re-export only or for a manufacturer's own use);
If the registration certificate was not issued to the applicant, a copy of the written authorization from the registration certificate holder appointing the applicant as his importing agent must also be provided.
- (ii) the applicant's licence to manufacture/supply dangerous drugs issued by the Director of Health;
- (iii) for those dangerous drugs which require import quota approval, the application must in addition be accompanied by:
 - (a) the original Form D2; and
 - (b) (if the application is lodged by an importer on behalf of a manufacturer) a copy of the purchase order or sales contract signed by the registered pharmacist of the manufacturer.

On approval, an *import certificate* will be issued. The importer should then send the original of this *import certificate* to the overseas supplier.

Application for an Import Licence

When the arrival details of that consignment are known, the importer should apply for an *import licence* (in pink) at the Pharmaceuticals Import/Export Control Unit using Form D4. Arrival details include: flight number or vessel name, air waybill number or bill of lading number and the expected arrival date. No accompanying documents are required to support the application.

On approval, an *import licence* will be issued. It should be used for clearance of goods at the Customs and Excise Department.

The used import licence should be stamped and signed on by a Customs and Excise officer and then returned to the Pharmaceuticals Import/Export Control Unit.

2. How to apply for export of dangerous drugs?

An exporter who wishes to export a consignment of dangerous drug should first obtain, from the overseas importer, the original import authorization issued by the overseas health authority. He should then apply for an *export licence* (in yellow) at the Pharmaceuticals Import/Export Control Unit using Form D5.

An application for *export licence* must be accompanied by:

- (i) the original import authorization issued by the overseas health authority; and
- (ii) a copy of the applicant's licence to manufacture/supply dangerous drugs issued by the Director of Health.

On approval, the original and a duplicate of the export licence will be issued. The duplicate should be attached to the dangerous drugs package when the latter is exported. The original is used for clearance of goods at the Customs and Excise Department.

The used original export licence should be stamped and signed on by a Customs and Excise officer and then returned to the Pharmaceuticals Import/Export Control Unit.

3. Notes on Applications

- (a) All application forms must be signed by the person in charge of dangerous drugs as indicated in the applicant's licence to manufacture/supply dangerous drugs issued by the Director of Health.
- (b) All application forms must also be dated and stamped with the company's chop.

- (c) Applications may be submitted by hand or by mail.
- (d) Applications for import and export licences must be submitted together with applications for Import Licence (Form 3) or Export Licence (Form 6) of the Trade and Industry Department, as the case may be. The Form 3 or Form 6 application forms should list only the dangerous drugs concerned and no other pharmaceutical products.
- (e) Collection of certificates and licences

Certificates and licences are normally ready for collection as follows (excluding the day the application is received):

Import Certificate	on the fourth working day
Export Licence	on the second working day at noon (not counting Saturday)
Import Licence	on the second working day at noon (not counting Saturday)

Any person collecting a certificate or a licence must bring the company chop of the applicant's company.

- (f) Clearance of goods should be arranged with the Customs and Excise Department ahead of time at the following phone numbers :

Airport	Goods to be imported	Goods to be exported
	21164130	21164145
	21164131	21164150
		21164151
Container Terminal	24108040	
	24108041	
	24108042	
	24108043	
	24108044	

- (g) The address of the Pharmaceuticals Import/Export Control Unit is:

3/F, Public Health Laboratory Centre,
382 Nam Cheong Street,
Shek Kip Mei, Kowloon,
Hong Kong
(Enquiries : 2319 8460)

Office hours: 9:00 am - 1:00 pm and (Monday to Friday)
2:00 pm - 6:00 pm (Monday)
2:00 pm - 5:45 pm (Tuesday to Friday)