Drug Office, Department of Health

Import and Export of Dangerous Drugs

Guidance Notes for Applicants

1. Applications for all licenses and certificates for the import, export, and transit of dangerous drugs are made through the 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.

2. 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]* through PLAMMS's "Import Certificate Application—Part I Dangerous Drugs" section.

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

- (a) for those dangerous drugs that are active pharmaceutical ingredients, if the application is lodged by an importer on behalf of a manufacturer, the application must be accompanied by a copy of the purchase order or sales contract signed by the registered pharmacist of the manufacturer;
- (b) applicant may be required if necessary to provide justification for the quantity of dangerous drug to be imported.

On approval by the Department of Health, an [import certificate] will be issued. The applicant should download the approved import certificate via PLAMMS and send the original of this [import certificate] to the overseas supplier. If requested by the overseas health authority, the applicant can print the approved import certificate via PLAMMS and send the print-out to the overseas supplier as appropriate.

Application for an [Import Licence]

When the arrival details of that consignment are known, the importer should apply for an *[import licence]* through PLAMMS's "Dangerous Drug License Application – DD Import Licence" section. Arrival details include: flight number or vessel name, air waybill number or bill of lading number and the expected arrival date.

On approval by Department of Health, an *[import licence]* will be issued. The applicant should download and print the approved import licence via PLAMMS, which is used for clearance of goods at the Customs and Excise Department.

The used *[import licence]* should be stamped and signed on by Customs and Excise Department and then returned to the Drug Information and Import/Export Control Division.

3. 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 <u>original</u> import authorization issued by the overseas health authority. He should then apply for an *[export licence]* through PLAMMS's "Dangerous Drug License Application – DD Export Licence" section.

An application for *[export licence]* must be accompanied by the <u>original</u> import authorization issued by the overseas health authority

On approval by the Department of Health, the original and a duplicate of the [export licence] will be issued. The applicant should download and print the approved original and duplicate of the export licence via PLAMMS. 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 Customs and Excise Department and then returned to the Drug Information and Import/Export Control Division.

4. How to apply for removal of dangerous drugs?

An applicant who wishes to remove a dangerous drug in transit should first obtain, from the overseas supplier, a copy of the export authorization issued by the overseas health authority of the exporting country and a copy of the corresponding import authorization issued by the overseas health authority of the importing country. He should then apply for a [removal licence] through PLAMMS's "Dangerous Drug License Application – DD Removal Licence" section.

An application for [removal licence] must be accompanied by:

- (a) a copy of export authorization issued by the overseas health authority of the exporting country; and
- (b) a copy of import authorization issued by the overseas health authority of the importing country.

On approval by the Department of Health, a *[removal licence]* will be issued by the Director of Health. The applicant should download and print the approved removal licence via PLAMMS, which is used for clearance of goods at the Customs and Excise Department.

The used [removal licence] should be stamped and signed on by Customs and Excise Department and then returned to the Drug Information and Import/Export Control Division.

5. How to apply for diversion of dangerous drugs?

An applicant who wishes to divert a dangerous drug in transit should first obtain, from the overseas importer, the <u>original</u> import authorization issued by the overseas health authority of the country to which the dangerous drug is to be diverted to. He should then apply for a *[diversion licence]* through PLAMMS's "Dangerous Drug License Application – DD Diversion Licence" section.

An application for [diversion licence] must be accompanied by:

- (a) the <u>original</u> import authorization issued by the overseas health authority to which the dangerous drug is to be diverted to; and
- (b) the export authorization that accompanied the dangerous drug when it was imported into Hong Kong.

On approval by the Department of Health, the original and a duplicate of the *[diversion licence]* will be issued. The applicant should download and print the approved original and duplicate of the diversion licence via PLAMMS. 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 [diversion licence] should be stamped and signed on by Customs and Excise Department and then returned to the Drug Information and Import/Export Control Division.

6. Notes on Applications

- (a) All applications must be submitted 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 via their registered PLAMMS account.
- (b) Once the import or export licences for DD is approved, an applicant must apply for an 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 applications should list only the dangerous drugs concerned and no other pharmaceutical products.
- (c) 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.

(d) Collection of certificates and licences

The electronic copies of the certificates and licences are normally ready for collection through PLAMMS as follows (excluding the day the application is received):

Import Certificate	after the fourth working day
Export Licence	after the second working day at noon
Import Licence	after the second working day at noon
Diversion Licence	after the second working day at noon
Removal Licence	after the second working day at noon

Applicants should download and print the approved certificates and licences via PLAMMS for clearance of goods at the Customs and Excise Department.

(e) 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 2116 4130 2116 4135 2116 4136	Goods to be exported 2116 4245
Container Terminal	2152 0133	

(f) The address of the Drug Information and Import/Export Control Division is:

Suites 2002-05, 20/F AIA Kowloon Tower, Landmark East 100 How Ming Street, Kwun Tong Kowloon, Hong Kong

(Enquiries: 3974 4180)

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)

7. Warning

The Dangerous Drugs Ordinance (Cap. 134) controls over the dealing, possession, import, export, supply and manufacture of dangerous drugs. Any person who fails to follow these guidance notes to apply for a licence for the import, export, transit or diversion of a consignment of dangerous drug shall be guilty of an offence and shall be liable on conviction to a maximum penalty of life imprisonment and a fine of \$5,000,000.