Drug Office, 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) using [Application form of Import Certificate] at the Drug Evaluation and Import/Export Control Division.

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

(a) 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.

(b) the applicant’s licence to manufacture/supply dangerous drugs issued by the Director of Health;

(c) 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;

(d) 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 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 Drug Evaluation and Import/Export Control Division using [Application form of Import Licence]. 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 by Department of Health, 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 Customs and Excise Department and then returned to the Drug Evaluation and Import/Export Control Division.

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 Drug Evaluation and Import/Export Control Division using [Application Form of Export Licence].

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

(a) the original import authorization issued by the overseas health authority; and

(b) a copy of the applicant’s licence to manufacture/supply dangerous drugs issued by the Director of Health.

On approval by the Department of Health, 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 Customs and Excise Department and then returned to the Drug Evaluation and Import/Export Control Division.

3. 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 import authorization issued by the overseas health authority of the importing country. He should then apply for a [removal licence] (in white) at the Drug Evaluation and Import/Export Control Division using [Application Form of Removal Licence].
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. It 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 Evaluation and Import/Export Control Division.

4. 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 original 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] (in white) at the Drug Evaluation and Import/Export Control Division using [Application Form of Diversion Licence].

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

(a) the original 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 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 Evaluation and Import/Export Control Division.

5. 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. Removal licence applications may be submitted in person, by fax or email. If removal licence application is submitted by fax or email, the original copy of the application form must be submitted to Department of Health when the approved [removal licence] is collected.

(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):

<table>
<thead>
<tr>
<th>Certificate/Licence</th>
<th>Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Import Certificate</td>
<td>on the fourth working day</td>
</tr>
<tr>
<td>Export Licence</td>
<td>on the second working day at noon</td>
</tr>
<tr>
<td>Import Licence</td>
<td>on the second working day at noon</td>
</tr>
<tr>
<td>Removal Licence</td>
<td>on the second working day at noon</td>
</tr>
<tr>
<td>Diversion Licence</td>
<td>on the second working day at noon</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Location</th>
<th>Goods to be imported</th>
<th>Goods to be exported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airport</td>
<td>21164130</td>
<td>21164245</td>
</tr>
<tr>
<td></td>
<td>21164135</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21164136</td>
<td></td>
</tr>
<tr>
<td>Container Terminal</td>
<td>21520133</td>
<td></td>
</tr>
</tbody>
</table>
(g) The address of the Drug Evaluation 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 2:00 pm - 6:00 pm (Monday to Friday)  
2:00 pm - 5:45 pm (Monday)  
2:00 pm - 5:45 pm (Tuesday to Friday)

6. 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.