Guidelines on Import Control Licensing Procedure for Importation of Drugs

1. Introduction

Public health considerations demand that Pharmaceutical products should not be treated in the same way as ordinary commodities. Their manufacture and subsequent handling within the distribution chain both nationally and internationally, must conform to prescribed standards and be rigorously controlled.

As per the Import and Export Control Regulation, published in the Extra Ordinary Gazette Notification No 1817/12 dated 05/07/2012, several categories of Pharmaceutical products are subjected to Import Control Licensing.

Accordingly Importers who imports Pharmaceutical products should obtain a license prior to import such products in conformity with the provisions of the Import and Export Control Act No. 01 of 1969.

1.1 Scope of Application

The guidelines are directed to all parties involved in the importation of Pharmaceutical products, including Cosmetic Devices and Drugs Authority, Customs Authorities, Importers and various other interested parties.

1.2 Categories of Pharmaceutical Importation

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>400</td>
<td>Category A</td>
</tr>
<tr>
<td>420</td>
<td>Category B</td>
</tr>
<tr>
<td>430</td>
<td>Category C</td>
</tr>
<tr>
<td>440</td>
<td>Category D</td>
</tr>
<tr>
<td>450</td>
<td>Category F</td>
</tr>
</tbody>
</table>

2. Issuing Import Control License for Pharmaceutical Importation

Import Licenses are issuing for importing Commercial or non-Commercial and/or exchange involved or not involved consignments. Accordingly, there are two types of Import Control license are issued as a General ICL and Block ICL.
2.1 General Import Control License

Required Documentation

As a prerequisite to issue Import Control License, the importer should require to be furnished following documentation.

- Duly filled Application form
- Recommendation letter or Registration Certificate (by the name of Applicant) from Relevant Authority by authorizing importation of such Product. (See Table I)

Items and Relevant Authorities

There are relevant authorities for each drug item to get Recommendation to obtain a Import Control license to import drugs.

<table>
<thead>
<tr>
<th>Type of Item</th>
<th>Relevant Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Western Drugs</td>
<td>The applicant should have Registration Certificates and Import Licenses issued by the Cosmetics Devices and Drugs Authority</td>
</tr>
<tr>
<td>Veterinary Drugs</td>
<td>The applicant should have the letter of Recommendation issued by the Department of Animal Production and Health</td>
</tr>
<tr>
<td>Homoeopathic Drugs</td>
<td>The applicant should have the letter of Recommendation issued by the Sri Lanka Homeopathic Council</td>
</tr>
<tr>
<td>Indigenous Medicine</td>
<td>The applicant should have the letter of Recommendation issued by the Department of Ayurveda</td>
</tr>
<tr>
<td>Surgical Sutures</td>
<td>The applicant should have Registration Certificates and Import Licenses and / or the letter of Recommendation by the Cosmetic Devices and Drugs Authority &amp; Department of Animal Production and Health (BSE Approval)</td>
</tr>
</tbody>
</table>

Table 1
• Two Copies of Performa Invoice
• Original copy and the Photocopy of the Business Registration certificate (if applicant is a Legal Person or National Identity Card (If applicant is a Natural Person)

Procedure

Step 1: Applicant should submit a duly filled application form together with aforesaid required documentation.

Step 2: Verify relevant documentation and entering data into license issuing computer system and forward approval of the Assistant Controller.

Step 3: After approving License request the system generates processing fee as pay in-voucher.

Step 4: Applicant should pay processing fee as fee of the license, thereafter he or she submit Receipt of payment to the officer in charge of the unit of drug importation.

Step 5: Licenses are issued with the signature of Assistant Controller on behalf of Controller General Imports and Exports.

2.2 Block Import Control License

Block License for drug importation is issued at the beginning of the year to use it throughout the year for larger value and without considering quantities at the time of issuing license to established importers. Such Importer can make use of this type of license to import product throughout the year. Licensee shall comply with the licensing conditions during the validity period of the license.

Eligibility

Should provide part shipment licenses for the last 3 years

Note: If the applicant has not abided by the licensing conditions the issue of his Block license will be rejected.
Required Documentation

- Request Letter
- Documents to show history of the importations

Step 1: Applicant should submit a duly filled application form together request letter and Documents to show history of the importations.

Step 2: Verify relevant documentation and entering data into license issuing computer system and forward approval of the Assistant Controller.

Step 3: After approving License request the system generates processing fee as pay in-voucher.

Step 4: Applicant should pay processing fee as fee of the license, thereafter he or she submit Receipt of payment to the officer in charge of the unit of drug importation

Step 5: Licenses are issued with the signature of Assistant Controller on behalf of Controller General Imports and Exports.

2.3 Good Received License

If the Importation is occurred without a license, the Import License is issued by considering incidental factors which are related to such importations. Following documents are needed to obtain Good Received Import Control License

- Cusdec
- Explanation letter
- Recommendation letter from the relevant Authority as stated above
- Commercial Invoices
- Application Form

Procedure is applied for issuing a Good Received Licenses as same as stated above.

2.3 Amended License for drug importation

If in any case that the applicant wishes to amend a license issued by this department, the
request should be forwarded to the Controller General. The Controller General will examine the request and decide whether to grant approval or not.

**Required Documentation**

- Explanation letter
- Duly filled application form
- Original ICL

Procedure is applied for issuing an amended license as same as stated above.

**3. General Information**

**Time Line for processing:** Within one day

**Note:** Upon receiving correct documentation

**Period of Validity of license**

All licenses are issued for drug importation will be valid for the date specified thereon except where otherwise stated.

In other cases, such as block license may be issued valid for one year.

**Costs Related to the Service**

Fee: License Fee – 0.2% of the Invoice value

**Submission Time Line**

<table>
<thead>
<tr>
<th>Time</th>
<th>– 8:30 am to 4:15 pm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working Days</td>
<td>– Monday to Friday</td>
</tr>
<tr>
<td>Holidays</td>
<td>– Public and Mercantile Holidays</td>
</tr>
</tbody>
</table>

**Obligation to import against License issued**

An importer, to whom an import license is issued, is required to import goods licensed before the date of expiry of the license unless it is extended by the Controller General of imports on application made to him. Further such importer is liable to fulfill and comply with the terms and conditions stipulated in the license.

**The Process of Debiting**
Importer who import drugs, should submit license together with following documents to this department for debiting

**Documents Required**

- Copy of Import Control License
- Recommendation letters as mentioned in table 1
- Way bills
- Commercial Invoices
- Customs Declaration Form (CusDec)
- Certificate of Analysis for each batch

**Procedure**

**Step 1:** Licensee should submit required documents as aforesaid

**Step 2:** Verify relevant documentation and entering data into license issuing and debiting system and forward approval of the Assistant Controller.

**Step 3:** After approving, debit note and other required documents are issued with the attestation of Assistant Controller on behalf of Controller General Imports and Exports.

**Process Time Line:** Within one day

**Submission Time Line**

<table>
<thead>
<tr>
<th>Counter</th>
<th>Unit 01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>8:30 am to 4:15 pm</td>
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