

| GENERAL INFORMATION | |
|---|---|
| Name of formality | Licensing Pharmacist to establish a Drug and Medical Product Import-Export Company |
| Type of formality | Certificate |
| Date of last modification | 03.10.2017 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Individuals or legal entities that intend to establish export-import companies in the field of drug and/or medical product |
| Qualifications needed by the business to get the formality | <p>1. Shall have a Lao pharmacist or pharmacist assistant (Mid-Level Practitioners) in Lao National which has a diploma or certificate of completion in the pharmaceutical profession granted by the relevant educational institution both domestic and international. Licensed by the MoH and have at least 5 years of experience in the pharmaceutical field. If is a government officer, must have an official appointment letter, must be a person that is not under trial or abandoning the position or facing disciplinary actions due to the error in pharmacist profession or dealing narcotics; 2. The setting of import-export business must have an area of at least more than 20 square meters, is a specific room, not mixed with residential or accommodation and other non-pharmaceutical or medical products retailer; 3. Have a clean place to store products and meet the standard of minimum width 6 meters, 12 meters length and an appropriate height, have the accounting clearing system, animals and insects prevention system and cooling system, lighting, temperature and humidity monitoring system. Inside the warehouse must have necessary equipment, a refrigerator with a temperature not to exceed 2-8 Celsius with temperatures measuring devices in the case of drugs to be kept in cold temperature such as rectal suppository or other drugs (Good Wholesaling Practice (GWP) and Good Storage Practice).</p> |

| LEGAL FRAMEWORK | | | |
|-----------------|--------|------|---------|
| Name | Number | Date | Comment |

| | | | |
|--|----------|------------|--|
| Law on Drugs and Medical Products (Amended) | 07/NA | 21.12.2011 | Part III, Chapter 1, Article 12, 14 and 17 |
| Order on the Establishment of Medicine and Medical Device Business Operation (Revised) | 1820/MOH | 25.08.2017 | Article 4, 8, 9.10, 14, 17, 18, 22 |
| Presidential Ordinance on Fees and Service Fees | 003/PO | 26.12.2012 | |

REQUIRED DOCUMENTS FORMALITIES

| Name | Type | Comment |
|------------------|------------------|---------------------|
| \${SUPPORT_NAME} | \${SUPPORT_TYPE} | \${SUPPORT_COMMENT} |

LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION

| Name of document | Type of document | File of document |
|---------------------|---------------------|---------------------|
| \${ATTACHMENT_NAME} | \${ATTACHMENT_TYPE} | \${ATTACHMENT_FILE} |

LIST OF ATTACHED DOCUMENTS FOR RENEW APPLICATION

| Name of document | Type of document | File of document |
|---------------------------|---------------------------|---------------------------|
| \${ATTACHMENT_NAME_RENEW} | \${ATTACHMENT_TYPE_RENEW} | \${ATTACHMENT_FILE_RENEW} |

MEAN OF PRESENTATION

| | | |
|--|--|--|
| Means of presentation | At the Authority Offices | |
| Address of authority | Food and Drugs Department, Ministry of Public Health | |
| Time it takes to the authorities to process the formality | 120 | Applications shall be submitted to the Food and Drug district bureau or the provincial Food and Drug section where the company is located. The application will then be evaluated, reviewed and approved by each level of local authority before transferring to the Food and Drug Department. Ultimately, the Minister of Health will be a signatory for the license. |

| RENEWAL INFORMATION | |
|--|---|
| Does the formality have a validity or an expiration date? | How long will the formality be valid for? (in months) |
| YES | 24 |
| What is the process and conditions to get the formality? | |
| What is the process and conditions to renew the formality? | The renewal shall be undertaken within 3 months before the expiration of the Formality. |

| ISSUING FEES | | | | |
|-------------------------|--|--|--|--|
| Has application fees? | Service fees businesses need to disburse | Certificate fees businesses need to disburse | Application fees businesses need to disburse | Total fees businesses need to disburse |
| YES | 0.00 | 1000000.00 | 0.00 | 1000000.00 |
| Comments | Refer to the Presidential Ordinance 003/PO | | | |
| ADDITIONAL ISSUING FEES | | | | |
| Additional fee names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional fee comments | | | | |

| RENEWAL FEES | | | | |
|-------------------------|--|--|--|--|
| Has renewal fees? | Service fees businesses need to disburse | Certificate fees businesses need to disburse | Renewal fees businesses need to disburse | Total renewal fees businesses need to disburse |
| YES | 0.00 | 500000.00 | 0.00 | 500000.00 |
| Comments | Refer to the Presidential Ordinance 003/PO | | | |
| ADDITIONAL RENEWAL FEES | | | | |

| | | | | |
|--|------|------|------|------|
| Additional renewal fees names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional renewal fees c omments | | | | |