

| GENERAL INFORMATION | |
|---|---|
| Name of formality | Certificate of Registration of International Drug Formula for Domestic Production |
| Type of formality | Certificate |
| Date of last modification | 19.11.2020 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Domestic pharmaceutical factory. |
| Qualifications needed by the business to get the formality | 1. For locally manufactured drugs, those who intend to produce drugs must submit an application for the production of a sample drug according to the Application Form 1. Once a permit for producing sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months. 2. For imported drugs, those who intend to import drugs from abroad must apply for a permit to import a sample drug according to the Application Form 1. Once a permit for importing a sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months. |

| LEGAL FRAMEWORK | | | |
|---|-----------|------------|---------|
| Name | Number | Date | Comment |
| Law on Drugs and Medical Products (Amended) | 07/NA | 21.12.2011 | |
| Provision on Medicine Registration | 1441/MOPH | 13.08.2003 | |

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

| LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION |
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| 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 | 0 | Pursuant to the regulation on drug registration No. 1441/MOH, the application period is 6 months. |

| RENEWAL INFORMATION | | |
|--|--|---|
| Does the formality have a validity or an expiration date? | | How long will the formality be valid for? (in months) |
| YES | | 36 |
| What is the process and conditions to get the formality? | | |
| What is the process and conditions to renew the formality? | Pursuant to the Presidential Ordinance No. 003/PO. | |

| 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 | 600000.00 | 0.00 | 600000.00 |
| Comments | Pursuant to the Presidential Ordinance on the Fees and Service Charges No. 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 | 100000.00 | 300000.00 | 0.00 | 400000.00 |
| Comments | Pursuant to the Presidential Ordinance on the Fees and Service Charges No. 003/PO. | | | |
| ADDITIONAL RENEWAL FEES | | | | |
| Additional renewal fees names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional renewal fees comments | | | | |