

| GENERAL INFORMATION | |
|---|--|
| Name of formality | Licensing Pharmacist to Establish a Medical Equipment Factory |
| Type of formality | Certificate |
| Date of last modification | 19.11.2020 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Individuals or Organizations that intend to manufacture medical equipment shall obtain the approval and technical permission of the Ministry of Health first. |
| Qualifications needed by the business to get the formality | Individuals or organization that intends to engage in the business of Medical equipment manufacturing must meet the additional conditions as follows:1. Have a pharmacist with at least five years of experience;2. Never be convicted on drugs or narcotics or medical products;3. Have pharmaceutical and business ethics;4. Have competent personnel;5. Have good health, no mental illness or infectious disease;6. Have measures to protect the safety and the environment;7. Have a suitable setting and necessary facilities, a standardized warehouse, and transporting vehicles.The factory also needs to have a production room, a laboratory with complete sets of equipment. |

| LEGAL FRAMEWORK | | | |
|---|---------|------------|---------------------|
| Name | Number | Date | Comment |
| Law on Drugs and Medical Products (Amended) | 07/NA | 21.12.2011 | Part III, Chapter 1 |
| Provision on the Manufacture of Medicine and Medical Products | 937/MOH | 12.05.2004 | Chapter II |
| 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 | 45 | The application's consideration period is within 45 days |

| 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? | |

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| What is the process and conditions to renew the formality? | Licensing Pharmacist is valid for 3 years. 3 months before the date of expiry, the business must apply for a renewal. Food and Drug Department is in charge of the license approval after the application got approved through the relevant authorities at the district, provincial-capital levels. The conditions for license renewal are related to Section III, Section IV of the Instructions on Drugs and Medical Products Manufacturing No. 937/MOH, 15.05.2004, and other relevant regulations. Conditions for non-renewal are stipulated in Article 6.3 (Instructions on the Drugs and Medical Products Manufacturing No. 937/MOH, 12.05.2004). Temporary suspension or termination of the business operation is subjected to: -Death of the pharmacist.-In case of warning and have been fined more than 3 times- In case of misconduct or violation of the Laws- Has been filed a lawsuit by the affected people and the victims or prosecuted by the court |
|---|---|

| 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 | 500000.00 | 0.00 | 0.00 | 500000.00 |
| Comments | Refer to the Ordinance on fees and service charges 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 | 250000.00 | 0.00 | 0.00 | 250000.00 |
| Comments | Refer to the Ordinance on fees and service charges 003/PO | | | |

| ADDITIONAL RENEWAL FEES | | | | |
|---|------|------|------|------|
| Additional renewal fees names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional renewal fees c omments | | | | |