

| GENERAL INFORMATION | |
|---|---|
| Name of formality | Licensing Pharmacist to establish Drug and Medical Product Factory |
| Type of formality | License |
| Date of last modification | 03.10.2017 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Individuals or organizations that intend to produce drugs and medical products must first obtain the approval and technical permission from the Ministry of Health. |
| Qualifications needed by the business to get the formality | Individuals or organizations that intend to operate drugs and medical products manufacturing business must comply with the additional conditions as follows: 1. A full-time pharmacist that has at least five years of experiences;2. Never been sanction on drugs or narcotics or medical products;3. Has a pharmacological and business ethics;4. Has skilled human resources;5. Healthy, no mental illness or contracted transmissible diseases;6. Has a safety and environmental protection measures;7. Has a suitable site and necessary infrastructures, has a standard warehouse and transport vehicle.Factory must have a manufacturing room, laboratory with full 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 | |

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|---------------------------------------|
| REQUIRED DOCUMENTS FORMALITIES |
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| 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 | | |
| Address of authority | Food and Drugs Department, Ministry of Public Health | |
| Time it takes to the authorities to process the formality | 45 | The application processing 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. (Article 6, Instructions on the Drugs and Medical Products Manufacturing No. 937/MOH, 12.05.2004). 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 |
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| 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 | 500000.00 | 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 | 0.00 | 250000.00 | 0.00 | 250000.00 |

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|---|---|------|------|------|
| 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 comments | | | | |