

| GENERAL INFORMATION | |
|---|---|
| Name of formality | Certificate of Registration for Domestic Manufactured Traditional Medicine |
| Type of formality | Other |
| Date of last modification | 09.12.2020 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Applicants that are eligible to register the traditional medicine are factories, import-export companies that operate the business in traditional medicine, which are properly licensed by the health sector. |
| Qualifications needed by the business to get the formality | All procedures must in accordance with the regulations of the Ministry of Health |

| LEGAL FRAMEWORK | | | |
|---|--------|------------|---------------------------------------|
| Name | Number | Date | Comment |
| Law on Drugs and Medical Products (Amended) | 07/NA | 21.12.2011 | Article 13 and 15 |
| Presidential Ordinance on Fees and Service Fees | 003/PO | 26.12.2012 | Chapter IX, Article 45-47, Page 89-92 |

| 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 | 180 | Each time the applicant has to submit Form 1 first, which will take 3 months to consider. After Form 1 has been considered, the applicant then will be able to submit Form 2 which will take 6 months to consider. |

| 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? | Certificate of registration for Traditional Medicine is valid for 3 years; 3 months prior to the expiry date, the applicant must apply for the renewal in accordance with the documents required by Food and Drug Department. |

| 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 | 100000.00 | 600000.00 | 5000.00 | 705000.00 |
| Comments | Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92) | | | |

| 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 | 600000.00 | 5000.00 | 705000.00 |
| Comments | Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92) | | | |
| ADDITIONAL RENEWAL FEES | | | | |
| Additional renewal fees names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional renewal fees comments | | | | |