

| GENERAL INFORMATION | |
|---|---|
| Name of formality | Import-Export-Transit Authorization of Drugs or Psychotropic Substances |
| Type of formality | Other |
| Date of last modification | 17.12.2020 |
| Responsible Authority | Food and Drugs Department |
| Who should apply for this formality? | Any individuals or organizations that intend to:- Import for production, distribution, or possession of drugs or Psychotropic Substances - Export- TransitMust obtain approval from the Ministry of Health first. |
| Qualifications needed by the business to get the formality | - Pharmaceutical factory and Import-Export of Pharmaceutical company which has been duly registered with the conditions that can import-export and distribution;- Pharmaceutical store class I and II which has been duly registered with the conditions that can retail in accordance with doctor's prescription;- State hospital at the central and local level or private hospital with a license in accordance with condition that can distribute or retail by a pharmacist as per doctor's prescription. |

| LEGAL FRAMEWORK | | | |
|--|----------|------------|--------------------------|
| Name | Number | Date | Comment |
| Law on Drugs and Medical Products (Amended) | 07/NA | 21.12.2011 | Article 12 |
| Order on the List of Narcotics and Psychotropic Substances | 08/MOPH | 04.01.2005 | Article 1 and 2 |
| Order on the Management of Narcotics and Psychotropic Substances | 456/MOPH | 19.04.2006 | Article 9, 10, 11 and 12 |

| 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 | 14 | |

| RENEWAL INFORMATION | | |
|---|--|--|
| Does the formality have a validity or an expiration date? | | How long will the formality be valid for? (in months) |
| YES | | 6 |
| What is the process and conditions to get the formality? | | |
| What is the process and conditions to renew the formality? | In case the certificate is expired, the renewal of the license can be extended until 31 December of that year. | |

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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 | 0.00 | 3000.00 | 3000.00 |
| Comments | Based on the recommendation from the authority | | | |
| 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 | 0.00 | 3000.00 | 3000.00 |
| Comments | Based on the recommendation from the authority | | | |
| ADDITIONAL RENEWAL FEES | | | | |
| Additional renewal fees names | | | | |
| NO | 0.00 | 0.00 | 0.00 | 0.00 |
| Additional renewal fees comments | | | | |