

| GENERAL INFORMATION   |   |
|---|---|
| <b>Name of formality</b>  | Import-Export-Transit Authorization of Controlled Drugs   |
| <b>Type of formality</b>  | Other   |
| <b>Date of last modification</b>                                  | 18.12.2020  |
| <b>Responsible Authority</b>                                      | Food and Drugs Department   |
| <b>Who should apply for this formality?</b>                       |   |
| <b>Qualifications needed by the business to get the formality</b> | - 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 a 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 |                          |
| Order on the Management of Narcotics and Psychotropic Substances | 456/MOPH | 19.04.2006 | Article 9, 10, 11 and 12 |
| Order on the List of Narcotics and Psychotropic Substances       | 08/MOPH  | 04.01.2005 | Article 1 and 2          |

| 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 authorization is expired. The authorization can be renewed until 31 December of that year. |   |

| 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 |  |  |  |  |