

| GENERAL INFORMATION                                               |                                                                                |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Name of formality</b>                                          | License to Import Raw Materials for the Production of Registered Drugs         |
| <b>Type of formality</b>                                          | Other                                                                          |
| <b>Date of last modification</b>                                  | 19.11.2020                                                                     |
| <b>Responsible Authority</b>                                      | Food and Drugs Department                                                      |
| <b>Who should apply for this formality?</b>                       | A company or factory that obtains a permit from the Food and Drugs Department. |
| <b>Qualifications needed by the business to get the formality</b> |                                                                                |

| LEGAL FRAMEWORK                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------|
| Name                                                                                                                                       |
| Law on Drugs and Medical Products (Amended)                                                                                                |
| Notice on the Required Documents for the Application on Import Raw Materials, Packaging, Medicine and Medical Equipments for Manufacturing |

| 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 | 3                                                    |  |

| RENEWAL INFORMATION                                        |                                                       |
|------------------------------------------------------------|-------------------------------------------------------|
| Does the formality have a validity or an expiration date?  | How long will the formality be valid for? (in months) |
| NO                                                         | 0                                                     |
| What is the process and conditions to get the formality?   |                                                       |
| What is the process and conditions to renew the formality? | It can be used only once.                             |

| 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                                     | 20000.00                                     | 0.00                                         | 20000.00                               |
| Comments                | Refer to the Ordinance No. 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 |
| NO                               | 0.00                                     | 0.00                                         | 0.00                                     | 0.00                                           |
| Comments                         |                                          |                                              |                                          |                                                |
| ADDITIONAL RENEWAL FEES          |                                          |                                              |                                          |                                                |
| Additional renewal fees names    |                                          |                                              |                                          |                                                |
| NO                               | 0.00                                     | 0.00                                         | 0.00                                     | 0.00                                           |
| Additional renewal fees comments |                                          |                                              |                                          |                                                |