

| GENERAL INFORMATION                                               |                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name of formality</b>                                          | License to Operate Business for the Production of Hazardous Chemicals for Household Use                                                                                                                                                                                                                                     |
| <b>Type of formality</b>                                          | Other                                                                                                                                                                                                                                                                                                                       |
| <b>Date of last modification</b>                                  | 23.12.2020                                                                                                                                                                                                                                                                                                                  |
| <b>Responsible Authority</b>                                      | Food and Drugs Department                                                                                                                                                                                                                                                                                                   |
| <b>Who should apply for this formality?</b>                       | Any individuals or organizations that intend to operate a business for the production of household chemical products.                                                                                                                                                                                                       |
| <b>Qualifications needed by the business to get the formality</b> | - Must be pharmacist or chemist or technical staff with experienced or has trained in this sector.- Have the necessary facilities to ensure the application of Good Manufacturing Practices such as the availability of a production room, a storage room that complies with requirements and with the necessary equipment. |

| LEGAL FRAMEWORK                                 |        |            |                |
|-------------------------------------------------|--------|------------|----------------|
| Name                                            | Number | Date       | Comment        |
| Law on Drugs and Medical Products (Amended)     | 07/NA  | 21.12.2011 | Article 12     |
| Presidential Ordinance on Fees and Service Fees | 003/PO | 26.12.2012 | Article 45.5.3 |

| 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 | 10                                                   | In case the document is completed as required. |

| RENEWAL INFORMATION                                        |                                                                                 |                                                       |
|------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------|
| Does the formality have a validity or an expiration date?  |                                                                                 | How long will the formality be valid for? (in months) |
| YES                                                        |                                                                                 | 24                                                    |
| What is the process and conditions to get the formality?   |                                                                                 |                                                       |
| What is the process and conditions to renew the formality? | The applicant applies for renewal within 3 months prior to the expiration date. |                                                       |

| 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                                     | 200000.00                                    | 5000.00                                      | 205000.00                              |
| Comments                | The fee is based on 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 |
| YES                              | 0.00                                         | 200000.00                                    | 5000.00                                  | 205000.00                                      |
| Comments                         | The fee is based on the Ordinance No. 003/PO |                                              |                                          |                                                |
| ADDITIONAL RENEWAL FEES          |                                              |                                              |                                          |                                                |
| Additional renewal fees names    |                                              |                                              |                                          |                                                |
| NO                               | 0.00                                         | 0.00                                         | 0.00                                     | 0.00                                           |
| Additional renewal fees comments |                                              |                                              |                                          |                                                |