

GENERAL INFORMATION	
Name of formality	License to Operate Business for the Production of Hazardous Chemicals for Household Use
Type of formality	Other
Date of last modification	23.12.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Any individuals or organizations that intend to operate a business for the production of household chemical products.
Qualifications needed by the business to get the formality	- 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				