

GENERAL INFORMATION	
<b>Name of formality</b>	Licensing Pharmacist to Establish a Medical Equipment Factory
<b>Type of formality</b>	Certificate
<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>	Individuals or Organizations that intend to manufacture medical equipment shall obtain the approval and technical permission of the Ministry of Health first.
<b>Qualifications needed by the business to get the formality</b>	Individuals or organization that intends to engage in the business of Medical equipment manufacturing must meet the additional conditions as follows:1. Have a pharmacist with at least five years of experience;2. Never be convicted on drugs or narcotics or medical products;3. Have pharmaceutical and business ethics;4. Have competent personnel;5. Have good health, no mental illness or infectious disease;6. Have measures to protect the safety and the environment;7. Have a suitable setting and necessary facilities, a standardized warehouse, and transporting vehicles.The factory also needs to have a production room, a laboratory with complete sets of equipment.

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	Part III, Chapter 1
Provision on the Manufacture of Medicine and Medical Products	937/MOH	12.05.2004	Chapter II
Presidential Ordinance on Fees and Service Fees	003/PO	26.12.2012	

REQUIRED DOCUMENTS FORMALITIES
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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	45	The application's consideration period is within 45 days

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	36
What is the process and conditions to get the formality?	

<b>What is the process and conditions to renew the formality?</b>	Licensing Pharmacist is valid for 3 years. 3 months before the date of expiry, the business must apply for a renewal. Food and Drug Department is in charge of the license approval after the application got approved through the relevant authorities at the district, provincial-capital levels. The conditions for license renewal are related to Section III, Section IV of the Instructions on Drugs and Medical Products Manufacturing No. 937/MOH, 15.05.2004, and other relevant regulations. Conditions for non-renewal are stipulated in Article 6.3 (Instructions on the Drugs and Medical Products Manufacturing No. 937/MOH, 12.05.2004). Temporary suspension or termination of the business operation is subjected to: -Death of the pharmacist.-In case of warning and have been fined more than 3 times- In case of misconduct or violation of the Laws- Has been filed a lawsuit by the affected people and the victims or prosecuted by the court
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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	500000.00	0.00	0.00	500000.00
Comments	Refer to the Ordinance on fees and service charges 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	250000.00	0.00	0.00	250000.00
<b>Comments</b>	Refer to the Ordinance on fees and service charges 003/PO			

ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees c omments				