

GENERAL INFORMATION	
Name of formality	Licensing Pharmacist to establish Drug and Medical Product Factory
Type of formality	License
Date of last modification	03.10.2017
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Individuals or organizations that intend to produce drugs and medical products must first obtain the approval and technical permission from the Ministry of Health.
Qualifications needed by the business to get the formality	Individuals or organizations that intend to operate drugs and medical products manufacturing business must comply with the additional conditions as follows: 1. A full-time pharmacist that has at least five years of experiences;2. Never been sanction on drugs or narcotics or medical products;3. Has a pharmacological and business ethics;4. Has skilled human resources;5. Healthy, no mental illness or contracted transmissible diseases;6. Has a safety and environmental protection measures;7. Has a suitable site and necessary infrastructures, has a standard warehouse and transport vehicle.Factory must have a manufacturing room, laboratory with full 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

What is the process and conditions to renew the formality?	Licensing Pharmacist is valid for 3 years. 3 months before the date of expiry, the business must apply for a renewal. (Article 6, Instructions on the Drugs and Medical Products Manufacturing No. 937/MOH, 12.05.2004).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	0.00	500000.00	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	0.00	250000.00	0.00	250000.00

Comments	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 comments				