

GENERAL INFORMATION	
Name of formality	Licensing Pharmacist to establish a branch of Drug and Medical Product Company
Type of formality	Certificate
Date of last modification	03.10.2017
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Individuals or legal entities that intend to establish a drug and medical branch (sales agent) for the parent company (import-export company) whose products have been registered or reported.
Qualifications needed by the business to get the formality	<p>1. Shall have a Lao pharmacist or pharmacist assistant (Mid-Level Practitioners) in Lao National which has a diploma or certificate of completion on pharmaceutical profession granted by the relevant educational institution both domestic and international Licensed by the MoH and have at least 4 years of experience in the pharmaceutical field. If is a government officer, must have an official appointment letter, must be a person that is not under trial or abandoning the position or facing disciplinary actions due to the error in pharmacist profession or dealing narcotics;</p> <p>2. The branch must be a clean place, with an area of at least 20 square meters or more, is a specific room, not mixed with residential or accommodation and other non-pharmaceutical or medical products retailer; There must be a clean and standard storage place with a width of 4 meters, a length of 8 meters and an appropriate height.</p> <p>3. Must have an accounting clearing system, animals and insects prevention system, a cooling system, lighting, temperature, and humidity monitoring device inside the warehouse and must be monitored on a regular basis, etc.</p> <p>4. The warehouse must have the necessary equipment, such as floor mats, product cabinets, and product handling equipment, tools used to monitor the warehouse system, and follow the principles of good storage, which are specified in good wholesale regulations. (GWP)</p>

LEGAL FRAMEWORK			
Name	Number	Date	Comment

Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	Part III, Chapter 1, Article 12, 14 and 17
Order on the Establishment of Medicine and Medical Device Business Operation (Revised)	1820/MOH	25.08.2017	Article 5, 8, 9.2, 14, 17, 18, 24, 25
Presidential Ordinance on Fees and Service Fees	003/PO	26.12.2012	

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		
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	90	Applications shall be submitted to the Food and Drug district bureau or the provincial Food and Drug section where the company is located. The application will then be evaluated, reviewed, and approved by each level of local authority before transferring to the Food and Drug Department. Ultimately, the Minister of Health will be a signatory for the license.

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 renewal shall be undertaken within 3 months before the expiration of the Formality.

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 Presidential 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	250000.00	0.00	250000.00
Comments	Refer to the Presidential Ordinance No. 003/PO			
ADDITIONAL RENEWAL FEES				

Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				