

GENERAL INFORMATION

Name of formality	Licensing Pharmacist to Establish a Domestic Wholesale of Drug and Medical Product
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 engage in the wholesale business of pharmaceuticals and medical products from local manufacturers or import-export companies to operate wholesaling activities for pharmacy in Lao PDR.
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 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;; 2. The setting of the wholesale business operation must have 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 non-medical products retailer;3. There must be a clean and standard storage place with a width of 6 meters, a length of 12 meters and an appropriate height.Must have an accounting clearing system, animals and insects' prevention system, a cooling system, lighting, temperature and humidity monitoring device. Inside the warehouse must have necessary equipment, a refrigerator with a temperature not to exceed 2-8 Celsius with temperatures measuring devices in the case of drugs to be kept in cold temperature such as rectal suppository or other drugs (Good Wholesaling Practice (GWP) and Good Storage Practice).</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 6, 8, 9.3, 14, 17, 18, 26
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.
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RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	12
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	600000.00	0.00	600000.00
Comments	Refer to the Presidential Ordinance 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	600000.00	0.00	600000.00
Comments	Refer to the Presidential Ordinance 003/PO			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				