

Datasheet for business formalities.

Technical Assistance for Business Regulation Review and Rationalization in Lao PDR

REGISTRATION DATA		
Name of formality	License to Operate the Retail Pharmacy Shop	
Type of formality	License	
Formality Code	Date of last modification	Responsible Authority
MoPH-FDD-4	03.10.2017	Food and Drugs Department

BACKGROUND DATA	
Means of presentation	At the Authority Offices
Specific sector linked to the formality	Q - Human health and social work activities
Purpose for enforcing the business formality	Pharmacy shop will provide direct advice and sale of all the medicine that are important to the human health to the customer so it is necessary to issue this Formality to ensure the qualifications of the owner of the pharmacy shop and to avoid all the risks that may be caused from bad advice.
Who should complete this business formality?	Any person or legal entity that intends to operate a pharmacy shop that means the place that sells medicine and medical devices and gives advice and information relating to medicine directly to the consumer.
The formality has online information?	YES
Link to online information	http://www.fdd.gov.la
The formality has an application form?	YES
Any additional comment concerning the formality	1. There are 3 types of pharmacy, depending on the qualification of the Formality as follows: Type 1: The Formality's holder is graduated with High Diploma Degree Type 2: The Formality's holder is graduated with Medium-Diploma Degree Type 3: The Formality's holder is graduated with Primary Diploma Degree In the municipal areas, the authority will only the establishment of Type 1 and Type 2 pharmacy. 2. Ministry will issue the Formality for the pharmacy of Type 1 and Type 2 whereas for the Type 3, the Provincial Department will issue the Formality after get prior consent from the Ministry of Public Health.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	60	The Law does not define the review period but according to the normal practice of the authority, it would take 60 working days.

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REQUIREMENTS AND SUPPORTING EVIDENCE	
Qualifications needed by the business to get the formality	1. The applicant shall either be (i) Lao citizen that has a permanent residence in Lao PDR for the period of 5 years at the minimum; (ii) foreigner who has the permanent residence in Lao PDR; passes pharmacy degree in Lao PDR and get the prior approval from the Ministry of Public Health; 2. A pharmacist who will apply for this Formality shall have a working experience of at least 2 years in case of the pharmacy in the remote area and at least 3 years in case of the pharmacy in the municipal; 3. The applicant shall not be convicted of any crime relating to pharmacy 4. A pharmacy shall be situated in a clean location, not in a fresh market and separate from residence area, and have a total area of at least 12 square meters.
Is there any reason for the authority to deny the issuing of the formality?	Deny in case that the applicant does not meet the required qualifications, in particular after an inspection by the relevant authorities.

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 renew the formality?	1. The renewal shall be undertaken within 3 months before the expiration of the Formality by submission of all the required documents; provided that the authority will inspect and review the past performance of such pharmacy. 2. The pharmacy Type 1 and Type 2 shall be renewed by the Provincial Department of Public Health but such renewal shall get prior consent from the Ministry of Public Health; while the pharmacy Type 3 shall be renewed by the Provincial Department of Public Health and report to the Ministry of Public Health.

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	0.00	200000.00
Comments	Reference: Presidential Edict 03/PR Certificate Fee shall be collected depending on the Type of the Pharmacy – Type 1 = 200,000 LAK; Type 2 = 160,000 LAK; and Type 3 = 100,000 LAK / 2 years			

RENEWAL FEES

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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	0.00	200000.00
Comments	Reference: Presidential Edict 03/PR Certificate Fee shall be collected depending on the Type of the Pharmacy – Type 1 = 200,000 LAK; Type 2 = 160,000 LAK; and Type 3 = 100,000 LAK / 2 years			

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Medicine and Medical Device (Revised)	07/ສພຊ	21.12.2011	Part III Medicine and Medical Device Business Chapter 1 Operation of Medicine and Medical Device (Article 12, 18)
Order on Retail Pharmacy Shop (Revised)	2922/ສທ	21.09.2016	Article 3, 5, 15, 19, 22 and 23

REQUIRED DOCUMENTS	
Document Name	Comment
Certificate for Enterprise Registration of Company Limited	
Site Inspection report	ໃບຢັ້ງຢືນການລົງກວດກາສະຖານທີ່ຂອງເຈົ້າໜ້າທີ່ກ່ອນອະນຸຍາດ
Criminal Certificate	
Certification of Health	
Location Map of the Enterprise	ແຜນວາດ ແລະ ແຜນຜັງສະຖານທີ່ຕັ້ງຮ້ານຂາຍຢ່ອຍຢາ
Photograph	ຮູບຖ່າຍຂະໜາດ 3x4 ຈຳນວນ 3 ໃບ
Education Qualification Evidence	ສຳເນົາໃບປະກາດສະນິຍະບັດ, ໃບຢັ້ງຢືນການຜ່ານງານ, ໃບຢັ້ງຢືນຂອງກົມກອງທີ່ສັງກັດໃນກໍລະນີເປັນພະນັກງານສັງກັດລັດ
Address Certification	

STATISTICS (Issue or/and renewed number)

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STATISTICS (Issue or/and renewed number)		
Year	Issued	Renewed
2016		

LIST OF ATTACHED DOCUMENTS		
Name of document	Type of document	File of document