

**Datasheet for business formalities.**  
**Technical Assistance for Business Regulation Review and Rationalization in Lao PDR**

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

REGISTRATION DATA		
Name of formality	License to Operate Foreign Medicine and Medical Device Distributor	
Type of formality	License	
Formality Code	Date of last modification	Responsible Authority
MoPH-FDD-8	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	The Foreign Medicine and Medical Device Distributor will represent the owner of the medicine and medical device that are operating in other countries and such company shall be the focal point for any communication with such company; therefore, it is necessary to keep record and registry of all these companies to prevent any possible risk to human health caused by foreign medicine or medical devices.
Who should complete this business formality?	Any person or legal entity that intends to operate as the representative and distributor of any foreign medicine or medical devices in Lao PDR.
The formality has online information?	YES
Link to online information	<a href="http://www.fdd.gov.la">http://www.fdd.gov.la</a>
The formality has an application form?	YES
Any additional comment concerning the formality	

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process	90	The application shall be submitted through the District Unit of Foods and Drugs or Food and Drug Office of the Provincial Department of Foods and Drugs where the company will be situated. Then, the

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REQUIREMENTS AND SUPPORTING EVIDENCE	
<b>the formality</b>	application will be assessed and approved by each level of authorities in the local before such application will be submitted to Department. Finally, the Minister of Ministry of Public Health shall execute this Formality.
<b>Qualifications needed by the business to get the formality</b>	1. The applicant shall have Lao pharmacist that has the Degree in Pharmacy field as issued by the relevant institutes either in Lao or from abroad and shall get a pharmacist permit from the Ministry of Public Health with at least 4-year working experience; and the applicant shall never been convicted of any crime relating to pharmacy or narcotic; 2. The applicant shall have the working area of at least 20 square metres that are separated from other area. 3. The applicant shall have clean and standardized storage with the total area of at least 4 x 8 metres and shall have all the necessary equipment for the storage pursuant to Good Whole Selling Practice.
<b>Is there any reason for the authority to deny the issuing of the formality?</b>	Deny in case that the applicant does not meet the required qualifications, in particular after an inspection by the relevant authorities.

RENEWAL INFORMATION	
<b>Does the formality have a validity or an expiration date?</b>	<b>How long will the formality be valid for? (in months)</b>
YES	24
<b>What is the process and conditions to renew the formality?</b>	The renewal shall be undertaken within 3 months before the expiration of the Formality.

ISSUING FEES				
<b>Has application fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Application fees businesses need to disburse</b>	<b>Total fees businesses need to disburse</b>
YES	0.00	200000.00	0.00	200000.00
<b>Comments</b>	Reference: Presidential Edict 03/PR			

RENEWAL FEES				
<b>Has renewal fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Renewal fees businesses</b>	<b>Total renewal fees businesses need to disburse</b>

**Datasheet for business formalities.**  
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RENEWAL FEES				
			need to disburse	
YES	0.00	200000.00	0.00	200000.00
<b>Comments</b>	Reference: Presidential Edict 03/PR			

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Order on the Establishment of Medicine and Medical Device Business Operation (Revised)	1820/ສທ	25.08.2017	Article 5, 9.2, 14, 17, 18, 24
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 and 14)

REQUIRED DOCUMENTS	
Document Name	Comment
Photograph	ຮູບຖ່າຍຂະໜາດ 3*4 ຈຳນວນ 3 ໃບ
Education Qualification Evidence	
Certification of Health	
Curriculum vate	ໃບຊີວະປະຫວັດຫຍໍ້ທີ່ມີຮູບຕິດ (ຮູບຖ່າຍບໍ່ໃຫ້ກາຍ 1 ປີ) ໃບຢັ້ງຢືນການອອກຈາກລັດຖະການ ຫຼື ໃບແຕ່ງຕັ້ງຂອງກົມກອງໃນກໍລະນີທີ່ເປັນລັດວິສາຫະກິດ
Permission to be the Distributor signed by the Parent Company	ສຳລັບສາຂາ ຫຼື ຕົວແທນຈຳໜ່າຍ
Feasibility Study	ບົດວິພາກກ່ຽວກັບການເຄື່ອນໄຫວທຸລະກິດດ້ານຢາແລະຜະລິດຕະພັນການແພດ, ສະໜອງຂໍ້ມູນຊື່ລະອຽດແລະແຫຼ່ງທີ່ມາຂອງຢາ ແລະ ຜະລິດຕະພັນການແພດ
Site Inspection report	ໃບຢັ້ງຢືນການລົງກວດກາສະຖານທີ່ຂອງເຈົ້າໜ້າທີ່ທີ່ກ່ຽວຂ້ອງກ່ອນການອະນຸຍາດ
Location Map of the Enterprise	ແຜນວາດກ່ຽວກັບທີ່ຕັ້ງ ສາຂາບໍລິສັດ/ໂຮງງານ
Criminal Certificate	ໃບແຈ້ງໂທດເລກທີ 3
Address Certification	ບໍ່ໃຫ້ກາຍ 3 ເດືອນ

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

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