

**Datasheet for business formalities.**

**Technical Assistance for Business Regulation Review and Rationalization in Lao PDR**

REGISTRATION DATA		
<b>Name of formality</b>	<b>License to Operate Medicine and Medical Device Import-Export Company</b>	
<b>Type of formality</b>	License	
<b>Formality Code</b>	<b>Date of last modification</b>	<b>Responsible Authority</b>
MoPH-FDD-9	03.10.2017	Food and Drugs Department

BACKGROUND DATA	
<b>Means of presentation</b>	At the Authority Offices
<b>Specific sector linked to the formality</b>	Q - Human health and social work activities
<b>Purpose for enforcing the business formality</b>	The Import-Export Company will be the first point of contact in case there is any problem or damage incurred from any medicine or medical device imported into Lao PDR; therefore, it is necessary to manage and control those companies in order to ensure that all the medicine and medical devices that will be imported and used will not cause any damage to the human health in Lao PDR.
<b>Who should complete this business formality?</b>	Any person or legal entity that intends to operate a Medicine and Medical Device Import-Export Company that carries the business of importing all the medicine and medical devices and registering all those products with the Department.
<b>The formality has online information?</b>	YES
<b>Link to online information</b>	<a href="http://www.fdd.gov.la">http://www.fdd.gov.la</a>
<b>The formality has an application form?</b>	YES
<b>Any additional comment concerning the formality</b>	

REQUIREMENTS AND SUPPORTING EVIDENCE		
<b>Time it takes to the authorities to process the formality</b>	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 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</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	

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<b>REQUIREMENTS AND SUPPORTING EVIDENCE</b>	
<b>the formality</b>	pharmacist permit from the Ministry of Public Health with at least 5-year working experience; and the applicant shall never been convicted of any crime relating to pharmacy or narcotic; 2. The applicant shall not import any products together with the medicine and medical devices; 3. The applicant shall have clean and standardized storage with the total area of at least 6 x 12 metres and shall have all the necessary equipment for the storage pursuant to Good Whole Selling Practice and Good Storage Practice. 4. The applicant shall have the working area of at least 20 square metres that are separated from other area.
<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.

<b>RENEWAL INFORMATION</b>	
<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.

<b>ISSUING FEES</b>				
<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	1000000.00	0.00	1000000.00
<b>Comments</b>	Reference: Presidential Edict 03/PR			

<b>RENEWAL FEES</b>				
<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 need to disburse</b>	<b>Total renewal fees businesses need to disburse</b>
YES	0.00	1000000.00	0.00	1000000.00
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LEGAL FRAMEWORK			
Name	Number	Date	Comment
Order on the Establishment of Medicine and Medical Device Business Operation (Revised)	1820/ສທ	25.08.2017	Article 4, 7, 8, 9.1, 14, 17, 18, 22
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, 14 and 16)

REQUIRED DOCUMENTS	
Document Name	Comment
Business Operation Report of the Parent Company for the Importation of Medicine	ໃບອະນຸຍາດຈາກບໍລິສັດທີ່ຕົນຈະເປັນຕົວແທນຈຳໜ່າຍ (ສຳລັບສາຂາ ຫຼື ຕົວແທນຈຳໜ່າຍ)
Feasibility Study	ບົດວິພາກກ່ຽວກັບການເຄື່ອນໄຫວທຸລະກິດດ້ານຢາ ແລະ ຜະລິດຕະພັນການແພດ, ສະໜອງຂໍ້ມູນຊີ້ລະອຽດ ແລະ ແຫຼ່ງທີ່ມາຂອງຢາ ແລະ ຜະລິດຕະພັນການແພດ
Site Inspection report	ໃບຢັ້ງຢືນການລົງກວດກາສະຖານທີ່ຂອງເຈົ້າໜ້າທີ່ທີ່ກ່ຽວຂ້ອງກ່ອນການອະນຸຍາດ
Location Map of the Enterprise	ແຜນວາດກ່ຽວກັບທີ່ຕັ້ງບໍລິສັດ, ສາຂາບໍລິສັດ/ໂຮງງານ, ຕົວແທນຈຳໜ່າຍ
Criminal Certificate	ໃບແຈ້ງໂທດເລກທີ 3
Education Qualification Evidence	ໃບປະກາດສະນິຍະບັດ
Photograph	ຮູບຖ່າຍຂະໜາດ 3x4 ຈຳນວນ 3 ໃບ (ຮູບຖ່າຍບໍ່ໃຫ້ກາຍ 1 ປີ)
Address Certification	ບໍ່ໃຫ້ກາຍ 3 ເດືອນ
Certification of Health	ບໍ່ໃຫ້ກາຍ 3 ເດືອນ
Curriculum vate	ໃບຊີວະປະຫວັດຫຍໍ້ທີ່ມີຮູບຕິດ (ຮູບຖ່າຍບໍ່ໃຫ້ກາຍ 1 ປີ) ໃບຢັ້ງຢືນການອອກຈາກລັດຖະການ ຫຼື ໃບແຕ່ງຕັ້ງຂອງກົມກອງໃນກໍລະນີທີ່ເປັນລັດວິສາຫະກິດ

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