

Datasheet for business formalities.

Technical Assistance for Business Regulation Review and Rationalization in Lao PDR

REGISTRATION DATA		
Name of formality	License to Operate Business relating to Narcotics and Psychotropic substances	
Type of formality	License	
Formality Code	Date of last modification	Responsible Authority
MoPH-FDD-14	18.10.2017	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	Narcotics and psychotropic substances are the medicines that have high risk that may cause adverse impacts on the users from the overdosed use or misuse of those medicines; therefore, it is mandatory to control, monitor and inspect the business operation of those medicine.
Who should complete this business formality?	Any person or legal entity that intends to import-export, produce, distribute or possess narcotics and psychotropic substances for the medical, pharmaceutical, scientific research, agriculture purposes or other legal purposes.
The formality has online information?	YES
Link to online information	www.fdd.gov.la
The formality has an application form?	NO
Any additional comment concerning the formality	1. Before the distribution or sale of any narcotics or psychotropic substances, those narcotics and psychotropic substances shall be registered with the Ministry of Public Health. 2. The Formality holder shall submit the annual plan for the import-export and production of those narcotics and psychotropic substances for approval by the Ministry of Public Health.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	90	The relevant legal act does not define the review period but the authority informed that the normal review process would not exceed 3 months.
Qualifications needed by the business to get	The applicant shall either be: (i) Licensed Medicine Production Factory or Medicine Import-Export Company for the importation-exportation and	

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REQUIREMENTS AND SUPPORTING EVIDENCE	
the formality	distribution business; (ii) Licensed Retail Pharmacy Shop Class I or Class II for the retailing sale pursuant to prescription; and (iii) Licensed Hospital for the distribution and sale pursuant to prescription.
Is there any reason for the authority to deny the issuing of the formality?	Deny in case that the applicant is not the licensed business operator under the relevant laws or in case that the narcotics and psychotropic substances will be used for purposes other than for legal purposes.

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
NO	0
What is the process and conditions to renew the formality?	Before each time of import-export, distribution of narcotics and psychotropic substances, the applicant shall get this 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	0.00	0.00	0.00
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	0.00	0.00	0.00
Comments				

LEGAL FRAMEWORK

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LEGAL FRAMEWORK			
Name	Number	Date	Comment
Order on the Management of Narcotics and Psychotropic Substances	456/ກຊສ	19.04.2006	Article 10 and Article 12
Law on Medicine and Medical Device (Revised)	07/ສພຊ	21.12.2011	Article 12
Order on the List of Narcotics and Psychotropic Substances	08/ກຊສ	04.01.2005	

REQUIRED DOCUMENTS	
Document Name	Comment
Request Letter	
Medicine Formula	

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

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