

Datasheet for business formalities.

Technical Assistance for Business Regulation Review and Rationalization in Lao PDR

REGISTRATION DATA		
Name of formality	License to Harvest Materia Medical Pharmacognosy Resources Listed in Class 1	
Type of formality	License	
Formality Code	Date of last modification	Responsible Authority
MoPH-FDD-13	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	In order to protect medical pharmacognosy resources, natural prosperity and assure the sustainable use of those resources, this Formality is required to avoid the illegal exploitation of medical pharmacognosy.
Who should complete this business formality?	Any person or legal entity that intends to excavate, harvest and hunt all the medical pharmacognosy that are originated in the nature and will be used as the raw material for the production of herbal or conventional medicine; provided that the Formality will only be required if those resources are listed in the Class 1 (the herbal resources that are scarce and likely to extinguish)
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	Formality holder shall comply with the agreement that they have with the Department relating to the restoration of ecosystem.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	90	The relevant law does not define the review timeline but the authority informed verbally that the maximum review period will not exceed 3 months.
Qualifications needed by the business to get the formality	The applicant shall submit the reforestation or offset plan for the resources that they will be exploiting and the applicant shall employ a proper methodology and technic to exploit and harvest in the right season to ensure a minimum impact and the sustainable expansion of those herbal resources.	
Is there any reason for	Deny in case that the herbal resources are about to extinguish or the	

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REQUIREMENTS AND SUPPORTING EVIDENCE	
the authority to deny the issuing of the formality?	reforestation / offset that the applicant proposed is not appropriate.

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?	

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	2000000.00	0.00	2000000.00
Comments	Reference: Presidential Edict No. 03/PR			

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
NO	0.00	0.00	0.00	0.00
Comments	Reference: Presidential Edict No. 03/PR			

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Instruction Implementing the Prime Minister Decree on Medical Pharmacognosy No. 155/PM	252/ກຊສ	06.06.2007	

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LEGAL FRAMEWORK			
Law on Medicine and Medical Device (Revised)	07/ສພຊ	21.12.2011	Article 13

REQUIRED DOCUMENTS	
Document Name	Comment
Request Letter	
Feasibility Study	
Certificate for Enterprise Registration of Company Limited	

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

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