

GENERAL INFORMATION	
Name of formality	Certificate of Imported Drug Formula Registration
Type of formality	Certificate
Date of last modification	19.11.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Those who are officially authorized to import international drugs for distribution in Lao PDR. The manufacturer or parent company that obtains the registration certificate from the relevant country to export drugs via a domestic agency that is officially authorized to operate an imported drug business, with the agreement between the two parties mentioned above.
Qualifications needed by the business to get the formality	A company operating a pharmaceutical business, a domestic pharmaceutical manufacturer obtains a license from the Ministry of Health.

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	
Provision on Medicine Registration	1441/MOPH	13.08.2003	

REQUIRED DOCUMENTS FORMALITIES		
Name	Type	Comment
#{SUPPORT_NAME}	#{SUPPORT_TYPE}	#{SUPPORT_COMMENT}

LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION		
Name of document	Type of document	File of document

\${ATTACHMENT_NAME}	\${ATTACHMENT_TYPE}	\${ATTACHMENT_FILE}
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LIST OF ATTACHED DOCUMENTS FOR RENEW APPLICATION		
Name of document	Type of document	File of document
\${ATTACHMENT_NAME_RENEW}	\${ATTACHMENT_TYPE_RENEW}	\${ATTACHMENT_FILE_RENEW}

MEAN OF PRESENTATION		
Means of presentation		
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	0	The application period is 6 months.

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	36
What is the process and conditions to get the formality?	
What is the process and conditions to renew the formality?	<p>Refer to the Edict on the Fees and Service Charges No. 003/POFor the license renewal, it shall meet the following conditions:</p> <ol style="list-style-type: none"> 1. Must be a person who has registered the drug in accordance with the prescribed conditions 2. The registration certificate must be renewed 3 months before the due date. 3. The authority will reject the license renewal in the cases:- <ul style="list-style-type: none"> Incomplete documents as specified in the application Form 3- Make no change when notified of some inaccuracies;- Drugs that are on the list of prohibited drugs in Lao PDR;- Drugs that the parent company has canceled or deregistered;- Drugs that the packagings and names have already been registered.

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	1500000.00	0.00	1500000.00
Comments	Refer to the Ordinance on the Fees and Service Charges No. 003/PO			
ADDITIONAL ISSUING FEES				
Additional fee names				
NO	0.00	0.00	0.00	0.00
Additional fee 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	100.00	600.00	0.00	700.00
Comments	Refer to the Ordinance on the Fees and Service Charges No. 003/PO			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				