

<b>GENERAL INFORMATION</b>	
<b>Name of formality</b>	Certificate of Imported Drug Formula Registration
<b>Type of formality</b>	Certificate
<b>Date of last modification</b>	19.11.2020
<b>Responsible Authority</b>	Food and Drugs Department
<b>Who should apply for this formality?</b>	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.
<b>Qualifications needed by the business to get the formality</b>	A company operating a pharmaceutical business, a domestic pharmaceutical manufacturer obtains a license from the Ministry of Health.

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

<b>REQUIRED DOCUMENTS FORMALITIES</b>		
<b>Name</b>	<b>Type</b>	<b>Comment</b>
#{SUPPORT_NAME}	#{SUPPORT_TYPE}	#{SUPPORT_COMMENT}

<b>LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION</b>		
<b>Name of document</b>	<b>Type of document</b>	<b>File of document</b>

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

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

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

<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	1500000.00	0.00	1500000.00
<b>Comments</b>	Refer to the Ordinance on the Fees and Service Charges No. 003/PO			
<b>ADDITIONAL ISSUING FEES</b>				
<b>Additional fee names</b>				
NO	0.00	0.00	0.00	0.00
<b>Additional fee comments</b>				

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