

<b>GENERAL INFORMATION</b>	
<b>Name of formality</b>	Permit of Imported Drugs Registration
<b>Type of formality</b>	Other
<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 the 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	Article 7 and 9

<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>

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

<b>MEAN OF PRESENTATION</b>		
<b>Means of presentation</b>	At the Authority Offices	
<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 3 months.

<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	6
<b>What is the process and conditions to get the formality?</b>	
<b>What is the process and conditions to renew the formality?</b>	The permit cannot be renewed and it can be used only once.

<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	100000.00	0.00	0.00	100000.00
<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>
NO	0.00	0.00	0.00	0.00
<b>Comments</b>				
<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>				