

<b>GENERAL INFORMATION</b>	
<b>Name of formality</b>	Certificate of Registration of International Drug Formula for Domestic Production
<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>	Domestic pharmaceutical factory.
<b>Qualifications needed by the business to get the formality</b>	1. For locally manufactured drugs, those who intend to produce drugs must submit an application for the production of a sample drug according to the Application Form 1. Once a permit for producing sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months.2. For imported drugs, those who intend to import drugs from abroad must apply for a permit to import a sample drug according to the Application Form 1. Once a permit for importing a sample drug is granted, the manufacturer shall submit the application for registration Form 2 within 3 to 6 months.

<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>
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Name of document	Type of document	File of document
#{ATTACHMENT_NAME}	#{ATTACHMENT_TYPE}	#{ATTACHMENT_FILE}

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	At the Authority Offices	
Address of authority	Food and Drugs Department, Ministry of Public Health	
Time it takes to the authorities to process the formality	0	Pursuant to the regulation on drug registration No. 1441/MOH, 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?	Pursuant to the Presidential Ordinance No. 003/PO.

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	600000.00	0.00	600000.00
Comments	Pursuant to the Presidential 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	100000.00	300000.00	0.00	400000.00
<b>Comments</b>	Pursuant to the Presidential 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>				