

<b>GENERAL INFORMATION</b>	
<b>Name of formality</b>	Import-Export-Transit Authorization of Drugs or Psychotropic Substances
<b>Type of formality</b>	Other
<b>Date of last modification</b>	17.12.2020
<b>Responsible Authority</b>	Food and Drugs Department
<b>Who should apply for this formality?</b>	Any individuals or organizations that intend to:- Import for production, distribution, or possession of drugs or Psychotropic Substances - Export- TransitMust obtain approval from the Ministry of Health first.
<b>Qualifications needed by the business to get the formality</b>	- Pharmaceutical factory and Import-Export of Pharmaceutical company which has been duly registered with the conditions that can import-export and distribution;- Pharmaceutical store class I and II which has been duly registered with the conditions that can retail in accordance with doctor's prescription;- State hospital at the central and local level or private hospital with a license in accordance with condition that can distribute or retail by a pharmacist as per doctor's prescription.

<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	Article 12
Order on the List of Narcotics and Psychotropic Substances	08/MOPH	04.01.2005	Article 1 and 2
Order on the Management of Narcotics and Psychotropic Substances	456/MOPH	19.04.2006	Article 9, 10, 11 and 12

<b>REQUIRED DOCUMENTS FORMALITIES</b>		
<b>Name</b>	<b>Type</b>	<b>Comment</b>

\${SUPPORT_NAME}	\${SUPPORT_TYPE}	\${SUPPORT_COMMENT}
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<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}

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

<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>	14	

<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>	In case the certificate is expired, the renewal of the license can be extended until 31 December of that year.

<b>ISSUING FEES</b>
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<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	0.00	3000.00	3000.00
<b>Comments</b>	Based on the recommendation from the authority			
<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	0.00	0.00	3000.00	3000.00
<b>Comments</b>	Based on the recommendation from the authority			
<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>				