

GENERAL INFORMATION	
Name of formality	Import-Export-Transit Authorization of Drugs or Psychotropic Substances
Type of formality	Other
Date of last modification	17.12.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	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.
Qualifications needed by the business to get the formality	- 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.

LEGAL FRAMEWORK			
Name	Number	Date	Comment
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

REQUIRED DOCUMENTS FORMALITIES		
Name	Type	Comment

\${SUPPORT_NAME}	\${SUPPORT_TYPE}	\${SUPPORT_COMMENT}
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LIST OF ATTACHED DOCUMENTS FOR FIRST TIME APPLICATION		
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	14	

RENEWAL INFORMATION		
Does the formality have a validity or an expiration date?		How long will the formality be valid for? (in months)
YES		6
What is the process and conditions to get the formality?		
What is the process and conditions to renew the formality?	In case the certificate is expired, the renewal of the license can be extended until 31 December of that year.	

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	0.00	3000.00	3000.00
Comments	Based on the recommendation from the authority			
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	0.00	0.00	3000.00	3000.00
Comments	Based on the recommendation from the authority			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				