

GENERAL INFORMATION	
<b>Name of formality</b>	Certificate of Registration for Domestic Manufactured Traditional Medicine
<b>Type of formality</b>	Other
<b>Date of last modification</b>	09.12.2020
<b>Responsible Authority</b>	Food and Drugs Department
<b>Who should apply for this formality?</b>	Applicants that are eligible to register the traditional medicine are factories, import-export companies that operate the business in traditional medicine, which are properly licensed by the health sector.
<b>Qualifications needed by the business to get the formality</b>	All procedures must in accordance with the regulations of the Ministry of Health

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	Article 13 and 15
Presidential Ordinance on Fees and Service Fees	003/PO	26.12.2012	Chapter IX, Article 45-47, Page 89-92

REQUIRED DOCUMENTS FORMALITIES		
Name	Type	Comment
\${SUPPORT_NAME}	\${SUPPORT_TYPE}	\${SUPPORT_COMMENT}

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	180	Each time the applicant has to submit Form 1 first, which will take 3 months to consider. After Form 1 has been considered, the applicant then will be able to submit Form 2 which will take 6 months to consider.

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?	Certificate of registration for Traditional Medicine is valid for 3 years; 3 months prior to the expiry date, the applicant must apply for the renewal in accordance with the documents required by Food and Drug Department.

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	100000.00	600000.00	5000.00	705000.00
Comments	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			

ADDITIONAL ISSUING FEES				
<b>Additional fee names</b>				
NO	0.00	0.00	0.00	0.00
<b>Additional fee comments</b>				

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	100000.00	600000.00	5000.00	705000.00
Comments	Ordinance on Fees and Service Charges, No. 003/PO, Dated 26.12.2012 (Chapter IX, Article 45-47, Pages 89-92)			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				