

GENERAL INFORMATION	
Name of formality	Certificate of Product Information Change
Type of formality	Certificate
Date of last modification	19.11.2020
Responsible Authority	Food and Drugs Department
Who should apply for this formality?	Owner of a pharmaceutical product (drug)
Qualifications needed by the business to get the formality	Owner of a pharmaceutical product (drug)

LEGAL FRAMEWORK			
Name	Number	Date	Comment
Law on Drugs and Medical Products (Amended)	07/NA	21.12.2011	
Provision on Medicine Registration	1441/MOPH	13.08.2003	

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}
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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	90	The application period is 3 months

RENEWAL INFORMATION	
Does the formality have a validity or an expiration date?	How long will the formality be valid for? (in months)
YES	0
What is the process and conditions to get the formality?	
What is the process and conditions to renew the formality?	Depends on the validity of the certificate

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	50000.00	0.00	0.00	50000.00
Comments	As advised by 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	50000.00	0.00	0.00	50000.00
Comments	As advised by the authority			
ADDITIONAL RENEWAL FEES				
Additional renewal fees names				
NO	0.00	0.00	0.00	0.00
Additional renewal fees comments				