REGISTRATION DATA		
Name of formality	**Certificiate for the Registration of Medicine**	
Type of formality	Certificate	
Formality Code	**Date of last modification**	**Responsible Authority**
MoPH-FDD-6	03.10.2017	Food and Drugs Department

BACKGROUND DATA	
Means of presentation	At the Authority Offices
Specific sector linked to the formality	Q - Human health and social work activities
Purpose for enforcing the business formality	In order to facilitate in the control and supervision of the production and importation of all the medicine in Lao PDR in order to ensure the safety, efficiency and quality of all the medicine that is one of the vital components for human life.
Who should complete this business formality?	Any person who produces and imports medicine for sale in Lao PDR; provided that the following medicines do not require this Formality: (i) medicine chemical that will be used as the raw material; and (ii) unprocessed herbal medicine.
The formality has online information?	YES
Link to online information	www.fdd.gov.la
The formality has an application form?	YES
Any additional comment concerning the formality	1. The Department will only accept the application once every week on Friday. 2. This Formality and the registration number shall be obtained before any production or importation of such medicine. 3. The holder of this Formality shall have sole and exclusive right to import such medicine into Lao PDR.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	180	The Medicine Registration Committee (as appointed by the Ministry of Public Health) is the authority that approves the registration but if such medicines are listed in the certified list of medicine approved and endorsed by the relevant lined agencies already, the Department can issue this Formality without getting any comment from the Committee.
Qualifications needed	The applicant shall either be: (i) the Licensed Medicine and Medical Devices	

REQUIREMENTS AND SUPPORTING EVIDENCE	
by the business to get the formality	Import-Export Company for the imported medicine that get the official license from the Ministry of Public Health; or (ii) the Licensed Medicine and Medical Devices Factory that get the official license from the Ministry of Public Health.
Is there any reason for the authority to deny the issuing of the formality?	Deny in the following circumstances: (i) the application package is incomplete; (ii) such medicine is listed in prohibited list; (iii) the registration of such medicine in the origin countries is revoked; (iv) such medicine that has not been registered in the origin country or has been registered for the period of less than 5 years; (v) such medicine has more than 3 active ingredients, except for the multi-vitamin medicine; or (vi) such medicine is similar or imitate other medicine that has been registered before.

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 renew the formality?	The renewal shall be undertaken within 90 days before the expiration of this Formality unless the registration will be revoked.

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	1500000.00	0.00	1500000.00
Comments	Reference: Presidential Edict No. 03/PR – The certificate fee shall be collected per ítem at the same rate for both the medicines that will be imported or produced domestically.			

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	1500000.00	0.00	1500000.00
Comments	Reference: Presidential Edict No. 03/PR – The certificate fee shall be collected per ítem at the same rate for both the medicines that will be imported or			

RENEWAL FEES	
	produced domestically.

LEGAL FRAMEWORK			
Name	**Number**	**Date**	**Comment**
Order on Medicine Registration	1441/ภฉส	13.08.2003	Article 2, 4, 7, 8, 9, 10, 11, 13 and 15
Law on Medicine and Medical Device (Revised)	07/สพฉ	21.12.2011	Article 13

REQUIRED DOCUMENTS	
Document Name	**Comment**
License to Operate Medicine and Medical Device Import-Export Company	
License to Operate Medicine and Medical Device Factory	
Medicine Formula	
Request Letter	

STATISTICS (Issue or/and renewed number)		
Year	**Issued**	**Renewed**
2016		

LIST OF ATTACHED DOCUMENTS		
Name of document	**Type of document**	**File of document**