REGISTRATION DATA		
Name of formality	**License to Operate Medicine and Medical Device Factory**	
Type of formality	License	
Formality Code	**Date of last modification**	**Responsible Authority**
MoPH-FDD-7	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	The owner of the medicine and medical device factory shall be fully responsible and liable for any damages incurred on any person from the use of the medicine or medical devices that they produced; therefore, it is necessary to manage and control those companies in order to ensure that all the medicine and medical devices that will be produced will not cause any damage to the human health.
Who should complete this business formality?	Any person or legal entity that intends to operate a factory that produces medicine and medical devices within Lao PDR.
The formality has online information?	YES
Link to online information	http://www.fdd.gov.la
The formality has an application form?	YES
Any additional comment concerning the formality	1. After the Department issued this Formality, the Industry and Commerce authority will then consier the application for the business registration of such enterprise. 2. For all the produced medicine and medical devices shall be subject to test that shall be approved by the Department and after completion of the successful test, those products shall be registered.

REQUIREMENTS AND SUPPORTING EVIDENCE		
Time it takes to the authorities to process the formality	45	The application shall be submitted through the District Unit of Foods and Drugs or Food and Drug Office of the Provincial Department of Foods and Drugs where the company will be situated. Then, the application will be assessed and approved by each level of authorities in the local before such application will be submitted to Department. Finally, the Minister of Ministry of Public Health shall execute this Formality.

REQUIREMENTS AND SUPPORTING EVIDENCE	
Qualifications needed by the business to get the formality	1. The applicant shall have Lao pharmacist that has the Degree in Pharmacy field as issued by the relevant institutes either in Lao or from abroad and shall get a pharmacist permit from the Ministry of Public Health with at least 5-year working experience; and the applicant shall never been convicted of any crime relating to pharmacy or narcotic. In case of foreign applicant, such applicant shall get the relevant pharmacy diploma from the institutes as endorsed by the Ministry of Public Health; 2. The location of the factory shall be free from any risk of contamination to environment; equipped with all the required standardized equipment and facilities to ensure the quality and safety of all the products; 3. The applicant shall have analysis lab with competent and experienced staffs sufficient to analyze all of their products; and 4. The applicant shall have standardized medicine storage for all the medicines and medical devices produced.
Is there any reason for the authority to deny the issuing of the formality?	Deny in case that the applicant does not meet the required qualifications, in particular after an inspection by the relevant authorities.

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 3 months before the expiration of the Formality; provided that the following documents shall be submitted: (i) request letter for the renewal; (ii) health certificate; (iii) land title deed of the factory; (iv) 1-year performance report and next-year plan; and (v) the former Formality.

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	500000.00	0.00	500000.00
Comments	Reference: Presidential Edict 03/PR			

RENEWAL FEES				
Has renewal fees?	**Service fees businesses need to**	**Certificate fees businesses need to**	**Renewal fees**	**Total renewal fees businesses**

RENEWAL FEES				
	disburse	**disburse**	**businesses need to disburse**	**need to disburse**
YES	0.00	500000.00	0.00	500000.00
Comments	Reference: Presidential Edict 03/PR			

LEGAL FRAMEWORK			
Name	**Number**	**Date**	**Comment**
Order on the Manufacture of Medicine and Medical Products	937/ภฉส	12.05.2004	Article 3, 4, 5 and 6
Law on Medicine and Medical Device (Revised)	07/สพฉ	21.12.2011	Part III Medicine and Medical Device Business Chapter 1 Operation of Medicine and Medical Device (Article 12, 14 and 15)

REQUIRED DOCUMENTS	
Document Name	**Comment**
Certificate for Enterprise Registration of Company Limited	
Land Title Deed	ใบຢັ້ງຢືนกำมะสิดเธือน ชุ ธ้าน
Copy of Passport	ใบຢັ້ງຢືนสำลับถินต่างปะเทด
Criminal Certificate	
Location Map of the Enterprise	แผนอาดที่ตั้งของโธงงาน และ แผนอาดพายในของโธงงาน
Photograph	ธูบถ่ายละขนาด 4*6 (บ่ทาย 1 ปี)
Address Certification	
Certification of Health	บ่ทาย 3 เดือน
Education Qualification Evidence	
Curriculum vate	ชีวะปะหวัดหย้ที่มิธูบติด

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

STATISTICS (Issue or/and renewed number)		
2016		

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