

**Datasheet for business formalities.**

**Technical Assistance for Business Regulation Review and Rationalization in Lao PDR**

REGISTRATION DATA		
<b>Name of formality</b>	<b>Approval of the Advertisement Content of Food, Medicine and Medical Device</b>	
<b>Type of formality</b>	Other	
<b>Formality Code</b>	<b>Date of last modification</b>	<b>Responsible Authority</b>
MoPH-FDD-12	03.10.2017	Food and Drugs Department

BACKGROUND DATA	
<b>Means of presentation</b>	At the Authority Offices
<b>Specific sector linked to the formality</b>	Q - Human health and social work activities
<b>Purpose for enforcing the business formality</b>	In order to ensure that the consumer will get an accurate and reasonable information about the products when they consume foods, medicine or medical devices that are the important factors / components for life.
<b>Who should complete this business formality?</b>	Any person or legal entity who intends to advertise or disseminate information relating to foods, medicine and medical device (including cosmetic products) in Lao PDR.
<b>The formality has online information?</b>	YES
<b>Link to online information</b>	<a href="http://www.fdd.gov.la">http://www.fdd.gov.la</a>
<b>The formality has an application form?</b>	YES
<b>Any additional comment concerning the formality</b>	For the advertisement of medicine, the anti-biotic medicine or other medicine that shall be prescribed by the doctor can only be disseminated in a limited scope of medical field, not to the general public.

REQUIREMENTS AND SUPPORTING EVIDENCE		
<b>Time it takes to the authorities to process the formality</b>	90	The relevant legal act does not define the review period but the Department informed the team that the normal review period is not more than 3 months.
<b>Qualifications needed by the business to get the formality</b>	1. The applicant shall either be: (i) the licensed import-export company; or the licensed factory; or the authorized distributor that gets the license from the Ministry of Public Health; 2. The contents for each products shall be accurate and contains the information as required under the Agreement No. 1494/MPH.	
<b>Is there any reason for the authority to deny</b>	Deny in case that the contents are: (i) inaccurate or exaggerated about its contents or its efficiency; (ii) not proven by any consumers or third party; (iii) in	

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<b>REQUIREMENTS AND SUPPORTING EVIDENCE</b>	
<b>the issuing of the formality?</b>	violation of good norms or traditions of the country; or (iv) the contents, photos and dissemination means are not in compliance with the principles defined by the Ministry of Public Health under the Agreement No. 1494/MPH.

<b>RENEWAL INFORMATION</b>	
<b>Does the formality have a validity or an expiration date?</b>	<b>How long will the formality be valid for? (in months)</b>
YES	12
<b>What is the process and conditions to renew the formality?</b>	The Formality for advertisement in publication shall be valid for 1 year. The Formality for advertisement in electronic media shall be valid for 3 months. The Formality for advertisement in the form of training, seminar or exhibition shall be valid only once.

<b>ISSUING FEES</b>				
<b>Has application fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Application fees businesses need to disburse</b>	<b>Total fees businesses need to disburse</b>
YES	0.00	100000.00	0.00	100000.00
<b>Comments</b>	Reference: Presidential Edict No. 03/PR Advertisement though publication = 50,000 LAK/year Advertisement via radio = 50,000 LAK/quarter Advertisement via television = 100,000 LAK/quarter Advertisement in the exhibition, seminar or website = 100,000/time			

<b>RENEWAL FEES</b>				
<b>Has renewal fees?</b>	<b>Service fees businesses need to disburse</b>	<b>Certificate fees businesses need to disburse</b>	<b>Renewal fees businesses need to disburse</b>	<b>Total renewal fees businesses need to disburse</b>
YES	0.00	100000.00	0.00	100000.00
<b>Comments</b>	Reference: Presidential Edict No. 03/PR Advertisement though publication = 50,000 LAK/year Advertisement via radio = 50,000 LAK/quarter Advertisement via television = 100,000 LAK/quarter Advertisement in the exhibition, seminar or website = 100,000/time			

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<b>LEGAL FRAMEWORK</b>			
<b>Name</b>	<b>Number</b>	<b>Date</b>	<b>Comment</b>
Order on the Management of Food, Medicine and Medical Device Advertisement	1494/ສທ	06.07.2016	
Law on Medicine and Medical Device (Revised)	07/ສພຊ	21.12.2011	Article 19 and 20

<b>REQUIRED DOCUMENTS</b>	
<b>Document Name</b>	<b>Comment</b>
Certificate for the Registration of Medicine	
Certificate for the Registration of Food	
Details of the Food / Drug Advertisement Method	ປະຫວັດຫຍໍ້ຂອງວິທະຍາກອນ (ປະຊຸມ, ສໍາມະນາ), ແຈ້ງສະຖານທີ່, ວັນເດືອນປີ ແລະ ຕາຕະລາງ (ປະຊຸມ, ສໍາມະນາ), ເປົ້າໝາຍ ແລະ ຈໍານວນຜູ້ທີ່ຈະເຂົ້າຮ່ວມ
Sample of Medicine or Food Advertisement	ຕົວຢ່າງເນື້ອໃນ ແລະ ຮູບການທີ່ຈະໂຄສະນາ (ເປັນພາສາລາວ, ຝະລັ່ງ ຫຼື ອັງກິດ), ຕົວຢ່າງຕາມຫົວໜ່ວຍມັດຕະຖານຂັ້ນທະບຽນ (ອາຍຸການນໍາໃຊ້ 6 ເດືອນຂຶ້ນໄປ)

<b>STATISTICS (Issue or/and renewed number)</b>		
<b>Year</b>	<b>Issued</b>	<b>Renewed</b>
2017		
2016		

<b>LIST OF ATTACHED DOCUMENTS</b>		
<b>Name of document</b>	<b>Type of document</b>	<b>File of document</b>