



PHARMACEUTICAL SECTOR

Lao industry profile

Prepared by
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PHARMACEUTICAL PRODUCTION



Similar to the rest of the healthcare industry, historically pharmaceutical production in Lao PDR has been monopolized by state-owned enterprises and only recently has been gradually opened for private sector investment. The Investment Law (2009) identified drug production as a promoted sector for private sector investment. It has, however, been removed from the list of promoted sectors in the latest updated Investment Promotion Law 2016¹.

As of August 2018, there are, in total, 1,449 drug items registered with the Lao Food and Drug Department². The Ministry of Health estimated that around 50% of the drugs in circulation in Laos (having a value of USD11.7 million) were manufactured locally in 2016³. Drugs produced in Laos are mainly essential medicines, whose patents have expired or are exempted under WTO agreements for LDCs. Laos does not export modern medicines; all local production is to serve the domestic market only, being used in a public hospital or being sold within one of more than 2,430 pharmaceutical stores in the country in 2016⁴. Currently, there are, in total, 8 pharmaceutical factories plus one herbal medicine factory and two medical product manufacturers in Laos. Medical product manufacturing in Laos involves mainly basic products such as compresses, injection needles and tubes or packaging of products.

According to The Study on Investment in Pharmaceutical Production in the Least Developed Countries - A Guide for Policy Makers and Investment Promotion Policy, UNTAD, 2011⁵, the last two decades have seen the global pharmaceutical industry reach a turning point when a number very successful drugs have their patents expired. This has forced a number of the large R&D-based, transnational corporations in developed countries to adjust their business models. Some of them have formed alliances through acquisition or joint venture with either smaller biotechnology firms or major generic drug manufacturers in developed or developing countries, with the intention of gaining access to new prospective medicines as well as lower costs of production and accessing the large market for generic drugs. Brazil, China and India are the primary developing countries leading global generic medicine production. China and India have become the main sources of foreign direct investment (FDI) in pharmaceutical production in LDCs, in particular in Africa and Asia.

China is already an important player in the Lao pharmaceutical industry. Chinese investment strongly influences both FDI and raw material importation used in pharmaceutical production in Laos. The aforementioned study further suggests that setting basic prerequisites to promote FDI in pharmaceutical industry are essential for Laos to safeguard access to essential and innovative medicines including:

1. Setting standards for human resources, e.g. pharmacists, and technicians
2. Basic infrastructure improvement – reliable power and clean water
3. An efficient functioning national drug regulatory authority supporting production and distribution
4. Timely and cost-effective access to key inputs, especially active pharmaceutical ingredients.

¹ http://www.investlaos.gov.la/images/IP_Law_2016_PDF/New_IP_Law_Amended_2016_for_Web_No.14_NA.17-11-2016.pdf

² Ministry of Health, Department of Food and Drugs (2016). List of Registered Medicines. Accessed at: http://fdd.gov.la/download/contents_documents/1463496546List%20of%20Drug%20Registration%20updated%20June%202016.pdf

³ Ministry of Health (2016) Annual report 2015-2016

⁴ IBID, p.62

⁵ http://unctad.org/en/Docs/diaepcb2011d5_en.pdf

Among others, government and institutional frameworks supporting local production are key elements to set up those prerequisites. This support should come in the form of a well-defined strategy and consistent set of policies regarding: common objectives, investment conditions and incentives, government procurement, drug registration, intellectual property rights protection and human resource development⁶.

It is the ECCIL's opinion that Laos can quickly provide some of the basics of each of the prerequisites mentioned above, especially number 2 and 4. Firstly, Laos already has the infrastructure in place to provide both reliable power and clean water in certain regions. Because of the prevalence of hydroelectric dams, Laos is seldom short of power. Further, its geographic position next to China – one of the main suppliers of pharmaceutical ingredients – allows for easier acquisition of pharmaceutical ingredients. There is, however, large room for improvement. In particular, the prerequisite number 3. From the experience of other countries with similar conditions as Laos, stronger national drug regulatory authorities can facilitate the establishment of better conditions for promoting and supporting investment in pharmaceuticals, the transfer of technology and the export of the products .

In its current form, the process of drug registration for both local products and imports normally takes longer than necessary and the MOH's capacity to conduct regular inspections of parallel and illegal products is also limited.

⁶ IBID

⁷ http://unctad.org/en/Docs/diaepcb2011d5_en.pdf

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PHARMACEUTICAL POLICY



Compliance with Good Manufacturing Practice (GMP) regulation is a requirement for all drug factories in Laos. The national GMP system has been recently developed, guided by ASEAN GMP standards. The enforcement of this compliance is yet to be fully implemented, however, there are currently only five factories that are certified for GMP by the Food and Drugs Department⁸.

Production and importation of drugs and medical equipment is primarily governed by the following pieces of legislation:

- The Law on Drug and Medical Products (amended), No 07/NA, dated 21 December 2011 (replaced the previous law adopted in 2000).
- Regulation No. 1820 on Pharmaceutical Import-Export Company, dated 25 August 2017, replaced the regulation no 1442/MOH, dated 13 August 2003; and
- Regulation No. 1441/MOH, dated 13 August 2003 on Medicine Registration
- Regulation No.1171/FDD, dated 19/01/2015 on List of Prohibited Drugs

The Medical Products Supply Centre is the authority in charge of procurement and supply of essential drugs and medical equipment for the public healthcare network including centrally located and provincial hospitals, community hospitals and village healthcare centres⁹. The Centre also sets technical specifications and possess a pre-selection of suppliers to be contracted by the hospitals for the items that hospitals buy directly.

The centralised procurement of drug and medical equipment has been implemented since 2009. In 2017, the programme covers four provincial hospitals in Savannakhet, Champasak, Xekong and Attapeu¹⁰. The MOH plans to roll out the centralised procurement nationwide by 2019. As of today, most of the hospitals still individually conduct the purchase of drugs, exempted essential drugs, and medical equipment.

The government procurement of drugs and medical equipment 2016 was summarised as follows¹¹:

- 783 drug items, signed with 23 suppliers for a value of USD 6,5 million
- 876 medical products, signed with 12 suppliers for a value of USD 5,1 million
- 939 Chemical items, signed with 14 suppliers for a value of USD 4,5 million

The procurement of medicines is done along the following steps:

1. Select qualified suppliers to be listed and allowed to participate in the next step of the bidding process on pricing competition
2. Submit Technical specifications and price offers by the selected suppliers to the procurement committee

⁸ Annual Report 2015-2016, Ministry of Health, 4.1.1 (only Lao language available) reported four factories, plus one new factory "Tongmeng (lao) Pharmaceutical Co.,ltd" <http://www.fdd.gov.la/showaFullnews.php?newsID=96>

⁹ ECCIL staff's interview with Mr. Thanom INSAL, Head of Medical Products Supply Center, Ministry of Health, LAO PDR on 01 September 2017

¹⁰ IBID

¹¹ Ministry of Health (2016) Health Sector Report 2015-2016, page 73

3. Contracts are signed between the Centre or hospitals with the awarded suppliers based on agreed technical specification, quantity and prices.

Government procurement uses the state budget, as provisioned in the Decree No.03/PM, granting privileges to local suppliers, in particular for the purchase of drugs and medical equipment. To be allowed to participate in the bidding process, companies must already be legally registered in Laos. This is to guarantee that suppliers can ensure after sales services and maintenance in a timely manner due to a limitation of foreign language use in the country. The companies that do not have an official entity in Laos but wish to sell their products to Lao healthcare system are suggested to partner with local suppliers¹².

Procurement of drugs and medical devices using ODA funds is conducted directly by the projects following the donors' procurement regulations. In general, the procurement regulations of multilateral donors adhere to standards of openness and transparency. Capital investment in public hospitals supported by some bilateral donors is often bundled into packages and the inputs are selected from the sources within the country of origin of the donors.

Currently, the announcements on state procurement of drug and medical equipment is only made available in the printed media. There is no centralised online platform providing information on government procurement. The announcement for participating in the pre-selection in the procurement tender of drug 2018 has been announced in the local Newspaper, the Vientiane Mai in August 2017. European companies have found it difficult to participate in the government procurement of drugs and medical devices - in particular heavy and specialised medical equipment - because of the weakness of Laos' existing public procurement system, which is not yet in line with international procurement practices.

Currently, there are two regulations that set the fees for drug registration: MOH's regulation No. 1441/MOH and the President's Edict on Fees and Service Charges No. 003/PO (Article 1 - 64)¹³. Inconsistently, both regulations indicate different fees for registration of pharmaceutical drugs. The Department of Drugs and Food, however, confirmed that the fee rates of MOH's regulation No. 1441/MOH are currently applied; for instance USD 30 for registration of one type of modern drug produced locally and USD 100 for one type of imported modern drug item.

Further inconsistencies in regulation create challenges for investment into the pharmaceutical industry. For instance, the Ministry of Industry and Commerce's List of Conditional Business for Foreign Investors (List D 02, 2015, currently under review) only allows foreign investors to hold a maximum 49% share in pharmaceutical manufacturing (ISIC 2100). This ownership limitation does not reflect actual practice. Foreign investors do, in some cases, own 100% in pharmaceutical factories; for example, Kodupha is 100% owned by a Vietnamese investor¹⁴.

¹² ECCIL staff's interview with Mr. Thanom INSAL, Head of Medical Products Supply Center, Ministry of Health, LAO PDR on 01 September 201

¹³ Lao PDR Trade Portal. Accessed at: <http://www.laotradeportal.gov.la/index.php?r=tradeInfo/view&id=8969>

¹⁴ Appendix 9

03

PHARMACEUTICAL IMPORT & DISTRIBUTION



Due to the limited capacity of local pharmaceutical production, which is limited primarily to essential medicines, imported drugs are necessary to fulfill the population's healthcare requirements. Thailand is the main source of Laos' imports of drugs, accounting for 40% of total imported drugs registered in 2017¹⁵.

Laos has a total of 81 companies that are permitted to conduct the import-export and distribution of drugs and medical equipment. Pharmaceutical distribution is allowed for several operators, such as domestic manufacturers and authorised importers, wholesalers, retailers, public hospitals, private pharmacies and clinics. All drugs and medical equipment imported into and distributed within Laos is required to be registered and labeled in Lao language. The price of medicines distributed in Laos is not controlled.

Import tariffs for pharmaceutical products and medical equipment within the ASEAN region range between 0 and 5% (0% under ASEAN Trade in Goods Agreement (ATIGA))¹⁶. Obtaining accurate statistics of drug importation is a challenge. According to the statistics of the Ministry of Industry and Commerce, Laos imported Pharmaceutical drugs (HSCODE¹⁷ 30) to the value of USD 15 million in 2016¹⁸. On the other hand, the Ministry of Health reported that Laos imported medicines to the value of USD 30 million in 2016¹⁹. Both figures are inconsistent with the International Trade Centre's mirror data on Lao import of drugs in 2016, which values the same items at USD 19 million.

Drugs imported from the EU are estimated to account for around 12% or 186 drug types registered with the MOH²⁰. The statistics of the Directorate General for Trade of the European Commission reports the value of pharmaceutical products (both medicines and medical equipment) exported to Laos to be EUR 8 million in 2016²¹. European products are well recognised for the quality by Lao healthcare professionals.

DKSH and Memesco are the two European companies that handle the import and export of pharmaceutical products in Laos. DKSH Laos, established in 1995²², is the largest distributor and wholesaler of pharmaceutical drugs and light medical products in Laos.

VAMED is an Austrian health technology company that was established in Laos in 2011 to provide planning, supply and installation of medical equipment at Mahosot Hospital. The company is further contracted to support an extension of the "Friendship Hospital" to setup a new radiation therapy centre there, which was officially launched in January 2017. The service included installing civil, electrical and mechanical and sanitary, radiotherapy equipment (Linear Accelerator, CT Simulator Unit, planning and related hardware & software), equipment for examination room, doctor's offices, hospital and office furniture, staff training etc.

¹⁵ See Appendix 2.

¹⁶ Lao PDR Trade Portal. Accessed at: <http://www.laotradeportal.gov.la/index.php?r=tradeInfo/index>

¹⁷ HS CODE is a coding system for all imported and exported goods developed by the World Customs Organization. For more information see the following link: <http://www.wcoomd.org/en/topics/nomenclature/overview/what-is-the-harmonized-system.aspx>

¹⁸ Import-Export Department of the Ministry of Industry and Commerce (2017)

¹⁹ Ministry of Health (2016) Health Sector Report 2015-2016, page 63

²⁰ Appendix 9)

²¹ http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_113410.pdf

²² DKSH. Accessed at: <http://www.dksh.com/la-en/home>

The government's ability to monitor and inspect illegal importation at the border is generally weak²³. The MOH conducted random inspections of 25,909 drug items (at provincial and district hospitals, pharmaceutical stores, and private clinics) and found that about 20% of these drug items are not registered²⁴. The Trade Working Group under Lao Business Forum 2016's estimated up to 50% of the drugs circulated in Laos are not officially registered. The unregistered drugs include both parallel imports and counterfeit products. Consumption of parallel import and counterfeit products can post serious health risks to the population. In the longer term, higher levels of parallel importing are likely to discourage investment by multinational pharmaceutical companies in the domestic market²⁵. This is an area where great strengthening is needed. Increased cooperation with the private sector, especially with the official drug importers, to monitor the distribution of parallel import and counterfeit products would also benefit Laos.

²³ ECCIL Phama group meeting notes November 2017

²⁴ Ministry of Health (2016) Health Sector Report 2015-2016, page 81

²⁵ ECCIL Phama group meeting notes November 2017

04

DIFFICULTIES EXPERIENCED BY THE PRIVATE SECTOR IN PHARMACEUTICAL INDUSTRY



Business operators have raised concerns over the long processes of drug registration, parallel imports and counterfeit drugs checks and a lack of necessary facility to store drugs as the main problems for drug and medical equipment importation²⁶.

- The drug registration process can take between 6 to 24 months to be completed²⁷. In addition, about 1 to 3 months is needed to get import permission for certain drug products. Such a lengthy process is regarded as the main barrier for businesses to legally import drugs into Laos²⁸. Some players, therefore, prefer selling their products illegally across the borders rather than through official channels into Laos. The lengthy process also frustrates local buyers, many of whom have become willing to take on the risks of parallel importation²⁹.
- Currently the importation of vaccines into Laos is not well guaranteed due to a lack of basic facilities, such as cold chain supply and storage. These are essential to keeping the vaccine in a suitable environment so as to maintain the vaccine's quality during customs clearance which could take several days³⁰.

²⁶ ECCIL Phama group, and the Trading working group under Lao Business Forum

²⁷ The trading working group under Lao Business Forum, 2016

²⁸ ECCIL Phama group meeting notes November 2017

²⁹ IBID

³⁰ IBID

Appendix 1: List of Pharmaceutical Factory in Laos, 2017

	Factory Name	Investors	Location	Capital (USD)	Remarks
1	Pharmaceutical Factory No.2	State Owned Enterprise	Vientiane		The oldest factory that is located near the center of Vientiane which limits its capacity to renovate and expand their production capacity.
2	Pharmaceutical Factory No.3,	State Owned Enterprise	Vientiane		100 items such as V. Infusions Group, oral tablet include beta-lactam group, and Oral syrup for pediatric use. GMP certified by MOH
3	CBF Pharmaceutical Factory	SOE, 1995 20%-80%	Pakse	3.5 M	http://www.cbfpharma.com/index.php?r=site/index GMP certified by MOH
4	Kodupha	100% by Vietnam	Vientiane		N/A GMP certified by MOH
5	KPN	Lao private	1992		http://www.kpn-pharma.com/ Certified ISO 9001:2008 & GMP from URS certification system. More than 60 products such as Flusa, Galno, Herolmycin, Roben, paracetamol.
6	Pharmaceutical Factory 104	Military	Vientiane		N/A
7	Chinchieng	Chinese	Luang Namtha		N/A GMP certified by MOH
8	Tongmeng (lao) Pharmaceutical Co.,Ltd	Lao-Chinese private (90%)	Vientiane		36 medical products registered in 2017
9	VT Greater Pharma Co., Ltd	Thailand's Greater Pharma Co., Ltd. and Laos' Viengthong Pharma Co., Ltd.	VITA Park Vientiane		Herbal health and cosmetics products for Laos and other countries. Commercial production in 2017

Appendix 2: Origins of medicines registered in Laos 2017, FDD, Ministry of Health,

Country of origin	Medicine types
Thailand	616
Laos	234
European Union	186
Malaysia	148
India	92
Pakistan	77
China	53
Vietnam	47
Korea	41
Bangladesh	39
Total	1,542



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