

**TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS  
(PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)**

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**REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES**

**1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

In Laos, the import, export, wholesale and retail distribution of drugs and medical products are primarily governed by the following laws and regulations:

- The Law on Drugs and Medical Products No. 85/NA, dated 25 June 2025, which sets out requirements for the registration, import, export, wholesale and retail distribution of drugs and medical products.
- The Decision on Business Establishments for Drugs and Medical Products Companies No. 1820/Ministry of Health (MoH), dated 25 August 2017, which prescribes the licensing conditions for importers, exporters, distributors and wholesalers of drugs and medical products.
- The Decision on Retail Pharmacies No. 2992/MoH, dated 21 September 2016, which regulates the operation of retail pharmacies.
- The Decision on the Registration and Notification of Medical Devices No. 1470/MoH, dated 11 July 2023, which introduces a risk-based classification system for medical device registration and notification, aligned with the principles set by the Association of Southeast Asian Nations (ASEAN).
- The Decision on the Registration of Modern Drugs No. 0622/MoH, dated 2 April 2025, which provides guidelines on the registration of modern drugs.
- The Decision on the Registration of Traditional Medicines No. 169/MoH, dated 25 January 2022, which provides guidelines for the registration of traditional drugs.
- The Decision on Drugs and Medical Products Price Management No. 3708/MoH, dated 21 December 2022, which sets guidelines on pricing for drugs and medical products.
- The Law on Consumer Protection No. 02/NA, dated 30 June 2010, which applies to a registered enterprise that is selling drugs and medical products to consumers in Laos.

The Food and Drug Department (FDD) within the MoH is the competent authority responsible for implementing and enforcing these regulations. As Laos is a unitary state, regulatory authority over drugs and medical products is centralised under the MoH, while provincial and district health offices are delegated enforcement responsibilities, but do not have independent rule-making powers.

Apart from the abovementioned specific laws and regulations, if business operators engage in wholesale and retail activities in partnership with foreign investors they must also comply with the Decision on Wholesale and Retail Business No. 1005/ Ministry of Industry and Commerce

(MoIC) DDT, dated 22 May 2015. The competent authority governing wholesale and retail business according to this Decision is the MoIC.

**2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences are attached to each classification with respect to trade and distribution? In particular, is the completion of a premarket review and approval process required by a competent authority?**

According to Article 11 of the Law on Drugs and Medical Products, drugs are classified into modern drugs and traditional drugs, while products deemed to be medical products include medical devices, health supplements, cosmetics, chemicals used in the health sector and hazardous household chemicals. As Lao law does not define the term ‘therapeutic products’, and based on our understanding that therapeutic products refer to items intended to prevent or treat diseases or medical conditions in humans, we will, for the purpose of this survey, focus exclusively on drugs and medical devices. Accordingly, we will use the term ‘drugs and medical devices’ instead of ‘therapeutic products’ to ensure alignment with Lao legal terminology.

Modern drugs are further divided into chemical drugs and biological drugs, with certain drugs designated as specially controlled modern drugs. Controlled modern drug are classified into four categories: drugs that are distributed and used according to a prescription issued by a doctor; drugs that are distributed and used under the control of a pharmacist; drugs that are distributed and used without a doctor’s prescription; and narcotics and dangerous drugs whose distribution and use are strictly controlled.

Traditional drugs comprise original traditional drugs and new traditional drugs, which must be used in compliance with the relevant technical principles under the supervision of qualified traditional medicine practitioners or trained medical personnel.

Medical devices are classified by the Law on Drugs and Medical Products and Decision No. 1470 into four risk-based classes (A–D), consistent with ASEAN principles: Class A (low risk), Class B (low–moderate risk), Class C (moderate–high risk) and Class D (high risk). The principles for risk classification are set out in Article 13 of Decision No. 1470. Devices classified as Class B, C and D must be registered with the FDD, while Class A devices require notification to the FDD.

In all cases, the completion of a premarket review and approval process by the competent authority, the FDD, is mandatory. Drugs and medical products must be registered or notified with the FDD before being imported or distributed in Laos to ensure compliance with the applicable safety and quality standards prior to market entry.

**LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS**

**3. What licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practice, facility standards, personnel-related requirements, insurance or financial guarantees) are attached to them?**

To engage in the wholesale distribution of drugs and medical devices in Laos, a business must obtain an enterprise registration certificate from the MoIC and a business operating licence from the MoH. To obtain a business operating licence, the business must comply with the following key conditions:

- hold an enterprise registration certificate;

- engage an authorised pharmacist, a graduate within any pharmacy field or a related discipline, who has the appropriate knowledge and experience;
- maintain suitable capital, premises, equipment and resources;
- the company’s products must be designed and developed according to the principles of good manufacturing, good wholesale, good retail, good storage and good laboratory practices, according to the guidelines issued by the MoH; and
- any other applicable conditions, as specified by the relevant laws and regulations, must be met.

According to Decision No. 1820, wholesalers must operate as an import–export company, a pharmaceutical factory branch, a company branch or sales agent or a domestic wholesale company that specifically supplies pharmaceutical products. This Decision provides detailed conditions that wholesalers of drugs and medical products must meet, which vary depending on the nature of the business (eg, import–export, branch, sales agent, domestic wholesale). Key conditions cover multiple aspects, including personnel qualifications, facility standards, storage and transportation requirements, as well as mandatory documentation.

Additionally, wholesalers with foreign shareholding must comply with Decision No. 1005, which requires them to obtain a business operating licence for wholesale activities. According to this Decision, a wholesaler with foreign investment must have a minimum registered capital of at least LAK 4bn (approx. \$187,000). The permitted proportion of foreign shareholding varies depending on the amount of registered capital.

It is important to note that wholesalers must ensure that the drugs and medical products they sell have been duly registered or notified with the FDD.

**4. Are there any distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?**

To engage in the retail distribution of drugs and medical devices in Laos, a retailer must obtain an enterprise registration certificate from the MoIC and a pharmacy registration certificate from the MoH. In addition, the retailer must employ qualified professionals who are authorised by the MoH and must comply with the requirements set out in Decision No. 2992. Furthermore, any retailer partnering with a foreign investor is required to obtain a business operating licence for retail activities, which is issued by the MoIC.

For online retailers, compliance with the Decree on Electronic Commerce No. 296/GOV, dated 12 April 2021 (the ‘E-Commerce Decree’), is also mandatory. According to this Decree, all e-commerce operators in Laos, including businesses selling through their own online platforms or via electronic marketplaces, must notify the MoIC of their e-commerce activities and obtain an official e-commerce acknowledgment certificate.

**5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?**

The sale of therapeutic products to consumers over the internet, including through social media and electronic marketplace platforms, is subject to the same regulatory framework outlined in response to question one, together with the provisions set out in the E-Commerce Decree.

**IMPORT**

<b>6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?</b>
<p>Under Lao law, drugs and medical devices (excluding Class A) must be registered with the FDD prior to their importation and distribution. In addition to registration, an import permit must be obtained before bringing these products into the country, and companies are required to hold a valid pharmaceutical business licence covering import and export activities.</p> <p>Drugs and medical devices are classified according to the ASEAN harmonised tariff nomenclature (AHTN) and the harmonized system (HS) codes, established by the World Customs Organization (WCO). Import duties range from zero per cent to 40 per cent, depending on the product’s classification and any applicable trade agreements. A ten per cent value-added tax (VAT) may also be imposed.</p> <p>Risk-based inspections are carried out at entry points (customs checkpoints), with cooperation between customs, the FDD and the MoIC in regard to the relevant verification of licences, registrations and labelling.</p> <p>Since 9 January 2024, the MoH has implemented an online process for obtaining import permits for therapeutic products through the National Single Window System. This platform allows licensed import–export companies to submit applications and receive import permits electronically, thereby streamlining regulatory procedures, reducing processing time and improving the overall efficiency and transparency of the importation process.</p>
<b>7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?</b>
<p>Under Article 10 of the Law on Drugs and Medical Products, individuals are permitted to possess drugs for personal use when traveling to Laos. However, the law does not specify any quantitative limits or include any detailed conditions for such personal imports.</p>
<b>8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?</b>
<p>Under Lao law, foreign suppliers are strictly prohibited from shipping drugs and medical devices directly to consumers via e-commerce platforms or mail order. All such products must be registered prior to importation and imported exclusively through locally licensed pharmaceutical import–export companies. These licensed entities are responsible for completing the product registration process with the FDD, obtaining an import permit for each shipment, ensuring that product labelling complies with the relevant regulatory requirements and includes the FDD registration number, as well as distributing products in accordance with the legal requirements. Direct-to-consumer shipments by foreign suppliers are strictly prohibited under Lao law. Furthermore, pursuant to the Law on Drugs and Medical Products, the online sale or purchase of modern and traditional medicines through social media platforms is expressly prohibited.</p>
<b>9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual</b>

**property rights, product re-labelling or re-packaging and requirements to maintain the product’s original quality, safety and traceability?**

The parallel importation of drugs and medical devices in Laos is permitted subject to strict regulatory conditions. Businesses must comply with the following requirements:

- Trademark protection: only trademarks registered in Laos are protected under the Law on Intellectual Property.
- Authorisation: when importing products registered by another company, the importer must obtain an official letter of authorisation from that company to act as its representative.
- Labelling: all products must bear labelling in Lao or a foreign language and such labelling must be approved by the FDD.
- Registration and import permits: all therapeutic products (except Class A medical devices) must be registered with the FDD and accompanied by a valid import permit prior to importation.
- Quality, safety and traceability: importers are required to maintain the original quality and safety of all of the products that they import. Comprehensive records, including batch numbers, expiry dates and sources, must be retained for a minimum of five years to ensure full traceability. Where re-examination is required prior to distribution, such testing must be conducted and certified by the MoH or by a regionally or internationally recognised institution. Additionally, the FDD-issued registration number must be clearly displayed on product labels before distribution.
- Prohibitions: importing unregistered products, counterfeit goods or products with altered packaging that compromises the integrity of the product is strictly prohibited.

**EXPORT**

**10. Are there any quantitative quotas, permits or other measures that restrict or apply conditions to the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

There are currently no published quantitative export quotas for drugs and medical devices under Lao law in ordinary circumstances. However, exports are subject to regulatory control through a permit system, which allows the MoH to intervene and restrict exports when necessary, for example, to mitigate shortages or address public health emergencies.

Under the Law on Drugs and Medical Products, any company wishing to export therapeutic products must hold a valid import–export licence and ensure that all products are fully registered with the FDD. Export permits are issued on a case-by-case basis, and compliance with the registration requirements is strictly enforced. This framework enables the MoH to monitor and, if required, limit exports to safeguard domestic supply.

**11. Is there any form of ‘export-only’ or ‘dual-labelling’ authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing purposes and, if so, what standards, labelling or record-keeping obligations apply?**

There is no legal provision in Laos allowing unregistered products to be manufactured or exported under an ‘export-only’ or dual-label framework. All therapeutic products require:

- full registration with the FDD;
- appropriate licensure for import–export activities; and
- compliance with strict labelling requirements that are applicable to both domestic and export markets.

## **LABELLING, TRACEABILITY AND PRODUCT INFORMATION**

### **12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products are allowed to circulate domestically or before therapeutic products may be exported?**

According to Articles 49 and 53 of the Law on Drugs and Medical Products, before imported drugs and medical devices are allowed to circulate domestically or be exported, they must be registered or notified with the MoH. Registration or notification requires the submission of specific information, such as the product name, ingredients or formula, strength, packaging unit, international code, source and other relevant information.

Labels applied to imported and exported drugs and medical devices must be in Lao language and/or a foreign language approved by the MoH, and the registration number issued by the FDD must appear on all of the labels and containers used to protect registered medicines.

Business operators are strictly prohibited from distributing counterfeit or improperly imported products. Any counterfeit or non-compliant drugs and medical products must be destroyed in accordance with MoH regulations, with all of the costs borne by the responsible business entity.

## **PRICING, REIMBURSEMENT AND MARKET ACCESS**

### **13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

Lao law establishes several regimes that, while not trade measures, may materially influence the distribution channels and availability of drugs and medical devices, as detailed below:

- Price control mechanism: Decision No. 3708 requires wholesalers and retailers of drugs and medical products to publicly display the relevant prices and prohibits them from setting prices higher than those notified by the manufacturers or importers to the government. This regime impacts the relevant pricing structures, profit margins and stock decisions made by such companies, thereby influencing distribution.
- Reference pricing and emergency controls: Decision No. 3708 empowers the FDD to determine referenced prices based on domestic and international market data. These average prices serve as benchmarks for procurement purposes and for setting charges within health facilities that participate in health insurance and social security schemes. In emergencies, the MoH may impose additional measures, such as establishing price structures, fixing maximum or minimum prices and adjusting supply and demand.

- Public procurement rules: the procurement of medicines and medical products by state-run medical facilities must comply with the Law on Public Procurement No. 30/NA, dated 2 November 2017 and related regulations, which include provisions favouring drugs and medical devices produced domestically. This requirement influences supplier distribution priorities.

## ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

### 14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

Pursuant to the Law on Drugs and Medical Products, the FDD, as the regulatory authority responsible for drugs and medical devices in Laos, possesses broad enforcement powers to address non-compliance with the applicable trade and distribution regulations governing these types of products. These powers include:

- Investigative powers: on-site inspections, document reviews, sampling and audits to verify compliance.
- Sanctions and remedial measures:
  - administrative: re-education (training on compliance with Lao laws and regulations), formal warnings and administrative fines;
  - civil: compensation for damages caused by non-compliance; and
  - criminal: penalties, including prosecution, for serious violations in accordance with the applicable laws.

In addition, pursuant to Decision No. 0622 and Decision No. 1470, the manufacture, importation and distribution of drugs and medical devices that are not registered or notified with the FDD will result in a formal warning and a fine equal to 100 per cent of the value of the unregistered products.

Further, pursuant to Decision No. 169, the following progressive enforcement measures apply:

- First violation: a formal warning and a written record of the violation.
- Second violation: a formal warning, a fine equal to 100 per cent of the value of the traditional medicine sold per item and closure of the business for 12 months.
- Third violation: confiscation of the product, a formal warning, a fine equal to 200 per cent of the value of the traditional medicine sold per item and permanent closure of the business.

### 15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of the trade, distribution or cross-border movement of therapeutic products in the future?

Yes, several recent developments in Laos are set to significantly reshape the regulation of the trade, distribution and cross-border movement of drugs and medical devices, as follows:

#### Online drug registration

On 10 November 2025, the FDD issued Notice No. 5960, introducing a mandatory online registration system for drugs, effective from 1 January 2026. This digital platform replaces paper-

based procedures and centralises drug registration, renewal and amendment-related processes. This initiative marks a significant step towards the digitalisation of regulatory processes in Laos.

### **Expanded scope for advanced therapeutics**

On 22 November 2024, the MoH issued Decision No. 3730, which became effective as of 18 January 2025, establishing a regulatory framework for biopharmaceuticals, gene therapies and stem cells. This law introduces facility standards, import–export controls, the required personnel qualifications and ethical sourcing rules, signalling an emerging focus on advanced therapeutic products.

### **Medical device registration**

The registration of medical devices in Laos is referenced in the Law on Drugs and Medical in 2011. However, a formal registration procedure was not previously in place. Historically, importers were only required to submit certain documents when importing medical devices.

In July 2023, the MoH issued a decision establishing a registration and notification process for medical devices through the FDD, aligning with the regulatory principles set out in the ASEAN Medical Device Directive (AMDD) of 2015, which Laos has ratified.

Subsequently, on 25 October 2023, the FDD issued a notification outlining its strategic plan for the phased implementation of the relevant registration and notification requirements for medical devices, as follows:

- Phase 1 (effective 1 January 2024): registration required for Class C (moderate–high risk) and Class D (high risk) devices. Operators handling Class A (low risk) and Class B (low–moderate risk) devices were permitted to continue applying for import permits without registration or notification.
- Phase 2 (effective 1 January 2025): notification required for Class A devices and registration required for Class B devices.

These developments collectively indicate a significant regulatory shift towards stricter compliance, digitalisation and alignment with international standards, which will impact the trade, distribution and cross-border movement of drugs and medical devices in Laos.