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?

The (Amended) Law on the Management of Pharmaceuticals (first adopted in 1996, and amended in 2007) broadly governs the import, wholesale distribution, retail sale, and export of therapeutic products in Cambodia.

Lower ministerial regulations (called 'Prakas') are adopted to implement the overarching law, frequently providing the practical guidance required to comply with the obligations set in the law.

The Prakas often specifically address the rules and procedures per product category, for example Prakas No. 1258 (8 November 2012) on the Procedures for the Registration of Medical Devices, specifically regulating medical device registration, and classification.

The main authority in Cambodia regulating the therapeutic products industry is the Ministry of Health (MoH). The Department of Drugs, Food, Medical Equipment and Cosmetics (DDF), as a department under the MoH, is the main authority regulating the import, wholesale distribution, retail sale, and export of therapeutic products. The DDF is responsible for a range of public health matters, including preparing and executing national policies and regulations on:

- pharmaceuticals;
- traditional medicines;
- health supplements;
- food;
- medical devices; and
- cosmetics.

Note that a draft Law on Pharmaceutical Products is reportedly under consideration, and a first draft consultation session was held in March of 2025. The current status of the draft is unknown, but it would be a welcome update to the regulatory framework, given the most recent amendment to the main law was back in 2007.

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 attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Under the law and regulations, prescription only and over-the-counter (OTC) classifications do not clearly exist for therapeutic products, but in reality, the DDF prepares lists of what products are seen as OTC.

The issue is this list has not been updated regularly, for many years, and the industry often complains the list is outdated. The DDF may rely on overseas lists, under ASEAN or WHO frameworks, but this approach lacks clear legal support and clarity.

A new draft 'Law on Pharmaceutical Products' is reportedly under consideration, and a first draft consultation session was held in March of 2025. Reports state: 'this draft outlined the classification of pharmaceutical products, including a subcategory of non-prescription pharmaceuticals and those prescribed by a pharmacist with a prescription.'

For medical devices, Cambodia has adopted a four-class risk classification, in line with the ASEAN Medical Device Directive (AMDD), starting at low risk (Class A), to a high-risk class (Class D). All risk classes require registration however, which can be frustrating for suppliers of low-risk devices. No devices are clearly exempt from registration, while other jurisdictions often provide an exemption list.

All types of therapeutic products must be registered with the DDF before entering the market. This means applying for a product registration licence and obtaining a registration ('visa') number.

The product registration licence is applied for by the local pharmaceutical import company or manufacturer, and it gives the company the right to import that product (based on the package it is registered with), and/or the right to distribute. Note that overseas entities may be named as a product registration licence holder, but a local, licensed pharmaceutical import company must submit the applications. Note that the MoH may desire an overseas manufacturer registration application in Cambodia as well, as a prerequisite for therapeutic product registration.

Retail sales must only take place at a licensed pharmacy, and represented by a Cambodian, licensed pharmacist. A pharmaceutical import company or manufacturer can only engage in wholesale and distribution activities and is not permitted to engage in the retail sale of therapeutic products.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Only a locally registered pharmaceutical import company or manufacturer, with a licence from the MoH, may import, or export therapeutic products, or wholesale these.

The company must be represented by a Cambodian licensed pharmacist, with the following requirements:

- Khmer nationality;
- a pharmaceutical diploma recognised by the MoH;
- not found guilty of any criminal offence;
- sufficiently good health to perform work; and
- membership of the Pharmacy Council of Cambodia.

The pharmacist will be responsible for all technical aspects within the company and therefore will be required to sign all technical applications to the MoH, alongside the director of the company, if applicable. The pharmacist responsible is mentioned on the licence, as the licence holder.

In addition, only a company with an approved warehouse for the storage of therapeutic products, or with the approved manufacturing capability for the therapeutic products, may be eligible for the required licensing. This storage/facility approval is a prerequisite to become licensed.

A local distributor must further submit an application to the DDF to obtain a certificate of Good Distribution Practice (GDP) and a certificate of Good Storage Practice (GSP) (Prakas 1190 (26 April 2019) and Prakas 014 (8 January 2019)).

4. Are there 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 attach to them?

Retail sales of therapeutic products must be only at a licensed pharmacy, and represented by a Cambodian, licensed pharmacist. Applications for the pharmacy licence can be made at the provincial MoH department.

The lay-out of the pharmacy requires approval, such as having a clear counter from which customers can purchase prescription therapeutic products, which must be kept secure (no consumer access). The pharmacist is required to maintain logbooks of stock, sales made, and implement a pharmacovigilance system, for the therapeutic products they sell.

Advertising, including for online sales, is only permitted for duly registered therapeutic product, and with an advertising permit from the MoH.

An additional permit under the Law on E-Commerce is required for any type of online sales.

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

Advertising, including for online sales is only permitted for duly registered therapeutic products, and with an advertising permit from the MoH. For online sales, the above-mentioned permit under the Law on E-Commerce is required.

Any sales, online or offline, are bound by the rules surrounding labelling requirements, point-of-sale requirements (eg, only a pharmacy may sell retail), and regular consumer protection requirements, such as a ban on misleading, or engaging in false advertising.

Social media is often used to advertise therapeutic products, which are often the target of enforcement action by the MoH.

IMPORT

6. What is 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)?

Therapeutic products must be registered with the DDF prior to import, after which, the importer can apply for an import permit from the MoH. This states the quantity to be imported into Cambodia, over a set time, usually a year.

Customs is permitted to check for import permits and confirm the product registration is valid. Customs classification and tariff determination follows the regulatory framework of Customs. At the time of writing, they are tax exempt of any import duties, and are only subject to ten per cent VAT.

Inspections of documents (permits especially) is routine, while inspections of shipments are risk-based.

Most ministries are moving to a National Single Window System integrating the company licensing, import permitting and product registration licensing from the MoH, with the systems for Customs declaration, through a single online portal. The MoH is yet to be fully part of this system.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

The import of therapeutic products for personal use generally requires special authorisation from the MoH. Individuals must typically obtain a prescription or medical certificate from a physician detailing their health condition and the necessity of the medicine.

Based on this, they must apply for and receive a permit from the MoH, especially for controlled, unregistered, or unapproved medications. The quantity imported should be limited to the amount necessary for personal use as specified in the prescription.

Upon arrival or when receiving by mail, therapeutic products must be declared to customs, and all required documentation must be presented. Therapeutic products should be kept in their original, clearly-labelled pharmacy packaging.

Goods with a customs value under US$300 require a Non-Commercial Customs Declaration Form, while those valued at US$300 or more require a standard Customs Declaration Form. Although therapeutic products may be exempt from import tariffs, a ten per cent VAT may apply. Imported therapeutic products must have a minimum remaining shelf life of 18 months on inspection.

8. May foreign suppliers 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?

No, foreign suppliers may not ship unregistered therapeutic products directly to Cambodian consumers via e-commerce or mail order. Such shipments are considered unauthorised imports and unlicensed sales, bypassing Cambodia's mandatory regulatory framework for therapeutic products.

To sell to Cambodian consumers, a foreign supplier must first ensure its therapeutic products are lawfully placed on the market according to the responses set out earlier in this survey. They require product registration, import permits, and a local, licensed importer, and eventually, a licensed retailer (a pharmacy) to sell to the consumer. This last step can be online.

Direct cross-border shipments of therapeutic products are not permitted.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual-property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

This is a complicated issue in Cambodia.

From an intellectual property laws point of view, parallel importing is generally prohibited. However, the enforcement authorities generally require a recorded exclusive distributorship to stop parallel imports of trademarked goods at the border. That recordal enables authorities to suspend imports by parallel importers, or to seize parallel imports already in country.

However, pharmaceuticals are notably *excluded* from the exclusive distributorship recordal option.

Nevertheless, parallel importation of therapeutic products into Cambodia could still be blocked by regulatory requirements: an import permit is required, and this in turn requires evidence of product registration, to be able to apply for the permit. The product registration itself requires the cooperation of the manufacturer, given registration requires a substantial dossier. This means that without the cooperation of the overseas manufacturer, it is practically not possible to register the product with MoH's DDF. Without registration, it is impossible to get an import permit. Without the permit, it is not possible to import the product, although the product is validly registered by another entity.

In practice, at least in the past, parallel imports have made it into Cambodia often, using loopholes. This includes parallel importing a product, that is already registered by another

importer, therefore being legal to market once in Cambodia. The import permit would still be an issue, but unscrupulous importers can find ways around this, and once in country the MoH would generally not action, as the product is duly registered and genuine. The enforcement authorities would not enforce an IP related claim regarding parallel importing, as there is no option to obtain a registered exclusive distributorship.

Relabelling and repackaging are controlled to protect quality, safety, and traceability. Labels and inserts should match what the DDF approved in the product's registration or notification. Unapproved 'stickering', over-labelling, or alterations render the product noncompliant, and action is possible. Opening packs, rebottling, or changing primary or secondary packaging is treated as manufacturing and requires an appropriate licence.

Authorised importers must source from the registered manufacturer and approved sites, preserve batch and lot numbers, expiry dates, storage conditions, and maintain chain-of-custody records. They must follow good storage and distribution practices and support recalls and pharmacovigilance reporting.

However, the enforcement against parallel imports or other noncompliance related to parallel import issues remains a problem, as the MoH and authorities have not taken a strong stance against this. This is likely in the case of genuine therapeutic products, as access to such products remains limited in many parts of Cambodia.

EXPORT

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

There are no known lists with export quotas for therapeutic products in ordinary circumstances. However, exports do require an export permit, as the MoH can take steps to limit exports of therapeutic products, where it deems necessary

During public-health emergencies or supply shortages, the government has authority to adopt temporary, product-specific export controls (as it has for emergency import approvals), through MoH directives or inter-ministerial prakas.

These measures are likely to target essential medicines or critical medical supplies to mitigate domestic shortages. We are not aware of this happening in recent history, and the practicalities are not known. Emergency import approvals were adopted during the Covid pandemic, allowing vaccines a quicker approval for import.

Compliance for export control is implemented at the export-permitting and customs-clearance stages, with verification of export permits, quantities, and product identity against approvals. Violations can result in shipment refusal or seizure, administrative fines, and suspension or revocation of establishment and import-export licences.

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, and if so, what standards, labelling, or record-keeping obligations apply?

Cambodian law does not set out a formal, standalone 'export-only' marketing authorisation for therapeutic products.

In practice, manufacturers may produce therapeutic products exclusively for export without obtaining domestic marketing approval, provided the products are not placed on the Cambodian market and the manufacturer holds valid licences and the necessary export permits.

'Dual-labelling' is not recognised under the law. A product for domestic sales requires registration, and the label must abide by local regulations. More than one language is technically allowed, providing local requirements for labelling and for product inserts are met.

Applicable standards track the ordinary GMP and quality-system obligations (eg, validated processes, batch release by a qualified person, stability as appropriate for the destination market).

There is no clear legal requirement for export products to clearly indicate 'for export only'. However, customs are likely to require this to be stipulated on the shipping boxes – this is also generally required for nontherapeutic products.

Recordkeeping must always ensure traceability (batch manufacturing and distribution records, export documentation, and retention samples) and be available for inspection.

Customs and MoH enforce compliance at the licensing and clearance stages. Any breaches can lead to seizure, administrative penalties, and suspension or revocation of establishment and import-export licences.

LABELLING, TRACEBILITY, 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 may circulate domestically or before therapeutic products may be exported?

Prakas No. 364 regulates the packaging and labelling of medicines. The outer part of a package, such as a box or bottle, must contain the following information:

- the international name of the medicine;
- the level, excipients and quality of treatment;
- contraindications;
- dosage and use;
- the marketing authorisation number; and
- expiry date.

The insert product leaflet must be in the local language of Khmer. There must be additional specifications of the lot number and expiry date on the strip, bottle, or tube itself. There must be a

special label and note stating 'sale with prescription only' on medicine containing a poisonous substance.

A local language requirement for the outer label itself is not clearly provided in regulations for pharmaceutical products label itself (only the insert is mandated). However, the general Law on the Management of Quality and Safety of Products and Services (21 June 2000) requires all manufactures, importers, merchants and service providers to have their products labelled in the Khmer language. In practice, French, Khmer and English labels are accepted, as long as the insert is in Khmer.

For medication that is prescription-only, the law indicates that the following packaging and labelling requirements must be met:

- the medication must be packaged in individual packages or boxes, bearing the name of the medication and the substance, and in a shipment, these must be sealed, stamped and wrapped with safety ties;
- the shipment's outer packaging may only bear the names and addresses of the sender and recipient, and must be sealed and stamped with the sender's mark;
- the labels must provide instructions about how to use the medication, as well as provide cautions and warnings, if these are necessary for the safety of users;
- additional packing and labelling requirements may be required based on the MoH's discretion – however, this is uncommon and depends on case-by-case basis.

Unique device identification and pharmaceutical serialisation are not yet mandated as universal, nationwide systems. Instead, traceability relies on batch/lot numbers, invoices, import permits, and distribution records maintained by the MAH/importer under good distribution practice controls.

The key points mandated under Prakas 1258 (for medical devices specifically) are:

- Labelling – device label must show name/model, intended purpose, manufacturer/country of manufacture, local authorised representative/importer, key warnings, storage;
- Khmer language insert is required for lay-use devices, professional-use may be in English if Khmer user information is provided;
- UDI/serialisation –national UDI number or serialisation mandate in Prakas 1258;
- Traceability – use model/catalogue number, lot/serial number, invoices, import permits, and distribution records maintained by the licensed importer/authorised representative; relabelling/repackaging require MoH approval.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

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

The MoH is reported as the largest purchaser of medical supplies, equipment, and pharmaceuticals in Cambodia. While the MoH uses these products to support the public health sector, the precise schematics by which the MoH repays pharmacies and hospitals for pharmaceuticals and services rendered is not published.

Although the government has noted its commitment to establishing a pricing scheme for pharmaceuticals, there is currently no regulation governing prices of medicinal products, including those for products listed on the National List of Essential Drugs. However, products on the list receive preferential treatment in terms of for example, access and assistance during registration.

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?

The MoH has the authority to issue instructions on and control any activities relating to the business and trade therapeutic products. MoH enforcement officers may conduct inspections at business engaged in the industry.

The MoH has regulated the enforcement officers under Prakas No. 0211 (30 March 2011) on the Roles and Responsibilities of Control Officers for Pharmaceuticals, Food, Medical Equipment, Cosmetics and Private Medical, Paramedical and Medical Aid Services. In case of investigate actions in line with the Prakas, officers should be given access to all existing information, results, and records which may be useful in monitoring an entity's compliance with necessary regulations.

The list of violations is given in the table, below.

Prohibited activity	Penalty
• advertising pharmaceuticals without prior approval from the DDF; or • violating the procedures for production, import, export, and trade of the pharmaceutical; or • opening or changing locations of pharmacies and establishments of production of pharmaceuticals without DDF approval; or • carrying out import-export of pharmaceuticals without DDF approval; or • producing, importing, exporting, or storing raw pharmaceutical materials without DDF approval; or	• A fine of KHR1–10m riels (approx. US$250–2,500); and/or • suspension of import, export, or trade of pharmaceuticals from one to three months. • In event of repeated offense, the fine amount and length of suspension shall be doubled. • All pharmaceuticals, raw materials, and equipment found in violation of the law shall be confiscated and/or destroyed.

• selling pharmaceuticals without the required certifications and DDF approval; or • failing to keep a logbook of all pharmaceuticals sold; or • selling pharmaceuticals that are banned by the DDF.	
• Preventing or obstructing any government investigatory agents while carrying out their inspection duties	• A fine of KHR1–5m (approx. US$250–1,250); and/or • six days to one month's imprisonment.
• Deliberately engaging in producing, importing, exporting, or trading pharmaceuticals 'containing additive substances', counterfeit pharmaceuticals, or damaged pharmaceuticals which affected the health of consumers	• A fine of KHR20–50m (approx. US$5,000–12,500); and/or • five to ten years' imprisonment.

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

We are eagerly awaiting updates on the draft Law on Pharmaceutical Products. The law is reportedly under consideration, and a first draft consultation session was held in March 2025. The current status of the draft is unknown, but it would be a welcome update to the regulatory framework, given the most recent amendment to the main law dates back to 2007.

The MoH actively enforces against online advertisements, but broader inspections would be welcomed.