

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?

Thailand regulates the trade and distribution of therapeutic products through a centralised national framework. The two principal statutes are the Drug Act B.E. 2510 (AD 1967), as amended, which governs pharmaceuticals and biologics, and the Medical Device Act B.E. 2551 (AD 2008), as amended, which governs medical devices. These laws regulate the full product lifecycle, including manufacture, import, wholesale distribution, retail sale and export.

The Thai Food and Drug Administration (FDA), operating under the Ministry of Public Health (MOPH), is the primary competent authority. Within the Thai FDA, responsibility is divided among specialised divisions, including the Drug Division, which oversees the pre- and post-market control of pharmaceuticals and biologics, and the Medical Device Control Division, which oversees medical devices. Border controls are carried out by the Import and Export Inspection Division with FDA quarantine officers, in coordination with customs authorities.

Thailand is a unitary state, so all regulatory authority for therapeutic products rests with the central government, primarily the MOPH and the Thai FDA. There is no division of legislative or regulatory powers between national and sub-national authorities. However, certain bodies, such as provincial public health offices (PPHOs), act as decentralised implementing agencies under the supervision of the MOPH, carrying out administrative and enforcement tasks in accordance with the regulations.

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 the conclusion of a premarket review and approval process required by a competent authority?

Therapeutic products in Thailand are classified based on the level of risk posed, intended use and control requirements. Classification directly affects the premarket approval, distribution channels and advertising of such products.

From a distribution perspective, drugs can be categorised according to the relevant restrictions imposed on them, as follows:

- Specially controlled drugs are highly regulated medicines that require a prescription and strict record-keeping requirements.

- Dangerous drugs, with the majority of modern medicines falling into this category. They must be dispensed by a pharmacist, but do not necessarily require a physician's prescription. These drugs are only available in pharmacies and medical facilities.
- Ready-packed drugs, which are not dangerous or specially controlled. They can be distributed by pharmacists, medical professionals or health professionals within dentistry, midwifery or nursing. These drugs are only available in pharmacies and medical facilities.
- Household remedies are non-prescription drugs that can be sold freely in general retail stores. They can be used for minor ailments and are deemed to be safe for consumer use.

Medical devices follow a risk-based classification system that is aligned with the Association of Southeast Asian Nations (ASEAN) Medical Device Directive (AMDD), as follows:

- Class 1 (listed – low risk);
- Classes 2–3 (detailed notification); and
- Class 4 (licensed – highest level of risk).

Premarket review and approval by the Thai FDA are mandatory for both pharmaceuticals and medical devices. The level of scrutiny may increase with the level of risk posed by the product.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which 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 practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

The wholesale distribution of pharmaceuticals requires a drug manufacturing licence (for manufacturers) or a drug import licence (for importers), issued by the Thai FDA. Licence holders may only distribute products covered by their marketing authorisations.

Key conditions include:

- The entity requirements for an applicant include that the applicant must be a resident of Thailand or a registered Thai juristic person. The manager of the business must meet age requirements and must not have any prior convictions for drug-related offences.
- Compliance with good distribution practice (GDP) and, where applicable, good manufacturing practice (GMP) standards.
- Adequate storage facilities, including temperature-controlled environments.
- The presence of a responsible pharmacist on the premises during operating hours.
- The maintenance of traceability and distribution records.

For drugs, a risk management plan (RMP) must be implemented as part of the authorisation process to identify and mitigate potential safety issues throughout the product's lifecycle.

For medical devices, wholesalers must hold a medical device sale licence. Importers and manufacturers also need to have been granted the corresponding licences. Facilities are inspected for compliance (eg, GDP, GMP/ISO 13485 for medical devices), and licences carry defined validity periods, with renewal requirements.

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?
<p>Retail distribution is predominantly restricted to licensed pharmacies, which must obtain a specific retail licence. However, a significant statutory exemption exists for hospitals and clinics. Under the Drug Act, healthcare practitioners, including physicians and dentists, are authorised to dispense medicines directly to their own patients without the need for a separate retail licence, positioning healthcare institutions as the most significant nodes in the distribution network for high-value therapeutics and complex biological products. The designated manager of any retail outlet must meet specific integrity requirements, including the absence of any prior convictions for offences related to narcotics or the Drug Act.</p> <p>For medical devices, sales depend on the level of risk posed and adhered to any applicable prescription-control status. Certain medical devices (eg, positive airway pressure equipment) may be sold to consumers only on prescription and by licensed sellers.</p>
5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?
<p>Thailand maintains a conservative regulatory stance regarding digital commerce in the healthcare sector. The sale of pharmaceuticals via internet platforms, social media or mail order is permitted only for household remedies, whereas other categories of drugs remain strictly prohibited under current legislation. Transactions for such drugs must occur under professional supervision to ensure patient safety and proper counselling. However, telepharmacy services are allowed if conducted under specified conditions by licensed pharmacists, who have been trained and certified by the Pharmacy Council. Importantly, advertising of drugs or products sold online is not permitted in cases involving dangerous drugs or specially controlled medicines.</p> <p>Online advertising of therapeutic products is tightly controlled and generally requires prior Thai FDA approval, with prescription medicines (dangerous drugs and specially controlled drugs) prohibited from being advertised directly to consumers. Medical devices are subject to similar advertising controls based on the level of risk posed and the intended audience. The advertising of medical devices to healthcare practitioners (HCP) does not require prior approval, but it must be notified to the FDA.</p>
IMPORT
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)?
<p>Imports are controlled under the Drug Act/Medical Device Act and related customs requirements. Drug importers must hold a drug import licence and product marketing authorisation (MA) for each product that they deal in. For imported drugs, GMP clearance for the foreign manufacturing site is required (the Thai FDA recognises Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP; GMP clearance validity aligns with the home authority's GMP certificate). Medical devices require an import licence and product authorisation (class appropriate). The customs classification, tariff treatment and inspections apply on a routine or risk basis. The documentation required typically includes MA/approval, labelling and any specialised certificates (eg, certificate of pharmaceutical product/certificate of free sale (CPP/CFS) for drugs as part of the dossier).</p>

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?
Personal importation by consumers is limited. Thailand permits tightly controlled personal carriage/mail of medicines in small quantities not exceeding 30 days of supplies for personal use. However, products that are controlled substances face stricter limitations and may require documentation, such as a prescription or a medical certificate, or may be prohibited. In practice, regulators enforce quantitative limits and prescription/documentation checks at the border, and controlled drugs/devices are not freely importable by consumers. Businesses must not rely on personal-use channels for distribution.
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?
Direct shipment by foreign suppliers to Thai consumers is generally not permitted for therapeutic products and such shipments are typically intercepted at the border. Without a local licensee and the relevant Thai FDA approvals, direct-to-consumer e-commerce importation is not allowed for medicines. Household remedies are treated more leniently, but they are still subject to advertising/sale restrictions. Digital platforms and sellers operating cross-border remain subject to Thai law in relation to authorisation, labelling and (for medical devices) product licensing. A local presence/licensee is effectively required in order to comply with the applicable regulations.
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 property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?
Parallel importation is not per se prohibited but is practically constrained. Importers must hold a drug import licence and secure MA for each product they import. In practice, obtaining MA requires the submission of a technical dossier from the originator/overseas owner, which creates a technical barrier to import activities. For medical devices, parallel importers likewise need the appropriate product authorisation and must maintain the quality, safety and traceability of the product. Product re-labelling/re-packaging must comply with the Thai requirements and must not infringe intellectual property (IP) rights or be misleading as to the quality/origin of the product. IP exhaustion principles exist but do not waive the regulatory authorisation obligations.
EXPORT
10. Are there any quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?
Exports may be conditioned by permits and due to public health considerations. During public health emergencies, the authorities may impose measures, such as quantitative quotas or issue permits to restrict or prioritise domestic supply, administered by the Thai FDA and the relevant ministries.

Under the Prices of Goods and Services Act B.E. 2542 (AD 1999), essential items can be designated as controlled goods, requiring specific export authorisation from the Ministry of Commerce in coordination with the MOPH.

Exporters of narcotics/psychotropics and certain controlled products require specific export licences. Compliance is monitored through licensing, recordkeeping and inspections, with sanctions imposed for breaches.

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?

Export-only authorisations exist in Thailand in limited contexts, as follows:

- Authorisation: manufacturers may produce for export products that are not approved for the domestic Thai market, provided they hold a valid manufacturing licence.
- Standards: for products manufactured exclusively for export, the manufacturing process must comply with all of the quality standards stipulated under the applicable ministerial regulations, including adhering to the GMP requirements. In cases involving importation for the sole purpose of re-export, the importer is required to obtain a valid import licence. Furthermore, comprehensive documentation must be maintained to demonstrate compliance with the regulatory requirements in the destination country.
- Labelling and record-keeping: while specific dual labelling requirements are not explicitly detailed in the Drug Act, products for donation or specific purposes must have labels displayed on them for all types of containers. The Thai FDA maintains premarketing control over these processes to ensure that such products are suitable for export.

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 may circulate domestically or before therapeutic products may be exported?

Therapeutic products must comply with Thai-language labelling and product information requirements. For drugs, the labelling must match the registered particulars (eg, package insert, summary of product characteristics or patient leaflet) and must include any specific warnings mandated by the Thai FDA (eg, antibiotics, sedatives). For biosimilars, the labelling must ensure it does not infringe on the patent rights of the originator company, especially regarding second medical use patents.

For medical devices, labelling must align with the approved dossier (common submission dossier template (CSDT)) and AMDD-aligned requirements. Thailand has implemented serialisation/traceability and anti-counterfeiting measures progressively, which require all packaging to display the MA number. Drug and device distributors must comply with the relevant GDP controls and maintain records to ensure traceability throughout the supply chain.

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?

Price controls primarily apply via the National List of Essential Drugs (NLED). NLED-listed medicines dispensed in public hospitals are subject to a median price policy overseen by the Ministry of Finance and related procurement controls. Private hospitals and drugstores are able to set prices but they must not exceed the sticker price set by the distributor. Distributors and private hospitals have reporting obligations in regard to prices. Reimbursement is available for NLED-listed products under various public schemes (eg, the Universal Coverage Scheme and the Social Security Scheme), with government reimbursement provided to public hospitals (and participating private providers for defined items).

For medical devices, reimbursement is more limited and tends to be tied to NLED-listed items or specific programmatic coverage. Public procurement under the Public Procurement and Supplies Administration Act B.E. 2560 (AD 2017) emphasises value for money, transparency and accountability.

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?

Regulators have broad investigative and sanctioning powers. The Thai FDA and the Office of the Consumer Protection Board (OCPB) monitor compliance through inspections and online surveillance.

For drug advertising violations, the Thai FDA may order cessation and corrective advertising. Monetary fines (eg, up to THB 100,000 per offence) can be imposed, with the severity of the fine reflecting the number of infringing materials and the duration of the offence.

For medical devices, advertising without approval can lead to imprisonment (up to six months), fines (up to THB 50,000) or both. Manufacturing/import licences can be suspended or revoked for violations.

Post-marketing safety reporting is strictly enforced under Thai law. Newly approved drugs must be accompanied by the implementation of a risk management plan (RMP), which includes defined pharmacovigilance activities and risk minimisation measures taken in accordance with the Thai FDA requirements. Periodic safety updates must be submitted as specified in the approved RMP. Manufacturers of generic medicines and medical device companies are required to report any adverse events through the Health Product Vigilance Center (HPVC).

GDP is a mandatory regulatory standard for drug manufacturers and importers, with GDP compliance inspections integrated into the licence renewal process.

15. Is there any 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?

Noteworthy developments and anticipated reforms in Thailand include:

- Biosimilar and biologics regulation: the Thai FDA requires evidence of comprehensive quality, non-clinical and clinical comparability, plus a risk management plan. eCTD submissions are adopted, and PIC/S GMP alignment continues for pharmaceuticals. Reliance pathways for medical devices can expedite reviews when approved by trusted foreign regulators (eg, Health Services Authority of Singapore reliance, concise evaluation for ‘big five’ approvals, ie, the US Food and Drug Administration, Health Canada,

Australia's Therapeutic Goods Administration, the European Medicines Agency and the UK Medicines and Healthcare Regulatory Products Agency).

- The AMDD-aligned device regime: since 2021, medical device classification and CSDT dossiers have been in force, with five-year validity for product authorisations and aligned advertising rules (including exemptions for HCP-directed materials subject to notification and access controls).
- Pricing and procurement: expanded reporting duties for private providers and continued emphasis on transparent procurement under the Government Procurement and Supplies Management Act.
- GDP implementation: GDP has been formally adopted and updated, tying compliance to licence renewals for drug manufacturers/importers.
- Cannabis/cannabinoids: cannabis/hemp plant parts have been delisted from the narcotics category and traditional formulas containing cannabis are accessible via a special access scheme. Additional controlled-herb sale restrictions apply, including prohibitions on digital sales of controlled herbs/products.
- Localisation/formalities: MA applicants/licenceholders must be established in Thailand. Foreign authorisations are not recognised, although reliance/abridged pathways can shorten timelines where certain criteria are met. The provision of CFS/ CPP and patent declaration forms are part of drug dossier expectations.