

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?
<p>Taiwan regulates therapeutic products through the Pharmaceutical Affairs Act (PAA) and the Medical Devices Act (MDA), which are supported by various subordinate regulations and guidelines issued by the relevant authorities. These laws create distinct yet complementary regulatory frameworks for pharmaceuticals (including biologics) and medical devices, covering aspects such as establishment licensing, good practices, marketing authorisation and advertising. The regulatory structures of the PAA and the MDA are similar.</p> <p>The Taiwan Food and Drug Administration (TFDA), operating under the Ministry of Health and Welfare (MOHW), serves as the primary regulatory authority. The TFDA oversees marketing authorisation, establishment licensing, quality control, importation, wholesale, distribution, retail, sales, exportation, post-market surveillance and enforcement of compliance with good manufacturing, distribution and clinical practices and advertising for therapeutic products.</p> <p>The National Health Insurance Administration (NHIA), operating under the MOHW, is responsible for deciding which pharmaceuticals (including biologics) and medical devices are covered by Taiwan’s National Health Insurance (NHI). This mandatory social insurance programme, which covers 98 per cent of the population, also relies on the NHIA to set prices and manage reimbursements for these covered items.</p> <p>Under the PAA and MDA, businesses involved in the manufacturing, importing, sale, distribution or promotion of pharmaceuticals and medical devices must obtain the appropriate pharmaceutical dealer’s licence or medical device dealer’s licence issued by the TFDA or the relevant municipal/county health authority. Prior to the legal manufacture, importation or marketing of any pharmaceutical products or medical devices in Taiwan, marketing authorisation must be secured. The TFDA is responsible for evaluating and approving these products based on stringent safety, efficacy and quality standards.</p> <p>Taiwan is a unitary state, and regulatory authority is centralised under the MOHW and TFDA. Local health bureaus assist in regard to enforcement and inspection at the municipal and county levels, but do not have independent regulatory authority over therapeutic products.</p>
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?

Medicines

In Taiwan, medicines are categorised into three groups based on their safety profile, potential for misuse and necessity for professional supervision: prescription drugs, pharmacist-directed drugs and over-the-counter (OTC) drugs.

Prescription drugs require a physician's diagnosis and prescription. These medications are dispensed by pharmacists, who also provide guidance on their proper usage and any necessary precautions. Direct-to-consumer (DTC) advertising of prescription drugs is strictly prohibited.

Pharmacist-directed drugs are available for purchase at pharmacies but must be used under the supervision or instruction of a physician, pharmacist or qualified pharmaceutical personnel, in accordance with the directions provided on the package insert.

OTC drugs can be purchased freely without the need for professional medical guidance. However, users are advised to carefully read the outer packaging and instruction leaflet before use.

Medical devices

Medical devices in Taiwan are classified into three risk categories: Class I (low risk), Class II (moderate risk) and Class III (high risk). These devices are further organised into 16 primary categories, closely aligned with the classification system used in the United States. All medical devices must comply with safety, performance and conformity assessment standards and must be used according to the manufacturer's intended purpose. Devices intended exclusively for professional use must be clearly indicated as such in the instructions for use (IFUs), as mandated by the TFDA. DTC advertising of medical devices designated for professional use is strictly prohibited. Although marketing authorisation is generally required for all types of medical devices, certain very low-risk devices, as specified by the TFDA, are subject to a simplified registration process.

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?

Under the PAA and MDA, businesses involved in the manufacturing, importing, sale, distribution or promotion of pharmaceuticals and medical devices must obtain the appropriate pharmaceutical dealer's licence or medical device dealer's licence issued by the TFDA or the relevant municipal/county health authority.

Adhering to good distribution practice (GDP) is not currently a prerequisite for obtaining a pharmaceutical dealer's licence or a medical device dealer's licence.

For medicines, GDP compliance was strongly encouraged before mid-2024. Then after mid-2024, GDP requirements have been implemented mandatorily according to a phased approach, as follows:

- Marketing authorisation holders, as well as dealers wholesaling blood products, vaccines or botulinum toxins that do not require cold-chain storage and transportation, were required to obtain GDP certification by 30 June 2024.

- Dealers wholesaling certain designated products (excluding blood products, vaccines or botulinum toxins), along with specified controlled drugs and essential drugs, were required to obtain GDP certification by 31 December 2024.
- Dealers wholesaling prescription drugs or those supplying formulations to more than ten other wholesale pharmaceutical businesses were required to obtain GDP certification by 31 December 2025.
- All other pharmaceutical dealers must obtain GDP certification by 31 December 2026.

For medical devices, GDP certification was required to be obtained before 1 May 2023 for the items identified by the TFDA, which are mostly Class II and III medical devices.

Key requirements for GDP compliance in regard to medicines and medical devices generally include a quality control system, appropriate organisation and facilities, qualified personnel, a designated person responsible for GDP compliance and the traceability of all transactions and batches.

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 are attached to them?

In Taiwan, the retail supply of therapeutic products is generally permitted only through physical stores operated by pharmacies, pharmaceutical dealers and medical device dealers, with rare exceptions for online sales (see the response to Question 5). For pharmaceutical and medical device dealers engaged in retail supply, the licensing procedures are the same as those for wholesale dealers. Pharmacies must also register with the municipal or county health bureau to obtain an establishment licence. A key distinction for pharmacies is that the licence application requires that the pharmacy be managed by a licensed pharmacist who holds a valid pharmacist licence issued by the MOHW, and the operation is not structured as a company but rather as a solo practice. The PAA mandates strict compliance with storage, handling and record-keeping requirements to ensure drug safety and efficacy.

Pharmacies can supply prescription drugs, while convenience stores or general retailers with a pharmaceutical dealer's licence are only permitted to sell OTC drugs. Additionally, those holding a medical device dealer's licence may only sell low-risk medical devices.

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

Medicines are prohibited from being sold through any online channels, including websites, social media and marketplace platforms.

Regarding medical devices, they are generally prohibited from being sold through any online channels, including websites, social media and marketplace platforms. However, exceptions apply to Class I devices and certain low-risk Class II devices designated by the TFDA (such as thermometers), which may be sold online in accordance with the Regulations on Items and Compliance Requirements for Selling Medical Devices through Communication Channels.

Under these Regulations, the following information must be clearly displayed on the sales webpage for eligible medical devices:

- The name of the medical device, licence or registration number and the name and address of both the licence holder or registrant and the manufacturer.
- The name, address, licence number and consultation hotline number of the medical device dealer/pharmacy.
- A notice stating: 'Consumers should read the medical device instructions carefully before use'.

- Information regarding the items and locations of periodic calibration services for products with measurement functions.

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)?

Prior to the legal importation of any pharmaceutical products or medical devices in Taiwan, marketing authorisation issued by the TFDA must be secured.

Specifically regarding medical devices, the Bureau of Foreign Trade (BOFT) may ban or restrict the import of certain medical devices classified under specific Harmonised System (HS) codes from mainland China for government safety reasons and to protect local industry, in accordance with the Foreign Trade Act and the Regulations Governing Trade between the Taiwan Area and the Mainland Area. In this context, the Customs Administration will apply heightened scrutiny to medical devices imported from mainland China.

Customs clearance of therapeutic products is regulated by the Customs Administration under the Customs Act. Therapeutic products are classified according to HS codes, with tariff rates varying based on the product classification in accordance with the Customs Act. Customs may detain shipments pending verification of the marketing authorisation status, BOFT restrictions and compliance with the relevant labelling and packaging requirements.

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?

In Taiwan, consumers may import therapeutic products for personal use under certain conditions set out in the PAA and the MDA.

For non-prescription drug applications for personal importation, applications cannot be submitted more than once within a six-month period. Each application's quantity must not exceed 12 bottles, 12 tubes or a total of 1,200 tablets.

For prescription drug applications for personal importation, applications must be accompanied by a diagnosis certificate and a physician's prescription issued by a domestic medical institution or by a foreign medical institution that is recognised by the MOHW, where the applicant was originally treated.

For medical device applications for personal importation, consumable items are limited to a quantity sufficient for six months' usage, and instruments are limited to one unit per model. However, these limitations do not apply if the devices are used at different locations or if there are other special circumstances that justify an exception. Applications must be accompanied by a diagnosis certificate and a physician's prescription issued either by a domestic medical institution or by a foreign medical institution that is recognised by the MOHW, where the applicant originally received treatment.

Additionally, applications for personal importation under any of the above scenarios must include an affidavit confirming self-use, along with detailed product information and international parcel details. Applications should be submitted to the TFDA for approval.

<p>Customs declarations, tariff classifications and the application of duties/value-added tax (VAT) follow ordinary customs law.</p>
<p>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?</p>
<p>Except in cases where the personal use requirements outlined above are met, foreign suppliers are not permitted to ship therapeutic products directly to consumers in Taiwan via e-commerce or mail order without involving a locally licensed entity.</p>
<p>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?</p>
<p>Except in cases where the personal use requirements outlined above are met, foreign suppliers are not permitted to ship therapeutic products (whether legally licensed and sold in other jurisdictions or not) into Taiwan without involving a locally licensed entity. In other words, parallel importation involves importing non-registered products under the PAA and the MDA, thus such activities may result in criminal liability.</p>
<p>EXPORT</p>
<p>10. Are there 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?</p>
<p>For the export of medicines and medical devices, an export-only licence for the product must be obtained from the TFDA. It is understood that the dossiers and information required to be submitted for export-only licences may be less comprehensive than those required for local market sales, due to more lenient regulatory requirements. Generally, the TFDA respects the regulatory standards of the destination jurisdiction, which may result in more flexible requirements regarding labelling and other aspects.</p> <p>Due to the insufficient supply of therapeutic products in local markets, the TFDA currently utilises special import and manufacturing approvals to increase local availability. However, the TFDA is in the process of drafting an amendment to the PAA aimed at strengthening drug shortage warning and response mechanisms. This amendment will require pharmaceutical companies to regularly report their drug supply status and establish a special approval mechanism to stabilise supply. Notably, the draft does not include any provisions to ban exports. The amendment is currently pending legislative approval. Once the draft amendment to the PAA is passed, similar changes may be proposed for the MDA.</p>
<p>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?</p>
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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?

Outer packaging, instruction leaflets and IFUs must be presented in traditional Chinese characters, except for certain items that may be provided in English.

For medicines, the required information includes the manufacturer's name and address, product name, marketing authorisation number, lot number, date of manufacture and period of validity or expiration date. Additionally, details on the active ingredient content, dosage, method of administration, primary medical efficacy, functions or indications, adverse reactions, contraindications and other warnings and precautions must be clearly stated. Traceability is ensured through batch numbers, expiry dates and related identifiers.

For medical devices, the required information includes the product name, marketing authorisation number, effectiveness, intended use or indications, date of manufacture and period of validity or shelf life. Additionally, it should include the model number, specifications or major components, warnings, cautions, usage limitations and any expected or foreseeable side effects. The name and address of both the marketing authorisation/registration holder and the manufacturer must also be provided, along with the lot number or serial number. Traceability is ensured through the inclusion of a lot number or serial number and related identifiers. The TFDA has announced a list of devices that are required to have a unique device identifier (UDI). This list includes approximately 200 Class II and III items that are subject to such requirements.

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?

The NHIA in Taiwan determines the reimbursement prices for medicines and medical devices listed under the NHI through the Pharmaceutical Benefit Scheme (the 'PB Scheme'). Brand-name drug prices are benchmarked against prices in ten developed countries, while generics and biosimilars are set at approximately 80 to 85 per cent of brand-name prices. To enhance pricing transparency and predictability, the NHIA employs a drug expenditure target (DET) and conducts an annual price volume (PV) survey to adjust reimbursement prices based on actual market data. Additionally, price volume agreements (PVAs) and managed-entry agreements (MEAs) are used for newly added medicines and indications. Marketing authorisation holders must accept these reimbursement prices to participate in the NHI programme. Due to NHI's extensive market coverage, pharmaceutical and medical device companies face challenges negotiating these agreements and supply contracts, with the Taiwan Fair Trade Commission (TFTC) refraining from intervening in NHIA's pricing policies as part of government policy formation.

Public hospitals and healthcare institutions in Taiwan procure therapeutic products primarily through centralised tendering processes managed by the government or authorised agencies. These procurement procedures emphasise cost-effectiveness and quality assurance, often favouring

products listed on the NHI reimbursement lists. This system helps to standardise product availability across public healthcare providers.

For essential medicines and medical devices designated by the TFDA, marketing authorisation holders must notify the TFDA at least six months in advance if they are unable to continue manufacturing or importing these products, or if there is a risk of insufficient supply. In cases where reporting within this timeframe is not possible due to natural disasters or other events beyond the control of manufacturers or importers, the relevant authorisation holders must report to the TFDA within 30 days of the occurrence of such an event.

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 MOHW periodically dispatches officials to inspect the premises of pharmaceutical and medical device companies, healthcare institutions and pharmacies, as well as to conduct sample testing of medicines and medical devices. These entities are required to comply with such inspections and sample tests unless there is a valid reason to refuse. Additionally, competent local sanitation authorities are responsible for conducting annual inspections of pharmaceutical firms and medical device firms and pharmacies.

Both the MOHW and local sanitation authorities are empowered to impose administrative fines for violations of statutory regulations. This includes the ability to levy consecutive fines for ongoing infractions, as well as issue orders to recall or destroy non-compliant products. In cases of serious violations or non-cooperation, authorities may take further action, such as publicly disclosing the names of offending pharmaceutical companies, denying renewal applications for medications, revoking marketing authorisations and suspending business operations. If a violation constitutes a criminal offence, such as the manufacture, importation or sale of counterfeit, prohibited or defective medications, the authorities may refer the case to the judicial system for prosecution.

The PAA and MDA also provide for criminal penalties for serious breaches, such as manufacturing or distributing counterfeit, adulterated or unregistered therapeutic products. Offenders may face imprisonment ranging from several months to multiple years, along with substantial fines. Corporate entities can be held criminally liable, and responsible individuals within companies, such as executives or managers, may also be prosecuted.

In practice, the TFDA actively monitors the market through regular inspections and targeted investigations initiated by consumer complaints or reports of adverse events. Enforcement actions are publicly disclosed to promote transparency and discourage non-compliance. The TFDA also collaborates closely with other government agencies, including customs and law enforcement, to combat illegal importation and distribution activities. While administrative sanctions are the most frequently imposed measures, criminal prosecutions are pursued in cases involving counterfeit products or serious threats to public health.

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?

Significant progress has been made in advancing key legislation such as the Biotechnology and Pharmaceutical Industry Development Act, the Regenerative Medicine Act and the Regenerative Medical Products Act, thereby continuously strengthening Taiwan's regulatory framework.

Notably, regenerative medical products that have successfully completed Phase II clinical trials, if demonstrating safety and preliminary efficacy, may qualify for conditional approval under the Regenerative Medical Products Act, expediting their entry into the market.

In 2025, a provisional budget of TWD 5bn was allocated specifically for new cancer drugs. The NHI programme during 2025 included several new cancer drugs and expanded reimbursement for several additional treatments within the same year. With the continued allocation of TWD 5bn planned for 2026, the cumulative investment in new cancer therapies is expected to reach tens of billions of TWD. This initiative will facilitate the gradual establishment of the TWD 100bn new cancer drug fund, aimed at encouraging innovative cancer drug manufacturers to participate in NHI coverage.

Regarding cancer precision medicine, starting in May 2024, reimbursement has been extended to dozens of types of next-generation sequencing (NGS) gene tests for cancer. Furthermore, reimbursement has been broadened to include minimally invasive surgeries, radiotherapy and other advanced cancer treatment technologies. These measures will expedite the adoption of new drugs and further incentivise innovative therapy companies to enter the Taiwan market and participate in the NHI reimbursement system.

In addition, a parallel review of drug registration and NHI inclusion was officially implemented in January 2024 to streamline the drug registration process and expedite inclusion in NHI coverage. Under this system, pharmaceutical companies applying for new drug registration with the TFDA can simultaneously submit applications for NHI coverage recommendations to the NHIA. This concurrent submission significantly reduces the waiting time for approval and authorisation. The primary objective is to enable new drugs to be covered by the NHI within approximately six months of receiving TFDA approval, substantially accelerating the process compared to previous procedures. This mechanism aims to encourage innovative companies to introduce more new drugs into the Taiwanese market.