

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

Author: Elvan Sevi Bozoğlu

Firm: Bozoğlu İzgi Attorney Partnership

sevi.bozoglu@bi.legal

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?

Turkey is a unitary state. Regulatory authority over therapeutic products is centralised at the national level under the Turkish Medicines and Medical Devices Agency (TİTCK), with Provincial Health Directorates acting as field-level inspection arms of the Ministry of Health (MoH). For the purposes of this analysis, ‘therapeutic products’ refers exclusively to medicinal products (including biologics) and medical devices.

Human medicinal products are governed principally by Law No. 1262 on Pharmaceutical and Medical Preparations, supplemented by the Regulation on Marketing Authorisation of Medicinal Products for Human Use, Good Distribution Principles regulations, and the Decree and Communiqué on Pricing of Medicinal Products.

Human medicinal products, including biologics, are governed principally by Law No. 1262 on Pharmaceutical and Medical Preparations, supplemented by the Regulation on Marketing Authorisation of Medicinal Products for Human Use, the Good Distribution Principles related regulations governing wholesale and retail distribution, and the Decree and Communiqué on Pricing of Medicinal Products.

Medical devices and in vitro diagnostic devices are regulated under the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation, harmonised respectively with EU MDR (EU) 2017/745 and EU IVDR (EU) 2017/746 as domestic secondary legislation. Note that these EU instruments do not apply directly but have been transposed into Turkish law.

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?

Medicinal products for human use are classified as either prescription-only or non-prescription pursuant to the Regulation on the Classification of Medicinal Products for Human Use. Non-prescription pharmaceuticals are defined residually as anything not requiring a prescription. Turkey does not maintain a separate over-the-counter regulatory regime, and in practice all

pharmaceutical products – including those categorised as OTC in the EU – must be sold exclusively through licensed pharmacies. Both categories are subject to the same importation, exportation, and marketing authorisation procedures, differing only in technical registration documentation requirements.

Premarket review and approval by TİTCK are mandatory for all medicinal products. In principle, TİTCK must conclude a marketing authorisation application within 210 days. In practice, however, the process can take approximately two to three years.

Prescription products include those presenting toxicity or addiction risks, parenteral administration, or limited post-licensing clinical experience, with sub-categories for narcotic and psychotropic substances. TİTCK publishes the annual classification list accordingly.

All pharmaceuticals have a unified QR code and are traceable through the mandatory national pharmaceutical tracking system (İTS).

Medical devices are classified into risk-based categories (Class I, IIa, IIb, and III) in alignment with EU MDR 2017/745 and IVDR 2017/746. CE-marked devices with EU Notified Body certificates follow a streamlined registration path. Classification determines the stringency of the conformity assessment process and registration timelines. All devices must be registered with the national Product Tracking System (ÜTS) prior to market placement.

Marketing or distributing a therapeutic product without the requisite authorisation may result in suspension of market placement, product withdrawal, administrative fines, and – where conduct constitutes a crime under the Turkish Penal Code – one to five years' imprisonment.

A product's classification determines its distribution channel and reimbursement eligibility. Prescription medicines are dispensed solely through pharmacies on valid prescription, while hospital-use products are procured through centralised hospital channels. Reimbursement is administered by the Social Security Institution (SGK), which covers approximately 95 per cent of the population.

The import and export of medicinal products are subject to TİTCK authorisation, and under Law No. 7151, the Social Security Institution and state institutions approved by the MoH may independently import medicines, reflecting a degree of state-directed market intervention alongside the standard commercial distribution regime.

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?

Wholesale distribution of medicinal products operates through a structured three-tier supply chain: pharmaceutical companies, licensed warehouses, and pharmacies, This is governed primarily by Law No. 984 on Pharmacy Trading Houses and the Regulation on Pharmaceutical Warehouses. To manage a wholesale pharmaceutical warehouse, a licence from the MoH's Provincial Health Directorate must be obtained, and the warehouse must comply with applicable storage conditions.

A central condition is compliance with Good Distribution Practice (GDP), harmonised with EU guidelines. In 2023, TITCK published a revised GDP inspection guideline reinforcing alignment with EU standards. Warehouses are subject to facility standards governing temperature control, storage conditions, traceability, qualified personnel requirements, and standard operating procedures covering receipt, storage, dispatch, and recall of products.

For medical devices, the Regulation on Sales, Advertisement and Promotion of Medical Devices requires any entity wishing to sell medical devices to obtain a sales centre authorisation certificate from the MoH's Provincial Health Directorate, accompanied by prescribed documentation including a responsible manager service contract, working certificates, trade registry and tax documents, and a commitment to sell only ÜTS-registered devices. For domestic manufacturers, an EN ISO 13485 certificate will additionally be required as of 1 January 2027. All devices sold must be registered in the ÜTS and bear CE marking, with unit-level movement notifications to ensure traceability. Certain low-risk devices listed in Annex 3 to the Regulation are exempt and may be sold through general retail channels. Foreign manufacturers must appoint a Turkish Authorised Representative, and all labelling and instructions must be in Turkish.

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?

In Turkey, all medicinal products – whether prescription or non-prescription – must be sold exclusively through licensed community pharmacies, governed by Law No. 6197 on Pharmacists and Pharmacies, and Law No. 1262 on Pharmaceuticals and Medical Preparations. There is no legally recognised general retail channel for medicines other than the pharmacy system.

Pharmacists must be Turkish citizens to practice their profession in Turkey. To open a pharmacy, a practitioner must hold a degree from a faculty of pharmacy recognised by the MoH, obtain a pharmacy diploma approved by the MoH, receive a pharmacy licence from the local health board, and complete at least one year of post-graduate experience as an assistant pharmacist.

Ownership and management of a community pharmacy is reserved for qualified pharmacists; corporate ownership is not permitted.

Pharmacies are subject to inspection by Provincial Health Directorates and must comply with storage and cold-chain requirements. Prescription medicines are only dispensed via a valid prescription through a nationwide electronic prescription system enabling real-time verification and reimbursement processing.

Online sales of medicinal products are banned under Law No. 1262, and the MoH is empowered to order the blocking of non-compliant platforms. Direct-to-consumer advertising of medicinal products is also forbidden, with limited exceptions for public health campaigns authorised by the MoH.

For medical devices sold directly to consumers – such as Class I devices, diagnostic tests, or assistive technologies – the framework is less restrictive than for medicines, and no equivalent pharmacy-only rule applies. All medical devices must carry CE marking or equivalent certification and be registered in the ÜTS before they may be placed on the market, regardless of the sales channel.

Non-compliance with retail distribution rules for medicines or devices may result in administrative sanctions and criminal liability described in the wholesale distribution section above.

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

Online sales and purchase of medicinal products via the internet or any other electronic environments are strictly prohibited under Turkish law. This ban covers all pharmaceuticals regardless of classification, and licensed pharmacists are barred from maintaining commercial pharmacy websites. Turkey’s approach is notably stricter than that of most EU Member States, which generally permit the online sale of at least non-prescription products.

The MoH is empowered to block access to online platforms promoting or selling medicinal products without prior judicial authorisation. Administrative monetary fines apply, and criminal liability under the Turkish Penal Code may be triggered where public health is endangered. Social media platforms are not treated differently: any social media activity – even on personal accounts – that could be construed as promoting medicines to the public, including likes or shares, is prohibited.

Under the Regulation on Sales, Advertisement and Promotion of Medical Devices, medical devices may not be sold through the internet or other electronic media. The sole exception applies to low-risk devices listed in Annex 3, which may be sold online provided the seller is registered with ÜTS and performs unit-level movement notifications. The advertising of devices intended exclusively for healthcare professionals to the general public is prohibited. For devices lawfully sold online, general consumer protection rules under Law No. 6502 on Consumer Protection apply.

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)?

The import of therapeutic products into Turkey combines pre-market regulatory authorisation, product registration, customs controls, and risk-based border inspections, with TİTCK as the central competent authority.

For medicinal products, a marketing authorisation from TİTCK is required before commercial importation; the licence incorporates permission to import. Only the marketing authorisation holder may clear pharmaceutical products through customs. Three lawful import pathways exist: commercial importation of licensed products; named-patient programmes for products licensed abroad but inaccessible in Turkey; and compassionate use for unlicensed investigational products. In May 2024, TİTCK updated its Guide for Import Applications and Market Placement Permits, consolidating conditions for various product categories. Parallel importation of pharmaceutical products is strictly prohibited.

Prior ÜTS registration is a non-negotiable prerequisite for the import of medical devices. Foreign companies must work through a Turkish legal entity. Required documentation includes CE certificates, Declaration of Conformity, ISO 13485 certification, technical file, and Turkish-

language labelling. Non-EU manufacturers must appoint a Turkish Authorised Representative. Devices imported from the EU with the required conformity documents and CE certificates can proceed through customs without physical inspection.

At the border, the Ministry of Trade's TAREKS risk-based control system conducts electronic safety and quality checks on medical devices and other product categories. Medicines and health-related products require a control certificate from the MoH alongside standard commercial documentation. Pharmaceutical products classified under HS Chapter 30 generally benefit from reduced or zero duty rates under the EU-Turkey Customs Union for products of EU origin. Other products are subject to the standard 'Most-Favored-Nation' US tariff schedule.

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?

Turkey's framework for personal importation distinguishes between products carried physically by travellers and those received by post, applying different rules depending on the product's regulatory status, origin, and quantity.

For travellers physically carrying medicines, personal-use quantities are permitted without prior authorisation, provided that medical documentation – such as a doctor's report or prescription – is presented to customs authorities.

Products should be in original packaging with clear labelling. Quantities exceeding a three-month supply may be treated as commercial importation and seized.

A valid prescription is required for controlled substances, including narcotic analgesics and psychotropic drugs. Customs authorities may require advance authorisation from the MoH for stronger narcotic substances. Travellers are advised to verify requirements with the Turkish consulate prior to travel.

These personal importation rules do not create any exception to the ban on the online commercial sale of medicines. The personal use pathway applies only to products lawfully available in the country of export and supported by valid medical documentation. Ordering foreign-sourced medicines online remains in breach of Turkish pharmaceutical law regardless of quantity, and the customs authorities may seize such shipments.

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?

Foreign suppliers cannot lawfully ship medicinal products directly to Turkish consumers via e-commerce, marketplace platforms, or mail order. This ban stems from multiple overlapping layers of Turkish law.

The foundational barrier is the marketing authorisation requirement. Foreign companies cannot hold marketing authorisation for human medicinal products in Turkey. Instead, multinational companies must establish local entities or work with local distributors. Without a marketing authorisation or a Turkish authorisation holder, a foreign entity has no legal basis to ship products to consumers.

Foreign e-commerce service providers operating in Turkey must register with the Electronic Commerce Information System (ETBİS), which practically necessitates establishing a local presence. Marketplace intermediaries must verify merchant authorisations and remove unlawful listings. Pharmaceutical listings on marketplace platforms are intrinsically unlawful under Turkish law.

All medicinal products and medical devices lawfully placed on the Turkish market must carry Turkish-language labelling, patient information leaflets, and instructions for use as approved by TİTCK.

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?

Turkey effectively bans parallel importation of medicinal products through regulatory rather than intellectual property law alone, maintaining one of the most restrictive positions among comparable jurisdictions.

Marketing authorisation must be obtained before importation, and a particular medicinal product may be authorised by only one entity. Since only the authorisation holder may clear pharmaceutical products through customs, a parallel importer – operating outside that holder’s distribution network – cannot obtain the necessary clearance, regardless of whether the product is genuine and lawfully marketed in the country of export.

For medical devices, the requirement for prior ÜTS registration and Turkish-language labelling has an equivalent practical effect, as a parallel importer cannot satisfy these requirements independently of the authorisation holder.

From an intellectual property perspective, Article 7 of the Turkish Industrial Property Code No. 6769 is interpreted to allow international exhaustion. Once a product is lawfully sold with the brand owner’s consent anywhere in the world, it can in principle be imported and resold in Turkey. However, this IP-law permissiveness is entirely negated for therapeutic products by the sector-specific regulatory barriers described above. Rights-holders therefore have two parallel enforcement tracks – regulatory and IP-based – although the regulatory route is more straightforward in practice.

Re-labelling and re-packaging compound the prohibition. The Regulation on Packaging and Labelling of Pharmaceuticals requires that packaging changes be reviewed and approved by the MoH, and all packaging information must be in Turkish. A parallel-imported product would invariably fail these requirements, making commercially viable parallel importation impossible.

Customs authorities actively enforce the ban. Turkish Customs has detained shipments of grey market goods under suspicion of counterfeiting or regulatory non-compliance, and rights-holders may file Customs IP applications under Customs Law No. 4458 to monitor and hold suspect shipments.

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?

Turkey's export control framework for therapeutic products is primarily driven by safeguarding domestic supply. The system has evolved through circulars, guidelines, and regulations administered by TITCK, with enforcement underpinned by the pharmaceutical serialisation and track-and-trace infrastructure.

The foundational measure is the absolute prohibition on re-exporting imported medicines, introduced by TITCK Circular No. 2014/11 in response to wholesalers purchasing imported medicines at controlled prices and re-exporting them, causing domestic shortages. The December 2023 Guidelines on Export Conditions Outside Pharmaceutical Warehouses reinforced this by requiring that all products to be exported must be procured directly from the manufacturer, and that no product may be exported without a valid export permit from TITCK. This 'manufacturer-sourcing' rule closes any residual pathway for re-export of imported products. TITCK enforces this through the İTS, which records every movement of a serialised pharmaceutical product and enables real-time detection of diversion attempts.

Both the licence-holding company and the exporter bear joint and several liability for all operations. Export-authorized companies must demonstrate their connection to Turkish marketing authorisation holders through the trade registry gazette and be registered on TITCK's Electronic Application System (EBS).

Pharmaceutical businesses carry out export activities by reporting through İTS. Products and active substances must move exclusively within the legal supply chain. TITCK uses İTS data to take precautionary measures against products at risk of leaving the supply chain unlawfully, including electronically terminating the sale authorisation of suspect products.

A parallel notification obligation was introduced in August 2024 for medical devices. Any economic operator that reasonably foresees a supply interruption which could cause serious harm to patients must notify TITCK at least six months in advance.

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?

According to the December 2023 export guidelines companies without a domestic marketing authorisation but wishing to export domestically manufactured products must apply for an export permit from TITCK. This functions as a de facto export-only authorisation but does not exempt the manufacturer from holding a GMP-compliant manufacturing licence. Turkey's PIC/S membership, formalised in 2018, has led TITCK to align its manufacturing certification with PIC/S standards.

Products manufactured exclusively for export are not required to carry Turkish-language labelling, as those requirements attach to products placed on the Turkish market. Export products may carry labelling in the format required by the destination country. There is no explicit 'dual-labelling' regime permitting a single manufacturing run to generate both domestically-labelled and export-labelled batches. In practice, Turkish manufacturers obtain a Certificate of

Pharmaceutical Product (CPP) or GMP certificate from TITCK to support registration in the importing country.

Export-oriented manufacturers are subject to the same GMP standards as domestic manufacturers, including batch records, deviation management, and quality control documentation. Both the licence-holding company and the exporter bear joint and several liability, and export activities must be reported through ITS. For medical devices manufactured in Turkey and exported to the EU, the near-verbatim transposition of EU MDR 2017/745 means that export-only manufacturers face substantively equivalent requirements regardless of the intended destination market.

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?

Turkey maintains a comprehensive framework of labelling, serialisation, traceability, and anti-counterfeiting requirements for therapeutic products. The requirements differ between medicinal products and medical devices but share the objectives of ensuring product authenticity, patient safety, and supply chain visibility.

Language and labelling requirements for medicinal products and medical devices

All medicinal products placed on the Turkish market must carry packaging and patient information leaflets exclusively in Turkish, as approved by TITCK. The Regulation on Packaging and Labelling of Pharmaceuticals specifies mandatory elements: product name, active ingredient (INN), dosage form, strength, batch number, expiry date, manufacturer and marketing authorisation holder details, storage conditions, prescription status, and a patient information leaflet. Any packaging changes must be approved by TITCK before implementation.

For medical devices, labels and Instructions for Use (IFU) must be in Turkish. The label fixed to the device packaging may be in an official EU language, provided that safety-relevant documents and assembly, use, and maintenance instructions are in Turkish. Graphical user interfaces are generally expected to be in Turkish, although this is waived for devices intended exclusively for healthcare professionals if a Turkish IFU is provided. Labels must display the CE mark, manufacturer and authorised representative details, the Unique Device Identifier (UDI), and safety instructions.

Serialisation and the ITS

Turkey operates one of the world's most advanced pharmaceutical track-and-trace systems. ITS uniquely identifies each drug unit through a GS1 GTIN combined with a serial number encoded in a GS1 DataMatrix 2D barcode, scanned at each supply chain step. The system commenced in 2008 and reached full implementation in 2012, covering all manufacturers, importers, approximately 700 wholesale warehouses, 40,000 pharmacies, and over 1,000 hospitals. Every product unit must be serialised and registered in ITS before release into the supply chain. The system enables real-time detection of expired, recalled, or suspect products and electronically prevents their continued sale.

Unique device identification and the ÜTS medical device registry

ÜTS registration for medical devices is mandatory for all manufacturers and importers before market placement. The process requires submission of the UDI-DI, technical file, Declaration of Conformity, and CE certificates. Importers must verify CE marking, ÜTS and EUDAMED registration, and Turkish labelling before placing a device on the market. Serious incidents must be reported through ÜTS, and manufacturers must submit annual safety reports. Turkey's UDI framework mirrors the EU's system, and ÜTS and EUDAMED are interconnected under a data-sharing agreement between TITCK and the European Commission.

Turkish-language labelling and ITS serialisation requirements do not apply to products manufactured exclusively for export; however, GMP batch documentation must remain accessible to TITCK. Export activities must be reported through ITS, and all products must remain within the legally authorised supply chain. Products exported to the EU benefit from mutual recognition of TITCK GMP certificates under Turkey's PIC/S membership and the Customs Union framework.

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?

Turkey's price control, reimbursement, procurement, and supply-security frameworks are deeply integrated and exert structural effects on distribution channels and commercial viability of therapeutic products.

Price controls and the reference pricing system

Pharmaceutical prices are subject to comprehensive government control under Presidential Decision No. 11031 on the Pricing of Human Medicinal Products, published on 12 March 2026, replacing the 2017 Pricing Decree. Implementing details are provided by the 2017 Pricing Communiqué, as amended, to the extent its provisions do not conflict with the Decision.

Under the Decision, maximum sale prices are determined by reference to the lowest ex-factory price among five to ten EU Member States selected by the MoH. The reference country basket may be changed with at least two months' notice. On the launch of the first generic, the originator's reference price is capped at 60 per cent of its true reference price. For products whose pharmaceutical form was first placed on the world market before 1 January 2000 ('price-protected products'), the cap is set at 80 per cent.

The euro conversion rate is calculated by multiplying the prior year's annual average Central Bank euro selling rate by an adaptation coefficient of 65 per cent. Transitional provisions fix the rate at TRY26.8767 per euro until 1 April 2026, rising to TRY29.1164 from that date. The persistent gap between the administered rate and the market exchange rate has produced chronic structural under-pricing of pharmaceuticals, creating incentives for parallel exports and contributing to domestic shortages. A separate pricing regime applies to specified categories including OTC medicines, blood products, orphan products, biosimilars, and products of critical public health importance, for which the Commission may determine prices outside the standard framework, including through value-based pricing models.

Mandatory reference price declaration and liability

Marketing authorisation holders must notify the MoH of any changes to their true reference price within prescribed periods. Failure to report reference price decreases constitutes unjust enrichment at public expense, triggering recovery of the resulting public receivable – alongside potential criminal liability under the Turkish Penal Code – from the licence holder by SGK and other relevant public bodies.

Distributor and pharmacist mark-up rates

The retail sale price is determined by applying regulated distributor and pharmacist mark-up rates to the company selling price. The applicable barem thresholds are set under the Decision at TRY406.76 and TRY814.77 (rising to TRY440.65 and TRY882.66 from 1 April 2026).

Reimbursement and its gate-keeping function

SGK administers Turkey’s universal health insurance system covering approximately 95 per cent of the population. Inclusion on the SGK reimbursement list (SUT List 4/A) is functionally essential for commercial viability. Turkey’s access rate to new medicines stands at approximately 15 per cent, well below the EU average of 46 per cent. An alternative reimbursement mechanism permits confidential risk-sharing arrangements between SGK and companies, covering price-volume agreements, outcomes-based contracts, and managed entry schemes.

Public procurement channels

Hospital procurement represents a distinct distribution channel. Pharmaceutical products are dispensed through pharmacy warehouses selling to pharmacies and hospital tenders; named-patient supply operates as a third route. For medical devices, public hospitals procure through the Public Procurement Authority, with standard devices purchasable through the State Supply Office (DMO). Private hospitals procure directly from distributors or manufacturers.

Supply and stock obligations

The Pharmaceutical Warehouses Regulation requires pharmaceutical businesses to hold sufficient quantities to supply at least three pharmacies in the province where they distribute. For medical devices, the August 2024 amendment introduced mandatory shortage notification obligations requiring six months’ advance notice of foreseeable supply interruptions. Foreign pharmaceutical suppliers under the procurement-from-abroad framework must maintain stock for a minimum of one month and a maximum of six months.

Taken together, these interlocking price-control, reimbursement, procurement, and stock-obligation regimes make Turkey a market where commercial distribution decisions are as heavily conditioned by administrative pricing and public payer dynamics as by regulatory approval status.

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 Turkish enforcement framework combines TİTCK's sector-specific regulatory powers with general criminal law, consumer protection, competition law, and customs enforcement regimes.

Investigative powers

TİTCK holds extensive investigative authority, including announced and unannounced on-site inspections of manufacturing facilities, warehouses, pharmacies, and distribution centres, with authority to review documentation, examine stock, collect samples, and access İTS and ÜTS in real time. The Ministry of Trade maintains parallel inspection powers through TAREKS, while Provincial Health Directorates conduct local facility inspections. For digital enforcement, TİTCK coordinates with the Information Technologies and Communication Authority (BTK) to block non-compliant websites.

Administrative sanctions

Administrative sanctions include suspension of market placement, mandatory product withdrawal, destruction of non-compliant products, suspension of promotional activities, and administrative monetary fines. Under Law No. 1262, fines for promotional violations may reach up to five times the relevant product's total annual sales; internet-based promotion attracts website blocking orders. For wholesale distribution violations, TİTCK may suspend or revoke warehouse operating permits and electronically terminate product movements through İTS.

For medical devices, the Regulation on Sales, Advertisement and Promotion of Medical Devices establishes a graduated enforcement regime. Sales centres are subject to mandatory inspection at least once every two years. The framework operates through a warning-and-suspension mechanism: non-compliant advertising or internet sales trigger a warning followed by suspension of activities for 15 days; repeated violations result in progressively longer suspensions of working certificates (three months, then one year). Violations of scientific activities rules follow a similar escalation, culminating in a one-year ban from participating in or supporting scientific meetings. Violations of warranty and technical service obligations result in warnings followed by 30-day suspensions. Permanent revocation of the sales centre authorisation follows where deficiencies are not remedied after temporary suspension; entities whose authorisation is revoked a second time may not reapply for one year, and those revoked three or more times may not reapply for two years. All sales centres in the supply chain bear joint and several liability for enforcement of sanctions. Additionally, sanctions under Product Safety Law No. 7223 include administrative fines, public disclosure of violations, compulsory corrective action plans, and market withdrawal orders.

Criminal sanctions

Under the Turkish Penal Code, anyone who sells or possesses medicines which have been altered in a way that endangers human health is subject to imprisonment from one to five years and a judicial fine. Under Law No. 1262, manufacturing pharmaceutical preparations without a licence or knowingly selling such preparations carries the same penalty range, increased by up to one-third where preparations lack claimed therapeutic effects or are made from impure ingredients.

Enforcement in practice

In practice, TİTCK routinely uses İTS to detect and interdict unlawful product movements, electronically terminating sale authorisations and requiring the physical removal of suspect

products. For medical devices, criminal investigations are initiated after patient deaths or serious injuries linked to devices or pharmaceuticals.

In 2025, the MoH through TİTCK imposed approximately TRY185m (approx. US\$4.3m) in administrative fines for misleading health-related marketing, blocked access to more than a thousand websites, and filed criminal complaints against operators of non-compliant platforms.

Judicial review and civil liability

Regulatory decisions may be challenged before the administrative courts, with appeal to the Council of State.

In parallel, civil liability arises under the Turkish Commercial Code for unfair competition between market participants.

Manufacturers and importers of pharmaceutical products and medical devices bear strict ‘hazard liability’ under the Code of Obligations for injuries caused by their products. Consumer associations may bring representative actions, and mandatory mediation applies to monetary consumer and commercial claims before civil proceedings.

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?

Several significant legislative, policy, and enforcement developments are reshaping the regulatory environment for the trade and distribution of therapeutic products in Turkey.

New pharmaceutical pricing framework (March 2026)

The most significant development is Presidential Decision No. 11031 on the Pricing of Human Medicinal Products (12 March 2026), replacing the 2017 Pricing Decree. Key changes include: the euro conversion coefficient raised from 60 to 65 per cent; the reference country basket expanded to five to ten EU Member States; mandatory annual reference price declarations with criminal liability for non-reporting; a value-based pricing mechanism for specified categories including orphan products, vaccines, and biosimilars; and a graduated generic entry framework with market share thresholds from İTS determining applicable pricing ratios.

The structural gap between the administered euro rate and the market rate narrows somewhat under the 2026 framework; the annual reference price declaration obligation and expanded criminal liability for under-reporting are the most significant new compliance requirements.

EU Legislation alignment and forthcoming regulatory changes

Turkey’s dynamic alignment with EU medical device legislation means that further EU-level amendments to MDR 2017/745 and IVDR 2017/746 – including those arising from the EU Pharmaceutical Package agreed in December 2025 – are expected to be transposed into Turkish law. TİTCK has also signalled forthcoming guidance on quantitative thresholds for the medical device shortage notification regime introduced in August 2024.

Digital enforcement and e-invoicing

The mandatory transition to electronic invoicing for pharmaceutical and medical device traders (deadline extended to December 2025; pharmacies to October 2026) adds a further layer of

supply chain transparency. Enforcement against online pharmaceutical marketing has intensified, with TITCK blocking over 1,000 websites and initiating criminal investigations in 2025.