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# PHARMACEUTICALS AND LIFE SCIENCES LAW IN TÜRKİYE KEY DEVELOPMENTS AND PREDICTIONS

2026

# Life Sciences

We provide a one-stop-shop legal service for life sciences companies combining the firm's strengths in all practice areas.

Our expertise cover wide range of life sciences products including pharmaceuticals, medical devices, food supplements, healthcare products and cosmetics.

We advise and represent trade organisations in the pharmaceutical and medical device sectors in relation to all local and international aspects of their field of activity and member interests, their relations with governmental organisations and peers, as well as establishing regulatory policies, position papers and the like.

We advise clients across all phases of the business cycle of life science products including clinical trials, marketing authorization procedures, pricing and reimbursement regulations, observational studies, promotional activities and ethical rules governing relations with healthcare professionals. We advise and represent clients in life sciences sector in relation to all types of commercial transactions and contracts including licensing, technology transfer, co-marketing, co-promotion and toll manufacturing agreements, joint research, collaboration and development schemes as well as on data privacy and competition law issues.

Combining our life sciences expertise with our employment, competition and anti-corruption expertise, we support corporate clients in compliance with the FCPA and UKBA and the corresponding Turkish rules and regulations as well as offering compliance audits and training programs.

# Introduction

The year 2026 presents both challenges and opportunities for the Turkish life sciences sector. Ongoing economic pressures, inflation, and currency fluctuations continue to impact supply chains, prompting pharmaceutical and medical device companies to carefully evaluate market strategies. At the same time, regulatory developments are strengthening the sector's framework, providing more clarity and predictability for stakeholders.

The Ministry of Health and the Turkish Medicines and Medical Devices Agency ("Agency") have continued to implement measures to enhance product safety, traceability, and compliance. Recent initiatives, from digital tracking systems to evolving reimbursement and Named Patient Program policies, reflect a growing emphasis on transparency, real-world evidence, and value-based decision-making, marking important progress in selected areas, but also highlighting the need for continued regulatory and institutional efforts to extend these principles across the wider healthcare and life sciences ecosystem in Türkiye.

This report provides a forward-looking overview of key regulatory and market trends in Türkiye's life sciences industry, highlighting developments that are shaping the sector today and may influence strategy in the years ahead.

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# Market Access - Alternative Reimbursement Models

Alternative reimbursement models in Türkiye provide pathways for innovative medicines to gain coverage outside standard pricing rules, allowing the Social Security Institution ("SSI") to negotiate terms such as discounts, budget caps, or other arrangements. These models, formalised under the 2016 Regulation on Alternative Reimbursement and updated in 2023, aim to improve patient access while managing healthcare expenditures.

The Regulation on Alternative Reimbursement published in February 2016 introduced complimentary provisions, offering companies and SSI the opportunity to negotiate the terms and conditions of alternative reimbursement models that would be applied to certain products. Through alternative reimbursement models, where pharmaceutical companies directly enter into contractual agreements with the SSI, the discount rates and payment terms are not disclosed to the public and are kept confidential. These models are not limited to authorised medicinal products but may also be applied to certain named patient programs ("NPP") products that are not yet licensed or commercially available in Türkiye, provided that they have been authorised by major regulatory authorities abroad.

In parallel, Turkish authorities are strengthening the evidence base underpinning reimbursement and regulatory decision-making in terms of NPP products. In January 2026, the Agency announced an initiative to systematically generate, analyse, and publish real-world clinical data and pharmacoeconomic evaluations for medicines supplied under the NPP framework. The program targets implementation by January 2027.

The initiative aims to (i) monitor clinical effectiveness and safety in real-world patient populations, (ii) assess budget

impact and value for money using scientific pharmacoeconomic methodologies, and (iii) support strategic decision-making for future licensing and reimbursement policies. Data collection and analysis will be conducted in line with international standards, patient privacy, and ethical principles, in collaboration with relevant stakeholders and academic bodies, with results to be shared publicly on a periodic basis.

Looking ahead, the systematic use of real-world evidence and pharmacoeconomic analyses is expected to reinforce value-based reimbursement approaches, particularly for products accessed through alternative reimbursement and NPP mechanisms. Companies should anticipate increasing expectations for post-access evidence generation to support ongoing reimbursement negotiations and policy decisions, signalling Türkiye's continued shift toward a more data-driven, transparent, and sustainable market access environment.

# Regulatory and Judicial Trends Shaping Access to NPP Products


NPPs operate as special import regimes that enable access to medicines that are either not authorised in Türkiye or are temporarily unavailable on the domestic market, upon the request of a treating physician. Fundamentally designed to address urgent or exceptional patient needs, the NPP framework has gradually evolved into a more structured and regulated supply mechanism.

A significant step in this evolution was the entry into force of the Regulation on the Importation of Medicines from Abroad in February 2023. This regulation clarified stakeholder roles across the NPP process and introduced new compliance expectations. Foreign entities supplying medicines were formally defined as foreign drug supply sources and were required to appoint representatives in Türkiye. At the same time, the Turkish Pharmacists' Association, the Social Security Institution, and Ministry-approved entities were designated as authorised foreign pharmaceutical product suppliers. Distribution of medicines supplied under the program was expressly aligned with good distribution practice requirements, reinforcing supply chain integrity.

In parallel, traceability and oversight were substantially strengthened. Medicines imported through the NPP channel became subject to mandatory recording in the Pharmaceutical Track and Trace System, using QR codes in the same manner as authorised products. Subsequent updates to the implementation guidelines introduced additional flexibility in how QR code procedures may be carried out, including within customs-free zones, while clarifying the allocation of financial and operational responsibilities among suppliers and their representatives. Together, these measures reflect a broader policy objective of ensuring transparency, accountability, and regulatory

visibility across all stages of the import process.

More recently, the regulatory approach to NPPs has begun to extend beyond access and logistics toward outcomes and value assessment. A policy initiative announced in January 2026 signals the authority's intention to systematically generate and analyse real-world clinical data and pharmacoeconomic evidence for medicines supplied under the NPP framework, with implementation envisaged by January 2027. This data is expected to support sustainability in healthcare financing and to inform regulatory and reimbursement decisions through evidence derived from routine clinical practice.

This development points to a strategic recalibration of the NPP model. While patient access remains central, continued reliance on the program may increasingly depend on demonstrable clinical benefit and economic justification. Real-world evidence and pharmacoeconomic analyses are, therefore, likely to become integral components of decision-making related to ongoing supply, future authorisation pathways, and reimbursement positioning.

Judicial developments in 2025 further reinforce this shift toward evidence and value-based assessment within the NPP framework, particularly in the context of reimbursement disputes. In a recent decision, the Council of State set aside lower court rulings that had favoured patient reimbursement by the Social Security Institution for a product supplied under the NPP regime, emphasising that regulatory approval alone does not automatically justify public reimbursement. The Court articulated a detailed evaluation framework requiring an individualised and data-driven assessment, including the patient's clinical history, genetic compatibility, disease stage, prior treatment outcomes, and the availability of reimbursed alternatives, alongside robust Phase 3 and Phase 4 clinical evidence and expert opinions. Importantly, the Court highlighted the need to balance potential clinical benefit, quality-of-life impact, and cost-effectiveness within the broader context of public health policy. This reasoning signals a judicial trend toward stricter scrutiny of NPP reimbursement claims, aligning court practice with administrative efforts to link access and reimbursement more closely to demonstrable medical necessity and economic justification.

# A New Era in Turkish Pharmaceutical Pricing: Market Incentives Updated

The Turkish pricing system relies on a reference price system, where the lowest wholesaler price for the relevant product in an EU Member State is used as a reference and determined to be the maximum possible wholesaler sales price in Türkiye. The reference price is then converted into Turkish lira.

The Presidential Decision No. 11031 dated 12 March 2026 ("New Pricing Decision") introduces major changes to the pricing system for human medicinal products, originally established by Decision No. 2017/9901 and updated multiple times.

Previously, the Turkish Lira value of the Euro for pricing human medicinal products was 60% of the previous year's average Euro value. The coefficient is now raised to 65% for the first time in years. Until 1 April 2026, the Euro value will temporarily remain at 60 percent. From 1 April 2026, the Euro/TRY rate will be 29.1164 TRY. While this adjustment addresses a long-awaited sectoral concern, it remains insufficient to fully resolve patient access issues, particularly for innovative therapies. Considering Türkiye's reference exchange rate mechanism and the limited public pharmaceutical budget, this increase alone is unlikely to provide a sustainable solution. OECD data indicate that both the share of pharmaceutical spending in Türkiye's healthcare expenditures and per-capita pharmaceutical spending remain below many OECD countries. Therefore, exchange rate adjustments alone cannot improve access, and the public pharmaceutical budget also requires strengthening.

The New Pricing Decision introduces a new incentive system allowing higher pricing for the first equivalent or generic products to enter the market. Normally, generic medicines are priced up to 60% of the lowest-priced EU reference product. Under the new system, first equivalent or generic products can receive 80% of the reference price in year one, 75% in year two, and 70% in year three. If locally

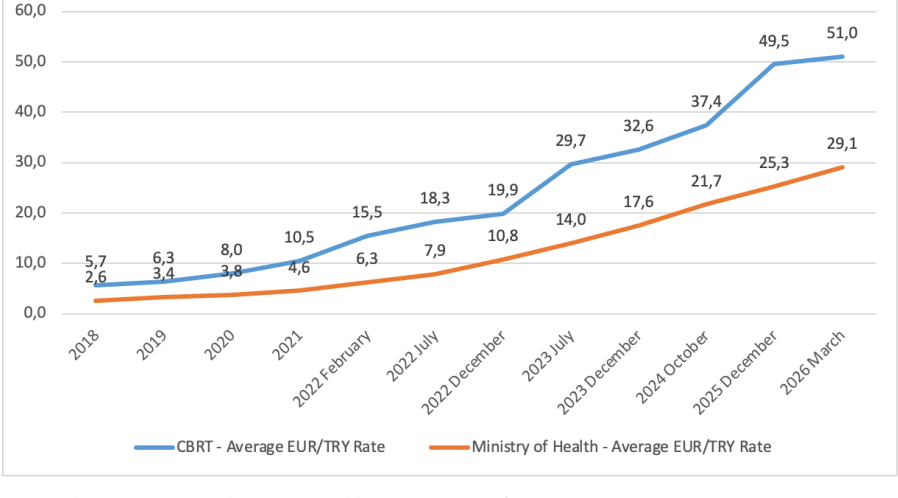
manufactured generics achieve certain market-share thresholds in years two and three, these percentages may increase. This approach resembles the U.S. system where the first generic benefits from temporary market exclusivity and is now implemented in Türkiye as a pricing advantage.

Flexible pricing mechanisms continue to apply for products such as blood products, allergy products, orphan drugs, biosimilars, vaccines, medicines critical to public health, and those under alternative reimbursement arrangements. In addition, "value-based pricing" has been introduced in Turkish legislation, signaling that value-based pricing and reimbursement methods, which the innovative pharmaceutical industry has advocated for many years, can now be implemented.

Transition details are critical. The new pricing system will be gradually implemented throughout 2026, with Euro/TRY calculations and certain price thresholds updated on specific dates. Tiered rates for equivalent products will apply only to products launched after the Decision enters into force. Existing products will retain current pricing during the transition.

The current Communiqué on the Pricing of Human Medicinal Products ("Communiqué") remains in effect for provisions not conflicting with the Decision until a new Communiqué is published. Companies must closely monitor updates regarding pricing applications and changes to ensure compliance during the transition. Full adoption of the new system will become clear once temporary arrangements are concluded and the secondary legislation, namely the Communiqué, is updated.

Graph 1. Average Euro/Turkish lira exchange rates according to the Turkish Central Bank (CBRT) and Ministry of Health, TÜRKİYE, 2018-2026




Sources: https://www.tcmb.gov.tr/ and https://www.titck.gov.tr/

# Market Availability of Products and Parallel Trade

Counterfeit and illicitly traded health products remained a persistent concern in Türkiye throughout 2025, as reflected both in enforcement statistics and in external reporting on supply chain integrity. Despite the legal prohibition on the online sale of pharmaceutical products, there has been a noticeable increase in the circulation of counterfeit medicines through online channels, alongside growing reports of products being illicitly exported from Türkiye to foreign markets. These trends continue to pose risks to product availability, patient safety, and the overall integrity of the regulated supply chain.

Enforcement activities conducted on the ground in 2025 were, in general, robust and operationally effective. Large-scale seizures and coordinated actions by law enforcement authorities served to prevent millions of counterfeit pharmaceutical products from entering the market. In parallel, authorities and professional stakeholders intensified scrutiny of both online and offline illicit markets where pharmaceuticals, health products, and other regulated items circulate outside formal distribution channels. While different public authorities followed distinct operational roadmaps, criminal enforcement mechanisms proved to be the most effective and deterrent, particularly in cases involving organised illicit trade and large-volume counterfeit distribution.

From an administrative perspective, the Guideline on Products that are Counterfeit, Smuggled, or Outside the Legal Supply Chain, introduced in 2021, was designed to clarify the responsibilities of relevant stakeholders in combating counterfeit, smuggled, and diverted products from a public health and safety perspective. The primary objective of the Guideline is to ensure a multi-stakeholder approach by assigning defined roles to regulatory bodies, industry actors, and other institutional stakeholders in the fight against illegal supply chain activities.

However, practical implementation challenges have limited the Guideline's overall effectiveness in fully addressing counterfeit pharmaceutical risks in Türkiye. In particular, the Guideline lacks sufficiently detailed operational steps and concrete enforcement mechanisms targeting counterfeit and diverted pharmaceutical products. Moreover, the Ministry of Health and the Agency primarily exercise regulatory and supervisory functions and do not possess direct enforcement powers. As a result, effective and deterrent action against counterfeit pharmaceuticals largely depends on close coordination between the Ministry of Health, the Turkish Medicines and Medical Devices Agency, and enforcement authorities such as the police, gendarmerie, and customs.

Looking ahead, strengthening inter-agency coordination, developing more operationally detailed administrative frameworks, and integrating regulatory oversight with criminal enforcement are likely to remain critical for enhancing supply chain integrity. In this context, a more structured alignment between regulatory monitoring and enforcement action would support a more proactive and deterrent response to the increasing sophistication of counterfeit and illicit pharmaceutical trade affecting the Turkish market.

# Interactions with Healthcare Professionals, Transfer of Values and Conditions of Payment

Interactions between life sciences companies and healthcare professionals ("HCPs") in Türkiye continue to be governed by a well-established regulatory framework. In the pharmaceutical sector, promotional activities remain subject to the Regulation on the Promotion of Medicinal Products for Human Use, which strictly limits promotion to healthcare professionals and prohibits direct or indirect advertising to the public. Engagements such as consultancy and service arrangements with HCPs are permitted, provided they are supported by written agreements, comply with ethical principles and the full-time work framework, and are transparently reported where value transfers exceed applicable thresholds.

Although draft amendments to the pharmaceutical promotion regime were circulated for consultation in 2024, no new regulation entered into force in 2025. As a result, the regulatory environment has remained formally unchanged. Nevertheless, this period of legislative stability should not be interpreted as reduced regulatory attention. On the contrary, supervisory practice increasingly emphasises strict adherence to existing rules, particularly in relation to the justification, documentation, and proportionality of HCP engagements.

In the medical devices sector, promotional activities continue to be regulated under the Regulation on Sale, Advertising, and Promotion of Medical Devices. While this framework traditionally offers more flexibility, particularly in comparison to pharmaceutical promotion, enforcement practice increasingly reflects converging expectations.

Across both sectors, the evolution of engagement models has introduced new compliance challenges. Digital meetings, hybrid scientific events, remote advisory boards, and distributor-mediated interactions are increasingly central to HCP engagement strategies. These formats, while operationally efficient, raise questions regarding attribution, transparency, and the delineation between scientific exchange and promotion.

# Medical Devices: New Sanctions and Technical Service Governance

Recent regulatory developments in the medical devices sector point to a shift from procedural compliance toward enforcement-driven market discipline, coupled with a gradual restructuring of technical service governance.

A major inflection point in this trajectory was the entry into force of Law No. 7557 in July 2025, which introduced Additional Article 20 to the Basic Law on Health Services. This provision significantly expanded the administrative sanctions framework applicable to medical devices, particularly targeting counterfeit products, unauthorised sales channels, and unlicensed technical service activities.

By introducing high-value administrative fines and extending liability beyond formally authorised actors, the legislator effectively closed a long-standing enforcement gap. Under the new framework, both authorised and unauthorised persons or entities may be held accountable for placing counterfeit devices on the market, engaging in sales or promotional activities outside permitted channels, or providing technical services without proper authorisation. The inclusion of recidivism-based penalty escalation further signals an intention to enhance deterrence and discourage systemic non-compliance.

From a governance perspective, this development marks a transition toward a more robust market surveillance model, where financial sanctions are positioned as a central tool for safeguarding patient safety, protecting intellectual property, and ensuring fair competition.

On the other hand, the Regulation on Technical Services for Medical Devices Used in Healthcare Services introduced a comprehensive framework governing the authorisation, qualifications, training, and supervision of technical service providers. While the regulation itself entered into force its upon publication, the deadline for

full compliance with its technical service requirements has been extended. Through an amendment to the transitional provisions, the deadline for ensuring conformity of technical service activities with the regulation has been postponed from 1 January 2026 to 1 July 2027.

This extension will allow the structural and operational adjustments required across the sector, particularly in relation to personnel qualifications and certification processes.

# Healthcare System Reforms

In July 2025, Türkiye introduced Law No. 7557, bringing wide-ranging updates to the healthcare system. These reforms aim to modernise services, improve efficiency, and strengthen oversight, responding to growing healthcare demands and technological developments.

For the life sciences sector, several provisions are particularly relevant:

- Physicians and dentists are now limited to practicing in a maximum of two healthcare institutions, marking a shift toward tighter workforce oversight. Physicians working under previous permits must apply for new authorisation by 1 June 2026, or their permits will be automatically revoked. While aimed at standardisation, the restriction has raised concerns about access to care in underserved regions.
- A complete advertising ban has been introduced for private healthcare institutions, allowing only limited informational content. Violations will trigger substantial administrative fines, prompting concerns about proportionality and the impact on smaller providers.
- Pharmaceutical regulation has been significantly strengthened by embedding the Pharmaceutical Tracking System ("İTS") into primary legislation and extending it to include specialised medical nutritional products.
- Electronic informed consent is now authorised, allowing patients to provide consent digitally. While this is more relevant to clinical operations, companies involved in digital health tools or connected devices may need to adjust processes to support compliance and usability.

The reforms do not directly change pricing rules but highlight ongoing challenges with drug supply, reimbursement, and currency-linked pricing distortions. Overall, these amendments formalise many existing practices and introduces stricter regulatory expectations. The key takeaway is that compliance, traceability, and supply chain integrity are becoming increasingly critical, while digital health integration and adherence to reporting requirements will be essential for operating successfully in Türkiye's evolving healthcare environment.

# Food Supplements

Following the structural changes introduced in 2023 to the regulatory framework governing health claims on food and dietary supplements, the subsequent period has been characterised less by new legislative intervention and more by regulatory consolidation and practical implementation. The removal of mandatory prior administrative approval for health claims has remained in effect, reshaping the compliance landscape by shifting greater responsibility onto economic operators.

During 2025, regulatory activity in this field primarily focused on operational clarification and supervisory practice, rather than the introduction of new primary rules. Administrative guidance and internal procedures have increasingly emphasised documentation quality, ingredient specifications, and labelling accuracy, signalling a move toward standardising enforcement expectations under the existing framework.

Regulatory attention is expected to intensify product classification, claim substantiation, and the differentiation between conventional food supplements and products with pharmaceutical-like characteristics. Although no comprehensive legislative overhaul has yet materialised, ongoing discussions suggest that authorities may seek to draw clearer regulatory boundaries for high-potency or functionally complex supplements.

# Plant Protection Products: Digital Governance and Traceability

Plant protection products ("PPPs") are defined in legislation in a broad and highly technical manner. They include preparations used to protect plants and plant products against harmful organisms or to prevent their effects, excluding products intended solely for plant nutrition. These products may also influence plant growth, control or prevent undesirable developments, or eliminate unwanted plants, and typically consist of one or more active ingredients that work synergistically or enhance reliability.

Production, sale, storage, and application of PPPs have been subject to stringent administrative regulation and oversight. In Türkiye, the primary legal framework is provided by Law No. 5996 on Veterinary Services, Plant Health, Food, and Feed, supplemented by detailed secondary legislation.

On 13 December 2025, two key regulations were introduced: the "Regulation on the Application and Supervision of Plant Protection Products" and the "Regulation on Wholesale and Retail Sales and Storage of Plant Protection Products". Both regulations signal a shift toward digitally enabled governance, emphasising process monitoring and traceability as central features of future compliance.

The B-Prescription system has been introduced which is a digital platform enabling the recording and supervision of PPP applications. By capturing data from prescription to application and harvest in a centralised database, this system enables a fully traceable supply chain. The B-Prescription system has the potential to evolve into a predictive tool, helping authorities identify risks and non-

compliance before they materialise, rather than solely responding when necessary.

The regulations also modernise the oversight of PPP sales and storage. Products may only be marketed through Ministry-authorised wholesalers and retailers, with online or remote sales prohibited.

The implementation of the tracking system will provide a more robust digital governance and continuous refinement of regulatory practices to respond to emerging risks.

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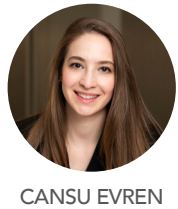

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# Firm Overview

We are one of the oldest and largest law firms in Turkey and are considered internationally to be among the top-tier of legal services providers.

We are a full-service law firm leading the intellectual property field among others, providing dispute management, advisory, transactional, prosecution, investigation, and regulatory markets law services to domestic and multinational corporations.

We are based in Istanbul, with working and correspondent offices in Ankara, Izmir and the major commercial centres in Turkey.

We operate mainly in Turkish and English and also work fluently in German and French.

We advise a large portfolio of clients in numerous fields of activity including life sciences, insurance and reinsurance, energy, construction & real estate, logistics, technology, media and telecoms, automotive, FMCG, chemicals and the defense industries.

Our vision is to be the leader in the services we provide, sensitive to wider society, the environment, and our employees as an innovative and sustainable institution.

Our clients' success is at the heart of our own success. We closely monitor developments in the business sectors in which our clients operate and invest in accumulating industry specific knowledge to understand their changing needs. We actively participate in professional, trade and business organisations in Turkey and internationally.

We are committed to adapt to our clients' changing business needs by delivering innovative, high quality and commercially prudent legal solutions.

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