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PHARMACEUTICALS AND LIFE SCIENCES LAW IN TÜRKİYE KEY DEVELOPMENTS AND PREDICTIONS

2025

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 2024 marks a challenging period for the Turkish healthcare industry. Economic fluctuations, inflation and increases in exchange rates have put a strain on supply chains in the life sciences sector, prompting various pharmaceutical and medical device companies to reassess their market strategies. During this process, the decisions of certain companies to suspend their plans to launch new products, in addition to issues related to access to medication, have fuelled the already present uncertainties in the industry.

Meanwhile, Türkiye's healthcare regulations have largely become aligned with international standards and have progressively evolved into a stronger structure. The Ministry of Health and the Turkish Medicines and Medical Devices Agency ("Agency") continue to implement new measures to ensure product safety and eliminate uncertainties in the regulations relevant for the sector. Developments in areas such as marketing authorisations, registration systems, and codes of conduct have contributed to creating a more transparent and reliable foundation for the sector. In addition, the 12th Development Plan 2024 – 2028 ("Development Plan") and the 2025 Annual Presidential Program define Türkiye's development goals and strategic policies for various sectors. These documents focus on enhancing sustainability in Türkiye's healthcare sector, improving domestic production capacity, and reducing dependence on imports. Supporting domestic production, increasing the effectiveness of healthcare services, and promoting innovative technologies are the key components of these objectives.

In this light, a significant transformation process is anticipated in the Turkish healthcare sector, with the hope that it will make a substantial contribution to economic development.

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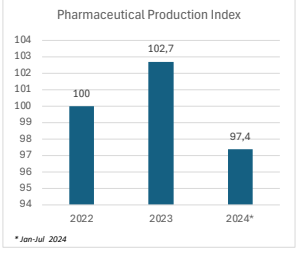
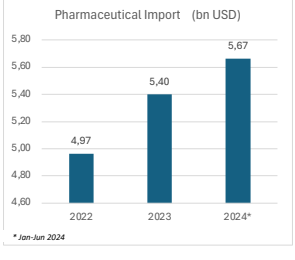
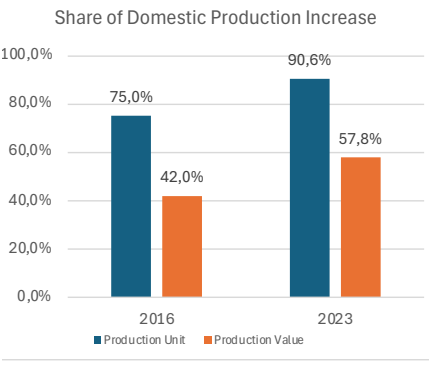
Medicines and Medical Devices Sectors: Current Status and Evolving Dynamics

The pharmaceutical sector saw a 2.7% increase in production in 2023. However, between January and July of 2024, there was a 5.2% decrease compared to the same period in the previous year. By 2023, pharmaceutical imports increased by 8.8% reaching a value of 5.4 billion USD, while pharmaceutical exports grew by 15.8% to the size of 2.2 billion USD. In the first half of 2024, exports rose by 1.9%, while imports increased by 4.9% [1].

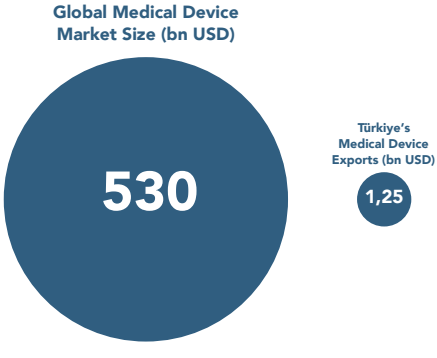


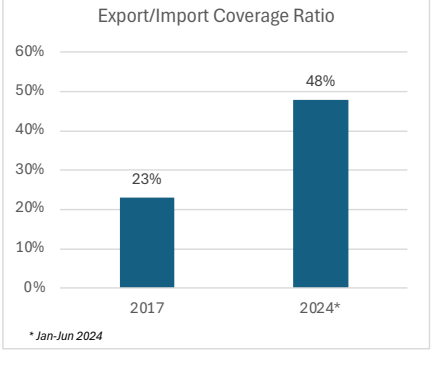


In 2023, the Turkish pharmaceutical market grew by 90.9% in value in hospitals and pharmacies, reaching 222.5 billion TRY. In this context, the share of domestic production also increased: in 2016, the proportion of manufactured medicines in terms of packaging was 75% and 42% in value, while by 2023, these rates increased to 90.6% in terms of packaging and 57.8% in terms of value [1]. These figures reflect Türkiye's increase in pharmaceutical production and changes in capacity utilisation rates.



The medical device sector has shown similar growth. By 2023, the global medical device market had exceeded 530 billion USD, while Türkiye's medical device exports amounted to 1.25 billion USD. In the Turkish medical device sector, the export/import coverage ratio was 23% in 2017, and by the first half of 2024, this ratio had increased to 48% [1]. These developments can be seen as tangible indicators of the importance placed on policies in support of domestic production.





However, this does not mean that important problems regarding quality, innovation, and external dependence should be overlooked, as these are still on the agenda for ensuring the sustainability of the improvements, particularly in the pharmaceutical sector. The exchange rate set by the Agency for imported pharmaceuticals and the importation of raw materials for domestic production have a significant impact on both product prices and the balance between production and export.

In additional, counterfeit medicines, smuggled pharmaceutical products, or medicines outside the legal supply chain have an adverse effect the dynamics of the sector in a variety of ways. Assessments made without considering these factors may hinder a proper understanding of the sectoral developments. Therefore, attributing growth and export increases solely to the rise in production capacity may be misleading.

In the medical device sector, since product prices are not set by the Agency, pricing depends on free market conditions. On the other hand, when considering the exchange rate and inflation in reimbursement prices for products, these remain insufficient.

An assessment of the increase in the export/import coverage ratio should also consider other factors (such as the inability of new technologies to enter the market and the withdrawal of imported products from the market due to exchange rate fluctuations), as these may not fully reflect the true dynamics of the sector.

[1] 2025 Presidential Annual Program, p. 126, 2.2.1.1.2. Medicines and Medical Devices.

Fixed Exchange Rate in Pricing of Pharmaceuticals and its Impact

The prices of pharmaceuticals to be launched on the market are determined in accordance with the Decision on the Pricing of Medicinal Products for Human Use ("Decision") and the Communiqué on the Pricing of Medicinal Products for Human Use ("Communiqué") dated 29 September 2017, published by the Ministry of Health, which has been authorised to regulate this area.

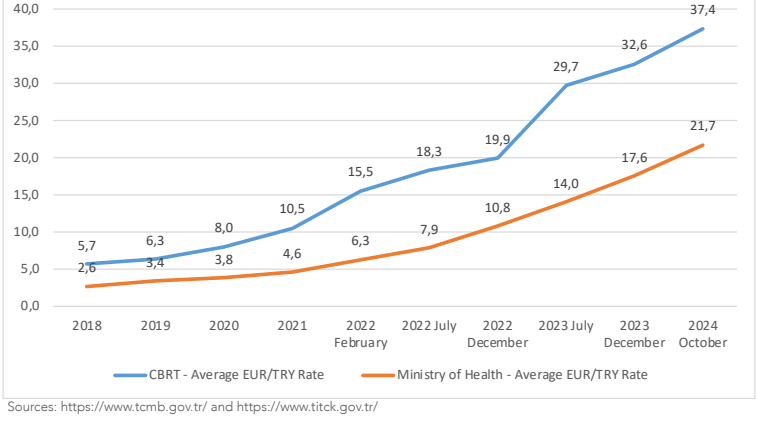
The Decision foresees a reference pricing system in which the lowest wholesaler price for the relevant product in an EU Member State is used as a reference and is determined to be the maximum possible wholesaler sales price in Türkiye. The reference price is then converted into Turkish lira. However, in order to prevent the impact of exchange rate fluctuations, the aim is to calculate and set a value using a fixed exchange rate each year. This ensures that the exchange rate applied to the reference price from the relevant EU country remains constant for one year, but is significantly lower than the current exchange rate.

According to the Decision, the exchange rate shall be determined as 60% of the average value in euro from the previous year. The Pricing Evaluation Commission meets within the first 45 days of each year and announces the Turkish lira value for 1 euro based on the calculation of 60% of the previous year's average value.

In line with this rule, although the exchange rate used for pricing of pharmaceuticals must be updated annually, updates have been made to the pricing at various times during the year due to the difference between the set exchange rate and the current rate increased, without waiting for the first 45 days of each year.

The most recent pricing update made in October 2024 indicated that a new update was necessary, as the euro value was increased by 23.5%, setting the new euro pricing value at 21.6721 TRY.

Graph 1. Average euro/Turkish lira exchange rates according to the Turkish Central Bank (CBRT) and Ministry of Health, TÜRKİYE, 2018-2024



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

Market Access - Alternative Reimbursement Models

In the presence of alternative reimbursement models developed globally for pharmaceutical reimbursement systems, such as payback, value-based, indication-based reimbursements, and performance-based models, the Turkish pharmaceutical industry has also required alternative reimbursement models that fall outside the usual pricing and reimbursement rules for innovative products, and that can be negotiated with the Social Security Institution (SSI) to determine reimbursement conditions.

With the enactment of Law No. 6552 on Social Security and General Health Insurances in September 2014, alternative reimbursement models became an important item of agenda for the Turkish healthcare sector. 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, it was expected that patients would gain faster access to innovative medicines. However, today, it appears that these models are sometimes preferred by companies to be able to have some control over the discount rates they offer. In these models, the discount rates and payment terms are not disclosed to the public and are kept **confidential**.

In May 2023, the new Regulation regarding General Health Insurance Alternative Reimbursement for the SSI was published. The new regulation aimed to establish a more predictable system by defining principles related to the determination of Alternative Reimbursement Committee meeting dates, setting time limits on agenda topics, and ensuring that the work is conducted confidentially.

The 12th Development Plan and the 2025 Presidential Annual Program aim to increase sustainability in Türkiye's healthcare sector and manage pharmaceutical and treatment expenditures more efficiently. In this context, the widespread adoption of **value-based reimbursement methods for innovative pharmaceuticals** emerges as an important strategy. It is expected that by 2025 (and beyond), this model will widely applied within the healthcare system and will become more effective. With value-based reimbursement methods, reimbursements will be made based on the effectiveness of the medicinal products, which will enhance the efficiency of the healthcare system and ensure greater transparency. This process will enable the more sustainable management of healthcare expenditures and foster a more balanced growth in the healthcare sector.

Market Availability of Products and Parallel Trade

The export of products that are produced for and imported to the Turkish market after being introduced to the market may restrict patients' access to treatment. Additionally, pharmaceutical products that are purchased at prices significantly lower than those in many other countries and then exported can influence the market prices in other countries. In this context, the Circular No. 2014/11 on the Availability of Pharmaceutical Products in the Market prepared by the Agency outlined the necessary measures to prevent potential pharmaceutical supply issues in the Turkish market.

On 29 December 2023, the Guideline on Export Conditions for those other than Pharmaceutical Wharehouses was published by the Agency and came into effect. The guideline aims for products to be exported by authorised companies which are not pharmaceutical warehouses to comply with Good Distribution Practices and relevant national and international standards. Export of products to other countries without a valid export permit has been prohibited.

Domestic manufacturers or companies that have authorised human medicinal products in Türkiye and/or abroad can export their products either directly through their own companies or via authorised companies. Authorized companies can only apply for an export permit certificate for the

products they are authorised to export. If a company is part of or affiliated with a domestic manufacturer or a company that is authorised for pharmaceutical products for human use in Türkiye and/or abroad, it must apply for an export permit certificate for the authorised products. Companies that wish to export products they have manufactured domestically under their own trademark but for which they do not have authorisation, they must also apply for an export permit.

While this guideline aims to prevent the export of pharmaceutical products without the knowledge of the holders of the product authorisation, no legal steps have yet been taken to prevent pharmaceutical warehouses from exporting legal products without the approval of the rightful holders of authorisation.

In 2021, the Guideline on Products which are Counterfeit, Smuggled, or Outside the Legal Supply Chain was prepared to define the responsibilities of stakeholders in combating counterfeit, smuggled or illegal supply chain products, from a public health and safety perspective. The main objective of this guideline is to involve various stakeholders in the fight against counterfeit products and assign specific responsibilities to them. However, some challenges in the implementation process by the Agency may limit the effectiveness of this Guideline in fully addressing the fight against counterfeit pharmaceutical products in Türkiye.

Named Patient Program

The Named Patient Programs (NPP) are import regimes that allow medicines not authorized in Türkiye or authorized but unavailable for various reasons to be imported from abroad upon request by a physician.

Following publication of the Regulation on the Importation of Medicines from Abroad ("NPP Regulation") published on 3 February 2023, the roles of stakeholders in the relevant process have been clarified. According to this NPP Regulation, institutions and organisations located abroad have been defined as "Foreign Drug Supply Sources," and it has become mandatory for them to have a **representative** in Türkiye. Furthermore, the Turkish Pharmacists' Association, SSI, and the institutions approved by Ministry of Health have been designated as "**Foreign Drug Suppliers**". It has been stipulated that the medicines shall be distributed in accordance with GDP regulations.

Additionally, pharmaceuticals obtained through these channels must be recorded in the Drug Tracking System ("İTS"), just as authorised pharmaceutical products and tracked through this system with a designated QR code.

In addition to this Regulation, the **Guidelines on the Importation of Medicines from Abroad** has also been updated. According to the updated Guidelines, the QR code process performed by foreign drug suppliers may also be carried out by the foreign drug supply source in the customs-free zones. Moreover, it has been stated that the financial obligations related to İTS notifications and QR code processes can be covered by the supplier's representative. This is an important development aimed at increasing transparency and traceability in the pharmaceutical product supply process.

The **12th Development Plan** and the **2025 Presidential Annual Program**, which hold significant place in Türkiye's healthcare policies, aim to include cost-effective options for pharmaceutical importation in the payment lists. This regulation is designed to contribute to the more efficient management

of healthcare expenditures and to expedite patient treatment. However, the primary goal of the exceptional import regime for the importation of drugs from abroad is to ensure the availability of drugs for patients that are not authorised in Türkiye or are not available on the market.

In this context, the effective use of the named patient program mechanism is crucial for both enabling patients to access treatment more quickly and supporting the sustainability of the healthcare system. The inclusion of cost-effective pharmaceuticals in the payment lists can especially have a positive impact on the healthcare budget. However, another important issue to consider in the supply of such pharmaceuticals is ensuring that the imported products are safe for use and are of high quality.

Furthermore, compliance with the regulations stated in the legislation will assist in preventing potential security and quality related problems that may arise in the importation of pharmaceuticals. For the effective operation of Türkiye's healthcare system, these regulations must be carefully adhered to by both manufacturing companies and relevant public institutions. These measures in the healthcare system will ensure that patients gain faster and safer access to the pharmaceutical products they need, while also being effective in **preventing the sale of counterfeit drugs.**

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

Promotion activities for pharmaceutical products for human use are regulated under the Regulation on the Promotion of Medicinal Products for Human Use dated 3 July 2015 ("Promotion Regulation").

The Promotion Regulation stipulates that the promotion of pharmaceutical products can only be conducted with healthcare professionals such as doctors, dentists, and pharmacists. As a result, the interaction of pharmaceutical companies with patients are limited, and direct advertisements to the public are prohibited.

Pharmaceutical companies may seek consulting services from healthcare professionals. However, such services agreements must be made through written contracts, must adhere to specific ethical guidelines, and must comply with the **Full-Time Work Principle**. Additionally, pharmaceutical companies are required to notify the Agency about any value transfers to healthcare institutions or professionals. These notifications are required if the amount of value transfer exceeds the legal limit.

In 2024, **a new draft regulation** regarding the promotion activities of medicinal products for human use was **opened for public consultation** twice. These drafts aim to impose stricter oversight and regulations on promotion of pharmaceuticals. The draft aims to establish a clear framework for promotional and advertising practices. It is seen as a positive development in that the draft creates a foundation for content related to **patient support programs** and product education. However, there is insufficient guidance on other common issues in the sector, such as the training requirements for healthcare professionals and market dynamics. While the new sanctions imposed on healthcare

professionals and institutions aim to increase the effectiveness of the regulations, the applicability of these sanctions and the lack of a comprehensive strategy to address sectoral problems are notable concerns. Although the Agency's steps to raise ethical standards in the sector are important, it should not be overlooked that other challenges also need addressing.

Promotion Activities in the Medical Devices Sector

Promotion activities in the medical devices sector are regulated under the Regulation on the Sale, Advertising, and Promotion of Medical Devices dated 15 May 2014 ("Medical Device Promotion Regulation").

In the Medical Device Promotion Regulation, rules concerning advertisements directed to consumers are specifically tailored to product categories. However, no such distinction is made regarding promotional activities targeted at healthcare professionals. A variety of methods can be used to promote medical devices to healthcare professionals and technical staff working in healthcare institutions. These methods include scientific publications in medical journals about devices and instructional manuals, scientific conferences, and visits by sales and promotion representatives.

Developments in the Field of Medical Devices

On 26 May 2023, significant changes were made to the Medical Device Promotion Regulation. These changes introduced several new procedures to the medical device sector. Rather than being regulated under separate legislation, these procedures were incorporated into the existing Medical Device Promotion Regulation.

According to the updated regulation, additional obligations have been introduced for authorised sales centres for medical devices. These include providing technical services, establishing a quality management system, offering training before the initial use of the device, and issuing warranty certificates. The effective date for these new obligations is 1 January 2025. The Implementation Guide for the regulation includes provisions regarding the issuance of technical service and warranty certificates. If companies fail to comply with these obligations, the penalties outlined in the regulation range from a receiving a warning to the suspension of operations of the sales centre.

On 26 May 2023, the Regulation on Technical Services for Medical Devices Used in Healthcare Services ("Technical Service Regulation") was also published. This regulation defines the qualifications of technical service providers, authorisation and inspection processes, staff training and obligations. With this new regulation, additional steps such as the preparation, certification, and tracking of training for technical service providers are expected to take place. The Technical Service Regulation will come into effect on 1 June 2026. The criteria set out in the regulation for technical services and the suspension or cancellation of authorised technical service working documents may require revisions to contractual agreements with service providers.

These regulatory changes in the medical device sector are expected to have a significant impact on both the operations of companies and Türkiye's healthcare infrastructure. The new rules provide an opportunity for companies to operate in a transparent and compliant manner while also

aiming to improve the overall quality within the sector. Additionally, the **Medical Device Sector Report** published by the Agency highlights the current state of the sector, presenting valuable data on rising healthcare expenditures and market development. To enhance Türkiye's competitiveness in the global medical device market, R&D investments and incentives are seen as critical, although there is an emphasis on the need to increase the production capacity within the country.

These dynamics not only provide medical device companies with opportunities to comply with the new regulations but also encourage the development of strong strategies in **R&D** and innovation. In the future, these innovations are expected to contribute to the sustainability of the healthcare system and the broader availability of medical devices to the population.

Food Supplements

On 20 April 2023, significant changes were made to the regulations regarding the use of health claims on food and dietary supplements. As a result, the previous regulation, the Turkish Food Codex Nutrition and Health Claims Regulation, has been repealed.

With the new regulation, the process of obtaining prior administrative approval for the use of health claims has been eliminated. As long as the claims comply with the regulation and guidelines, **health claims can be used without notification** or submitting an application to the Agency. However, in an announcement made on 16 January 2024, the Agency stated that despite the removal of the administrative approval process, a fee will be charged for each request for an opinion regarding health claims submitted by companies.

Use of Hemp in Production of Pharmaceuticals

Hemp cultivation in Türkiye came to the forefront with the "Symposium on Local Governments in the Presidential Government System" held on 9 January 2019, followed by the preparation of the "Report and Action Plan on Industrial Hemp Cultivation in Türkiye". The hemp cultivation reached a significant stage with the publication of the Law on Amendments to the Forestry Law and Certain Laws on 5 April 2025. This law encourages the production of fibre, seeds, and stems, with the permission of the Ministry of Agriculture and Forestry.

As of 2024, Türkiye has undergone a significant regulatory change in the field of hemp cultivation and the production of pharmaceutical active ingredients. The Regulation on Hemp Cultivation and Control for the Purpose of Pharmaceutical Active Ingredient Production, published on 13 September 2024, not only regulates hemp cultivation but also encompasses the oversight of every stage of the production process.

This regulation introduces a comprehensive application and approval process for individuals and legal entities wishing to engage in hemp cultivation. Furthermore, universities conducting scientific research and Ministry research institutes must obtain the necessary research permits before cultivating cannabis.

The regulation aims to ensure that hemp cultivation and the production of pharmaceutical active ingredients are carried out safely and under supervision.

The control of hemp production is reinforced with measures that support the proper conduct of scientific research regarding health claims and the use of hemp in drug production. Moreover, in all licensing and application processes, coordination among the relevant institutions ensures the prevention of misuse and illegal activities related to hemp. With these regulations, Türkiye is not only increasing the use of cannabis for pharmaceutical active ingredient production but also taking an important step in scientific research and treatment.

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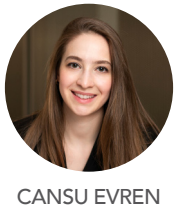

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Firm Overview

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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