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PHARMACEUTICALS AND LIFE SCIENCES LAW IN TÜRKİYE KEY DEVELOPMENTS AND PREDICTIONS

2024

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

In Türkiye, a rapid rise in exchange rates and adverse economic developments have led to difficulties in sourcing certain life sciences products on the market, and even caused some pharmaceutical companies to, either partially or fully, withdraw from the Turkish market, or to abandon the decision to introduce new products to the market. Moreover, news of counterfeit products related to the practices of product procurement from abroad have further increased concerns about the reliability of the available products on the market.

It can be said that the healthcare industry regulation in Türkiye, in particular licensing, registration systems, ethics, and compliance rules are in line with the standards of developed countries and EU legislation.

Last year, the Turkish Medicines and Medical Devices Agency ("Agency"), established under the Ministry of Health ("Ministry"), and the Social Security Institution ("SSI") have started to take several additional measures to ensure the continuity of the supply of products to the market.
With this paper, we outline the most up-to-date issues in life sciences.

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Pricing of Pharmaceuticals and the Fixed Exchange Rate

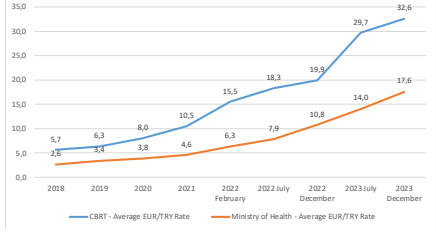
Due to the rapid increase in the current exchange rates, pharmaceutical prices have been one of the most controversial issues in Türkiye in 2023. The price of medicines for sale are set under the Decision on Pricing of Human Medicinal Products ("Decision") and the Communiqué on the Pricing of Human Medicinal Products ("Communiqué") of September 29, 2017, issued by the Ministry, which is vested with the competencies to regulate this area.

The Decision provides a reference pricing system, whereby the least expensive ex-factory price in one of the referenced EU countries for the relevant product is taken as the ex-factory price in Türkiye. The currency is then converted into Turkish liras; but to ensure that this calculation is not affected by fluctuations in the exchange rates, it is done at a fixed exchange rate every year. Thus, it is aimed that the exchange rate applied to the reference price taken from the respective EU country is fixed for one year, and the applied exchange rate is considerably lower than the current exchange rate.

As of the Decision of 2017, a number of changes were made to the ratio of the fixed exchange rate to the current exchange rate. Pursuant to the final version of the Decision, the exchange rate is determined as 60% of the average value of the Euro during the previous year. Accordingly, the main rule is that the Price Evaluation Commission gathers in the first 45 days of each year and announces the value of Turkish lira equivalent to 1 Euro based on a calculation of 60% of the average value of the previous year.

Pursuant to this rule, the exchange rate to be used in the pricing of pharmaceuticals should be increased once a year, whereas it has increased 5 times in the last 2 years.

Average EURO/TRY Exchange Rates
2018-2023



Source:

- *The Central Bank of the Republic of Türkiye (CBRT) - https://www.tcmb.gov.tr/*
- *Pharmaceuticals and Medical Devices Agency of Türkiye - https://www.titck.gov.tr/*

However, the rapid increase in the value of the exchange rate required quick measures to be taken in updating the prices of pharmaceuticals to ensure the availability of products in the market. Therefore, it was deemed necessary to update the prices again in July 2023, and with an increase of 30.5%, the exchange rate determined as TRY 14.0387. Similarly, to be in force on December 25, 2023, the value of 1 Euro was increased by 25% to TRY 17.5483.

On February 23, 2024, a provisional article was added to the Decision stating that no adjustment will be made for the year 2023 with the calculation procedure stipulated in the Decree. It is anticipated that a new exchange rate will be determined later in the year.

Market Access- Alternative Reimbursement Models

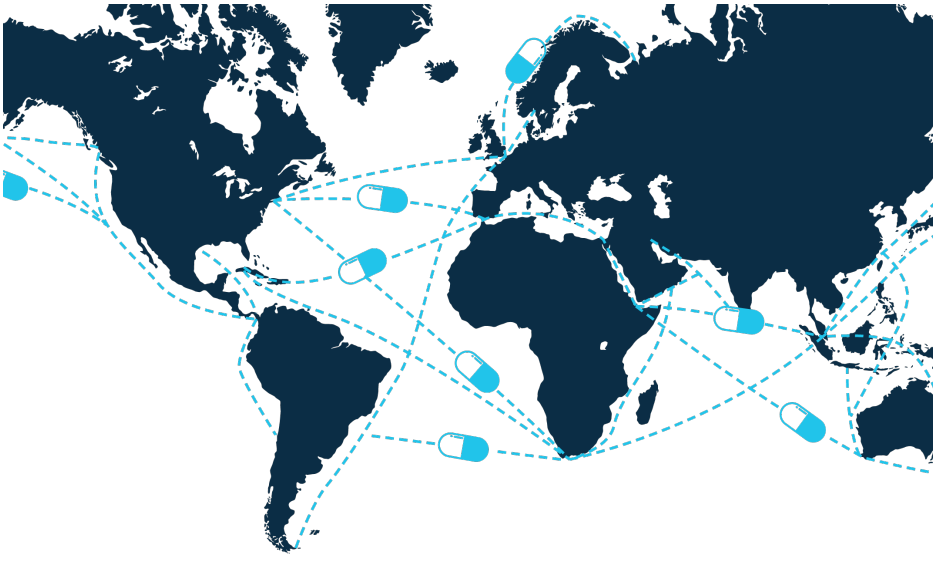
In the presence of alternative reimbursement models such as payback, value-based, indication-based reimbursement, performance-based, etc., developed for drug reimbursement systems throughout the world, the Turkish industry has long required a unique model for price setting where its conditions could be negotiated with the Social Security Institution (SSI), exempt from regular price and reimbursement rules given to innovative products.

With the enactment of the Social Security and General Health Insurance Law numbered 6552 in September 2014, alternative reimbursement models became an essential topic in the Turkish healthcare industry. The complementary provisions introduced with the Regulation on the Alternative Reimbursement of Pharmaceuticals, published in February 2016, allow companies and the SSI to discuss the terms and conditions of an alternative reimbursement model for particular products. It was expected that alternative reimbursement models, in which the SSI would enter a direct contractual relationship with pharmaceutical companies, would ultimately ensure patients to access pharmaceuticals faster. However, this model is currently preferred to control the discount rates offered by companies, since in these models the discount rates and payment terms are not disclosed to the public and kept confidential.

After the conclusion of one of the lawsuits filed against specific provisions of Regulation on the Alternative Reimbursement of Pharmaceuticals, some articles of this regulation, which were published without consultation with the Ministry, were annulled due to procedural deficiencies. Following the annulment decision, the Alternative Reimbursement Commission could not convene for quite some time to examine new applications. Then, on May 12, 2023, a Social Security Institution General Health Insurance Alternative Reimbursement Regulation was published.

The regulations set with the new Regulation on the Alternative Reimbursement of Pharmaceuticals on scheduling the Alternative Reimbursement Commission's meetings, the time limits for agenda topics, and the confidentiality principles for its activities, indicate a move towards establishing a more predictable system.

Market Availability of Products and Parallel Trade



The export of products manufactured and imported for the Turkish market, may restrict patients' access to treatment after their launch. In addition, pharmaceutical prices in Türkiye are much cheaper compared to many other countries, and this has an impact on prices in other markets. The Circular No. 2014/11 on the Availability of Medicines in the Market issued by the Agency stated that necessary measures will be taken to prevent problems in pharmaceutical supply that may occur in the Turkish market.

On 29 December 2023, the Agency published Guidelines on the Conditions for Pharmaceutical Export Made by Companies Other than Pharmaceutical Warehouses (the "Guidelines"). The Guidelines has been prepared to ensure the shipment and export of pharmaceutical products and dietary foods for special medical purpose in compliance with national and international standards, while protecting public health.

The Guidelines aims to ensure that authorized companies export products by good fistribution practices and relevant national and international standards. The export of the products without a valid export permit has been prohibited.

Domestic manufacturers or companies that have licensed pharmaceutical products in Türkiye and/or abroad in their own name will be able to export their products through their own companies or their authorized companies. These authorized companies will be able to apply for an export permit only for the authorized products. Domestic producers

or a company controlled and affiliated with a company with a pharmaceutical product for human use licensed in its own name in Türkiye and/or abroad should apply for the issuance of an export permit for the products they have been authorized. Companies without a license but wishing to export products domestically manufactured under their own trademarks should also apply for an export permit.

Export-authorized companies must demonstrate their connections with Turkish market authorization holders through the trade registry gazette and to have a company registration on the Agency's electronic application system (EBS).

Both the company holding the marketing authorization and the exporter will be jointly and severally liable for the transactions carried out. In the event of any problems with the products exported by such companies, the authorized exporter is obliged to inform the health authority of the country of export and the Agency.

With these new rules, it is evident that the supervision mechanism for pharmaceutical exports has also been improved in addition to the monitoring and supervision of pharmaceutical manufacturing, import, and distribution through the Drug Tracking System (ITS) developed by the Agency. Unauthorized and uncontrolled exports of pharmaceuticals, which have been increasing over the last decade, are expected to decrease thanks to the conditions imposed by the new Guidelines. The introduction of regulations on exports is beneficial for the industry, especially as there are increasing examples of products imported into Türkiye being exported without the authorization and knowledge of the marketing authorization holders and products being sold in various countries, sometimes without complying with the required conditions of special storage, transportation and distribution, which subsequently harms public health. Although everyone is expected to comply with the Circular on the Availability of Medicines in the Market, it was impossible to prevent parallel exports without the control mechanisms outlined in the Guidelines. Legal barriers are now preventing pharmaceutical warehouses or other entities from exporting drugs without proper authorization from the Agency and the necessary notifications of the products are made through the ITS.

The Guidelines is an important reference source for pharmaceutical exporters and provides guidance on a wide range of issues, from authorization processes to the responsibilities of companies and the required documentation. Therefore, companies should carefully review the new regulations outlined in the Guidelines and update their export procedures accordingly.

Named Patient Program

Named Patient Programs ("NPP") is one of the exceptional pharmaceutical importation regimes for products that are not authorized or authorized but unavailable in the Turkish market for various reasons.

In cases where a product does not have marketing authorization in Türkiye or has marketing authorization but cannot be found on the market, and patients need the product in question, it is possible to procure the pharmaceutical via this method upon the request of a physician. The program is regulated by the Guidelines published by the Agency.

There were numerous allegations in the news that the drugs supplied from abroad and used in the treatment of cancer were only products containing painkillers and that the products were counterfeit. The Agency and the SSI made press statements on this issue, mentioning that criminal complaints had been filed against those involved in supplying counterfeit products. As a result of these developments, the Regulation on the Supply of Medicines from Abroad ("NPP Regulation") was published on February 3, 2023 and the roles of stakeholders in the procurement process have been defined more clearly:

- Foreign institutions and organizations that supply medicines from abroad have been identified as Foreign Supply Sources, and having a Representative in Türkiye has become mandatory.
- The qualifications of the Foreign Supply Sources and where it should supply the product, if it is not a manufacturer, are regulated.
- It is stipulated that the Turkish Pharmacists Association, the SSI, and the public institutions which are deemed appropriate by the Ministry that supply products from abroad ("Foreign Drug Suppliers") shall distribute the products by the legislation to which pharmaceutical warehouses are subject.

In addition, it has been provided that the products procured through these means must be registered on the Drug Monitoring System ("ITS"), just as the authorized medicines, and will be tracked through this system and a QR code must be applied on the products procured.

In line with the new rules stipulated in the Regulation, the Guidelines on the Supply of

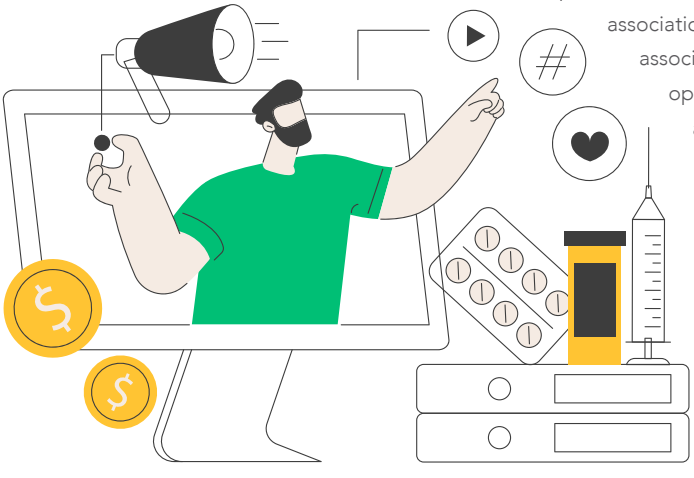
Pharmaceuticals from Abroad ("Guidelines"), which indicates the guiding provisions regarding the implementation of the Regulation, has been updated.

According to the Guidelines:

- The QR code process, which Foreign Drug Suppliers must perform, can be performed by the Foreign Supply Sources in the customs-free zone.
- The Representative can meet the financial obligation regarding ITS notifications and QR coding transactions.

Interactions with HCPs, Transfer of Values and Payments

The Regulation on the Promotional Activities of Pharmaceutical Products for Human Use ("Promotion Regulation"), dated July 3, 2015, regulates the promotional activities of medicinal products for human use.



Under the Promotion Regulation, any advertisement of products to the general public, whether directly or indirectly, through any public media or communication channels, including the Internet, is prohibited. Pharmaceutical products may be promoted only to physicians, dentists, and pharmacists. Therefore, the interaction between the companies and the patients should be minimized.

The companies may enter into written agreements with physicians to obtain consultation services. The Agency does not regulate the conditions of such service agreements. The industry sets the rules for such contracts via Ethical Codes.

The pharmaceutical companies must notify the Agency of any value transfers that exceed 10% of the current monthly gross minimum wage, made to health institutions, organizations, universities, health professionals, and members of professional associations, trade unions, associations, and foundations, operating in the field of health, and non-governmental organizations established for the protection and development of health. This applies to sponsoring scientific meetings, donating, or obtaining consultancy services. The companies must obtain the consent of healthcare professionals or healthcare organizations before any value transfer occurs to fulfill this obligation.

Similarly, promotional activities for medical devices are regulated by the Regulation on Sales, Advertising, and Promotion of Medical Devices dated May 15, 2014 ("Regulation on Promotion of Medical Devices"). Although the Regulation on Promotion of Medical Devices regulates consumer-targeted advertising activities specifically for different product categories, it does not make a similar distinction for promotional activities targeting healthcare professionals. Promotion is possible by publications distributed and sold to healthcare professionals and technical staff working with medical devices within

healthcare institutions and organizations or publications in medical-professional journals with scientific content; supporting or organizing scientific meetings, visiting by sales and promotion staff; providing information about the device, the application of the device and the user manual.

Both in the field of pharmaceuticals and medical devices, another critical aspect of relations with physicians and health institutions is the principle of full-time employment for physicians working in a public health institution or university hospital. In accordance with the legislation, these physicians are prohibited from engaging in trade and other profitable activities. Therefore, all payments made for the services provided by these physicians must be made to the institution they are affiliated with.

In recent years, individual lawsuits have been brought by physicians, who are employed at the university hospitals, against provincial health directorates that refused their applications to establish private clinics. These cases are not considered collectively, as each case binds the physician concerned. The companies must decide whether the payments shall be made to those clinics, considering the possibility that the higher courts may overturn the decision of the first instance court.

Developments in the Field of Medical Devices

The Regulation on the Sale, Advertisement, and Promotion of Medical Devices ("Medical Device Promotion Regulation"), the legislation containing detailed provisions on the sales, advertising, and promotion activities of companies, was significantly amended on May 26, 2023, and introduced number of new procedures to the medical device sector. These procedures, which are not essentially considered as promotional activities, are governed by the Medical Device Promotion Regulation rather than being regulated in a separate legislation .

According to the new provisions of the Medical Device Promotion Regulation, sales centers authorized to sell medical devices are obliged to provide technical services, establish a quality management system, offer training before first use of the device, and issue warranty certificates. As the effective date of these new obligations has been set as January 01, 2025, it is thought that the implementation will be clarified with announcements to be made by the Agency when the effective date approaches. The sanctions to be imposed in case of non-compliance with these new obligations increase gradually, starting with a warning, and can reach severe sanctions, such as suspension of activities of the sales center.

On May 26, 2023, the Regulation on Technical Services for Medical Devices Used in the Scope of Healthcare Service Provision ("Technical Services Regulation") was published and regulated the qualifications, authorization and audit processes, personnel training and obligations of technical services for medical devices. With the new regulation, new processes are expected to occur such as the preparation, certification and monitoring of training in the appointment of technical services. In addition, the Technical Service Regulation, which will enter into force on June 1, 2026, may require revisions in the contracts with technical services in accordance with the technical service criteria and the suspension and revocation of the certificate of authorized technical services.

Application Fee for Scientific Meetings of Pharmaceuticals and Medical Devices Has Been Introduced

The Agency first announced on its official website on 4 January 2024, that the Guidelines on Scientific Meetings and Educational Activities to be Conducted within the Scope of the Regulation on the Sales, Advertisement and Promotion of Medical Devices ("Guidelines") was amended, and that the most significant change introduced by the amendment to the Guideline is the collection of fees by the Agency for scientific meetings and applications for educational activities. According to this amendment, it will not be possible to refund the payments made to the Agency for scientific meetings or educational activities applications that are subsequently canceled. In this context, the application fee for scientific meetings and educational activities notifications applications to be made has been set as TRY 1,114.02 (approximately EUR 34) in the 2024 Price Tariff of the Agency. Within the scope of the amendment, no distinction is made between web-based meetings and physical meetings in terms of the payment of the application fee.

Subsequently, the Agency made an addition to the 2024 Fee Tariff and then announced on its website on 18.01.2024 that a service fee would be charged for "Human Medicinal Product Scientific Meeting Support Application", "Human Medicinal Product Promotion Meeting Application" and "Human Medicinal Product Press Announcement Application".

The fact that the application fee regulation is made through guidelines and announcements raises questions about the soundness of the legal basis of the relevant regulation in terms of administrative law. Also, considering that the main motivation of the Agency making amendments to the Regulation and the Guidelines is to facilitate notifications for scientific meetings and educational activities, to increase the number of notifications and to ensure transparency in the activities of the industry, the amendment to introduce an application fee may have the opposite effect by imposing a financial burden on companies or may lead to a decrease in number of the promotional activities.

Food Supplements

With the regulations published in the Official Gazette numbered 32169 and dated April 20, 2023, comprehensive amendments were made to the legislation on the use of health claims for food and food supplements and the use of nutrition claims. Thus, the Turkish Food Codex Regulation on Nutrition Claims under the authority of the Ministry of Agriculture and Forestry and the Regulation on Health Claims for Food and Food Supplements under the authority of the Agency, has entered into force. The Turkish Food Codex Regulation on Nutrition and Health Claims, which previously included regulations on nutrition and health claims has been repealed.

However, with the new regulation, the process of obtaining prior administrative authorization for the use of health claims has been abolished and they can be used without an application for authorization or notification to the Agency, provided that they comply with the provisions of the regulation and guidelines. On the other hand, on January 16, 2024 the Agency announced on its official website that, despite the abolishment of the administrative permission process for the use of health claims, requests for opinion regarding health claims have been received from companies and that, in order for the Agency to evaluate these requests, a fee of

In this framework, since health claims to be used in food and food supplements are different in nature, it is appropriate and long-awaited by the sector that they be subject to a separate legal regime from nutrition claims and regulated in detail in a special regulation and that the executive authority of the new regulation be vested in the Agency under the Ministry of Health.

TRY 1,208.19 (approximately EUR 37) will be charged for each health claim evaluation as per the 2024 Fee Tariff.

In addition to these developments, on December 11, 2023, a draft law was proposed to the Commission on Agriculture, Forestry, and Rural Affairs to amend Law No. 5996 on Veterinary Services, Plant Health, Food,

and Feed. The draft law stipulates that food supplements in a pharmaceutical form containing active pharmaceutical ingredients and food supplements for particular medical purposes will be authorized and inspected by the Ministry of Health instead of the Ministry of Agriculture and Forestry; they can only be sold in pharmacies, and that production, import and export controls of these products will be carried out by the Ministry of Health.

In light of all these developments, it can be seen that the administration has taken steps in 2023 to clarify that the Agency is the competent administrative authority for the marketing of food supplements with health claims.

The Use of Cannabis in Pharmaceutical Production

After the "Symposium on Local Governments in the Presidential Government System" held on January 9, 2019, the issue of cannabis production in Türkiye was reconsidered, and the "Report and Action Plan on Industrial Cannabis Cultivation in Türkiye" was prepared, and legislative regulations and incentives have been provided, and especially the production of fibers, seeds and stems were supported.

On April 5, 2023, another important step was taken regarding Article 1 of the Law Amending the Forestry Law and Certain Laws, which was published in the Official Gazette and entered into force. Within the scope of the relevant article, the cultivation of cannabis to produce fiber, seeds and stems, and the production of flowers and leaves for the production of pharmaceutical active ingredients have become subject to the permission of the Ministry of Agriculture and Forestry, and within this framework, the Turkish Grain Board was assigned responsibility for the cultivation and/or processing of cannabis for pharmaceutical production.

Within the framework of the regulation to be prepared by the Ministry of Agriculture and Forestry, the Turkish Grain Board will be able to carry out the cultivation and/or processing of cannabis itself, as well as real or legal persons, when necessary, in accordance with the quotas determined on the basis of supply and demand in Türkiye. In this regard, cannabis cultivation was authorized to support the development of cannabis cultivation in Türkiye and to produce pharmaceutical active ingredients.

In November 2023, the Ministry of Agriculture and Forestry prepared the "Draft Regulation on the Cultivation and Control of Cannabis for the Production of Pharmaceutical Active Ingredients" to take necessary measures to prevent the illicit production of marijuana in the cultivation of cannabis for the production of pharmaceutical active ingredients and to establish the procedures and principles for the harvesting, processing, exportation, exportation or selling of cannabis.

Considering that the field of activity of the Ministry of Health is directly related to the

production process of pharmaceutical active ingredients, it is expected that new and more comprehensive regulations will be developed by both the Ministry of Agriculture and Forestry and the Ministry of Health to meet the needs arising from practice in the field of cannabis cultivation to produce pharmaceutical active ingredients in 2024. Since Türkiye's procedures for marketing authorization and supply of medicines to the market is in parallel with the European Union (EU) and its close trade relations with the EU, it is expected that steps will be taken to align legislation on the cultivation of cannabis to produce active pharmaceutical ingredients with the EU over time.

OUR TEAM

MEHMET GÜN
SENIOR PARTNER

mehmet.gun@gun.av.tr

BEGÜM YAVUZDOĞAN OKUMUŞ
PARTNER

begum.yavuzdogan@gun.av.tr

GÖRKEM BİLGİN
PARTNER

gorkem.bilgin@gun.av.tr

HANDE HANÇAR
PARTNER

hande.hancer@gun.av.tr

ÖZGE ATILGAN KARAKULAK
PARTNER

ozge.atilgan@gun.av.tr

SELİN SİNEM ERCİYAS
PARTNER

selin.erciyas@gun.av.tr

OUR TEAM

DİCLE DOĞAN
MANAGING ASSOCIATE

dicle.dogan@gun.av.tr

FATMA SEVDE TAN
SENIOR ASSOCIATE

fatmasevde.tan@gun.av.tr

BESTE TURAN
ASSOCIATE

beste.turan@gun.av.tr

ECE ATASEVEN
ASSOCIATE

ece.ataseven@gun.av.tr

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.