GÜN + PARTNERS
AVUKATLIK BÜROSU

LIFE SCIENCES LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS

2022

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.

Key Developments and Predictions for Life Sciences in Turkey

With Turkey having a population of more than 80 million is covered by an extensive social healthcare system, the size and volume of the Turkish life sciences industry are significant.

This growth potential brings many opportunities. However, it is also balanced with strict regulations that **pharmaceutical** and **medical device** industries are subject to, ranging from market access to pricing and reimbursement. The Turkish Medicines and Medical Devices Agency ("**TITCK**"), established under the Ministry of Health, and the Social Security Institution ("**SSI**"), are the primary controllers of this balance.

The increase in the quality of health services and patients' access to medicines has, inevitably, increased the demand for health services and pharmaceuticals, and there has been an associated increase in public spending. This increase led to a rigid pharmaceutical **pricing policy** prompting the government to seek new ways.

In addition, the SSI requests a considerable discount for **reimbursement**. Strict precautions in pricing and reimbursement may hinder the patient's access to incredibly innovative pharmaceuticals. **Procurement from abroad** (NPP) of pharmaceuticals on a prescription basis that cannot be found in the domestic market due to rigid pricing and reimbursement policy has dramatically increased in recent years. Alternative reimbursement models and even localisation policies have also been implemented to control health expenditures.

Apart from some limitations specific to Turkey and the lack of transparency, it can be said that the healthcare industry regulation in Turkey, in particular licensing, registration systems, ethics and compliance rules, are in line with the standards of developed countries and EU legislation.

With this paper, we are pleased to outline the most up-to-date issues in pharmaceuticals, medical devices, and other healthcare law areas.

This paper provides an overview of the following topics:

- Pricing of Pharmaceuticals and the Fixed Exchange Rate
- Market Access-Reimbursement Agreements
- New Regulation on Licensing of Human Medicinal Products
- Named Patient Program
- Interactions with HCPs
- Transfers of Value
- Patient Support Programs
- Harmonisation with the EU Medical Devices Regulation
- Promotion of Medical Devices
- Food Supplements
- Cosmetics and other Products
- Personal Health Data Protection

Pricing of Pharmaceuticals and the Fixed Exchange Rate

Pharmaceutical prices in Turkey have always been one of the most controversial issues. The prices of medicines that are to be marketed 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 of Health ("MoH"), 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 listed EU countries for the relevant product is taken as the ex-factory price in Turkey. The currency is then converted into Turkish liras; however, this transaction is done at a fixed value every year so that it is not affected by fluctuations in the exchange rates. Thus, the exchange rate applied to the reference price taken from the respective EU country is fixed for one year, and the price reached is considerably lower than the current exchange rate.

With the Decision entered into force in 2017, the rate was determined as 70% of the average Euro value of the previous year. Accordingly, the Price Evaluation Commission is to gather within the first 45 days of each year and is expected to announce the 1 (one) Euro value, based on the 70% calculation of the average value of the previous year.

Just prior to the announcement of the Euro rate applicable for the year 2018, on January 22 2018, a provisional clause was added to the Decision regulating that the value of Euro would not exceed more than 15% of the value set for the previous year.

As a result of the referendum held on April 16 2017, an amendment was made to the Constitution, and a transition to Presidential Government System in Turkey has started. The most fundamental feature of this system is the transfer of all executive authorities to the President with the annulment of the Office of Prime Ministry. Therefore, the Cabinet of Ministers determined the rules and procedures for deciding pharmaceutical prices, and, as of July 2018, the President now determines them.

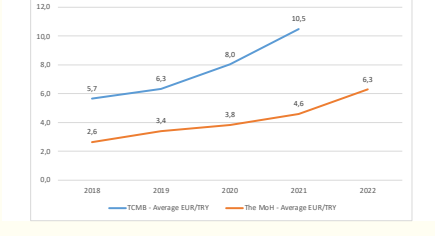
Right before the announcement of the rate applicable for 2019, with a Presidential Decree published in the Official Gazette on February 14 2019, the rate of "70%" provided in the Decision was amended to "60%".

On February 14 2020, the Price Evaluation Commission determined the Euro rate for 2020 as 60% of the previous year, TRY 3.8155, bringing an automatic increase of 12% compared to 2019.

On February 19 2021, by adding a provisional article to the Decision dated 2017, it was regulated that the fixed Euro value for 2021 would not exceed 20% of the 1 (one) Euro value applied in the previous period. In this context, the Euro value for 2021 was determined as 4.5786 TL by the TITCK on February 19, 2021.

As for 2022, the Euro value was determined as 6,2925 TL on February 14 2022.

Graphic 1 TCMB and the MoH Average EUR/ TRY, TURKEY, 2018-2022



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

Market Access-Reimbursement Agreements

For an extended period, the pharmaceuticals industry needed a unique model of reimbursement where its conditions could be set together through negotiation with the SSI, and the regular price and reimbursement rules did not apply for innovative products.

With the enactment of the Social Security and General Health Insurance Law numbered 6552 in September 2014, alternative reimbursement models also 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 benefit from discussing the terms and conditions of an alternative reimbursement model for particular products. It was expected that alternative reimbursement models, in which the SSI will enter into a direct contractual relationship with pharmaceutical companies, will ultimately allow patients to access innovative pharmaceuticals faster. Today, however, these models also appear to control pharmaceutical prices. Lawsuits filed against several provisions of the Regulation on the Alternative Reimbursement of Pharmaceuticals are still pending.

In parallel with the SSI's amendments regarding alternative reimbursement, the TITCK has also introduced guidelines for prioritising MA applications of particular products with advantages in public health and public finance. A commission established under the TITCK, composed of MoH and the SSI representatives, evaluates companies' prioritisation applications.

Although these amendments made in the last few years are significant developments, there are still no specific licensing, pricing and reimbursement rules for orphan drugs.

New Regulation on Licensing of Human Medicinal Products

The New Regulation on Licensing of Human Medicinal Products (the "Regulation") prepared by the TITCK entered into force upon its publication in the Official Gazette numbered 31686 and dated December 11 2021. It has been seen that the purpose aimed with the Regulation is reflecting up-to-date processes present in the TITCK practice but did not exist in the previous regulation dated 2005 and providing compatibility of the legislation with the EU directive numbered 2001/83/EC.

In this context, the Regulation Article defines the terms and definitions of already existing concepts such as human medicinal products and active ingredients have been detailed. In contrast, new definitions regarding the concepts such as biosimilar products, hybrid application and production facility have been listed. Abridged license application types have been rearranged for compatibility with EU legislation, and the application requirements are defined more precisely.

An exception has been introduced for the products to prevent the problems on availability of drugs, which is the only diagnosis or treatment method available for disease in Turkey as acceptance of the transfer application regarding the license/permit or registration certificate without waiting for the court decision. In addition, with the addition to the provision regarding the suspension of the license, if at least one commercial batch of a licensed human medicinal product is not available in the domestic or foreign markets for an uninterrupted 30 months, the license is suspended instead of the license cancellation. If the product available on the market cannot be provided for any reason, the TITCK must be notified at least 30 days before this condition arises, per the amendment made to the responsibilities of the license owner.

The new EU-compliant legislation includes significant amendments regarding licensing process. Since some articles have not been implemented yet, we recommend that the announcements regarding the TITCK implementations should be followed frequently by the sector stakeholders.

Named Patient Programs

Named Patient Programs ("NPP") is one of the exceptional importation regimes of pharmaceuticals without marketing authorisation ("MA") in Turkey, or with marketing authorisation, but which are unavailable in the Turkish market for various reasons.

In cases where a pharmaceutical does not have an MA in Turkey or has an MA but cannot be found on the market, and patients need the pharmaceutical in question, it is possible to procure the pharmaceutical via this particular method upon the request of a physician. Institutions authorised to import pharmaceuticals within the scope of the supply of pharmaceuticals from abroad are Uluslararası Sağlık Hizmetleri A.Ş. ("USHAŞ"), Turkish Pharmacists' Association ("TEB") or the İbn-i Sina Health Social Security Center ("İbn-i Sina"), within the Social Security Institution ("SSI").

If NPP approves the products, they are added to the Foreign Drugs List (the "List") of the TITCK and imported from abroad by authorised institutions. If SSI decides to reimburse the relevant product, it is published in Annex-4/C list of the SSI's Communique on the Implementation of Healthcare.

The Guidelines on Drug Supply from Abroad (the "Guidelines") has also been updated several times within a short period. With the new Guidelines published on October 23 2021, the most significant amendments made in the Guidelines are on the suppliers, supply conditions, and terms that regulate the removal of a product from the List. Following this amendment, the Agency published an announcement on November 24 2021, which lists the products that will be removed from the List.

The Guidelines preserved the authority of the Turkish Pharmacists' Association, the Social Security Institution İbn-i Sina Pharmaceutical Warehouse, and Uluslararası Sağlık Hizmetleri A.Ş for supplying drugs from abroad. However, the Guidelines also regulated that the public institutions and organisations deemed appropriate by the Agency for the foreign drug supply can also be authorised as suppliers. Nevertheless, no explanation or Agency announcement has been published regarding the new suppliers deemed appropriate by the Agency.

The previous version of the Guidelines regulated that drugs could be supplied if they were authorised by FDA/EMA or PIC/s member countries. However, the new Guidelines removed this provision and stated that products supplied from abroad must be placed on the market and licenced in the relevant countries by primarily providing their scientifically acceptable effectiveness, quality and safety, which have been authorised by ICH (International Council for Harmonization) founding or permanent member competent authorities, MHRA (Competent Authority

of United Kingdom) or TGA (Competent Authority of Australia).

Additionally, the Guidelines regulated the documents that the suppliers need to receive from the product owner in detail. In this context, during the product delivery, it is mandatory to obtain a Certificate of Origin, a Certificate of Analysis approved by the technical manager of the production facility for every batch, a Certificate of Batch Release in applicable situations for every batch.

As of the Guidelines' publication date, products that are not compliant with the supply conditions have been removed from the List. In this context, it has been stated that an application can be made to the Agency for products excluded from the List within 30 days to include the products to the List again, and those deemed appropriate will be included again.

Finally, the Law on Amending Certain Laws and Decree Laws Concerning Health dated December 5 2018 ("Law") now foresees that it is mandatory to apply for marketing authorisation for foreign products imported within three years from the date of entry in the Foreign Drug List, and it is also required to obtain marketing authorisation within two years from the date of application. After completing given periods, the decision on the continuation of the supply of drugs that did not obtain marketing authorisation or for which no marketing authorisation application has been filed will be at the discretion of the President of the Republic.

Therefore, when the said article entered into force on December 5 2018, the 3-year marketing authorisation application period started for the products already been on the List. In this regard, an announcement on products that do not have a marketing authorisation application was expected to be published on June 5 2021. However, the Agency published the products to be included in this evaluation on November 24 2021. The Foreign Drug Evaluation Commission will now evaluate these products and submit the suitable products to remain on the List for Presidential approval. Neither the Law nor the Guidelines specify the criteria that the products should meet to be submitted to the President's approval in the evaluation of the Foreign Drug Evaluation Commission and for the President's review.

The amendments show that the efficacy, quality, and safety elements of the products supplied will be scrutinised more strictly by the TITCK. As of the publication date of this Guidelines, products that do not comply with the supply conditions were removed from the List, supplier countries have been limited with countries that have robust marketing authorisation inspection mechanisms, and provisions have been implemented to allow making decisions taking into account product safety based on the country or the product.

Interactions with HCPs

Promotional activities of human medicinal products ("HCPs"), enteral nutrition products, and infant formulas for special medical purposes are regulated under the Regulation on the Promotional Activities of Pharmaceutical Products for Human Use ("Promotion Regulation") dated July 3 2015.

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. The promotion of pharmaceutical products may be made only to physicians, dentists and pharmacists. Therefore, the interaction between companies and patients shall be minimum.

Companies may enter into written agreements with HCPs to obtain consultation services. The TITCK does not regulate the conditions of such service agreements. The industry sets the rules for such agreements via Ethical Codes.

On the other hand, rules regarding payments to physicians and HCOs are regulated by the law. Amendments to various laws were made in 2014, establishing the full-time employment principle for physicians working for a public health institution or university hospital. In this respect, in principle, all payments for services rendered by these physicians must be made to the revolving funds of their relevant institution.

The rule does not apply to physicians who had a private clinic before introducing this principle in 2014, and there are other exceptions.

Transfers of Value

There is no public disclosure rule for value transfers made by pharmaceutical companies. However, according to the Regulation on the Promotional Activities of Pharmaceutical Products for Human Use ("Promotion Regulation") dated July 3 2015, the pharmaceutical companies shall notify the TITCK of any value transfers that exceed 10% of the current monthly gross minimum wage, to health institutions, organisations, universities, health professionals, and members of professional associations, trade unions, associations and foundations, operating in the field of health, and non-governmental organisations established for the protection and development of health, in terms of sponsoring scientific meetings, making donations, or obtaining consultancy services. The notification for the mentioned value transfers that materialise in one calendar year shall be made in the format determined by the TITCK, in detail, and within the first six months of the following year. The notifications must be made via an electronic system launched by the TITCK.

Companies must obtain the healthcare professionals' or healthcare organisations' consent before any value transfer occurs to fulfil this obligation. All consent forms were updated, together with the Code on the Protection of Personal Data, published in 2016.

Patient Support Programs

An obligation for marketing authorisation holders to apply to the TITCK and obtain permission for training and support programs for patients/healthcare professionals for the rational use of drugs was regulated via Circular numbered 2016/4 dated March 14 2016, published by the TITCK.

With the program, the marketing authorisation holder signs a contract with an organisation that has been licensed within the framework of the "Regulation on the Delivery of Home Care Services" to train patients or their relatives or healthcare professionals in the clinic/health institution about the product application, or to establish a call centre to obtain information about the product application by the patients' relatives.

Due to the COVID-19 pandemic, it has become necessary for many companies to convert face-to-face training meetings of the ongoing patient support programs to online or electronic meetings. This issue required both contract amendments, and the preparation of new clarification and consent texts, due to the processing of personal data through different methods.

Harmonisation with the EU Medical Devices Regulation

After the long-awaited Regulation on Medical Devices numbered 2017/745 ("MDR"), prepared by the EU Commission, has entered into force, Medical Device Regulation ("Regulation") which has been designed following MDR, has been published in the Official Gazette numbered 31499 on June 2 2020. Various effective dates have been foreseen for several articles in accordance with the EU transition process to provide a transition period for the new regulations introduced by the Regulation.

In this context, new noteworthy provisions are the definition of a medical device and classification of products and distance sales, manufacturer, importer and distributor liabilities in placing products on the market, the EUDAMED system, clinical research in medical devices, notified bodies.

Primarily, the Regulation qualifies medical devices in 4 different risk classes (class I, IIa, IIb and III). However, classification amendments are stipulated for specific devices with new regulations in the classification rules. In particular, the variation of the risk class of some Class I medical devices will require notified body inspection and EC certificate in the new period.

Besides, the liabilities of manufacturer, importer and distributor of medical devices have been separately regulated in detail in the Regulation. However, there is no regulation whether the sales centres are defined as where the devices are sold in the Regulation on Medical Device Sales, Promotion and Advertising, fall in the group of manufacturers, importers or distributors.

Manufacturers are required to have at least one person in charge of regulatory compliance within their organisation, called the "person responsible for regulatory compliance", with the necessary expertise in the field of medical devices. There is no regulation as to whether the person responsible for regulatory compliance can be the same as the "responsible person" regulated in the Regulation on Medical Device Sales, Promotion and Advertising.

The EUDAMED system of the European Union Commission has been included in the Regulation under the MDR to improve transparency and increase traceability in the medical device industry. In this context, registration purposes and the information to be registered are regulated. In addition, it has been held that the obligations on the Product Tracking System ("ÜTS") will continue. The EUDAMED system, which will be open to the public, will be ready for use in six months after publication in the Official Journal of the European Union and a notice that its functional specifications are met.

Finally, the Regulation introduces more control and monitoring by the TITCK and

the EU Commission, the EU executive body, and stricter conditions for the appointment of Notified Bodies. Notified Bodies are organisations assigned to assess the conformity of medical devices with the applicable fundamental technical requirements before placing them on the market. The evaluation of the appointment application of the conformity assessment bodies that apply to be a notified body will be carried out by the "joint assessment team" consisting of the TITCK, the EU Commission representatives, and the representatives of the assignment authorities of two different EU member states. The TITCK has already started to accept the Notified Body applications.

The conformity assessment bodies appointed by the TITCK are notified to the EU Commission and EU member states by the Ministry of Commerce through NANDO, the EU Notified Bodies Information System. Unless an objection is raised, the notification is published on NANDO within 42 days as of the notification. The TITCK published an announcement on May 26 2021, regarding how long the current EC certificates will be valid. During this transition period, manufacturers should start cooperating with Notified Bodies to plan the new certification schedule for their medical devices and the existence of the Notified Body. The additional data needed on devices and the transitional provisions in the Regulation should be taken into consideration.

The Regulation entered into force on the same date as the MDR, to which it is compatible, and announcements of the TITCK guide industry stakeholders to ensure compatibility with all EU practices. Nevertheless, while it was necessary to plan the compatibility with the MDR in the preparation of the Regulation, it is observed that not all of the other regulations in force in Turkey are taken into account, and it is expected that other Turkish regulations of the TITCK will also be updated within this context.

Promotion of Medical Devices

With medicines, the rule is clear: The general public cannot be the audience of any promotional activity whatsoever of pharmaceutical products. However, with medical devices, the rule in place in the Regulation on the Sales, Advertisement and Promotion of Medical Devices ("Medical Device Promotion Regulation") notes more confusing regulation. The rule states that medical devices sold, adapted or applied in hearing aid centres, custom-made prosthesis and orthotics centres, optician institutions or dental prosthesis laboratories must exclusively be used by healthcare personnel and cannot be advertised in any manner to the general public.

By making a detailed amendment in the Medical Device Promotion Regulation on September 2 2020, restrictions on medical device sales and advertising activities, notifications for personnel changes and sanctions were rearranged.

The advertising of:

i. Devices that are sold, adapted, or implemented, only in hearing aid centres, tailored prosthetics and orthotics centres, opticians or dental prosthetics laboratories;

ii. Devices that are intended to be used or implemented, exclusively by healthcare professionals, or that require implementation in medical device sales centres;

addressed to the consumer, is prohibited.

The advertising of:

iii. Devices other than these devices addressed to the consumer, only in the internet environment where the device is sold;

iv. Devices included in Annex-3, without limitation;

is allowed.

Besides, the term "internet environment" is not defined in the Regulation in the Article regulating advertising. For this reason, it is not clear whether the advertisement can only be made from the website where the sale is made or from the page where it is located, or whether it can be made by redirecting to the site where the sale is made by an advertisement on another website.

Laws that govern medical device companies are becoming more extensive each day, with medical device companies as members of international and local associations finding themselves governed by both rules. Following the rules of ethics and other advertising and promotion rules that both global and regional associations set can sometimes confuse medical device companies, especially when local conditions beckon different, sometimes more stringent, rules on member companies. In Turkey, the provision of sponsorship to

HCPs by medical device companies for congressional attendance is regulated with the Medical Device Promotion Regulation that provides a system in which HCPs are subject to annual quotas for support. Companies are required to notify the HCPs of such sponsorships. Therefore, as members of MedTech Europe, Turkish medical device companies implemented a new sponsorship model as of the beginning of 2018. As the MedTech Code requires indirect sponsorship and, in the meantime, local regulations require notification of the HCPs by the companies, the member companies ceased to initiate the communication for sponsorship with the HCPs offering them to be their sponsors. The selection of HCPs is made by HCOs (associations, non-profit organisations, hospitals). The names are obtained, and the quotas are checked while notifying the TITCK. Thus, both systems may be applied without breaching the local Regulation and the spirit of the MedTech Code.

The industry now expects the publication of a new Promotion Regulation that will introduce new rules and, as well, amend some of them concerning the advertising of medical devices.

Food Supplements

The Regulation on the Importation, Production, Processing and Supply of Food Supplements (the "Regulation") was published by the Ministry of Food and Forestry (the "MoA") on May 2 2013, in the Official Gazette and came into force as of August 2 2013.

The said Regulation is not only the first regulation that has been drafted, particularly on food supplements, but also includes special provisions about the control and approval mechanism to be established over food supplements.

The requirements for manufacturing or importing food supplements are set out in the Regulation. An application must be made to the provincial directorate with specific information and documentation regarding the product's content and manufacturing and its commercial name and qualities. Although the Regulation was expected to cover the advertising of food supplements, it does not truly satisfy this need, and therefore the issue is governed by general rules. However, when a food operator submits its application to obtain approval for a food supplement, the application will only be processed if the applicant provides an undertaking that it has put into place the necessary measures to eliminate any ongoing advertising/promotion on third-party domain names/URLs or those under its control.

Under the new Regulation on Health Claims published in Official Gazette No. 28670 on June 7 2013, health claims in advertisements for food supplements must comply with the rules set out in the Turkish Food Codex on Labelling. If an ad does not comply with these rules, the MoH may order the cessation of sales and the collection or destruction of the products in question.

Because of an increase in the number of deaths amongst persons using certain types of food supplements (especially those used for weight loss or weight control purposes), the MoH, the Turkish Radio, and Television Supreme Council ("RTUK"), as well as the Advertisement Board, have decided to collaborate with the MoA in the fight against the use of misleading information and health claims in advertisements for food supplements. The collaboration appears to be effective, as the Advertisement Board and the RTUK have imposed heavy sanctions against advertisers and media channels regarding misleading food supplement advertisements.

Cosmetics and Other Products

The packaging and labelling requirements for cosmetic products are regulated under Cosmetic Law numbered 5324 (the "Law") and the Regulation on Cosmetics (the "Regulation") of the TITCK of the MoH.

In addition to the Law and the Regulation, the Guidelines on the Promotional Activities of Cosmetic Products and the Regulation on the Health Claims of the Products Offered for Sale with a Health Claim ("Health Claim Regulation") are still applicable, which means administrative sanctions are still being applied to the ones selling and promoting products with health claims, without any prior permission of the MoH.

The MoH performs regular inspections concerning the safety and advertising of cosmetics. In 2018, inspections had been initiated for skincare products, hair styling products, and baby product groups and, in this respect, a total of 1144 products in 2020 and 752 products in the first three quarters of 2021 were inspected. As a result of the inspection activities, administrative fines, withdrawals and destruction orders relating to cosmetic products were applied.

The TITCK has accelerated the harmonisation of its Regulations with the EU Regulations and, accordingly, has shared a draft regulation that includes parallel provisions. The TITCK has updated all Guidelines and has commenced implementing the EU rules in this respect.

Finally, with the announcements dated November 30, 2021, and December 7 2021, it has been announced that the license applications for Biocidal Product type-1 and product type-19 that directly contact the human body and license deficiency applications which have not been finalised, will start to be accepted over ÜTS Biocidal Module as of December 9 2021.

In addition, TİTCK announced the extension of the license validity period of product type-1 and product type-19 Biocidal Products, which were previously licensed by the General Directorate of Public Health and whose validity term expired on December 31 2021, until December 31 2022.

However, it is stated that for the license renewal processes of these companies; the physicochemical, accelerated stability, long-term stability and open package stability tests and irritation test reports in the current license files will be accepted provided that they are compatible with the provisions of the "Instruction on Analysis of Biocidal Product type-1 and product type-19" published by TITCK. Otherwise, the tests stated will have to be renewed in compliance with the Instruction. If these companies cannot complete the license processes by the end of this term, their licenses will be cancelled.

Subsequently, the Regulation on the Amendment of the Regulation on Biocidal Products was published in the Official Gazette

on December 30, 2021, and amendments were introduced regarding the tests submitted in the application file for active substances and biocidal products, the inspections by the Ministry of Health, with the practice of 2-d barcode.

In this context, recent developments indicate that TITCK aims to regulate the market of biocidal products that directly contact the human body more strictly.

Personal Health Data Protection

The protection of personal data (including personal health data) is regulated under Personal Data Protection Law ("DPL") numbered 6698. The DPL provides legal reasons for the processing of personal data and sensitive personal data (data relating to race, ethnic origin, political beliefs, philosophical beliefs, religion, denomination, or other faiths, clothing and attire, membership of an association, charity or union, criminal convictions, and security measures, as well as biometric and genetic data). Data processing conditions are more regulated and subject to the explicit consent of the data subjects, or such data may be processed if case processing is required by law. It must be noted that personal data relating to health or sexual orientation is protected more strictly than other sensitive data, as the scope of the additional legal grounds for processing is quite limited.

Personal data related to health or sexual data may only be processed with the explicit consent of persons under the obligation of confidentiality or by authorised institutions and establishments to protect public health, protective medicine, medical diagnosis, and treatment and care services.

Sensitive and non-sensitive personal data may be transferred to third parties if the data subject's explicit consent is obtained or if one of the additional legal grounds mentioned above is applicable.

While the data protection legislation affects all companies located in Turkey, it poses some practical challenges to pharmaceutical and medical device companies collecting vigilance information and quality complaints. The gathering of data means that the company must sometimes directly interact with patients, collect and store data, and obtain their explicit consent for the processing, sharing, and transferring the data abroad to their global companies. In the field of medicines and medical device promotion, interaction with physicians also entails data privacy concerns, and privacy rules must be followed.

The Agency published the Guidelines on Protection of Personal Data in Pharmacovigilance Activities (the "Guidelines") on August 1 2019, to overcome the challenges faced by pharma companies. The Guidelines state that no explicit consent is required to process patient data reported by an adverse effect notification, regardless of whether the person making the adverse effect notification is a patient, healthcare professional or relative. Additionally, according to the Guidelines, the persons under the confidentiality obligation stated in Article 6 of the DPL shall process adverse effect data without explicit consent to protect public health and preventive medicine.

According to Article 6 of the DPL published in 2016, personal data related to health or sexual information may only be processed by persons under an obligation of confidentiality, or by

authorised institutions and establishments, for protection of public health, protective medicine, medical diagnosis, and treatment and care services.

The Guidelines do not refer to any consultation with the Turkish Institution of Protection of Personal Data to prepare the Guidelines. Therefore, the Institution of Protection of Personal Data has not confirmed the Guidelines' interpretation of Article 6 of the Data Protection Law as of the date of this paper.

Even though the Guidelines entered into force as of the date of its publication, the pharmaceutical industry awaits guidance from the Turkish Institution of Protection of Personal Data as to whether pharma companies may be defined as persons under an obligation of confidentiality, as this obligation shall be explicitly stated in law and cannot be introduced through Guidelines.

CONTACTS

MEHMET GÜN
PARTNER

Life Sciences
Intellectual Property
Dispute Management
Corporate and M&A
Competition
Finance

mehmet.gun@gun.av.tr

ÖZGE ATILGAN KARAKULAK
PARTNER

Life Sciences
Intellectual Property
Patent and Utility Models
Competition

ozge.atilgan@gun.av.tr

SELİN SİNEM ERCİYAS
PARTNER

Life Sciences
Intellectual Property
Patent and Utility Models

selin.erciyas@gun.av.tr

BEGÜM YAVUZDOĞAN OKUMUŞ
PARTNER

Life Sciences
Data Protection and Privacy
Corporate and M&A
Competition
Technology, Media and Telecom

begum.yavuzdogan@gun.av.tr

GÖRKEM BİLGİN
PARTNER

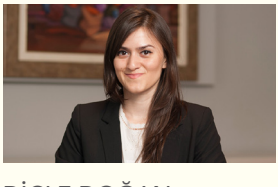
Life Sciences
Corporate and M&A
Energy and Natural Resources
Insurance and Reinsurance
Construction and Real Estate

gorkem.bilgin@gun.av.tr

HANDE HANÇAR
PARTNER

Life Sciences
Intellectual Property
Trademarks and Designs
Copyrights
IP Prosecution
Technology, Media and Telecom

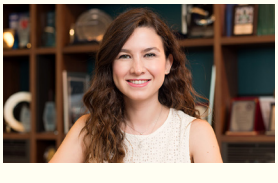
hande.hancer@gun.av.tr



DİCLE DOĞAN
YÖNETİCİ AVUKAT

Life Sciences
Intellectual Property
Trademarks and Designs
Data Protection and Privacy

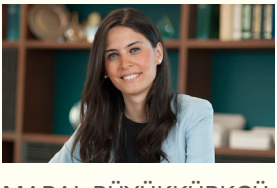
dicle.dogan@gun.av.tr



FATMA SEVDE TAN
KIDEMLİ AVUKAT

Life Sciences
Intellectual Property
Patent and Utility Models

fatmasevde.tan@gun.av.tr



MARAL BÜYÜKKÜRKÇÜ
KIDEMLİ AVUKAT

Life Sciences
Intellectual Property
Patent and Utility Models
Trademarks and Designs

maral.sayan@gun.av.tr

CONTACTS

YALÇIN UMUT TALAY
KIDEMLİ AVUKAT

Life Sciences
Data Protection and Privacy
Corporate and M&A
Technology, Media and Telecom
Business Crimes and Anti-Corruption

umut.talay@gun.av.tr

ZEYNEP ÇAĞLA ÜSTÜN
KIDEMLİ AVUKAT

Life Sciences
Intellectual Property
Patent and Utility Models
Trademarks and Designs

zeynep.ozcebe@gun.av.tr

FIRM OVERVIEW

We are one of the oldest and largest business law firms in Turkey and are ranked among the top tier legal service providers. We are widely regarded as one of the world's leading IP law firms.

Based in Istanbul, we also have working and correspondent office in Ankara, Izmir and all other major commercial centers in Turkey.

We advise a large portfolio of clients across diverse fields including life sciences, energy, construction & real estate, logistics, technology media and telecom, automotive, FMCG, chemicals and the defence industries

We provide legal services mainly inn Turkish and English and also work in German and French.

We invect to accumulate industry specific knowledge, closely monitor business sector developments and share our insight with our clients and the community We actively participate in various professional and business organisations.

GÜN + PARTNERS
AVUKATLIK BÜROSU

Kore Şehitleri Cad. 17
Zincirlikuyu 34394
İstanbul, Turkey

T: + 90 (212) 354 00 00
F: + 90 (212) 274 20 95
E: gun@gun.av.tr

www.gun.av.tr