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LIFE SCIENCES LAW IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS - 2020

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 offices 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 in Turkish and English and also work in German and French.

We invest 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.

Key Developments and Predictions for Life Sciences in Turkey

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

Despite many opportunities that accompany this potential for growth, it should also be noted that both the Turkish pharmaceutical and medical device industries remain heavily regulated in all aspects, ranging from market access, to pricing and reimbursement being covered by industry-specific regulations. The said measures are strictly enforced by the Turkish Medicines and Medical Devices Agency ("TITCK") established under the relevant body of the Ministry of Health, and the Social Security Institution ("SSI").

The increase in the quality of health services and patients' access to medicines has, inevitably, increased the demand for health services, as well as pharmaceuticals, and there has been an associated increase in public spending. This has prompted the government to seek ways of reigning in public expenditure by incorporating a rigid pharmaceutical pricing policy.

In addition, the SSI requests a considerable discount for reimbursements. These difficulties in pricing and reimbursements have caused hindrance in the access to pharmaceuticals. Procurement from abroad of pharmaceuticals that cannot be found in the domestic market has greatly increased. To control the budget, the SSI developed alternative reimbursement models, regulated named patient programs, and even implemented localization policies.

Nevertheless, the healthcare industry regulation in Turkey is mostly aligned with worldwide standards. Promotional restrictions both to pharmaceuticals and medical devices, as well as the rules of ethics and compliance, are in parallel with the EU legislation.

This paper provides an overview on the following topics:

- Pricing of Pharmaceuticals and the Fixed Exchange Rate
- Market Access-Reimbursement Agreements
- Localisation of Previously Imported Products
- Named Patient Programs
- Interactions with HCPs
- Transfer of Value
- Harmonization with the EU Medical Devices Regulation
- Promotion of Medical Devices
- Food Supplements
- Cosmetics
- Personal Health Data Protection

Pricing of Pharmaceuticals and the Fixed Exchange Rate

Healthcare and pharmaceuticals make up a highly regulated industry sector in Turkey, and the pricing of medicines is no exception. The prices of medicines that are to be marketed in Turkey are set in accordance with the Decision on Pricing of Human Medicinal Products ("Decision") and the Communiqué on the Pricing of Human Medicinal Products ("Communiqué") of 29 September 2017, issued by the Ministry of Health ("MoH") who is vested with the competencies to regulate the area.

The Decision provides for a reference pricing system, whereby the least expensive ex-factory price in one of the listed EU countries, for the same product, is taken as the ex-factory price, in Turkey. The currency is then converted into Turkish liras, albeit not at the current exchange rate. In order to avoid the reflection of exchange rate fluctuations onto the prices of medicines, the Decision includes a provision that helps the MoH to issue a fixed exchange rate to be applicable in the pricing of medicines. Thus, the exchange rate applied to the reference price taken from the respective EU country is converted to Turkish Liras at a rate that gives out a much lower price than if it is converted at the current rate. Below is the history of the developments in the FX rate determination by the Turkish Government.

The Decision of 2015 set a much lower fixed rate than reasonably expected. The industry actors eagerly awaited an improvement in the rate, bearing in mind the ongoing lawsuits on the matter initiated by pharmaceutical companies. With the entry into force of the Decision of 2017, the rate was determined as 70% of the average Euro value of the previous year. Accordingly, the Price Evaluation Commission was to gather within the first 45 days of each year, and would announce the 1 (one) Euro value, based on the 70% calculation of the average value of the previous year.

After entry into force of the Decision, and just prior to the announcement of the Euro rate applicable for the year 2018, on 22 January 2018, a provisional clause was added to the Decision regulating that the value of one Euro would not exceed more than 15% of the one Euro value set for the previous year. Thus, although 70% of the average value for the year 2017 was greater, the Euro exchange rate applicable to medicine prices in 2018 was increased only by 15% as against the previous year, and it was determined as TRY 2.6934.

Initially, the Decision was issued by the Cabinet of Ministers. As a result of the referendum held on 16 April 2017, an amendment was made to the Constitution, and a transition was made to the Presidential Government System. 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 rules and procedures for determination of pharmaceutical prices are

now determined by the President, not by the Cabinet of Ministers, as of July 2018.
Considering that the average Euro value for the year 2018 was approximately TRY 5.65, the rate applicable for 2019 should have been announced at a value close to TRY 4 as per the Decision. However, with the amendment made through a Presidential Decree, which was published in the Official Gazette on 14 February 2019, the rate of "70%" provided in the Decision was amended to "60%." Thereafter, the Price Evaluation Commission decided that the rate was determined as TRY 3.40, with an increase of 26.4% compared to the previous year.

Finally, on 14 February 2020, the Price Evaluation Commission determined the FX rate for 2020 as TRY 3.8155, which brings an automatic increase of 12%, when compared to 2019.

Market Access-Reimbursement Agreements

Until recently, there was no direct contractual relationship between the SSI and the pharmaceutical companies ("pharma companies") regarding the pharmaceuticals purchased by the State. The pharma companies applied for the reimbursement of their products to the SSI and, once listed, companies sold their products to warehouses, which then distributed the products to the hospitals and pharmacies. In line with this sale and distribution chain, the SSI reimbursed the hospitals, or the pharmacies, for the prices of the listed products.

For a long period of time, the industry needed a special type of reimbursement where the conditions could be set, together with the SSI, and the normal price and reimbursement rules did not apply for specific special products.

With the enactment of Law of the Social Security and General Health Insurance Law numbered 6552 in September, 2014, alternative reimbursement models also became a hot topic in the Turkish healthcare industry. The complementary provisions introduced with the Regulation on the Alternative Reimbursement of Pharmaceuticals, published in February, 2016, allows companies and the SSI the benefit of discussing the terms and conditions of an alternative reimbursement model for special products.

The system has the ultimate purpose of providing swifter access for patients with respect to innovative pharmaceuticals concerning their reimbursement.

In parallel to the SSI's amendments, the TITCK has also introduced guidelines for the prioritization of MA applications of special products that have advantages in terms of public health and public finance. A commission established under the TITCK, and composed of members working both under the MoH and the SSI, evaluates companies' prioritization applications.

Although the regulatory developments in the last few of years are significant, the industry is still expecting the preparation and publication of a guidelines specific to orphan drugs. On the other hand, with the acceptance of the TITCK as an official member to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the period for a locally manufactured product to access the global market is expected to be shortened.

Localisation of Previously Imported Products

In Turkey, the innovator pharmaceutical market is dominated by originator companies of foreign origin, with local companies active in the generics market. The government's unease with the emphasis on imported products in the Turkish market beckoned the state development plan to procure local production in the pharmaceutical market, a political act affecting the activities of many pharmaceutical companies of foreign origin. The aforementioned state development plan triggered the SSI's administrative decisions to delist pharmaceutical companies of foreign origin from the reimbursement list unless they gave the undertaking that they would shift to local production.

The largest buyer of medicines in the Turkish market is the SSI through the reimbursement scheme in place. With this scheme, the prescribed products that are on the reimbursement list of the SSI are bought by patients from pharmacies, with little or no contribution from the patient. The pharmacies are later reimbursed by the SSI for these products and, thus, being listed for reimbursement is a practical precondition that exists in the pharmaceutical market.

This forced localisation left many foreign pharmaceutical companies with the need to enter into projects with local companies to localise the production of their products.

However, the complex nature of many of the products previously imported leaves some companies unable to localise the manufacture of their products, which leads to the delisting of these same products. This governmental act forecloses the market for foreign products unable to localise production, which could be said is unjustly detrimental to foreign companies. The unjust nature of this foreclosure is due to the state development plan not being a legislative act with legal grounds to surpass the legislative measures that had listed these foreign products for reimbursement in the first place.

On 2 April 2019, the European Union ("EU") made a request for consultation before the WTO regarding the measures Turkey had taken concerning production, importation and marketing of pharmaceutical products, which it claimed to be in contradiction with international agreements. As the matter has been brought before the WTO panel, we may expect changes in the Turkish regulatory system, especially with respect to the SSI's approach on the forced localization policy.

Named Patient Programs

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

Only the Turkish Pharmacists' Association ("TEB") and the İbn-i Sina Health Social Security Center, established under the SSI, were authorized to import NPP products until December 2018. An amendment in the law was introduced in December, 2018, stating that this special importation shall be made by the SSI and the TEB, as well as institutions / organizations deemed appropriate by the MoH. No criteria have been determined for the selection of such institutions/ organizations to date.

The law now foresees that for foreign products imported, it is mandatory to apply for marketing authorization within three years from the date of entry onto the Foreign Drug List, and it is also mandatory to obtain marketing authorization within two years from the date of application for marketing authorization. However, no sanction has been determined in the event this rule is breached. After the completion of the given durations, the President of the Republic is authorized to decide on the continuation of the supply of drugs that has not obtained a marketing authorization, or for which no marketing authorization application has been filed.

For the products that had been supplied from abroad, prior to the entry into force of the Law, which was 5 December 2018, the application period for marketing authorization, and the products for which previous marketing authorization had been applied, the period to obtain marketing authorization commenced 5 December 2018. In addition, without making any change in the Regulation on the market authorization, or NPP, and by only amending the legislation on pharmacies, the obligation to obtain market authorization within three years after being listed on the Foreign Drug List, and to obtain market authorization within two years after the application for the market authorization, has been established for the drugs that are included on the Foreign Drug List. As well, for the drug that has been prescribed for a patient by a physician, but for which no application for a market authorization has been filed, or which did not obtain market authorization within the specified periods, the decision to continue the supply from abroad is left to the President's discretion. Also, if the company who owns the product in question does not have any subsidiary or representative in Turkey, it is understood that the discretionary power on the decision to continue supplying that product has been also given to the President.

On 10 January 2020, the TITCK published the New "Guidelines on Named Patient Program ("Guidelines").

The Guideline includes some changes regarding the execution of the named patient program. Among the suppliers of the NPP, Uluslararası Sağlık Hizmetleri A.Ş. ("USHAŞ"), a public enterprise established by law, was added next to TEB and SSI.

In addition, only active ingredients that are supplied from abroad will be published; thus, the list of the products supplied from abroad will no longer be published. The responsibility for the risks that may arise in terms of patient health due to the supplied medicines is now clearly burdened on USHAŞ, TEB and/or SSI. In addition, the TITCK clearly regulated its right to conduct any kind of examination and research, including GMP inspection, on human medicinal products supplied from abroad by the NPP, if deemed necessary.

As of the publication of the Guidelines, the TITCK has ceased to share the list of the products supplied from abroad, and has already published new lists of active ingredients supplied from abroad.

Although it is not given in the legislation, there is a practice to grant some of the NPP with alternative reimbursement agreements in which SSI signs an agreement with foreign suppliers or their Turkish representatives. The alternative reimbursement agreements may guarantee that the products of a company that do or do not have an affiliate in Turkey, or which did or did not apply for an MA, will be reimbursed. In addition, this agreement allows confidentiality between the parties; the prices, discounts, and other conditions are not publically available.

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 3 July 2015. Pursuant to 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. Interaction between companies and patients shall, therefore, be at a minimum level.

Companies are required to apply to TITCK for patient support programs in order to implement a support and tracking program via third party companies authorized by TITCK in order to render Home Care Services. Companies may enter into written agreements with HCPs to obtain consultation services. Conditions of such service agreements are not regulated by TITCK. The rules for such agreements are set by the industry via Ethical Codes.

On the other hand, rules regarding the payments to physicians and HCOs are regulated by the law. Amendments in various laws were made in 2014, setting 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 for physicians who had a private clinic prior to the introduction of this principle in 2014, and there are other exceptions, as well.

Transfer 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 3 July 2015, the pharmaceutical companies shall notify TITCK about any value transfers that exceed 10% of the current monthly gross minimum wage, 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, in terms of sponsoring scientific meetings, making donations, or obtaining consultancy services. The notification for the mentioned value transfers that materialize in one calendar year shall be made in the format determined by TITCK, in detail, and within the first six months of the following year. The notifications must be made via electronic system launched by TITCK.

In order to fulfil this obligation, companies are required to obtain the consent of the healthcare professionals or healthcare organisations before any value transfer takes place. All consent forms had to be updated, together with the Code on the Protection of Personal Data, published in 2016.

Harmonization with the EU Medical Devices Regulation

Regulations on Medical Devices numbered 2017/745 ("MDR"), prepared by the EU Commission, has been published and will enter in force on 26 May 2020. As a non-EU country, TITCK published an announcement on 30 December 2019 that harmonization of the new rules established by the MDR with the Turkish regulations continues.

On 1 February 2020, Presidential Circular numbered 2020/1 was published in Official Gazette numbered 31026 on the transition period for the UK's exit from European Union membership. This Circular states that the UK will continue to be subject to EU law until 31 December 2020.

Upon publication of this Circular, TITCK published an Announcement concerning the effects of this transition period on medical devices whose EC certificates were issued by the notified bodies named as the British Standard Institute (BSI) Assurance UK Ltd, Lloyd' Register Quality Assurance Ltd and SGS United Kingdom Limited, located in the UK.

According to the Announcement, the expiry dates of EC certificates whose validity period will expire after 31 December 2020, will automatically expire on 31 December 2020. The Announcement also gave detailed information for EC certificates whose expiry dates had been extended or shortened prior to this Announcement.

The harmonization of the Regulation has been long awaited by the industry, and it is expected that the year 2020 introduces many changes in the medical device sector.

Promotion of Medical Devices

With medicines, the rule is clear: The general public cannot be the audience to 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") has caused confusion in the past. The rule states that medical devices that must exclusively be applied by healthcare personnel, and those that are included in the reimbursement scheme of the SSI, cannot be advertised in any manner, whatsoever, to the general public.

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

In Turkey, the provision of sponsorship to HCPs by medical device companies for the purpose of congressional attendance is regulated with the Medical Device Promotion Regulation that provides a system in which HCPs are subject to annual quotas for support, and companies are required to notify the HCPs of such sponsorships. Therefore, Turkish medical device companies, as members to MedTech Europe, implemented a new sponsorship model as of the beginning of 2018. As the MedTech Code requires indirect sponsorship, and local regulations require the notification of the HCPs by the companies, the member companies ceased to initiate the communication for sponsorship, and offered HCPs the sponsorship. The selection of HCPs is made by HCOs (associations, non-profit organizations, 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 the rules with respect to the advertising of medical devices.

Food Supplements

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

The said Regulation is not only the first regulation that has been drafted, particularly on food supplements, but also includes unique provisions with regard to 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, as well as 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 the issue is, therefore, 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 the on-going 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 7 June 2013, health claims in advertisements for food supplements must comply with the rules set out in the Turkish Food Codex on Labelling. If an advertisement does not comply with these rules, the MoH may order the cessation of sales, as well as 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 for 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

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 that are 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 with respect to safety and advertising of cosmetics. In 2018, inspections had been initiated for skin care products, hair styling products, and baby product groups; and in this respect, a total of 154 inspections were carried out, and a total of 371 cosmetic products 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 harmonization of its Regulations to the EU Regulations and, accordingly, has shared a draft regulation that includes parallel provisions. In this respect, the TITCK has updated all Guidelines and has commenced implementing the EU rules.

Personal Health Data Protection

The protection of personal data and personal health data is regulated under Personal Data Protection Law ("DPL") numbered 6698. The DPL provides that the general rule for the processing of personal data is that such data may only be processed with the explicit consent of the data subject.

As for 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, health, sexual orientation, criminal convictions and security measures; and biometric and genetic data), these can only be processed with the explicit consent of the data subject. 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 very limited.

Personal data related to health or sexual data may only be processed with the explicit consent by persons under the obligation of confidentiality, or by authorized institutions and establishments for the purposes of protection of 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 explicit consent of the data subject is obtained, or if one of the additional legal grounds mentioned, above, is applicable for such transfer.

While the data protection legislation affects all companies located in Turkey, it poses some practical challenges to pharmaceutical and medical device companies that are collecting vigilance information and quality complaints and, as such, the gathering of information means that the company must sometimes directly interact with patients, collect and store information, and obtain their explicit consent for the processing, sharing, and transfer of the data abroad to their global companies.

In order to overcome the challenges faced by pharma companies, the Agency published the Guidelines on Protection of Personal Data in Pharmacovigilance Activities on 1 August 2019. The Guidelines state that no explicit consent is required for the processing of 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, pursuant to the Guidelines, the persons under the confidentiality obligation stated in Article 6 of the Data Protection Law shall process adverse effect data without explicit consent for the protection of the public health and preventive medicine.
According to Article 6 of the Data Protection

Law published in 2016, personal data related to health or sexual data may only be processed by persons under an obligation of confidentiality, or by authorised institutions and establishments, for the purposes of protection of public health, protective medicine, medical diagnosis, and treatment and care services.

The Guidelines do not refer to any consultation made with the Turkish Institution of Protection of Personal Data for the preparation of the Guidelines and, therefore, the Guidelines' interpretation of Article 6 of the Data Protection Law has not been confirmed by Institution of Protection of Personal Data as of the date of this paper.
Even though the Guidelines entered into force as 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 a Law and cannot be introduced through Guidelines.

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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.

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