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PHARMACEUTICALS AND LIFE SCIENCES IN TURKEY

KEY DEVELOPMENTS AND PREDICTIONS

2023

LIFE SCIENCES

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Key Developments and Predictions of 2023 for Pharmaceuticals and Life Sciences in Turkey

The year 2022, in which we have left behind the significant effects of the Covid-19 pandemic, has been a hectic year for the life sciences industry. It is expected that 2023 will be at least as busy as 2022 due to the amendments in the pharmaceutical and medical device legislation in the EU and the fact that presidential elections will be held in Turkey.

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 public institutions to impose a rigid pharmaceutical pricing policy. However, especially the rapid increase in currency exchange rates and adverse economic developments cause some products to become challenging to find on the market, and even pharmaceutical companies to exit the Turkish market partially or entirely or abandon the decision to offer new products on the market.

The Turkish Medicines and Medical Devices Agency ("**TMMDA**"), established under the Ministry of Health ("**Ministry**"), and the Social Security Institution ("**SSI**") have started to take several measures to ensure the continuity of the supply of products. However, the irregularities in some procedures and the allegations of counterfeit drug supply indicate that stricter measures should be taken.

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. We will closely follow the developments of the year 2023 in this field and continue to inform our stakeholders about these developments.

This paper provides an overview of the following topics:

- Pricing of Pharmaceuticals and the Fixed Exchange Rate
- Market Access-Alternative Reimbursement Models
- Market Availability of Products
- Named Patient Programs
- Interactions with HCPs
- Developments in the field of Medical Devices
- Food Supplements, Foods for Special Medicinal Purposes and Other Products
- Development of Telemedicine in Turkey

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, which is vested with the competencies to regulate this area.

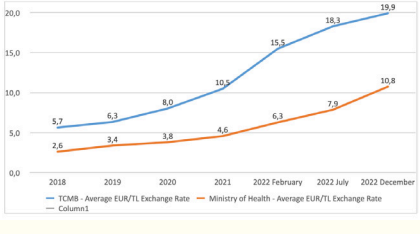
The Decision provides a reference pricing system, whereby the least-expensive ex-factory price in one of the listed EU countries for the relevant product is taken as the ex-factory price in Turkey. The currency is then converted into Turkish liras; however, this transaction is done at a fixed value every 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 60% of the average euro value of 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 euro 1 based on a calculation of 60% of the average value in the previous year.

According to this rule, on February 14, 2022, the exchange rate to be used in the pricing of medicines was set as TL 6.2925. However, due to the rapid change in the exchange rate in 2022, with the provisional article added to the Decision, on July 8, 2022, the value of 1 Euro was increased by 25%, and the new exchange rate was set as TRY 7.8656. Subsequently, on December 14, 2022, the value of 1 Euro in Turkish Lira to be used in the pricing of pharmaceutical products for human use was increased by 36.77% to TL 10.7577 in December 2022.

For 2023, it was stated that this last amount would continue to be applied and that the Price Evaluation Commission would not announce a new value in the first 45 days of the year. However, although it has not been regulated in the legislation yet, one can expect an increase to be made again in 2023 due to the fluctuations in the current exchange rate.

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



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

Özge Atılgan Karakulak, Dicle Doğan, Fatma Sevde Tan

Market Access- Alternative Reimbursement Models

For an extended period, the pharmaceutical 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 to 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, allowed 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 a direct contractual relationship with pharmaceutical companies, will ultimately allow patients to access innovative pharmaceuticals faster. However, nowadays, these models also appear to control pharmaceutical prices.

In addition, with the conclusion of one of the actions filed against specific provisions of the Regulation on the Alternative Reimbursement of Pharmaceuticals, some articles were annulled on the grounds of procedural deficiency, as the SSI issued the regulation without receiving the opinion of the Ministry. Since the entire text is not the subject of the action, only some of the provisions were brought before the court, and essentially the entire Regulation is still in force, including the article of the law on which the alternative reimbursement models are based.

Following the annulment decision, the SSI was expected to update the Regulation on the Alternative Reimbursement of Pharmaceuticals by duly re-publishing the annulled articles. Instead, the SSI published the new Regulation on the Reimbursement of Pharmaceuticals, including the articles that will update the principle of confidentiality of the discount rates applied in these alternative models. In this context, the rule regarding confidentiality, implemented with the Alternative Reimbursement Regulation, has been re-introduced with the amendment made in the Pharmaceutical Reimbursement Regulation. However, it is unclear whether the Alternative Reimbursement Commission will be convened or the pharmaceutical companies will make new reimbursement agreements with the SSI with confidential and special discounted prices. It is thought that the elections, to be held in 2023, also play a role in how the implementation will continue in this issue, which is highly critical for the country's economy and companies.

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Market Availability of Products

The New Regulation on Licensing of Human Medicinal Products prepared by the TMMDA 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 on Licensing of Human Medicinal Products is reflecting up-to-date processes present in the TMMDA practice but did not exist in the previous regulation dated 2005 and provide compatibility of the legislation with the EU directive numbered 2001/83/EC.

An exception has been introduced for the products to prevent problems with the 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. Secondly, with the addition made to the provision on suspension of the marketing authorization, 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 marketing authorization is suspended instead of cancellation. In addition, if the marketing authorization holder fails to notify the Agency at least 30 days before the occurrence of a situation in which the marketing authorization holder will not be able to place a product on the market for any reason, fails to fulfil other obligations listed in the Regulation, or if the medicinal product for human use, which is essential for public health and the sustainability of access to medicines, is not placed on the market by the marketing authorization holder within 6 months from the date of the request, despite being requested by the TMMDA, the marketing authorization will be suspended. The TMMDA decides on the suspension of the marketing authorization based on the assessment results, including the safety of the relevant nonconformity.

At the end of 2022, an export ban was introduced to guarantee the availability of products in the market and to prevent the export of imported products to Turkey. Similarly, it is aimed to initiate an application for the "Declaration of Supply and Maximum Production Capacity" of pharmaceutical companies to the Pharmaceutical Track and Trace System ("ITS"). It has been stated that ITS will be opened for data entry in the first week of each month, and both entries and updates must be completed within the first week of each month. With the processed data, it is thought that the TMMDA can observe the supply and demand balance in the market and intervene to protect public health when needed.

Dicle Doğan, Fatma Sevde Tan

Named Patient Program

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

In cases where a pharmaceutical does not have a marketing authorization in Turkey or has a marketing authorization 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. The program is regulated by the Guidelines published by the TMMDA until 2023.

On February 03, 2023, the Regulation on the Supply of Medicines from Abroad ("NPP Regulation") was published in the Official Gazette with the number 32093. Before the publication of the NPP Regulation, allegations of counterfeit products supplied recently appeared in the news, and the TMMDA and SSI made press statements on this issue. It is also stated in the press releases that criminal complaints have been filed against those involved in the supply of counterfeit products. As a result of these developments, the NPP Regulation has been published, and the roles of stakeholders in the procurement process have been defined more clearly:

- Foreign institutions and organizations that will supply medicines from abroad have been identified as Foreign Medicine Supply Sources, and it has become mandatory for them to have a Representative in Turkey.
- The representative is defined as a natural or legal person residing in Turkey who has been authorized in writing to fulfil the obligations of the Foreign Medicine Supply Source on its behalf.
- It is stipulated that the Turkish Pharmacists Association, the SSI and the public institutions deemed appropriate by the Ministry, which will supply the product from abroad, will distribute the products in accordance with the legislation to which pharmaceutical warehouses are subject.

In addition, it has been provided that the products procured through these means will be registered to the Medicine Monitoring System ("ITS"), just as it is done for licensed medicines, and will be tracked through this system.

The effective dates of various provisions of the NPP Regulation vary, and the guidelines that are supposed to guide the implementation of the regulation have not yet been published. The guide is expected to be published soon, and an increase in the number of inspections in this area is expected in 2023.

Özge Atılgan Karakulak, Dicle Doğan, Beste Turan

Interactions with HCPs

Promotional activities of human medicinal products 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. Pharmaceutical products may be promoted only to physicians, dentists and pharmacists. Therefore, the interaction between companies and patients shall be minimum.

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

In addition, the pharmaceutical companies shall notify the TMMDA of 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. Companies must obtain the healthcare professionals' or healthcare organizations' consent before any value transfer occurs to fulfil this obligation.

Apart from these consents, one of the critical points to be considered in relations with physicians and health institutions is making payments per 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 to be made for the services provided by these physicians must be made to the institution they are affiliated.

Recently, individual lawsuits have been filed against the refusal of the provincial health directorates by the physicians working in the university hospital to open a private clinic. These cases are not considered collectively, and as each case binds the physician concerned, it is necessary to decide on the payments, considering the possibility that the higher courts may overturn the decision of court of first instance given in the case.

Dicle Doğan, Fatma Sevde Tan

Developments in Medical Devices

After the long-awaited Regulation on Medical Devices numbered 2017/745 ("MDR"), prepared by the EU Commission, has entered into force, Medical Device Regulation, which was designed following MDR, was 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.

The Medical Device Regulation entered into force on the same date as the MDR, to which it is compatible, and announcements of the TMMDA 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 regulations in force in Turkey are considered. The definitions in the Medical Device Regulation taken directly from the EU legislation have caused incompatibilities with other local legislations.

However, separate legislation exists, which is not included in the EU legislation and contains detailed provisions on companies' sales, advertising, and promotional activities. The Regulation on Medical Device Sales, Advertising and Promotion ("Medical Device Promotion Regulation") regulates the obligation of medical device companies in Turkey to register their products in the Product Tracking System ("UTS"), as well as imposes several additional obligations.

Although a significant development was not introduced in the field of medical devices in terms of legislation in 2022, the economically damaging practices that have been going on for years due to the failure to update the exchange rate applied to medical device prices have made it difficult for medical device companies to continue their activities without making a loss. For this reason, although no changes are foreseen in the legislation in this area, there may be some differences in the implementation.

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Food Supplements, Food for Special Medical Purposes and Other Products

The Regulation on the Importation, Production, Processing and Supply of Food Supplements was published by the Ministry of Food and Forestry on May 2, 2013, in the Official Gazette and came into force on August 2, 2013. The said Regulation is not only the first regulation drafted, particularly on food supplements but also includes special provisions about the control and approval mechanism to be established over food supplements. However, this legislation is carried out by the Ministry of Agriculture and Forestry. With the many legislative changes that have taken place, it can be expected that the TMMDA will carry out the legislation related to this product group.

With the Regulation on Licensing of Foods for Special Medical Purposes published on January 28, 2023, a new regulation was made regarding food for special medical purposes, previously regulated by the guidelines. The TMMDA has introduced a license requirement for placing foods on the market for special medical purposes. In this context, we think that the issues regulated by the TMMDA with regulations instead of guidelines will continue in 2023 as well. The TMMDA published the Traditional Herbal Medicinal Products Licensing Regulation in the Official Gazette dated February 03, 2023, right after the Regulation on Licensing of Foods for Special Medical Purposes was published.

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Development of Telemedicine Activities in Turkey

Telemedicine is one of the areas that are not explicitly regulated under Turkish law. Within the scope of the existing legal framework, the Medical Deontology By-law and Ethical Principles for Physicians prohibit remote examination, diagnosis, and treatment of patients.

During the COVID-19 pandemic, the legal gap in telemedicine became a more serious issue as private hospitals especially started to provide online healthcare services to patients who cannot visit the healthcare centres due to COVID-19 risk. The fact that the number of hospitals providing telemedicine services increased also attracted the Ministry's attention. Accordingly, the Ministry prepared a highly anticipated Regulation on Remote Provision of Healthcare Services, published in the Official Gazette dated February 10, 2022, numbered 31746. The basis of the Regulation is shown as Articles 9 and 11 of the Fundamental Law on Healthcare Services No. 3359 and Articles 335 and 508 of the Presidential Decree No. 1 on the Presidential Organization, allowing Ministry to publish regulations within the scope of its authority.

Within the scope of the Regulation on Remote Provision of Healthcare Services, a remote healthcare information system infrastructure will be developed or authorized by the Ministry, and healthcare centres will use healthcare information systems to enable written, voice or video communication. The developed remote healthcare information system infrastructure shall be registered to the Ministry's database.

In accordance with the Regulation on Remote Provision of Healthcare Services, the healthcare centres that would like to provide remote healthcare services shall obtain authorization by applying to the General Directorate of Healthcare Services (the "General Directorate") with the required documents. The Ministry shall issue an authorization certificate if the healthcare centre's information system is registered in the Ministry's database and its application is appropriate by the General Directorate. In addition, for healthcare centres affiliated with the Ministry, a remote authorization certificate for healthcare service may be issued by the Ministry ex officio.

Regarding the scope of the provision of remote healthcare services, numerous activities may be conducted remotely, including examination, consultation, prescription, follow-up of parameters such as blood sugar and blood pressure, provision of services supporting healthy life and psychosocial health, conducting invasive and surgical operations upon receiving approval from the Ministry, protection of people's health during endemic and epidemic outbreaks, monitoring the health status of elderly and high-risk groups and people requesting monitoring of their health data via wearable technologies.

Also, the healthcare centres authorized for international healthcare tourism may provide remote healthcare services internationally.

Considering the provision of remote healthcare services, the physician shall inform the patient of his/her expertise, the scope of the service, the differences between remote and applied healthcare services and data protection-related matters. The healthcare centres shall be responsible for protecting patient privacy and health data within this framework. Accordingly, the healthcare centres store and send the transactions and activities regarding remote healthcare services to the Ministry's database.

The entry into force of this Regulation will lead to the beginning of a new era in the digitalization of the healthcare services industry in Turkey. There are also criticisms on the fact that the Regulation on Remote Provision of Healthcare Services is prepared as a regulation prepared by the Ministry instead of a Law prepared by the parliament, contradicting the principle that constitutional rights such as the right to live and healthy living right can only be limited by law. There are also some concerns about implementing this Regulation as the Ministry still did not publish a guideline on how to standardize the technical infrastructure required for the provision of remote healthcare and the training to be provided to staff in healthcare centres providing services at different care levels. Nevertheless, it is indisputable that healthcare services will become more accessible, a crucial step for improving public health overall.

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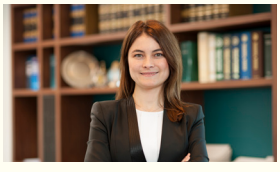

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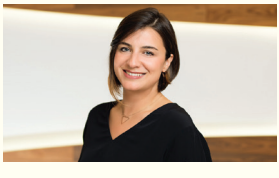

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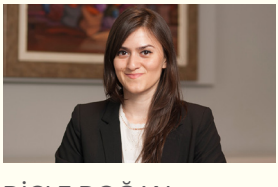

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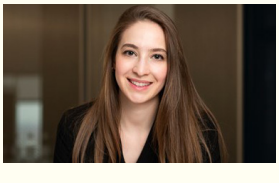

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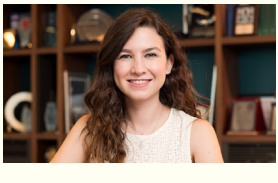

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FIRM OVERVIEW

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