The Pharma Legal Handbook

Turkey

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Turkey

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Turkey.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Moroğlu Arseven, a leading Turkish law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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MOROĞLU ARSEVEN

Moroğlu Arseven is a full-service law firm with broadly demonstrated expertise and experience in all aspects of business law. Established in 2000, the firm combines a new generation of experienced international business lawyers and acclaimed counsels who have academic, judicial and practical experience in private law. Its dynamic and dedicated team is able to analyse the legal framework and provide flexible solutions for clients doing business in Turkey. The firm serves local clients in international markets and international clients in Turkey. Clients appreciate the firm's responsive, clear and concise answers to legal questions, as well as its knowledge of their business goals, usually based on long relationships.

The firm represents and serves a diverse clientele, in a wide range of industries. In-depth sector knowledge ensures seamless service across practice areas, enabling Moroglu Arseven to meet all of a client's legal needs in Turkey. Key areas include pharmaceuticals, life sciences, manufacturing, retail, energy, banking and financial markets, construction, real estate, TMT and sports.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Turkey's Ministry of Health ("Ministry") is the main regulatory and responsible authority for drugs, biologicals and medical devices.

Regulatory authorities with jurisdiction over drugs, biologicals and medical devices in Turkey are the:

- Ministry of Health,
- Turkish Medicines and Medical Devices Agency ("TİTCK" - *"Türkiye İlaç ve Tıbbi Cihaz Kurumu"*)
- Social Security Institution.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

There are various regulations on authorization, pricing and reimbursement of drugs, biologicals and medical devices in Turkey. In general, these are based on the Law on Pharmaceutical and Medical Preparations numbered 1262 published in the Turkish Official Gazette dated 26 May 1928 and numbered 898 *(İspençiyari ve Tıbbi Müstahzarlar Kanunu)*.

In addition to the main law, other regulations in this area include:

- Law on the Pharmacists and Pharmacies numbered 6197 published in the Turkish Official Gazette dated 24 December 1953 and numbered 8591 *(Eczacılar ve Eczaneler Hakkında Kanun)*,
- Main Law on Medical Services numbered 3359 published in the Official Gazette dated 15 May 1987 and numbered 19461 *(Sağlık Hizmetleri Temel Kanunu),*
- Regulation on the Safety of Medicinal Product published in the Turkish Official Gazette dated 15 April 2014 and numbered 28973 (*İlaçların Güvenliliği Hakkında Yönetmelik),*
- Regulation on Pharmacists and Pharmacies published in the Turkish Official Gazette dated 12 April 2014 and numbered 28970 *(Eczacılar ve Eczaneler Hakkında Yönetmelik),*
- Council of Ministers Decree on the Pricing of Human Medicinal Products published in the Turkish Official Gazette dated 24 February 2017 and numbered 29989 *(Beşeri Ürünlerin Fiyatlandırılmasına Dair Karar)*,
- Regulation on Manufacturing Plants for Human Medicinal Products published in the Turkish Official Gazette dated 21 October 2017 and numbered 30217 *(Beşeri Tıbbi Ürünler İmalathaneleri Yönetmeliği)*,
- Implementing Regulation for Labelling, Package Leaflet and Tracing of Human Medicinal Products published in the Turkish Official Gazette dated 25 April 2017 and numbered 30048 *(Beşeri Tıbbi Ürünlerin Ambalaj Bilgileri, Kullanma Talimatı ve Takibi Yönetmeliği)*,

- Regulation on the Licensing of Human Medicinal Products published in the Turkish Official Gazette dated 11 December 2021 and numbered 31686 *(Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği)*,
- Regulation on the Surveillance and Examination of Human Medicinal Products published in the Turkish Official Gazette dated 22 March 2005 and numbered 25763 *(Beşeri Tıbbi Ürünlerin Güvenliğinin İzlenmesi ve Değerlendirilmesi Hakkında Yönetmelik)*,
- Communiqué on the Pricing of Human Medicinal Products published in the Turkish Official Gazette dated 29 September 2017 and numbered 30195 *(Beşeri Tıbbi Ürünlerin Fiyatlandırılması Hakkında Tebliğ)*,
- Regulation on Promotion of Medicinal Products for Human Use published in the Turkish Official Gazette dated 3 July 2015 and numbered 29405 *(Beşeri Tıbbi Ürünlerin Tanıtım Faaliyetleri Hakkında Yönetmelik)*,
- Guidelines for the Labelling, Instructions and Tracing of Human Medicinal Products issued by Ministry of Health *(Beşeri Tıbbi Ürünlerin Ambalaj Bilgileri ve Kullanma Talimatına İlişkin Kılavuzlar)*,
- Regulation on Clinical Research for Medication and Biological Products published in the Turkish Official Gazette dated 13 April 2013 and numbered 28617 *(İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik)*,
- Regulation on Traditional Herbal Medical Products published in the Turkish Official Gazette dated 6 October 2010 and numbered 27721 *(Geleneksel Bitkisel Tıbbi Ürünler Yönetmeliği)*,
- Regulation on Clinical Research for Medical Devices published in the Turkish Official Gazette dated 6 September 2014 and numbered 29111 *(Tıbbi Cihaz Klinik Araştırmaları Yönetmeliği)*,
- Regulation on Sales, Advertisement and Promotion of Medicinal Devices published in the Turkish Official Gazette dated 15 May 2014 and numbered 29001 *(Tıbbi Cihaz Satış, Reklam ve Tanıtım Yönetmeliği)*,
- Regulation on Medical Devices published in the Turkish Official Gazette dated 7 June 2011 and numbered 27957 *(Tıbbi Cihazlar Yönetmeliği)*,
- Regulation on Test, Control and Calibration of Medical Devices published in the Turkish Official Gazette dated 25 May 2015 and numbered 29397 *(Tıbbi Cihazların Test, Kontrol ve Kalibrasyonu Hakkında Yönetmelik).*
- Guideline on Good Pharmacovigilance Practices issued by Turkish Medicines and Medical Devices Agency (İyi Farmakovijilans Uygulamaları Kılavuzu)
- Guideline on Good Manufacturing Practices issued by Turkish Medicines and Medical Devices Agency (*İyi İmalat Uygulamaları Kılavuzu*)
- Guideline on Good Distribution Practices issued by Turkish Medicines and Medical Devices Agency (*İyi Dağıtım Uygulamaları Kılavuzu*)

Turkish texts and unofficial translations for some of these can be found at TİTCK's official website: **https://www.titck.gov.tr/mevzuat**

3. What are the steps to obtaining authorization to develop, test, and market a product?

Developing a medicinal product takes considerable time in Turkey. The Ministry requires strict criteria for each step during this process (testing, licensing or marketing).

The authorization process generally involves:

- Preliminary examination,
- Evaluation of application,
- Approval or denial of application,
- Receiving the authorization of sale.

Pharmaceutical products cannot be launched on the market before obtaining a license, which is granted by the Ministry. To obtain a license, an application must be made to the Ministry by submitting the documents listed under the Licensing Regulation on Medicinal Products.

Before submitting a license application, the applicant must conduct toxicological and pharmacological tests, as well as clinical trials. The Regulation on Clinical Research outlines the procedure for conducting clinical trials. The application procedure begins with submitting a clinical trial dossier simultaneously to both TİTCK and the Ethics Committee (appointed by the Ministry). The Ethics Committee submits its review and assessments to TİTCK. The approval process takes approximately 7 to 15 days. Following the Ethics Committee's assessment, TİTCK delivers a report to the Ministry within 30 days for administrative evaluation and approval.

Subsequently, to distribute the drug, the applicant must obtain marketing authorization, which is regulated under the Licensing Regulation on Medicinal Products. TİTCK is the responsible administrative body. To obtain marketing authorization, real persons or legal entities who are resident in Turkey must file an application to the Ministry, including the documents listed under the Licensing Regulation on Medicinal Products. When granting marketing authorizations, the Ministry considers whether *(Article 16, Licensing Regulation on Medicinal Products)*:

- Efficacy of the envisaged usage conditions have been proved,
- The pharmaceutical's reliability has been proved,
- The quality has been displayed with adequate technical and pharmaceutical properties.

Real person(s) applying for marketing authorization must be graduates from pharmacy, medicine, or chemistry faculties, and be entitled to operate in these disciplines in Turkey. Legal person(s) applying for marketing authorization must employ a person who meets these criteria (Article 7, Licensing Regulation on Medicinal Products).

If a medicinal product will be imported into Turkey or manufactured under license, the following certificates (issued by the license owner of the medicinal product) must be obtained from the local marketing authorities abroad and submitted to TİTCK with Turkish translations (Article 8, Licensing Regulation on Medicinal Products):