Commercialisation of healthcare in Turkey: overview

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A Q&A guide to the commercialisation of healthcare in Turkey.

This Q&A provides an overview of the regulatory framework for the commercialisation of medical products in Turkey. It covers the key requirements for manufacturing, advertising and selling drugs, medical devices, biological products and natural health products.

To compare answers across multiple jurisdictions, visit the commercialisation of healthcare *Country Q&A tool*.

This Q&A is part of the Commercialisation of Healthcare Global Guide. For a full list of jurisdictional Q&As visit *www.practicallaw.com/healthcare-guide*.

Regulatory overview

1. What is the regulatory framework for medical products?

Legislation

The healthcare system is principally governed by the Fundamental Law on Healthcare Services No. 3359, which establishes a healthcare system providing equal and equitable access and gives the Ministry of Health (MoH) authority to issue healthcare-related regulations.

The regulations of the MoH further regulate the pre- and post-market conditions for the commercialisation of medical products. These regulations include the:

- Regulation on Licensing of Medicinal Products for Human Use published in the *Official Gazette* No. 25705 on 19 January 2005, and last amended on 14 November 2013.
- Regulation on Labelling and Packaging of Medicinal Products for Human Use, published in the *Official Gazette* No. 30048 on 25 November 2017.
- Regulation on Safety of Medicinal Products for Human Use, published in the *Official Gazette* No. 28973 on 15 April 2014.
- Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation) published in the *Official Gazette* No. 29405 on 3 July 2015.

Medicinal products are reimbursed by the health insurance provided by the Social Security Institution (SSI) in accordance with the Health Implementation Communiqué of the SSI.

Regulatory authorities

The Medicines and Medical Devices Agency (Agency), is the authority responsible for the regulation of medicinal products, medical devices, cosmetics, traditional herbal medicinal products, and all other products that are marketed with a health claim. The 'Agency's duties include:

- Granting marketing authorisations.
- Monitoring compliance with legal requirements and imposing sanctions where necessary.
- Setting out the standards for the marketing authorisation, pricing, manufacturing, storing, sales, import, export, marketing, distribution, promotion, monitoring, recall and usage-related activities of medicinal products.
- Regulating, approving and controlling clinical trials relating to the products falling under its authority.
- Taking the necessary precautions to maintain the accessibility of pharmaceuticals, medical devices and other products that are of vital importance.

The Social Security Institute (SSI) is the authority responsible for the reimbursement of drugs. The SSI was established by Law No. 5502 published on 16 May 2006.

Private parties

The private parties that play major roles in the Turkish healthcare industry include:

- Pharmaceutical companies.
- Pharmaceutical warehouses.
- Pharmacies.
- Private health institutions.

The distribution of pharmaceuticals on the Turkish market operates through a regulated distribution chain. Pharmaceutical companies supply medicinal products to warehouses, which supply them to pharmacies and hospitals' pharmacies (both public and private), which finally supply them to patients.

To ensure the efficacy of the supply chain, there is an online barcode system that traces medicinal product sales at each stage of the distribution process.

2. What types of medical products are regulated?

All products with a health claim are regulated by the Ministry of Health, including:

- Medicinal products.
- Medical devices.
- Biological products.
- Natural health products.
- Homeopathic medicines.
- Traditional medicines.
- Cosmetics.

However, there are no regulations on homeopathic medicines (*see Question 20*).

Drugs

3. What are the general requirements for a drug to be manufactured, advertised and sold?

Manufacturing
Under the Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation), no medicinal product for human use can be sold and marketed unless it is licensed (authorised) in Turkey. The Licensing Regulation sets out the standards and procedures to ensure that registered products satisfy the safety and quality requirements. As part of the licensing process, companies that manufacture drugs must provide information and documentation on the place and method of manufacturing.

The manufacturer must submit a good manufacturing practice (GMP) document that is provided by either (*Article 8, Licensing Regulation*):

- The MoH.
- An international institution that is approved by the competent authority of the relevant country and acknowledged by the MoH.

However, where the drugs are manufactured in Turkey but the licence applicant is not the manufacturer, the applicant must provide a notarised agreement made with the local manufacturer which satisfies the conditions set out in the Regulation on Manufacturing Sites of Medicinal Products' for Human Use, published in the *Official Gazette* No. 30217 on 21 October 2017 (GMP Regulation).

Under the GMP Regulation, on submission of the information and documents regarding the manufacturing premises, the MoH will make an onsite inspection of the premises to verify the accuracy of the information provided.

The onsite inspection must be made personally by the inspectors of the MoH. The process can take between one and three years for pharmaceuticals manufactured outside Turkey, due to the lack of workforce within the MoH. Therefore, the licensing application process generally ends much later than the 210 days set by the MoH under Article 15 of the Licensing Regulation.

The parallel inspection procedure allows the inspection of GMP and the review of marketing authorisation applications to take place at the same time. The parallel inspection procedure is however restricted to Category 1 (unmet medical need) products.

GMP certificates are granted for three years. Renewal applications must be made before the expiry of this period for a new onsite examination to be determined.

Advertising

The advertising of drugs is governed by the Promotion Regulation. It is strictly forbidden to advertise all types of drugs to the general public. Only licensed (authorised) products can be promoted to healthcare professionals, within the scope of the approved labelled information. There are certain exceptions to these rules under the Promotion Regulation.

Sale

No medicinal product for human use can be sold and marketed unless it is licensed (authorised) in Turkey. Licences (marketing authorisations) are issued by the Medicines and Medical Devices Agency. There are exceptions to the licensing requirements in cases of:

- Compassionate use, which is regulated by the Guidelines on Compassionate Use Programme and defined as the provision, free of charge, of a pharmaceutical to a patient by the manufacturer or supplier company for humane reasons, where the drug has no marketing authorisation in Turkey.
- "Special importation" of pharmaceuticals that have no marketing authorisation in Turkey, or which have a marketing authorisation but are not available in Turkey. These products can be imported from abroad on a named patient basis. The system is regulated by the MoH's Guidelines on the Supply from Abroad of Drugs of 21 April 2017.

The licensed medicinal products are placed on the market with a unique barcode, which allows them to be traced online at each step of the distribution process.

The Regulation on Labelling and Packaging of Medicinal Products for Human Use sets outs the procedures and essential requirements concerning the information that must be included on labels and packages.

The Regulation on Safety of Medicinal Products for Human Use regulates the activities that can be conducted for monitoring, researching, recording, archiving and assessing the safety of medicinal products for human use that have been granted marketing authorisation, as well as natural or legal persons that can conduct such activities.

The principles relating to the inspections and examinations conducted by the MoH, and the recall procedures for products found to pose a threat to human health, are also regulated under various separate regulations.

4. Are there different requirements for patented and generic drugs?

Patented drugs generally go through the regular licence application process as new medicinal products (*Article 8, Licensing Regulation*). Applications for generic drugs can be processed under the abridged application procedure (*Article 9, Licensing Regulation*).

The abridged application does not require the submission of documents related to safety and efficiency.

Under the abridged application procedure, the applicant is not required to present the results of toxicological and pharmacological tests and clinical trials in any of the following circumstances:

- The medicinal product is essentially similar to a medicinal product that has been previously registered in Turkey and the marketing registration holder of the original medicinal product has consented to the use of the toxicological, pharmacological and clinical references contained in the dossier of the original medicinal product for the purpose of assessing the generic application.
- Any constituent of the medicinal product has a well-established medical use determined in detailed scientific bibliography, a reasonable efficiency and an acceptable level of safety.
- The regulatory period of data exclusivity for the original medicinal product has expired.

In addition, there are different rules on pricing and reimbursement of generic drugs.

5. What authority is responsible for regulating the manufacture, advertising and sale of drugs?

The Agency of the Ministry of Health is the national body responsible for regulating the licensing, sale and advertising of drugs.

6. Are there fewer or different requirements for drugs that have already been licensed or approved in another jurisdiction?

There are no specific provisions for drugs that have already been licensed/approved in another jurisdiction. Usually, drugs without a marketing authorisation in the EU and the US go through a relatively long registration process compared to drugs with such authorisations. However, there is no reciprocity principle concerning the authorisation of drugs. In addition, there is no principle of reciprocity regarding good manufacturing practice onsite inspections (*see Question 3, Manufacturing*).

7.Is it possible to sell drugs to or buy drugs from other jurisdictions?

The sale of drugs to other jurisdictions is not regulated by law. It is therefore possible to sell drugs to other jurisdictions.

No pharmaceutical product for human use can be sold in Turkey unless it is either (*Article 5, Licensing Regulation*):

- Licensed/authorised by the MoH in accordance with the provisions of the Licensing Regulation.
- Exempt from licensing requirement.

Medicinal products from other jurisdictions cannot freely enter the Turkish market, as only the licence (marketing authorisation) holder can clear medicinal products from customs.

If a medicinal product is not available in the Turkish market and the patient's need is justified, drugs can be imported from other jurisdictions by the Turkish Pharmacists' Association and the social security institution, subject to the approval of the Medicines and Medical Devices Agency (*MoH's Guidelines on the Supply from Abroad of Drugs of 21 April 2017*).

8. Is it permitted to advertise drugs to consumers? Are there restrictions on advertising?

It is strictly prohibited to advertise any type of drugs to the general public. Licensed (authorised) products can be promoted to healthcare professionals within the scope of the approved labelled information. There are certain exceptions to these rules under the Regulation on Promotional Activities of Human Medicinal Products.

Medical devices

9. What is the definition of medical device in your jurisdiction?

Under the Medical Device Regulation (*see Question 10, Manufacturing*), a medical device is defined as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used on human beings for any of the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of diseases.
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Birth control.

Additionally, a medical device must not achieve its principal intended action in or on the human body through pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

The definition of medical device is identical to that under Directive 93/42/EEC concerning medical devices. Therefore, the difference between pharmaceuticals and medical devices is interpreted in line with the EU definition. Medicinal products are effective when absorbed into the human body, whereas most medical devices act through physical interaction with the body or a body part, or may sometimes not require any physical contact with the human body.

10. What are the general requirements for a medical device to be manufactured, advertised and sold?

Manufacturing

The manufacturing of medical devices is governed by the:

- Medical Device Regulation (MD Regulation), published in the *Official Gazette* No. 27957, adopted by the MoH on 13 March 2002 and last amended on 7 June 2011. The MD Regulation is in line with Directive 93/42/EEC concerning medical devices, as amended by Directive 2007/47/EEC.
- Regulation on Active Implantable Medical Devices, adopted by the MoH on 9 January 2007 and amended on 7 June 2011, and which is in line with Directive 90/385/EEC on active implantable medical devices, as amended by Directive 2007/47/EEC.
- Regulation on In Vitro Diagnostic Medical Devices, adopted by the MoH on 9 January 2007, and which is in line with Directive 98/79/EC on in vitro diagnostic medical devices.

The Law on Adoption and Implementation of Technical Legislation for Products No. 4703 (Technical Law) and the Law on Fundamental Healthcare Services No. 3359 are the legal base of these regulations.

Medical devices must meet the essential requirements set out under the above regulations or bear a CE mark to be placed on the market.

The following devices are exempt from the CE mark rule (*Article 6(2), MD Regulation*):

- Devices intended for clinical investigation which are made available to medical practitioners or authorised persons for that purpose.
- Custom-made devices and class IIa, IIb and III devices that must be available to a particular patient identified by name, acronym or numerical code, accompanied by the statement referred to in Annex VIII to the MD Regulation.

Medical devices that do not comply with the MD Regulation or bear a CE mark can be displayed in commercial expositions and exhibitions, provided that they bear an explicit indication that they will not be put on the market until they comply with the MD Regulation (*Article 6(3), MD Regulation*).

Medical devices that meet the essential requirements or bear the CE mark must be registered on the MoH's online database (*Article 14, MD Regulation*). The registration must be made by the entity placing the device on the market or through an authorised representative. The online registration is made through the Product Tracking System (ÜTS), which replaced the Turkish National Databank for Pharmaceuticals and Medical Devices (TITUBB) of the MoH. No medical device can be marketed in Turkey without being registered on the Product Tracking System. Unlike under the licensing process for drugs, registration is made on submission, without verification of the authenticity or correctness of the submitted documents. The registrant must provide an undertaking for bearing all criminal and civil liabilities arising from any inaccurate or incomplete submission.

Advertising

The advertising of medical devices to the public and healthcare professionals is regulated by the Regulation on Sales, Advertising and Promotion of Medical Devices, published on 15 May 2014 and amended on 25 July 2015 and 22 September 2016. The devices that must be exclusively used or applied by healthcare professionals or that are reimbursed by the Social Security Institution cannot be advertised to the general public. Registered products can be promoted to healthcare professionals within the scope of the registered labelled information. The rules on interactions with healthcare professionals are similar to those that apply to the pharmaceutical industry.

Sale

Companies that sell and distribute medical devices must obtain a sales centre certificate to conduct their commercial activities (*Regulation on Sales, Advertising and Promotion of Medical Devices*). Each branch of the company must follow the same application and certification procedure.

To be certified, each sales point must have one authorised person, at least one sales and promotion staff and clinical support staff. Such personnel must successfully complete the MoH training programmes, pass the final examination and obtain a "competence document" from the MoH.

Companies must fulfil the requirements above and obtain the applicable certifications to be able to carry out their commercial activity.

Therefore, medical devices will only be sold in sales points certified by the MoH, except for consumable products listed under Annex 3 to the Regulation on Sales, Advertising and Promotion of Medical Devices (for example, toothpaste, condoms, incontinence pads and so on). These products can be sold freely in supermarkets and similar sales venues.

11. What authority is responsible for regulating the manufacture, advertising and sale of medical devices?

The Agency is responsible for regulating the manufacture, advertising and sale of medical devices.

The SSI is responsible for the reimbursement of medical devices.

12. Are there fewer or different requirements for medical devices that have already been licensed/ approved in another jurisdiction?

There is no typical authorisation process for medical devices. Products that have conformity documents and a CE mark can be sold on the Turkish market. In addition, in accordance with the Customs Union Agreement between Turkey and the EU, medical devices imported from the EU with the required conformity documents and CE certificates can go through customs clearance easily, without any need for physical inspection. However, all medical devices must be registered in the ÜTS, which replaced the TITUBB, before being placed on the market.

13. Is it possible to sell devices to or buy devices from other jurisdictions?

It is possible to sell medical devices to, or buy devices from, other jurisdictions, as there is no specific provision on the issue. However, to be placed on the Turkish market, all devices must both:

- Have the CE mark.
- Be registered with the ÜTS, which replaced the TITUBB.

14. Is it permitted to advertise medical devices to consumers? Are there restrictions on advertising?

Under the Regulation on Sales, Advertising and Promotion of Medical Devices, devices that are reimbursed by the Social Security Institution or that must be exclusively used or applied by healthcare professionals cannot be advertised to the general public. Advertisements of other devices must comply with the general rules set out in consumer protection and advertising legislation. Accordingly, advertisements must not be misleading, and all claims must be true and provable.

Additionally, under Article 11/2 of the Law on Establishment and Broadcasting of Radio and Television Institutions No. 6112, no advertisements for prescription medical products or treatments can be broadcasted. Although this provision does not expressly refer to medical devices, it is accepted that advertisements for prescription medical devices cannot be broadcasted on TV and radio.

Biological products

15. What are the general requirements for a biological product to be manufactured, advertised and sold?

Manufacturing
The same requirements apply as for drugs (*see Question 3, Manufacturing*).

Advertising
The same requirements apply as for drugs (*see Question 3, Advertising*).

Sale

The same requirements apply as for drugs (*see Question 3, Sale*).

16. What authority is responsible for regulating the manufacture, advertising and sale of biological products?

See *Question 5*.

17. Are there fewer or different requirements for biological products that have already been licensed/ approved in another jurisdiction?

See *Question 6*.

18. Is it possible to sell biological products to or buy biological devices from other jurisdictions?

See *Question 7*.

19. Is it permitted to advertise biological products to consumers? Are there restrictions on advertising?

See *Question 8*.

Natural health products

20. Is there a category for natural health products (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

Natural health products are governed by the Regulation on the Importation, Production, Processing and Supply of Food Supplements (Food Supplement Regulation), which was published by the Ministry of Food, Agriculture and Livestock in the *Official Gazette* No. 28635 on 2 May 2013, came into force on 2 August 2013 and was amended on 21 November 2015 and 28 March 2017.

Food supplements are defined as products prepared in the form of capsules, tablets, powder packets for single use, liquid ampoules, dropping bottles or other liquid and powder forms of nutritional elements such as (*Article 4/h, Food Supplement Regulation*):

- Vitamins.
- Minerals.
- Proteins.
- Carbohydrates.
- Fibres.
- Fatty acids and amino acids.
- Plants with nutritious and physiological effects.
- Substances of herbal or animal origin with determined daily doses.

Dietary supplements, vitamins, minerals or similar products that fall within the scope of the definition above are considered to be food supplements.

Additionally, traditional herbal medicinal products are covered by the Regulation on Traditional Herbal Medicinal Products, which was published in the *Official Gazette* No. 27721 on 6 October 2010. The Agency is responsible for regulating the licensing and market surveillance principles of these products.

There is no regulation on homeopathic medicines yet. However, the Regulation on Traditional and Complementary Medical Applications, published in the *Official Gazette* No. 29158 on 27 October 2014, provides in its Annex that the Agency will be responsible for regulating the licensing and sales of medicines to be used in homeopathic treatments.

As most natural health products fall within the definition of food supplements, *Question 20 to 24* will cover the regulation of food supplements.

21. What are the general requirements for natural health products to be manufactured, advertised and sold?

Manufacturing

The requirements for manufacturing or importing food supplements are set out in Article 12 of the Food Supplement Regulation. An application must be made to the competent provincial directorate with specific information and documentation regarding the product's content and manufacturing, as well as its commercial name and qualities. The provincial directorates examine the application and issue an official letter allowing the manufacture of the product.

Advertising

Although the Food Supplement Regulation was expected to cover the advertising of food supplements, it does not really satisfy this need and the issue is therefore governed by general rules (*see Question 25*).

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 in place the necessary measures to eliminate the ongoing advertising/promotion on third-party domain names/URLs, or those under its control.

Sale

Food supplements must be sold from the importer's, producer's and processor's premises, the wholesale storage premises, and using the domain name and URL address(es) that are indicated by the food operator in its application for approval.

22. What authority is responsible for regulating the manufacture, advertising and sale of natural health products?

The Ministry of Food, Agriculture and Livestock (MoA) regulates the manufacture, advertising and sale of natural health products. The advertising of natural health products is also monitored by the Advertisement Board, the Turkish Radio and Television Supreme Council and the MoH. The Agency is responsible for regulating the licensing and market surveillance principles of traditional herbal medicinal products.

23.Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

The requirements for natural health products are the same regardless of any foreign licence/approval. To be introduced on the Turkish market, a food supplement must comply with the general requirements outlined in *Question 21*.

24. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

A food operator can sell food supplements electronically, provided that the transaction is made through the domain name or URL address(es) declared by the food operator in its application file.

The Regulation on the Importation, Production, Processing and Supply of Food Supplements does not cover the export of natural health products or their sale abroad, and the rules of the buyer's country apply to such transactions. However, it is possible to export food supplements from Turkey.

Natural health products can be bought from abroad for personal use. Such transactions are not subject to any particular customs regulation.

25. Is it permitted to advertise natural health products to consumers? Are there restrictions on advertising?

There is no specific regulation governing the advertising of food supplements in Turkey. The only relevant regulation is the Turkish Food Codex Regulation on Food Labelling and Consumer Information (published in the *Repetitive Official Gazette* No. 29960 (*Bis*) on 26 January 2017), which provides that advertisements of food products must not contain any claims other than those stated on their label, and must therefore not contain any misleading information.

In addition, the Law on Pharmaceutical and Medical Preparations No. 1262 provides that the marketing or advertisements of any product cannot contain claims that the product diagnoses and treats diseases. These provisions apply to both foods and food supplements.

The advertising of food supplements is governed by general rules under the:

- Consumer Protection Law.
- Advertising regulations.
- Turkish Commercial Code, with regards to unfair competition.

Under the Consumer Protection Law, advertisements must comply with the applicable laws, the general principles determined by the Advertisement Board of the Ministry of Customs and Trade, general ethics, public order, individual rights and good faith principles. Advertisements must not be misleading, and all claims must be true and provable.

In addition, under Article 8/3 of the Regulation on Commercial Advertisements and Unfair Commercial Practices (which took effect on 10 January 2015 and was amended on 4 January 2017), comparative advertising for food supplements is prohibited.

The Turkish Radio and Television Supreme Council (*Radyo ve Televizyon Üst Kurulu*) (RTUK) can also monitor advertisements for food supplements that are broadcasted on television or radio on the basis of the RTUK Law and the Regulation on Procedures and Principles of Broadcasting Services (RTUK Law). The main principle is that advertisements must not be misleading. Therefore, food supplements, herbal products, various devices and any other products advertised with health claims must not create the impression that the product is a pharmaceutical product.

Advertisements for food supplements cannot include any testimonials, acknowledgements or approvals (*Article 9/A/1/d, RTUK Law*). Additionally, advertisements cannot state that a person's health may be negatively affected if food supplements are not used.

The MoH has authority to:

- Investigate any advertisement and promotion containing a health claim (that is, a claim regarding the diagnosis or treatment of a disease).
- Take administrative action where health claims are found to be untrue or are not sufficiently proven (for example, through the cancellation of advertising activities).

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 (*see above*). If an advertisement does not comply with these rules, the MoH can 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 among persons using certain types of food supplements in recent years (especially those used for weight loss or weight control purposes), the MoH, RTUK and the Advertisement Board have decided to collaborate with the Ministry of Food, Agriculture and Livestock 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 RTUK have imposed heavy sanctions against advertisers and media channels regarding misleading food supplement advertisements.

Reform

26. Are there any plans to reform the rules on the development, manufacture, advertising and sale of medical products?

Drugs

The Agency is expected to make amendments to some of the substantial regulations regarding the authorisation of medicinal products. The Agency requested the industry associations to submit their opinion and amendment requests with respect to the:

- Regulation on Licensing of Medicinal Products for Human Use.
- Regulation on Bioavailability and Bioequivalence Evaluation of Pharmaceutical Preparations.
- Regulation on Promotional Activities of Human Medicinal Products.

In the course of 2019-2020, there may be some amendments to the rules on pharmaceuticals market access and promotion.

It may also be worth following up on the industry's initiatives to facilitate and speed up the licence application process and minimise delays caused by good manufacturing practice inspections of the MoH (*see Question 3, Manufacturing*).

Medical devices

On 9 May 2019, the Agency published draft amendments to the law titled Regulation on Sales, Advertisement and Promotion of Medical Devices due to needs and problems arising from the implementation of the current law. The draft updated regulation preserves many provisions of the current regulation. However, there are a few amendments to the existing provisions and also new articles are introduced.

One of the significant changes is that, the draft regulation proposes to regulate the prohibition of the direct or distance sale of some devices to consumers. Therefore, the following devices that are sold to or applied for on behalf of the patient cannot be placed on the market for sale to consumers:

- Hearing aid centres.
- Custom-made prosthetics and orthotics centres.
- Optician facilities.
- Medical devices intended to be used exclusively by healthcare professionals.

The above medical devices also cannot be advertised directly or indirectly to the public.

In relation to the notifications made regarding the sponsorship of healthcare professionals, only certified personnel can make the required notifications. These personnel must receive their certification from a local health authority.

The draft regulation has been open to public consultation and is expected to be published in 2019 or early 2020.

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Recent transactions

- Advised six pharmaceutical companies on risk-sharing schemes and alternative reimbursement agreements with the Social Security Institute (SSI).
- Advised and represented a multinational pharmaceutical company in an action against the SSI for the reversal of a reimbursement delisting decision based on non-localisation of the manufacture of the imported product.
- Advising the Association of Research-Based Pharmaceutical Companies and the Association of Research-Based Medical Technologies Manufacturers in Turkey on a number of regulatory policy papers, and drafting laws and regulations proposed to the Turkish governmental authorities.
- Advised a UK based pharmaceutical company on toll manufacturing agreements with two local companies within the scope of the Turkish Government's localisation policy.

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Areas of practice. Life sciences; intellectual property; trade marks and designs.

Recent transactions

- Advising corporate clients from the life sciences sector, especially multinational pharmaceutical and medical device companies, on a wide range of issues including promotional activities, advertisement, labelling requirements, clinical trials, marketing authorisation procedures, pricing and reimbursement regulations, and assisting them in their day-to-day business activities.
- Advising the Association of Research-Based Pharmaceutical Companies (AIFD) and the Association of Research-Based Medical Technologies Manufacturers (ARTED) in Turkey.
- Consulting clients on many regulatory policy papers and drafting laws and regulations proposed to the Turkish governmental authorities.
- Conducting trade mark infringement and unfair competition actions, and trade mark invalidation and revocation actions.

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