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.

This Q&A is part of the Commercialisation of Healthcare Global Guide.

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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, including the:

- Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation) 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 (Labelling Regulation), published in the *Official Gazette* No. 25904 on 12 August 2005, and amended in 2009 and 2010.

- Regulation on Safety Monitoring of Medicinal Products for Human Use (Monitoring Regulation), published in the *Official Gazette* No. 25763 on 22 March 2005.
- Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation) published in the *Official Gazette* No. 28037 on 26 August 2011 and last amended on 31 December 2014.

Drugs 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 Drug and Medical Device Institution, established by the Decree Law on Foundation and Duties of the Ministry of Health and Affiliated Institutions No. 663 published on 2 November 2011, is the authority responsible for the regulation of pharmaceuticals, medical devices, cosmetics, traditional herbal medicinal products, and all other products that are marketed with a health claim. The institution's duties include:

- Granting licences and authorisations.
- Monitoring compliance with legal requirements and imposing sanctions where necessary.
- Setting out the standards for the licensing, pricing, manufacturing, storing, sales, import, export, marketing, distribution, promotion, monitoring, recall and usage-related activities of medical 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 SSI is the authority responsible for the reimbursement of drugs. The SSI was established by Law No. 5502 published on 16 May 2006.

For more information on the Drug and Medical Device Institution see box: *The regulatory authorities*.

Private parties

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

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

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

To ensure the efficacy of the supply chain, there is a barcode system that traces drugs sales online 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 (MoH), including:

- Drugs.
- Medical devices.
- Biological products.
- Natural health products.
- Homeopathic medicines.

- Traditional medicines.
- Cosmetics.

However, there are no regulations on homeopathic medicines (*see Question 19*).

Drugs

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

Manufacturing

Under the Licensing Regulation, no medicinal product for human use can be sold and marketed unless it is licensed 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.

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

- The Ministry of Health (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 Drug Manufacturers, published in the *Official Gazette* No. 28630 on 27 April 2013 (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 of 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.

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. However, as the MoH already has difficulties in carrying out initial onsite inspections for new applications, the validity date of current GMP certificates has been prolonged by a Communiqué published on May 2015.

The manner in which the MoH handles the manufacturing process is strongly criticised for resulting in long delays in the licence application procedures and patients' access to drugs.

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 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 in Turkey. Licences (marketing authorisations) are issued by the Drug and Medical Device Institution. 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. Such products can be imported from abroad on a named patient basis. The system is regulated by the MoH's Guidelines on Importation and Use of Drugs from Abroad.

The drugs are placed on the market with a unique barcode, which allows them to be traced online at each step of the distribution process (that is, from pharmaceutical companies to warehouses and then to hospitals and pharmacies).

The Labelling Regulation sets outs the procedures and essential requirements concerning the information that must be included on labels and packages.

The Monitoring Regulation 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 the three 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/or 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 Drug and Medical Device Institution of the Ministry of Health (MoH) is the national body responsible for regulating the licensing, sale and advertising of drugs.

For more information on the Drug and Medical Device Institution see box: *The regulatory authorities*.

6. Are there fewer or different requirements for drugs that have already been licensed/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 (GMP) 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 Ministry of Health (MoH) in accordance with the provisions of the Licensing Regulations.
- Exempt from licensing requirement.

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

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 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.

Medical devices

9. 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), adopted by the Ministry of Health (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 (Medical Devices Directive), 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 (Active Implantable Medical Devices Directive), 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 (IVD Directive).

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 also relevant.

Accordingly, medical devices must meet the essential requirements set out under the above regulations and/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 of 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 and/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 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 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. The devices that are for use by healthcare professionals or reimbursed 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 by 15 November 2015 to be able to carry on 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 of the regulation (for example, toothpaste, condoms, incontinence pads and so on). Such products will be free to be sold in supermarkets and/or similar sales venues.

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

The Drug and Medical Device Institution is responsible for regulating the manufacture, advertising and sale of medical devices.

The Social Security Institution (SSI) is responsible for the reimbursement of medical devices.

For more information on the Drug and Medical Device Institution see box: *The regulatory authorities*.

11. 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 with the Turkish National Databank for Pharmaceuticals and Medical Devices (TITUBB) before being placed on the market.

12. 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 Turkish National Databank for Pharmaceuticals and Medical Devices (TITUBB).

13. 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 or intended for use by healthcare professionals cannot be advertised to the general public. The 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 the Law on Establishment and Broadcasting of Radio and Television Institutions No. 6112 (RTUK Law), 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

14. 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*).

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

See *Question 5*.

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

See *Question 6*.

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

See *Question 7*.

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

See *Question 8*.

Natural health products

19. 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 (MoA) in the *Official Gazette* on 2 May 2013 and came into force on 2 August 2013.

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 which daily doses are determined.

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* on 6 October 2010.

There is no regulation on homeopathic medicines yet. However, the Regulation on Traditional and Complementary Medical Applications, published in the *Official Gazette* of 27 October 2014 provides in its Annex that the Drug and Medical Device Institution 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, *Questions 20* to *24* will cover the regulation of food supplements.

20. 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 provincial directorate with specific information and documentation regarding the product's content and manufacturing, as well as its commercial name and qualities. The Food Supplement Commission examines the application and issues an official letter allowing the manufacture of the product.

The Food Supplement Commission must determine whether a product is a food supplement or not, conduct a risk analysis and share the outcomes with the Ministry of Food, Agriculture and Livestock (MoA) (*Article 6/1(b), Food Supplement Regulation*).

The Food Supplement Regulation distinguishes two groups of food supplements and provides for a specific approval mechanism for each group:

- The first group includes food supplements that are stated as positive in the plant list of MoA, or which consist of a single component which limit is determined in related legislation. These supplements must be approved by the provincial directorate (*Article 6/1(a), Food Supplement Regulation*).
- The second group includes food supplements that consist of the components whose use is allowed under relevant legislation, and are subject to the approval of the Food Supplement Commission (*Article 6/1(b), Food Supplement Regulation*).

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 24*).

However, when a food operator submits its application to obtain approval for the food supplement, the advertisements or promotions submitted alongside will also be examined (*Article 9/3, Food Supplement Regulation*). For the application to be accepted, the advertisement or promotion must comply with the law. If not, the food operator must take such actions as are necessary to remove the advertisement or promotion. In cases of illegal advertisements or promotions regarding food supplements, the food operator faces administrative sanctions under the relevant legislation (*Article 9/4, Food Supplement Regulation*).

Sale

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

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

The Drug and Medical Device Institution of the 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 (RTUK) and the Ministry of Health (MoH).

For more information on the MoH see box: *The regulatory authorities*.

22. Are there fewer or different requirements for natural health products that have already been licensed/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 20*.

23. 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 and/or URL address(es) declared by the food operator in its application file.

The Food Supplements Regulation 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 provided that they are for personal use. Such transactions are not subject to any particular customs regulation.

24. 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 Labelling, which provides that the advertising of food products must not contain any claims other than those stated on its label, and must therefore not contain any misleading information. In addition, food advertisements must not contain any claim that food products are pharmaceuticals or can be used for avoiding, diagnosing and treating an illness. 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 in January 2015), comparative advertising for food supplements is prohibited.

The Turkish Radio and Television Supreme Council (RTUK) can also monitor advertisements for food supplements that are broadcasted on television or radio on the basis of Article 11/3 of the RTUK Law. Article 11/3 provides that advertisements for pharmaceuticals and medical treatments that are not subject to prescription must be prepared in accordance with the principle of integrity, and in such manner that they reflect the truth and can be verified.

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.

Under Decree Law No 663, the Ministry of Health (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 (for example, cancellation of advertising activities) where health claims are found to be untrue or are not sufficiently proven.

Under the new Regulation on Health Claims published 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 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 RTUK have imposed heavy sanctions against advertisers and media channels regarding misleading food supplement advertisements.

Reform

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

Drugs

The Ministry of Health (MoH) has been working on revisions to the Regulation on Promotional Activities of Human Medicinal Products. The most striking amendment is the introduction of transparency provisions in the rules governing interactions with healthcare professionals and organisations. The draft regulation requires pharmaceutical companies to:

- Record transfers of value made to healthcare professionals and organisations.
- Register such transfers with the MoH in the following year.

While the innovator industry has already adopted and implemented the European Federation of Pharmaceutical Industries and Associations's (EFPIA's) transparency and disclosure scheme through self regulation, the proposed provisions are likely to increase the overall level of transparency in the sector by covering the whole pharmaceutical industry.

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 (GMP) inspections of the MoH (*see Question 3, Manufacturing*).

Medical devices

It will be interesting to see how the implementation of the Regulation on Sales, Advertising and Promotion of Medical Devices of 15 May 2014 will be handled and how the current medical devices companies will adapt to the new regulated distribution chain as of 15 November 2015.

Recent amendments to consumer protection and advertising legislation allow the use of comparative advertising (using the competitor's name and product) for devices that can be advertised to public (that is, devices that are not for use by healthcare professionals and those that are reimbursed). It will be interesting to see how the MoH and Advertisement Board handle this new type of advertising.

The regulatory authorities

Ministry of Health

W www.saglik.gov.tr

Principal responsibilities. The MoH has authority to issue healthcare-related legislation.

Drug and Medical Device Institution

W www.titck.gov.tr

Principal responsibilities. The Drug and Medical Device Institution is the authority responsible for the regulation of pharmaceuticals, medical devices, cosmetics, traditional herbal medicinal products, and all other products that are marketed with a health claim.

Online resources

Drug and Medical Device Institution

W www.titck.gov.tr

Description. Official website of the Drug and Medical Device Institution of the MoH. The website is both in Turkish and English, with limited English content. The website provides access to all the legislation and applicable provisions relating to healthcare-related products (that is, drugs, medical devices, biological products, homeopathic medicines, traditional medicines and cosmetics). The website is up-to-date.

Ministry of Food, Agriculture and Livestock

W www.tarim.gov.tr

Description. Official website of The Ministry of Food, Agriculture and Livestock. The website is both in Turkish and English. This website provides access to legislation on natural health products (food supplements) in both English and Turkish. The website is up-to-date.

Turkish Radio and Television Supreme Council (RTUK)

W www.rtuk.org.tr

Description. Official website of the RTUK. This website is in both Turkish and English, with significant English content. The website provides access to legislation on TV and radio broadcasting, including provisions on advertisement of prescribed medicines and treatments (in both English and Turkish). The web site is up-to-date.

Ministry of Customs and Trade, DG for Consumer Protection and Market Surveillance

W www.tuketici.gov.tr

Description. Official website of the Ministry of Customs and Trade, DG for Consumer Protection and Market Surveillance. This website is in both Turkish and English, with significant English content. The website provides access to legislation on advertising and consumer protection (in both English and Turkish). It also contains the decisions of the Advertising Board on the reviewed advertisements. The website is up-to-date.

Contributor profiles

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Recent transactions

- Conducting patent infringement actions against generic pharmaceutical companies and initiating the first pharmaceutical data protection and exclusivity action in Turkey.
- Advising multinational life sciences companies on a wide range of matters, including registration procedures, promotion practices, pricing and reimbursement regulations, distribution relationships and co-marketing deals, as well as issues of merger control, vertical restraints and abusive conduct.
- Advising the Association of Research-Based Pharmaceutical Companies and the Association of Research-Based Medical Technologies Manufacturers in Turkey.
- Advising on many IP and regulatory policy papers, and drafting laws and regulations proposed to the Turkish governmental authorities.

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Areas of practice. Life sciences; intellectual property; white collar crimes; competition law.

Recent transactions

- Advising originator pharmaceutical and medical device companies on overall compliance and anti-corruption matters with a focus on interactions with healthcare professionals, relations with third party providers, distribution channels, tender, reimbursement and pricing procedures, advertising/promotion issues and product liability
- Assisting multinationals in adapting local preventive procedures, training their teams and in audits and internal investigations.
- Representing trade associations at both national and EU level, and taking part in policy issues in the sector.

Resource information

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Overview of IP issues in health and life sciences (http://global.practicallaw.comtopic7-538-6729)

Standard Document

Pharmaceutical patent and know-how licence agreement (http://global.practicallaw.comtopic6-544-3805)

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