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Commercialisation of Healthcare 2021 in Turkey

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, marketing and advertising medicines, medical devices, biological products and natural health products.

Medicines

1.What is the definition of medicine (or equivalent) in your jurisdiction?

Under the Law on Pharmaceuticals and Medical Preparations No. 1262 (Pharmaceuticals Law), a pharmaceutical and medical preparation is defined as any simple or formulated curative preparation commercialised under the manufacturer's name or under a private name in a fixed form compliant with scientific rules (except in a form or formulation described in the codex).

Under the Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation) based on the Pharmaceuticals Law, a medicinal product for human use is defined as any natural and/or synthetic origin active substance or combination of substances administered to human beings with a view to treating and/or preventing a disease, making a diagnosis, or correcting or modifying a physiological function.

2.What authorities are responsible for regulating the manufacture, marketing and advertising of medicines?

The Medicines and Medical Devices 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 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 medicines. The SSI was established by Law No. 5502 published on 16 May 2006.

3. What notifications, registrations, approvals and licences are required to manufacture and market medicines and their active pharmaceutical ingredients?

Manufacturing

Under the 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 medicines must provide information and documentation on the place and method of manufacture.

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.

(Article 8, Licensing Regulation.)

However, where the medicines 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, once the information and documents on the manufacturing premises are submitted, the MoH will make an onsite inspection of the premises to verify the accuracy of the information provided. The inspectors of the MoH must carry out the onsite inspection personally. 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 carried out.

Marketing

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 medicine has no marketing authoriation 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, updated on 25 September 2020.

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 about 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 these 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. What are the differences between the regulation of new innovative medicines and generic or biosimilar versions of those medicines?

New innovative medicines generally go through the regular licence application process as new medicinal products (Article 8, Licensing Regulation). Applications for generic medicines 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 authorisation 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 medicines.

5. What are the differences between the regulation of prescription and over-the-counter medicines?

The Regulation on the Classification of Medical Products for Human Use distinguishes between prescription and non-prescription pharmaceuticals. Although the Regulation defines in detail what prescription pharmaceuticals are, it only defines non-prescription pharmaceuticals as anything not available on prescription. Due to the lack of regulation on over-the-counter (OTC) pharmaceuticals, the number of non-prescription pharmaceuticals in Turkey are considerably limited and all different types of pharmaceutical products must be sold in pharmacies.

6. Are there fewer or different requirements for the approval of medicines that have already been licensed or approved in another jurisdiction?

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

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

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

No pharmaceutical product for human use can be sold in Turkey unless it is either:

- Licensed (authorised) by the MoH in accordance with the Licensing Regulation.
- Exempt from the licensing requirement.

(Article 5, Licensing Regulation.)

Medicinal products from other jurisdictions cannot freely enter the Turkish market, as only the licence (marketing authorisation) holder can clear medicinal products from customs. Therefore, parallel trade is not possible for medicines.

If a medicinal product is not available in the Turkish market and a patient's needs justify its use, it can be imported from other jurisdictions by the Turkish Pharmacists' Association and the Social Security Institution, subject to approval by the Medicines and Medical Devices Agency (MoH's Guidelines on the Supply from Abroad of Drugs, updated on 25 September 2020).

8. How is medicine promotion and advertising activity regulated, and what are the general requirements to advertise medicines?

Article 13 of the Pharmaceuticals Law and the Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation) prohibits the advertising of medicinal products for human use to the public in Turkey. However, the Promotion Regulation introduces an exception to this rule. Information can be provided to the general public on products that are used in vaccination campaigns, organised actions to combat epidemics or other campaigns run by the MoH to promote health (as they are important to safeguard the public) with permission from the MoH and within the confines of principles and procedures set out by the MoH for the products.

Licensed (authorised) products can be promoted to healthcare professionals within the scope of the approved labelled information. The fundamental rule is that marketing authorisation holders and their representatives cannot provide,

offer or promise benefits to healthcare professionals through promotional activities. Under the Promotion Regulation, products that are not granted permits or authorisation in Turkey cannot be promoted (off-label promotion is strictly forbidden), and advertisements directed at healthcare professionals must contain information consistent with the approved products, and an updated summary of product characteristics.

"Promotion" includes objective, informative and factual medical data to enable healthcare professionals to form their own opinion about the product. The promotional activities must:

- Not be used to encourage unnecessary use of a product.
- Delivered by certified representatives.

All promotion representatives receive certificates when they successfully complete training organised by the MoH or on submission of diplomas from the departments of universities educating medical sales representatives. The examinations required for certification are conducted according to guidelines published by the MoH and based on the Promotion Regulation. Individuals without the certification cannot work as promotion representatives for pharmaceutical companies.

9. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

There are no regulations on special types of medicines or medicines intended for particular types of patients or diseases.

10. What controls apply to medicines or components of medicines that derive from humans or animals or incorporate modified genetic material?

As part of the licensing procedure of blood products, control tests are conducted to:

- Determine whether there is viral contamination in blood products.
- Prove that the product is reliable.
- Identify the source of the plasma used in the preparation of the products.

Where radiopharmaceuticals/kits contain animal-derived substances in their formulations, a public authority letter is required confirming the absence of the BSE virus. Where they contain blood and plasma products, viral contamination, AIDS, hepatitis and similar tests are required (Article 17, Licensing Regulation).

After obtaining a licence for a blood product or human medicinal product containing a blood product, the licensee must apply to the MoH to obtain a sales permit for each category of the product before placing it on the market. Analysis of the products in the category is conducted after testing in a national laboratory or a laboratory designated by the MoH for this purpose (Article 26, Licensing Regulation).

In addition, where the licensed product is an immunological product, the licensee must apply to the MoH to obtain a sales permit for each category of the product before placing it on the market.

Before placing medicines that derive from animals on the market, marketing authorisation holders must apply to the provincial directorate of agriculture and forest with the required information and documents and samplings that will be used in the controls for the sales permit. This applies to each category of veterinary biological product produced in Turkey and for each import of each category of product produced abroad (Article 18, Regulation on Veterinary Medicinal Products).

Biological medicines

11. What is the definition of biological medicines in your jurisdiction and what are the main laws that specifically apply to them (if any)?

Biological medicines are mainly regulated by the Law on Fundamental Healthcare Services No. 3359 and the Licensing Regulation. A biological medicine is defined as "a product whose active ingredient is a biological substance, that is, a substance manufactured or extracted from a biological source that requires a combination of physicochemical, biological tests combined with the manufacturing process and control to determine its nature and quality" (section 1, Annex to the Licensing Regulation). Unlike other medicines, the active ingredient of biological medicines are biological substances, such as vaccines and products derived from plasma.

12. Are there any additional or alternative regulations that apply specifically to biological medicines?

There are no regulations that apply specifically to biological medicines. The answers to Question 2 to 10 generally apply to the commercialisation of biological medicines.

Medical devices

13. What is the definition of medical device (or equivalent) in your jurisdiction? What is the significance of any legal classifications?

Under the Medical Device Regulation published in the Official Gazette No. 27957, adopted by the MoH on 13 March 2002 and last amended on 7 June 2011 (MD Regulation), 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 of 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 can be assisted in its function by such means.

The definition of medical device is identical to that under the Medical Devices Directive (93/42/EEC). Therefore, the difference between pharmaceuticals and medical devices is interpreted in line with the EU definitions. 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.

In the event of doubt as to the classification of a product, information on the nature of the product can be requested from the Medicines and Medical Devices Agency. There is no specific rule on how the question can be asked. A product will generally be considered a medical device if it is marketed as a medical device in the EU.

In recent years, software and mobile application medical devices have been increasing and the Medicines and Medical Devices Agency accepts software and mobile applications as medical devices, taking into consideration their intended use.

14. What authorities are responsible for regulating the manufacture, marketing and advertising of medical devices?

The Medicines and Medical Devices Agency is responsible for regulating the manufacture, marketing and advertising of medical devices.

The SSI is responsible for the reimbursement of medical devices.

15. What notifications, registrations, approvals and licences are required to manufacture and market medicinal devices?

Manufacturing

The manufacturing of medical devices is governed by the:

- MD Regulation, which is in line with the Medical Devices Directive.
- Regulation on Active Implantable Medical Devices, adopted by the MoH on 9 January 2007 and amended on 7 June 2011, which is in line with the Active Implantable Medical Devices Directive (90/385/EEC).
- Regulation on In Vitro Diagnostic Medical Devices, adopted by the MoH on 9 January 2007, which is in line with the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

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 bases of these regulations. The Technical Law will be abolished once the Law on Product Safety and Technical Regulations No. 7223 enters into force on 12 March 2021.

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:

- Devices intended for clinical investigation that 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.

(Article 6(2), 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, which replaced the Turkish National Databank for Pharmaceuticals and Medical Devices 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 medicines, registration is made on submission, without verification of the authenticity or correctness of the submitted documents. The registrant must provide an undertaking to bear all criminal and civil liabilities arising from any inaccurate or incomplete submission.

Marketing

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. The 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 in 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.

16. Are there fewer or different requirements for medical devices that have already been licensed or 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 Product Tracking System before being placed on the market.

17. 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 Product Tracking System.

18. What are the general requirements to advertise medical devices?

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, 22 September 2016 and 2 September 2020. The following devices cannot be advertised to the general public:

- Devices that must be exclusively used or applied by healthcare professionals.
- Devices that require implementation in medical device sales centres.
- Devices that are sold, adapted or implemented only in hearing aid centres, tailored prosthetics and orthosis centres, opticians or dental prosthetics laboratories.

Medical devices that are allowed to be advertised and sold through the internet by registered sales centres include those that fall outside the scope of devices listed above and any that fall within Annex 3 to the Regulation.

In addition, advertisements for prescription medical products or treatments cannot be broadcast (Article 11/2, Law on Establishment and Broadcasting of Radio and Television Institutions No. 6112). Although this provision does not expressly refer to medical devices, it is accepted that advertisements for prescription medical devices cannot be broadcast on TV and radio.

19. What product marking is required for authorised medical devices?

To be placed on the Turkish market, all medical devices must bear the CE mark, unless an exemption applies (Article 6(1), MD Regulation) (see Question 15).

Combination products

20. Does your jurisdiction recognise combination products? What are the main laws that specifically apply to them (if any)?

The Licensing Regulation recognises combination medicines as products that have at least two active ingredients. In addition, the MD Regulation recognises single use medicine-medical device combinations and provides that such products are subject to the Licensing Regulation. For matters relating to the safety and performance of a medical device, the fundamental requirements set out in Annex I to the MD Regulation apply.

21. Are there any additional or alternative regulations that apply specifically to combination products?

There are no regulations that apply specifically to combination products. General provisions on the commercialisation of medicines covered in Question 2 to 10 also apply to combination products.

Natural health products

22. Is there a category for natural health products (or equivalent) (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:

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

(Article 4/h, Food Supplement Regulation.)

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 Medicines and Medical Devices 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 Medicines and Medical Devices Agency will be responsible for regulating the licensing and sale of medicines used in homeopathic treatments.

As most natural health products fall within the definition of food supplements, Question 23 to 27 will cover the regulation of food supplements.

23. What authorities are responsible for regulating the manufacture, marketing and advertising 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 Ministry of Health.

The Medicines and Medical Devices Agency is responsible for regulating the licensing and marketing of traditional herbal medicinal products and homeopathic treatments.

24. What notifications, registrations, approvals and licences are required to manufacture and market natural health products?

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.

Marketing

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.

25. 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 onto the Turkish market, a food supplement must comply with the general requirements outlined in Question 24.

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

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. These transactions are not subject to any particular customs regulation.

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.

27. What are the general requirements to advertise natural health products?

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 Pharmaceuticals Law provides that the marketing or advertisements for 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, comparative advertising for food supplements is prohibited (Article 8(3), Regulation on Commercial Advertisements and Unfair Commercial Practices (which took effect on 10 January 2015 and was amended on 4 January 2017)).

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 Regulation on Health Claims published in Official Gazette No. 28670 on 7 June 2013, health claims in advertisements for food supplements must comply with 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.

Data

28. What data and information laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps)?

The protection of personal data and personal health data is regulated by the Personal Data Protection Law (DPL) No. 6698. The general rule under the DPL

is that personal data can only be processed with the explicit consent of the data subject.

Sensitive personal data (data relating to race, ethnic origin, political beliefs, philosophical beliefs, religion, denomination or other faiths, clothing and attire, membership of an association, charity or union, health, sexual orientation, criminal convictions and security measures, and biometric and genetic data) can only be processed with the explicit consent of the data subject. Personal data relating to health or sexual orientation is protected more strictly than other sensitive data, as the additional legal grounds for processing are very limited.

Personal data related to health or sexual data can only be processed with the explicit consent of data subjects by persons under the obligation of confidentiality or by authorised institutions and establishments for the purposes of protection of public health, protective medicine, medical diagnosis, and treatment and care services.

Sensitive and non-sensitive personal data can be transferred to third parties if the explicit consent of the data subject is obtained, or if one of the additional legal grounds mentioned above applies to the transfer.

While data protection legislation affects all companies located in Turkey, it poses some practical challenges to pharmaceutical and medical device companies that are collecting vigilance information and quality complaints. These companies must sometimes directly interact with patients, collect and store information, and obtain their explicit consent to process, share, and transfer the data abroad to their global companies.

Research

29. What restrictions and regulatory requirements apply to the testing of life sciences products on human and animal subjects?

The testing of life sciences products on human subjects is regulated by the:

- Regulation on Clinical Trials of Medicines and Biological Products.
- Regulation on Clinical Trials of Medical Devices.

- Guidelines on Clinical Research Applications Submitted to the Medicines and Medical Devices Agency, Department of Clinical Research.
- Guidelines on Clinical Research Applications to Ethics Committees.
- Guidelines on Good Clinical Practice.

An application for a clinical trial on human subjects must be submitted to the Medicines and Medical Devices Agency and Ethics Committee along with the trial application file, within the framework of the Guidelines on Good Clinical Practice. Where the Ethics Committee believes that the benefits that will be obtained are greater than the risks that may arise from the trial, the trial can be started after obtaining approval from the Ethics Committee and permission from the Agency. Personality rights must be taken into consideration and an informed subject consent form must be obtained.

The testing of life sciences products on animal subjects is mainly regulated by the:

- Animal Protection Law No. 5199.
- Regulation on the Working Procedures and Principles of Animal Testing Ethics Committees.
- Regulation on the Welfare and Protection of Animals Used for Testing and Other Scientific Purposes.

Organisations that use, produce or procure animals for testing must have a working permit from the Ministry of Food, Agriculture and Livestock. Organisations that have this permit can use animals for testing purposes once they establish an Animal Testing Local Ethics Committee and an Animal Wealth Unit (Article 8, Regulation on the Working Procedures and Principles of Animal Testing Ethics Committees).

Reform

30. Are there any plans to reform the rules on the development, manufacture, marketing and advertising of life sciences products and services?

The Medicines and Medical Devices Agency is expected to amend some of the main regulations on the authorisation of medicinal products. The Agency requested that industry associations submit their opinions and amendment requests on the:

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

The Medical Devices Regulation ((EU) 2017/745) will enter in force on 26 May 2021. The Agency is expected to publish an updated regulation to harmonise Turkish laws with the new EU rules.