Overview of Medicinal Product Regulation and Product Liability in Turkey (2015)

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Regulatory overview

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

In this chapter, medicinal products and medical devices are considered as two different categories, with no overlap between them.

Medicinal products are only permitted to enter the Turkish market if they have a valid marketing authorisation. Marketing authorisations are issued in accordance with the Regulation on Licensing of Medicinal Products for Human Use (Official Gazette No. 25705, dated 19 January 2005 (Licensing Regulation on Medicinal Products). The various requirements and conditions for medicinal products are regulated under different pieces of legislation.

The main legislation governing medicinal products in Turkey includes the:

- Code on Pharmaceutical and Drugs No. 1262 (*İspençiyari ve Tıbbi Müstahzarlar Kanunu*).
- Licensing Regulation on Medicinal Products for Human Use (*Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği*).

Regulatory authorities

The state is one of the biggest purchasers in the pharmaceutical sector, and is also the regulator. The Ministry of Health is the primary regulator, responsible for health affairs in Turkey. Marketing authorisation is obtained from the Ministry of Health. The Medicines and Medical Devices Authority (Authority) is a body of the Ministry of Health which deals with medicinal products marketing authorisation and pricing.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

Biological medicinal products are defined as products where the active substance is a biological substance (*First Annex, Article 3.2.1.1(b), Licensing Regulation on Medicinal Products*). Biological products are regulated in detail under the Biosimilar Medicinal Products Guidelines (Product Guidelines). Accordingly, a biological medicinal product is a product made from a biological source (or extracted), where a combination of physicochemical biological tests together with the production process, and control are required to determine the quality of its active substance (*Article 1.3, Product Guidelines*).

Applications for marketing authorisation for combination products are regulated under Article 9(a)(3) of the Licensing Regulation on Medicinal Products.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

The main regulations for medical devices and diagnostics are:

- Sale, Marketing and Promotion of Medical Devices Regulation (*Tıbbi Cihaz Satış, Reklam ve Tanıtım Yönetmeliği*) (*Official Gazette No. 29001, 15 May 2014*) (Medical Device Marketing and Sales Regulation).
- Medical Device Regulation (*Tıbbi Cihaz* Yönetmeliği) (*Official Gazette No. 27957, dated 7 June 2011*) (Medical Devices Regulation).
- Clinical Trials of Medical Devices Regulation (*Tıbbi Cihaz Klinik Araştırmaları Yönetmeliği*) (*Official Gazette No. 29111, dated 6 September 2014*) (Regulation on Clinical Trials of Medical Devices).

The definition of medical devices includes all kinds of tools, equipment, and accessories, including software (*Article 3(o), Medical Devices Regulation*).

Pricing, state funding and reimbursement

4. What is the structure of the national healthcare system, and how is it funded?

The state is responsible for organising and regulating the healthcare system, and for procurement of public healthcare services. The Ministry of Health is responsible for operating protective and remedial healthcare services. However, healthcare services are also carried out by other ministries, universities, and private institutions, as permitted by legislation.

The national healthcare service is primarily financed by the state budget, revolving funds, fund incomes, and taxes. Social security premiums (public and private health insurance) and other private payments (for example, donations) support the public healthcare system's funding.

5. How are the prices of medicinal products regulated?

The pricing system for medicinal products is controlled by the Ministry of Health. The Ministry of Health determines the price for the innovator's base price when the first product (original) enters the market (*Council of Ministers' decree No. 2007/12325; Communiqué concerning Pricing of Pharmaceuticals, Official Gazette No. 28851, 22 September 2007*).

The Ministry of Health has applied a reference pricing system since 2004 to determine prices of original and generic medicinal products. Accordingly, the price of medicinal products in reference countries influences their pricing in Turkey. The details of the system and calculations are determined by the Ministry of Health annually. EU member states can be used as reference countries for Turkish pricing estimates.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

The Social Security Institution Code No. 5502 combines all social security institutions under the umbrella of the Social Security Institution.

The Social Security Institution has issued a list of medicinal products which are reimbursed, including products which combat a range of diseases. Any product which is not included in the list will not be reimbursed.

Where a patient benefits from public social security and the medicinal product is funded in that scheme, patients must pay part of the medicinal product's cost. However, medicinal products listed in the annex to the Communiqué on Health Implementations issued by the Social Security Institution (*Sağlık Uygulama Tebliği; Official Gazette No. 28597, 24 March 2013*) are funded by the state in full.

The Communiqué on Health Implementations provides that on submitting sales receipts for each qualifying medicinal product, the state will reimburse pharmacists for the remaining amount. In practice, consumers pay a reduced amount to the pharmacist, then the pharmacist will recoup the difference from the state.

Clinical trials

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials for drugs are regulated by the Clinical Trials of Drugs and Biological Products Regulation (*İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik*; Official Gazette No. 28617, dated 13 April 2013) (Regulation on Clinical Trials of Drugs). Clinical trials for medical devices are regulated by the Regulation on Clinical Trials of Medical Devices. Both regulations are based on:

- The Fundamental Healthcare Services Law No. 3359 (*Sağlık Hizmetleri Temel Kanunu*).
- EU directives on good clinical practices.
- The Good Clinical Practice Guideline issued by the Ministry of Health.

The Clinical Practice Guideline is based on the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964 (Helsinki Declaration), which is endorsed as a premise for human subject protection policy in Turkey.

Clinical trial applications for both medicinal products and medical devices are made to the Authority.

Authorisations

The Helsinki Declaration forms the basis of human subject protection policy in Turkey. The Ministry of Health's Clinical Practice Guideline is based on the Helsinki Declaration, providing researchers with internationally recognised ethical and scientific quality standards. These standards address designing, performing, recording, and reporting clinical studies involving the participation of human subjects.

Applications for a clinical trial must be prepared in accordance with the Clinical Practice Guideline and other applicable guidelines (*Article 12, Regulation on Clinical Trials of Drugs; Article 13, Regulation on Clinical Trials of Medical Devices*). The application form and its appendixes are available in Turkish on the Authority's website, at www.titck.gov.tr/Detail.aspx?mode=1&pages=PortalAdmin/Uploads/UnitPages/UDPDSC13b1c05f-a7348.htm.

For clinical trial applications regarding medicinal products and medical devices, the clinical trial's sponsor must first apply to the Authority and an Ethics Committee, which is convened by the Authority. The Ethics Committee's role is to provide an independent opinion on:

- The methods and documents used to inform volunteers.
- Necessary consents.
- Other relevant issues to protect the rights, safety, and well-being of the clinical trial volunteers.

The sponsor can also appoint a contract research organization (CRO) domiciled in Turkey to make the application. If the sponsor has no representative domiciled in Turkey, the clinical trial application must be submitted through a CRO which is domiciled in Turkey (*Article 12, Regulation on Clinical Trials of Drugs; Article 13, Regulation on Clinical Trials of Medical Devices*).

Consent

Before participating in a clinical trial for both medicinal products and medical devices, a volunteer (subject), or their legal representatives, must provide written consent stating they participate in the trial of their own free will (*Article 5(1)(i), Regulation on Clinical Trials of Drugs; Article 5(1)(i), Regulation on Clinical Trials of Medical Devices*).

The subject must be informed of the study's (*Article 5(1)(ı), Regulation on Clinical Trials of Drugs; Article 5(1)(ı), Regulation on Clinical Trials of Medical Devices*):

- Objective.
- Methodology.
- Expected benefits.
- Foreseeable risks, challenges, and any aspects unfavorable to the subject's health or personal characteristics.
- Conditions under which the study will be conducted and carried out.

The written consent must include reference to the information noted above.

Trial pre-conditions

Clinical studies must first be performed in a non-human in vitro environment, or on a sufficient number of test animals (*Article 5(1)(a), Regulation on Clinical Trials of Drugs; Article 5(1)(a), Regulation on Clinical Trials of Medical Devices*).

Clinical trials in Turkey can only be conducted at (*Article 11, Clinical Trials Regulation on Clinical Trials of Drugs; Article 12, Regulation on Clinical Trials of Medical Devices*):

- Centres for health practice and research established in universities.
- Approved centres for research and development in universities.
- The Ministry of Health's teaching and research hospitals.
- Gülhane Military Medical Academy.
- Military teaching and research hospitals.

Clinical trials must be performed at locations dedicated to clinical research which have appropriate staff, equipment, and laboratory facilities, to ensure:

- Safety and monitoring of the clinical trial.
- Access to research subjects.
- Proper conduct of appropriate emergency care.

For clinical trials of medicinal products, insurance which meets minimum regulatory requirements must be provided to clinical trial subjects (*Article 5(1)(l), Regulation on Clinical Trials of Drugs*). Observational drug studies and Phase IV clinical studies are excluded from this requirement (*Article 10, Regulation on Clinical Trials of Drugs*).

Phase IV is the stage of clinical research involving a large number patients where (*Article 10(ç), Regulation on Clinical Trials of Drugs*):

- Products authorised in Turkey are further investigated in terms of their approved indications, posology, and method of administration.
- Products permitted in Turkey are further investigated for their safety and efficacy characteristics against their recommended use, or to compare them with other established treatments, products or procedures.

For clinical trials of medical devices, the subject must be insured. However, no insurance is required during clinical trials conducted on medical devices bearing the CE mark and conducted in line with the purposes of use determined by the producer of such medical devices, provided that the Ethics Committee deems it appropriate after taking into account the risk-benefit ratio (*Article 5(l), Regulation on Clinical Trials of Medical Devices*).

Procedural requirements

Clinical trials must be conducted by a team appropriate to the nature of the study, led by a principal investigator (*Article 13(3)(a), Regulation on Clinical Trials of Drugs; Article 14(3)(a), Regulation on Clinical Trials of Medical Devices*).

If new circumstances emerge during the clinical trial or investigation product which may impact on subjects' safety, urgent safety measures must be taken. Responsibility for these safety measures can rest with the sponsor, principal investigator, or investigators who are physicians or dental practitioners (*Article 13(3)(b), Regulation on Clinical Trials of Drugs; Article 14(3)(b), Regulation on Clinical Trials of Medical Devices*).

The principal investigator or an investigator appointed by the principal investigator must immediately report adverse events to the sponsor (*Article 18, Regulation on Clinical Trials of Drugs; Article 19, Regulation on Clinical Trials of Medical Devices*). Reporting is not required for events specified in the research protocol, the investigator's brochure, or those deemed not to require immediate reporting.

If serious adverse reactions occur during the clinical trial, the sponsor must inform the Ethics Committee and the Authority within seven days of receiving such information (*Article 19, Regulation on Clinical Trials of Drugs; Article 20, Regulation on Clinical Trials of Medical Devices*).

Manufacturing

8. What is the authorization process for manufacturing medicinal products?

Application

Real and legal persons must obtain a manufacturing site permit to manufacture medicinal products in Turkey. A manufacturing permit is obtained from the Authority by submitting the documents outlined in Annex 1 of the Manufacturing Sites for Medicinal Products for Human Use Regulation (*Beşeri Tıbbi Ürünlerin İmalathaneleri*

Hakkında Yönetmelik; Official Gazette No. 28630, dated 27 April 2013) (Regulation on Manufacturing of Medicinal Products).

Manufacturers must also obtain a good manufacturing practice (GMP) certificate from the Authority. This certifies that the manufacturer complies with the principles of GMP for medicinal products outlined in the Authority's guideline for quality assurance of pharmaceutic products.

Conditions

To obtain a manufacturing site permit from the Authority, applicants must:

- Employ a responsible manager meeting the requirements under the Regulation on Manufacturing of Medicinal Products.
- Employ a quality assurance and quality control manager.
- Establish a quality control unit.
- Ensure the manufacturing facility complies with the guidelines of good manufacturing for the medicinal products.
- Submit an original or certified copy of a non-sanitary enterprise certificate.
- Present an environmental impact assessment report (if required).

Restrictions on foreign applicants

Foreign applicants must follow the same procedures for manufacturing site permits or GMP certificates as Turkish applicants.

Key stages and timing

Inspectors from the Authority will visit the manufacturing site to verify the accuracy of the application information and documents. Manufacturing site permits are granted within 90 days of the application date (*Article 6, Regulation on Manufacturing of Medicinal Products*). If the Authority requires further documents regarding the application or responsible manager, the 90 day evaluation period pauses until the applicant supplies the requested documents (*Article 8, Regulation on Manufacturing of Medicinal Products*).

Fee

Fees for obtaining the manufacturing site permit vary depending on the application details and type of transaction. The Authority issues a list of fees on its website each year (in Turkish), at www.titck.gov.tr/DisplayDynamicModule.aspx?mId=UW5stMcU+pk

Period of authorisation and renewals

Manufacturing site permits are not issued for specific periods of time. However, permit holders must continue to comply with the application requirements outlined in the Regulation on Manufacturing of Medicinal Products, and report any change to the manufacturing site or the manufactured products.

Monitoring compliance and imposing penalties

The Authority can inspect a manufacturing site before granting the manufacturing permit, or at any later time it deems necessary, without being required to provide prior notice. Any documents or records related to

manufacturing, quality control, or quality assurance can be examined during the inspection. The Authority prepares a report indicating whether the site complies with the Regulation on Manufacturing of Medicinal Products' requirements.

The manufacturing permit or the responsible manager's authority can be partly or completely canceled or suspended (on a temporary or permanent basis) if the site fails to comply with the Regulation on Manufacturing of Medicinal Products' requirements.

Administrative fines range from TRY10,000 to TRY500,000 for manufacturing, selling, and supplying non-compliant products (*Article 18, Code on Pharmaceutical and Drugs*). Breaches of advertising restrictions attract administrative fines (starting at TRY100,000), as well as potential sanctions from the Information and Communication Technologies Authority (for online advertising). The administrative fine imposed will be doubled for repeat offenses.

Persons who manufacture drugs which endanger human life or health are also subject to imprisonment of between one and five years, and punitive fines (*Article 187, Criminal Code No. 5237*). Sanctions are increased by one third where the crime is committed by a doctor, pharmacist, or within the scope of performing a profession subject to public authority permission.

Marketing

Authorization and abridged procedure

9. What is the authorization process for marketing medicinal products?

Application

Marketing authorization for medicinal products is regulated by the Licensing Regulation on Medicinal Products. Medicinal products cannot be launched on the market before obtaining marketing authorization from the Ministry of Health (*Article 5, Licensing Regulation on Medicinal Products*). To obtain marketing authorization, real persons or legal entities resident in Turkey must file an application to the Ministry of Health, including the documents listed under the Licensing Regulation on Medicinal Products.

Authorization conditions

When granting marketing authorizations, the Ministry of Health considers whether (*Article 16, Licensing Regulation on Medicinal Products*):

- Efficacy of the envisaged usage conditions has been proved.
- The pharmaceutical's reliability has been proved.
- Adequate technical and pharmaceutical properties exist.

The Ministry of Health can choose to waive some of these criteria on public health grounds, such a decision on the basis of pharmaco-economic data (*Article 16, Licensing Regulation on Medicinal Products*).

Real person marketing authorisation applicants must be graduates from pharmacy, medicine, or chemistry faculties, and be entitled to operate in these disciplines in Turkey. Legal person marketing authorisation applicants must employ a person who meets these criteria (*Article 7, Licensing Regulation on Medicinal*

Products).

If a medicinal product will be imported into Turkey, the following certificates (issued by the medicinal product's licence owner) are required to obtain local marketing authorisation, together with Turkish translations (*Article 8, Licensing Regulation on Medicinal Products*):

- Certificate showing that the importer is the sole representative authorised to manufacture and/or sell the medicinal product in Turkey.
- If co-marketing will occur, a certificate showing that a real person or legal entity other than the sole authorised representative in Turkey is also authorised for co-marketing purposes. Written consents from the real persons or legal entities which will be engaged in co-marketing activities are also required.

Key stages and timing

The preliminary evaluation period lasts a maximum of 90 days. If documents or information are missing from the application file, the applicant is allowed 30 days to rectify these omissions (within the overall 90 day period). On completing the 90 day preliminary evaluation period, the Ministry of Health must evaluate and conclude marketing authorisation applications within 210 days, except in extraordinary circumstances (*Article 15(1), Licensing Regulation on Medicinal Products*).

However, the Ministry of Health must complete its consideration within 180 days for marketing authorisation applications regarding pharmaceutical products which are (*Article 15(3), Licensing Regulation on Medicinal Products*):

- Original (in treatment or diagnosis).
- Innovative.
- Required from a public health perspective to reduce public healthcare expenditure and to ensure rapid public access to the drug.

Fee

Fees relating to marketing authorisation vary depending on the application details and type of transaction. The Authority issues a list of fees on its website each year (in Turkish) at www.titck.gov.tr/DisplayDynamicModule.aspx?mId=UW5stMcU+pk

For instance, the marketing authorisation application fee is TRY2,155.92, and the renewal fee for marketing authorisation is TRY1,088.16.

Period of authorisation and renewals

Marketing authorisation for medicinal products intended for human use is valid for five years, starting from the date the Ministry of Health issues the authorisation.

To renew a marketing authorisation, information on the medicinal product's quality, safety, and efficacy must be submitted to the Ministry of Health, as well as pharmacovigilance data. The information must be submitted at least three months before the five year marketing authorisation term expires (*Article 21, Licensing Regulation on Medicinal Products*).

Monitoring compliance and imposing penalties

The Regulation on Safety of Drugs (*İlaçların Güvenliliği Hakkında Yönetmelik*; Official Gazette No. 28973, dated 15 April 2014) (Regulation on Safety of Drugs), issued by the Authority, regulates medicinal product safety in Turkey. The Regulation on Safety of Drugs outlines responsibilities for marketing authorisation holders, healthcare providers, health institutions and organisations, as well as for the Authority itself.

The Authority evaluates all data scientifically through pharmacovigilance systems. It must track the results of precautions taken within the scope of risk management plans prepared by marketing authorisation holders, and evaluate updates in risk management plans.

The Authority can give marketing authorisation holders time to rectify failures to comply with the Regulation on Safety of Drugs. Depending on the nature of the breach, the period can range between 15 days and three months. Marketing authorisation will be suspended if the breach is not rectified within the period.

Following market entry, the medicinal product's effectiveness and safety must be maintained. The medicinal product must also bear the appropriate technical and pharmaceutical specifications.

If the marketing authorisation holder fails to comply with the related regulations, the Ministry of Health can suspend the marketing authorisation (*Article 22, Licensing Regulation on Medicinal Products*). If a medicinal product's marketing authorisation is suspended, manufacturing and import of this medicinal product must also cease (*Article 22, Licensing Regulation on Medicinal Products*). The marketing authorisation holder is allowed six months to submit rebuttal documents to the Ministry of Health regarding the suspension. If the marketing authorisation holder fails to do so, the authorisation will be cancelled.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Holders of marketing authorisation have certain responsibilities to the Ministry of Health relating to their authorised medicinal product, including (*Article 24, Licensing Regulation on Medicinal Products*):

- The medicinal product must be manufactured in compliance with Ministry of Health specifications.
- Any amendment to the medicinal product's manufacturing or control must be notified to the Ministry of Health.
- When necessary, the medicinal product characteristics summary and package insert must be updated to enable correct and safe use of the product.
- Any medicinal product variations must be notified to the Ministry of Health.
- Pharmacovigilance obligations must be fulfilled.
- For biological products, measures must be taken to prevent contamination of infections.
- The medicinal product must be made available in the market.
- Requirements under applicable legislation must be fulfilled.
- Any measure taken in relation to suspending the marketing authorisation or withdrawing from the market to secure product efficacy or public health must be notified to the Ministry of Health.
- Relevant fees and charges must be paid.

The Regulation on Safety of Drugs introduces contractual pharmacovigilance service organisations to carry out all pharmacovigilance activities. Responsibilities for holders of marketing authorisation, healthcare providers, health institutions and organisations, and for the Authority itself, are outlined in the Regulation on Safety of Drugs (*see Question 20*).

The Packaging and Labelling of Medicinal Products for Human Use Regulation (*Beşeri Tıbbi Ürünler Ambalaj ve Etiketleme Yönetmeliği*; Official Gazette No. 25904, dated 12 August 2005) (Packaging and Labelling Regulation on Medicinal Products) regulates distribution of the medicinal product for human use (*see Question 18*). Accordingly, holders of marketing authorisation must (*Article 16, Packaging and Labelling Regulation on Medicinal Products*):

- Use transport packages during shipment of more than one product to ensure product reliability. Transport packages can be packs, parcels, boxes, or bundles, and can be placed inside one another, as well as display descriptive product information.
- Notify the Pharmaceutical Track and Trace System of the two dimensional barcode for the products which they manufacture, stock (for sale), accept return, or destroy.

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Article 9 of the Licensing Regulation on Medicinal Products outlines an abridged procedure for obtaining marketing authorisation. Accordingly, if an applicant meets the following criteria, it is not required to provide the results of pre-clinical tests or clinical trials to the Ministry of Health:

- The medicinal product is similar in principle to a medicinal product which has previously been granted marketing authorisation in Turkey, and the marketing authorisation holder of the original product gives its consent for the applicant to use this information for the purpose of obtaining a marketing authorisation.
- The medicinal product's components have reasonable activity and admissible reliability settled in medical use.
- The data exclusivity period for the original medicinal product, which is similar in principle to the generic product, has expired. The original medicinal product must either be:
    - granted marketing authorisation for the first time after 1 January 2001 in a Turkish Customs Union country and no generic registration applications were filed in Turkey before 1 January 2005; or
    - granted marketing authorisation for the first time after 1 January 2005 in a Turkish Customs Union country.

12. Are foreign marketing authorisations recognised in your jurisdiction?

Foreign marketing authorisations are not recognised in Turkey. If a medicinal product is licensed abroad and is imported or manufactured in Turkey, a Turkish marketing authorisation is still required. Applicants for marketing authorisation must submit original and up to date copies of a medicinal product's (*Article 8, Licensing Regulation on Medicinal Products*):

- Summary of characteristics.
- Patient information leaflet and packaging samples (with translations).

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Medicinal product imports are strictly regulated in Turkey and parallel imports of medicinal products are not allowed. The Code on Pharmaceutical and Drugs regulates importing, exporting, and manufacturing of medicinal products, including penalties for non-compliant medicinal products or activities. Marketing authorisation from the Ministry of Health must be obtained before a medicinal product is released into the Turkish market (medicinal products manufactured in Turkey) or before the medicinal product is imported or exported (medicinal products produced outside Turkey) (*Article 3, Code on Pharmaceutical and Drugs*).

An importer must have marketing authorisation to import medicinal products into Turkey. In principle, marketing authorisation for a particular medicinal product can be held by only one entity. However, two or more companies can agree to market and sell the same medicinal product under two different brand names, by entering into a co-marketing agreement. Therefore a product can be subject to co-marketing if the company holding authorisation gives authorisation to another company. Accordingly, parallel imports of medicinal products are legally not possible. Import of medicinal products into Turkey without local market authorisation constitutes smuggling (*Article 19, Code on Pharmaceutical and Drugs*), punished according to the Anti-Smuggling Law No. 5607.

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Medical devices

The Medical Device Marketing and Sales Regulation outlines restrictions, clear rules, and procedures for marketing medical devices in Turkey:

- Medical devices cannot be advertised to the public if they can only be operated by healthcare professionals or parties on the Social Security Institution's reimbursement list.
- Promotion can be done through brochures, symposiums, meetings, or personal visits. The Medical Device Marketing and Sales Regulation outlines detailed rules on permitted promotional activities.
- The value of promotional materials must be worth less than 2.5% of the monthly minimum wage in Turkey.
- An authorised sales centre (Sales Centre) is a centre for distribution and sale of medical devices. To become an authorised medical device sales centre, an applicant must submit the documents listed in the Medical Device Marketing and Sales Regulation to the local health authorities. If a Sales Centre wishes to sponsor a healthcare professional or medical device personnel to attend a scientific event or meeting, it must provide details to the Authority. No such event or meeting can be held or sponsored at coastal or ski centres during high-season, except for international congresses regularly held in different countries. Sponsorship of participation in scientific events or meetings is subject to certain conditions (from 15 May 2015 onwards):
    - meetings must only target the healthcare professional or medical device personnel's areas of expertise;
    - healthcare professionals and medical device personnel can be sponsored for a maximum of three events per year, two events by the same sales centre per year, or two events outside Turkey per year;

    - sponsorship must go directly to the hosting organisations, not to the healthcare professional or medical device personnel.

- It is prohibited to give benefits or incentives to healthcare professionals or medical device personnel with the intention of incentivising prescription, use, purchase or recommendation of a particular medical device.
- Donations can be made to healthcare professionals. A Sales Centre can donate to public or non-profit healthcare institutions if a number of conditions are met. These include prior approval from the authorities and properly recording the donation in the Sales Centre's accounts and records. The donation must not influence decisions on public tenders, or constitute unethical behaviour regarding the sale of medical devices. Donations must be intended for general use by the recipient entity, not a specific individual.
- Free samples of medical devices are permitted, provided they meet certain technical requirements, including:

    - packaging must include the phrase "free promotional sample, not for sale"; and
    - the sample's value cannot exceed 2% of the medical device's turnover for the previous year (not applicable for the first year which a product enters the market).

Medicinal products

The Promotion of Medicinal Products for Human Use Regulation (*Beşeri Tıbbi Ürünlerin Tanıtım Faaliyetleri Hakkında Yönetmelik*; Official Gazette No. 28037, dated 26 August 2011) (Regulation on Promotion of Medicinal Products) regulates promotion of medicinal products for human use. It generally includes similar provisions to the Medical Device Marketing and Sales Regulation (*see above, Medical devices*).

The Regulation on Promotion of Medicinal Products governs the relationship between pharmaceutical companies and healthcare professionals:

- Companies must not encourage prescription of their products by offering any kind of benefit to healthcare professionals (*Article 6/10(c), Regulation Promotion of Medicinal Products*).
- The value of the gifts given by companies to healthcare professional is restricted to 2.5% of the monthly minimum wage in Turkey (*Article 8, Regulation Promotion of Medicinal Products*).
- Healthcare professionals are prohibited from asking for benefits (*Article 6, Regulation Promotion of Medicinal Products*).

The Public Servants Law No. 657 (*Devlet Memurları Kanunu*) prohibits public servants from receiving or requesting gifts or credits from those for whom they perform their duties, with the purpose of taking advantage of their duties (*Article 29*). All employees working in the public sector are deemed to be public servants, including employees of public hospitals.

The Criminal Code establishes bribery as a crime. The Criminal Code defines the bribery where any person secures directly (or through other persons) an undue advantage to a public official such as an employee of the Ministry of Health (or another person indicated by the public official) to perform or not to perform a task with regard to his duty (*Article 252, Criminal Code*).

The Criminal Code equally punishes the public official who receives the bribe and the person who provides the bribe. If a legal entity receives an unfair advantage as a result of bribery, the legal entity is also subject to, for example, cancellation of official authorisations (such as marketing authorisation), seizure of property, or

seizure of earnings. Turkish laws in this respect still apply if a Turkish citizen commits bribery outside Turkey. Therefore, if healthcare professionals are involved in illegal promotion of pharmaceuticals, they will be subject to the Criminal Code.

Sales and marketing

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Online sale of medicinal products is prohibited in Turkey. The Law on Pharmacists and Pharmacies No. 6197 (*Eczacılar ve Eczaneler Hakkında Kanun*) (Pharmacy Law) requires the following to be sold exclusively by pharmacies (*Article 28, Pharmacy Law*):

- Certain dietary food for special medical purposes.
- Infant formulas for special medical purposes.
- Medicinal products for human use.
- Licensed traditional herbal products.
- Homeopathic medicinal products subjected to the licence of the Ministry of Health.
- Enteral nutrition products.

Turkish law prohibits advertising medicinal devices through any media or communication platform, including the internet (*Article 15, Medical Device Marketing and Sales Regulation*). Announcement of the medicinal devices' launch onto the Turkish market is permitted in newspapers or magazines with the Ministry of Health's consent.

Advertising

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The Code on Pharmaceuticals and Drugs sets out the general principles for the advertisement and promotion of medicinal products. The Ministry of Health regulates the details of advertisement and promotion of medicinal products under the Regulation on Promotion of Medicinal Products.

Restrictions

Advertisements that misrepresent or exaggerate the curative properties of medicinal products are prohibited. Additionally, advertisements of prescription medicinal products can only be published in medical magazines with prior approval by the Ministry of Health (*Article 13, Code on Pharmaceuticals and Drugs*).

Moreover, advertising and promotion of medicinal products to the general public either directly or indirectly without making any distinction between prescription and non-prescription medicines is prohibited (*Article 5(3), Regulation on Promotion of Medicinal Products*). Promotional activities for medicinal products can only be carried out to healthcare professionals.

Medicinal products which do not hold marketing authorisation cannot be promoted to healthcare professionals in Turkey. Even with the appropriate marketing authorisations, promotion of medicinal products must be

limited to the information which has been outlined in the brochure. Exemptions to this general rule include (*Article 6(2), Regulation on Promotion of Medicinal Products*):

- Promotional activities relating to medicinal products without marketing authorisation during international conferences convened in Turkey.
- Briefings by a marketing authorisation holder's science department representatives which are made on written request by healthcare professionals.

Internet advertising

Turkish legislation does not allow internet advertising for medicinal products (*Article 5(3), Regulation on Promotion of Medicinal Products*).

Data protection

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

Protection of personal data is addressed by general provisions of the Constitution, civil, and penal legislation. Accordingly, if a person has their personal rights infringed due to inappropriate use of their personal data, that person is able to claim compensation for any damages incurred. Such a claim would be based on these general provisions.

Protection of personal data is also regulated under the Regulation on Clinical Trials of Drugs and the Regulation on Clinical Trials of Medical Devices. Accordingly, trials can only be registered with a publicly available database if the personal data is protected.

Additionally, there is a Draft Law on Personal Data Protection which aims to protect the privacy, rights, and freedoms of persons in connection with the processing of their personal data. This draft law was prepared in 2008 in line with EU Directive 95/46/EC on data protection and the Strasbourg Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data 1981. The draft law is currently being considered by the commission of the Grand National Assembly (*see Question 26*).

Packaging and labelling

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The Ministry of Health's Packaging and Labelling Regulation on Medicinal Products outlines what information must be inserted on the inner and outer packages of medicinal products. It also lists the minimum requirements for usage instructions, and for labels of medicinal products.

Information requirements

The Packaging and Labelling Regulation on Medicinal Products outlines information requirements for the inner and outer packaging of medicinal products. The following information must appear on the outer package (if a product has both inner and outer packaging) or on the inner package (if there is no outer packaging for a particular product) (*Article 5, Packaging and Labelling Regulation on Medicinal Products*):

- The product's name, dosage, and pharmaceutical form.
- If the product contains up to three active substances, the international non-proprietary name (INN), or common name (if no INN exists).
- Whether the product is intended for babies, children, or adults (if applicable).
- The unit amounts or administration routes and the weight or volume amounts of the active substance's pharmaceutical form (indicated by the INN or common name).
- The number of units in the package, such as number of tablets, ampoules, or bottles.
- The volume, weight, or dose number of active substances in pharmaceutical form (if these cannot be regarded as net content).
- Excipients such as colourings, preservatives, antioxidants, flavouring substances, and alcohol must be indicated by name.
- Excipients known to have an apparent effect must be presented as a list (qualifying excipients are specified in the Packaging and Labelling Regulation on Medicinal Products). However, if the product is injectable, applied locally, or is an ocular preparation, all excipients must be indicated.
- Method of use and route of administration (if necessary) must be indicated.
- Other special warnings relating to the product must be indicated (where applicable).
- Storage conditions and special storage conditions for the product (if any).
- Special warning relating to the disposal of unused products or waste of products and, where necessary, the appropriate collection system must be indicated.
- Packaging must include the recyclable symbol, number, and abbreviation of the package type.
- The registration or permit holder's name and address.
- The name of the company marketing the product which has been authorised to represent the registration or permit holder (optional).
- Manufacturer's name and address.
- The product's registration or permit number.
- The product's batch number.
- The product's expiry date.
- Instructions for users (if the product is used for self-medication purposes).
- Warnings stating:
    - "*keep out of reach of children*";
    - "*do not purchase packages that have been cut or opened*";
    - "*read the package insert before use*";
    - "*consult your doctor if any undesirable effects appear*";
    - other warnings issued by the Ministry of Health.
- Information about whether the product requires a prescription or not.
- A two dimensional barcode (as a secondary identifier) and legible information relating to the content of the barcode.
- The product's barcode (optional).
- The product's price (optional).

Where a product has both inner and outer packaging, most of the information listed must also be included on the inner packaging.

Other conditions

Labelling is not required on transparent outer packages. However, for such packaging arrangements, all the information required to be on the outer package (listed above), must be included on the inner package instead.

The Packaging and Labelling Regulation on Medicinal Products also outlines the requirements for instructions and labelling. However, the requirements for instructions and labels are less extensive than those for outer packaging (listed above).

Information must be in Turkish on the outer and inner packages, as well as in the instructions for use. In addition to the mandatory Turkish information, information can also be presented in any official language used by EU member countries.

Packaging of medicinal products which contain radionuclides must be labelled in accordance with the regulation regarding the Turkish Atomic Energy Agency, as well as other relevant international legislation.

Product liability

19. Outline the key regulators and their powers in relation to medicinal product liability.

The Ministry of Economy has released a draft Law called the Law on Product Safety and Technical Regulation (*Ürün Güvenliği ve Teknik Düzenlemeler Kanun Taslağı*) (Draft Product Safety Law). Until the Draft Product Safety Law comes into force, liability for products (including medicinal products) arises under the general provisions of the Code of Obligations 6098 (Code of Obligations) and the Consumer Protection Law 6502 (Consumer Law).

Liability with respect to manufacturing and distributing products (including medicinal products) can also arise under the Preparation and Implementation of Technical Regulation of Products Law 4703 (Ürünlere İlişkin Teknik Mevzuatın Hazırlanması ve Uygulanmasına Dair Kanun)(Technical Regulation Law). The Technical Regulation Law outlines the general legal framework and conditions for placing all kinds of products on the market and recall from the market. Among other matters, it addresses:

- Producer and manufacturer obligations and liabilities.
- Market surveillance.
- Prohibition of placement of products on the market.
- Recalls from the market.
- Disposal of products.

The Recall of Pharmaceutical and Medical Drugs, Substances, Compounds and Herbal Preparates Regulation (*Sağlık Bakanlığı Farmasötik ve Tıbbi Müstahzar, Madde, Malzeme, Terkipler ile Bitkisel-Preparatların Geri Çekilmesi ve Toplatılması Hakkında Yönetmelik*; Official Gazette No. 19196, dated 15 August 1986) (Recall Regulation on Pharmaceutical and Medical Drugs) outlines principles which apply to recalling medicinal products found to be defective or faulty in terms of consumer health and safety, or which fulfill other legislative reasons for recall.

20. Are there any mandatory requirements relating to medicinal product safety?

During manufacturing

A medicinal product manufacturer must comply with GMP, as well as general provisions for product manufacturing under the Technical Regulation Law.

Following marketing authorisation

The Regulation on Safety of Drugs, issued by the Authority, regulates the safety of medicinal products which are authorised or during an application for authorisation. The Regulation on Safety of Drugs introduces contractual pharmacovigilance service organisations to carry out all pharmacovigilance activities, including detection, assessment, understanding, and prevention of adverse effects. Contract organisations are subject to approval and audit by the Authority. Marketing authorisation holders can outsource activities in relation to pharmaceutical product safety. The Regulation on Safety of Drugs outlines responsibilities for authorisation holders, healthcare providers, health institutions and organisations, as well as for the Authority.

Marketing authorisation holders must assure the safety of medicinal products after obtaining authorisation (*Article 5 and 22, Regulation on Safety of Drugs*). In this context, authorisation holders must continuously:

- Pursue safety of medicinal products.
- Inform the Authority about any changes which may impact the benefit/risk evaluation.
- Update product information to reflect the current scientific data.
- Establish a pharmacovigilance system to carry out pharmacovigilance activities.
- Employ at least one pharmacovigilance expert perpetually and continuously.
- Periodically prepare a benefit/risk evaluation report and risk management plan.
- Keep and archive documents on all suspected adverse reactions.
- Record every suspected serious adverse reaction, which the marketing authorisation holder becomes aware of, irrespective of whether it occurs in or outside Turkey.
- Immediately inform the Authority on becoming aware of an adverse reaction either in or outside Turkey, within 15 days at the very latest.

If a marketing authorisation holder fails to comply with the The Regulation on Safety of Drugs, the Authority can allow a period between 15 days and three months for the authorisation holder to rectify the breach, depending on the breach's nature. If the breach is not resolved in that period, the relevant authorisation will be suspended.

Recall regime for medicinal products

The Recall Regulation on Pharmaceutical and Medical Drugs outlines the principles and procedures for recalling medicinal products which are found defective or faulty in terms of consumer health and safety. The primary reasons for recall are product quality, lack of GMP, and labelling errors (*Article 8, Recall Regulation on Pharmaceutical and Medical Drugs*). The Recall Regulation on Pharmaceutical and Medical Drugs categorises these recall reasons as errors regarding packaging, labelling and printing, ingredients, effects, or other types of error.

Product recalls can be initiated by the Ministry of Health, or based on a decision by the product's manufacturer, toll manufacturer, marketer, or importer (Responsible Company) (*Article 4/II, Recall Regulation on Pharmaceutical and Medical Drugs*). If a Responsible Company decides to recall its products, it must begin the recall process and notify the Ministry of Health of its decision by submitting certain documents and information (outlined by the Recall Regulation on Pharmaceutical and Medical Drugs).

If the Ministry of Health decides a product recall is necessary, it must notify the Responsible Company and request initiation of the recall process.

Different procedures must be followed during and after the recall, depending on which party initiated the recall. Various obligations and liabilities arise during each stage of the recall (before, during and after the recall) for a product's manufacturer, importer, and marketer.

The Recall Regulation on Pharmaceutical and Medical Drugs does not clearly outline the consequences if a Responsible Company fails to make a product recall, despite a recall being required in the circumstances. Provisions of related law and the Criminal Code apply, according to the level of adverse effects to health which are caused by the defective product and the nature of the defect (*Article 26, Recall Regulation on Pharmaceutical and Medical Drugs*).

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Medicinal product liability arises from the Code of Obligations and the Consumer Law in the following ways.

Liability in tort

A person who damages another person through an unlawful act and due to his own fault is liable to pay compensation for those damages (*Article 49, Code of Obligations*). Generally, a claimant must establish four elements to successfully claim under tort law:

- Existence of an unlawful act.
- Fault by the perpetrator.
- Damage.
- Reasonable causality between the unlawful act and the damage.

Contractual liability

The delivery chain (manufacturer, wholesaler, retailer/seller to consumer) consists of a series of contracts, most of which are contracts of sale. Typically, there is no direct contractual link between the manufacturer and the consumer. However, there is usually a contract of sale between the consumer and the retailer.

Contractual liability based on a contract of sale can arise from a breach of contract or product defect. The phrase product defect does not necessarily have the same meaning under both product liability and contract law, despite both legal concepts being expressed with the same word in Turkish.

Product liability. Defect refers to the lack of safety expected from such products.

Contract law. Defect refers to either of a product's (*Article 219, Code of Obligations*):

- Failure to meet the qualities or specifications warranted by the seller under the sale contract.
- Material, legal, or economic insufficiencies, which significantly reduce or effect the value with regard to the product's purpose of use and expected benefit.

Previously, product liability involved strict liability for manufacturers in the case of death, personal injury, or damage to property under the Regulation on Liability of Damages Raised from Defective Products (*Ayıplı Malın*

Neden Olduğu Zararlardan Sorumluluk Hakkında Yönetmelik). However, this regulation is no longer in force. A Draft Product Safety Law proposes to fill this gap, but is yet to be enacted.

Failure to comply with what is undertaken under the sale contract (*ayıba karşı tekeffül*) gives rise to seller liability. However, the manufacturer may not necessarily have a direct contractual relationship with the buyer.

Most contracts regulate the consequences of product defects in detail. However, some contracts do not include such provisions, or the provisions are insufficient to resolve disputes arising from defective products. In such circumstances, contracting parties must refer to the Code of Obligations to determine their rights and obligations with respect to defective products.

Situations may arise where the two defect concepts both arise in a product. In such circumstances, the seller's contractual liability and manufacturer's product liability both exist concurrently.

Risk liability

The proprietor of an enterprise which exposes a serious danger, or the manager of such an enterprise (if one exists), is liable for the damages caused by the enterprise's activities. The key element is the existence of an enterprise exposing an imminent danger, which is of a severe degree (Article 71, Code of Obligations).

Product liability

Product liability is a type of risk liability and addressed by the Draft Product Safety Law. However this has not entered into force and is not yet on the Grand National Assembly's agenda. The Draft Law aims to improve conformity assessment and market surveillance systems. It is in line with EU amendments to rules regarding:

- CE marking.
- Notified bodies.
- Accreditation.
- Market surveillance.
- Customs inspections of products from third countries.
- Free movement of goods in the non-harmonised area.

It also proposes to regulate manufacturer liability to injured persons for defective (unsafe) products.

Professional liability

This is usually based on a medical treatment agreement. Under such agreements, doctors and healthcare professionals must carry out medical intervention and treatment in accordance with professional standards. Treatment without the patient's informed consent is a ground for liability.

For treatment in hospitals, the medical treatment agreement is executed between the patient and hospital management. However, doctors and other healthcare personnel employed by private hospitals are deemed to be auxiliaries in the medical treatment (*see below, Auxiliary person liability*).

In case of malpractice, the liability of physicians and health institutions covers all bodily injuries and material damages, as well as immaterial damages.

Auxiliary person liability

The principal is liable for misconduct by auxiliary persons in the exercise of his duties. Fault by the auxiliary person has no impact on the principal's liability. The principal is not liable if he can prove he did not fail to exercise due care with regard to the auxiliary person's employment, instruction, and supervision (*Article 66, Code of Obligations*).

Liability to consumers

Any consumer transaction and its implementation is regulated under the Consumer Law. The liability of manufacturers, importers, and sellers/retailers to consumers is included in this scope.

22. Who is potentially liable for defective medicinal products?

Parties can attract liability under the Code of Obligations and Consumer Law in the following ways.

Manufacturers

Liability in tort. Since there is usually no contractual relationship between the consumer and the manufacturer, claims against the manufacturer must generally be made in tort. An action in tort can be based on risk liability or auxiliary person liability.

Risk liability. Sellers, distributors, agents, and importers who participate in introducing the product into the market are legislatively released from liability for defects in the product. Therefore, only the product's manufacturer can be liable for product liability claims based on the risk liability.

Auxiliary person liability. A manufacturer can be liable for damages caused by its employees or other auxiliary persons in the course of their employment or business (Article 66, Code of Obligations).

Liability to consumers. Consumers can request free repair or exchange of the product from the seller, manufacturer, or importer. In this respect, the manufacturer is liable together with the seller and/or importer jointly for the repair or exchange of the defective product (Article 11/2, Consumer Law).

Product liability. Only the product's manufacturer or importer (if the product is imported) is responsible for any loss and damage which arises (Article 7, Draft Product Safety Law, if enacted in current form).

Distributors

Liability to consumers. The Consumer Law requires sellers, who can also be a distributor, to deliver products to consumers in conformity with the consumer agreement. Therefore, consumers (claimants) can choose to base a defective product claim on the Consumer Law. In such a case, the distributor becomes the defendant (Article 9, Consumer Law).

Product liability. If a product's manufacturer, authorised representative, or importer cannot be determined, a distributor who fails to advise a person who suffers loss of the economic enterprise's name and contact information in a reasonable time will be liable as a manufacturer. If the distributor does not have this information, it must supply the name and contact information of the previous economic enterprise involved in the supply chain (Article 12(3), Draft Product Safety Law, if enacted in current form).

Retailer/seller

Contractual liability. Since there is usually a contract of sale between the consumer and the retailer/seller, a consumer can only sue the retailer/seller in contract. The consumer cannot sue the manufacturer, since there is no direct contractual relationship.

If products are defective and the consequences of product defects are not contractually outlined, the contracting parties must refer to the Code of Obligations to determine their rights and obligations. Under the Code of Obligations, the retailer/seller is responsible for representations made to the buyer, as well as for any material, legal, or economic defects which significantly reduce or effect the value with regard to the product's purpose of use and expected benefit (*Article 219, Code of Obligations*).

The retailer/seller is responsible even if it is unaware of the defects. However, the retailer/seller is not liable if the consumer was aware of the defect when concluding the contract (*Article 222, Code of Obligations*). Agreements which seek to limit or discharge the retailer/seller's liability are null and void if gross negligence by the retailer/seller occurs (*Article 221, Code of Obligations*).

Liability to consumers. The Consumer Law requires sellers to deliver products to consumers in conformity with the consumer agreement. Therefore, consumers (claimants) can choose to base a defective product claim on the Consumer Law. In such a case, the seller becomes the defendant (*Article 9, Consumer Law*). In this context, the phrase product defect refers to either the product's:

- Failure to meet the qualities or specifications warranted by the seller under the sale contract.
- Material, legal, or economic insufficiencies which significantly reduce or affect the value with regard to the product's purpose of use and expected benefit.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Defences to product liability claims vary according to the type of liability.

Liability in tort

Generally, to claim product liability based on tort, a claimant bears the burden of showing the following elements:

- The product is defective or dangerous.
- Damage arose as a result of the defect or danger.
- A causal relationship between the product defect and the damage.

However, decisions by the Court of Appeal have established that in tortious product liability cases, the burden of proof is reversed onto the defendant. The reasoning is that in most situations, it is very difficult (if not impossible) for the victim to prove the defendant acted with fault, since the victim does not have any knowledge of the production process. Therefore, when considering liability, the burden of proof lies with the defendant to show that it does not have any fault.

Risk liability

To establish that product liability based on risk liability has not occurred, a defendant must prove:

- There is no damage.

- The product is not dangerous.
- The damage was not caused by the product.

Product liability

To establish product liability against a manufacturer or importer, the claimant must prove:

- The non-compliance of the product.
- The loss the claimant has suffered.
- The casual relationship between the non-compliance and the loss.

According to the event's characteristics, if the product is likely to cause loss of an emergent type, the casual relation will be deemed to exist.

Contractual provisions which exclude or limit the liability of the producer for defective products are null and void (*Article 7,Draft Product Safety Law, if enacted in current form*).

Auxiliary person liability

To establish that product liability based on auxiliary person liability has not occurred, a defendant must prove:

- There is no damage.
- The products are not dangerous due to an act or omission of the principal's employees.
- The damage was not caused by the product.

Contractual liability

To establish contractual liability, claimants must prove:

- The claimant has suffered damage.
- The defendant breached the contract.
- A causal relationship between the breach and claimant's damage.

Agreements limiting or discharging a debtor's liability (manufacturer, distributor, or seller of the medicinal products) are null and void if gross negligence of the debtor exists (*Article 115, Code of Obligations*).

Moreover the seller is not liable for defects known to the buyer at the time of purchase. The seller is only liable for defects the buyer should know on detailed examination if the seller guaranteed the non-existence of such defects (*Article 222, Code of Obligations*).

Consumer law

A seller is not bound to the content of a statement if the seller establishes (*Article 9, Consumer Law*):

- It is not aware of statements made in publications which the seller did not produce and cannot be expected to be aware of these statements.
- The statement's content was corrected when the contract was entered into.
- There is no causal link between the statement and the decision to enter the sale contract.

The Consumer Law states that manufacturers or importers will not be liable if they can prove the defect occurred after releasing the product onto the market (Article 11, Consumer Law).

24. How can a product liability claim be brought?

Limitation periods

Different limitation periods apply according to the type of the liability.

Tort, auxiliary person liability and risk liability. A two year limitation period applies for bringing product liability claims for all liability arising out of tort, auxiliary person liability, and risk liability provisions (*Article 72, Code of Obligations*). The period begins when the claimant becomes aware of both the damage and identity of the person who caused the damage. Claims become time barred ten years after being initiated.

Product liability. Under the Draft Product Safety Law, provisions of the Code of Obligations pertaining to tortious acts will apply for determining the amount of the material and moral indemnities to be paid for the loss caused by a non-complying product, as well as the limitation period (*Article 7(5), Draft Product Safety Law*). Accordingly, a two year limitation period applies for bringing product liability claims (*Article 72, Code of Obligations*). The period begins when the claimant becomes aware of both the damage and identity of the person who caused the damage. Claims become time barred ten years after being initiated.

Contractual liability for defective products. A two year limitation period applies for bringing product liability claims (*Article 231, Code of Obligations*) for liability arising out of defective products, unless the seller undertakes a longer period. However, if the seller sells the product with gross fault, the two year limitation period to initiate a claim will not apply.

Consumer law. If a consumer bases a claim on the Consumer Law, the limitation period for making a claim is two years from the date the consumer receives the defective product (unless a longer term is determined by legislation or in the contract). The two year period begins on that date, even if the defect appears later. However, if the defect was hidden with gross fault or fraud, no limitation period will apply.

Class actions

The concept of a class action is applied in Turkey in a different way to common law jurisdictions. Under the Code of Civil Procedure No. 6100 (Civil Procedure Code), associations and legal entities can initiate a class action within the framework of their status and on behalf of themselves to protect their members' and associates' rights to remove an illegal situation, or to prevent any future breach of their rights (*Article 113,Civil Procedure Code*). Claims can seek to establish a right or legal status, cessation of unlawful acts, or prevention of unlawful acts which are deemed imminent.

Therefore, consumer associations can bring class actions in Turkey to protect their members' interests, to determine consumer rights or to eliminate an illegal situation or prevent a breach of a consumer's future rights.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Code of Obligations

Tort, auxiliary person liability, and risk liability. Claimants can bring a general claim based on tort, auxiliary person liability or risk liability for damages and losses incurred, both for material and immaterial damages. No minimum threshold exists for the damage or losses which must exist in order to bring such a claim. The judge determines compensation in each case by evaluating the case's elements. Punitive damages are not permitted in Turkey.

Contractual liability for defective products. If a defect is revealed in a product, sellers must perform whichever option the claimant chooses (*Article 227, Code of Obligations*):

- Rescind the contract by returning the purchased products.
- Claim a discount from the sale price proportional to the defect.
- Claim free repair of the products.
- If possible, request the product be exchanged for a non-defective version.

Draft Product Safety Law

Claimants will be able to bring a general claim based on product liability for damages and losses incurred, under the Draft Product Safety Law (*Article 7, Draft Product Safety Law, if enacted in current form*).

Consumer Law

If a defect is revealed in a product, the Consumer Law grants optional rights to consumers, and sellers must perform whichever option the consumer chooses (*Article 11, Consumer Law*):

Terminate the contract, stating that the consumer is ready to return the product.
Keep the defective good, but request a discount on the sale price proportional to the defect.
Request the good be repaired at the seller's expense, provided an excessive expense is not required.
If possible, request the good be exchanged for a non-defective version.
Consumers' right to free repair and exchange with a non-defective version can also be exercised against the product's manufacturer or importer (Article 11, Consumer Law).

If the consumer is aware of a product defect when entering the contract (or is expected to be aware), the consumer is deemed to have accepted the product as is, without any contradiction of the contract. The consumer's optional rights are reserved for other unknown defects (*Article 10(2), Consumer Law*).

Reform

26. Are there proposals for reform and when are they likely to come into force?

No proposals for reform exist or are expected in the short term. However, minor amendments of existing laws and regulations may occur.

A draft law amending the Code on Pharmaceuticals and Drugs is currently being considered by the commission of the Grand National Assembly. The proposal is the insertion of braille forms in packages, and a prospectus to support people with limited vision.

A draft Law on Personal Data Protection is currently being considered by the commission of the Grand National Assembly. It is expected to be enacted in the near future.

A draft Regulation on Processing of Personal Health Data and Protection of Data Privacy has been released to the public. However, it is not yet on the Grand National Assembly's agenda.

A draft Law on Product Safety and Technical Regulation is expected but is not yet on the Grand National Assembly's agenda.

In January 2015, the Ministry of Health announced the e-pulse project (Communiqué No. 2015/5). The project will allow each person to access and manage their own health records. It aims to improve health service provision by:

- Reducing the length of diagnosis and treatment.
- Preventing repetition of unnecessary examinations.
- Protecting a patient's economic benefits.
- Positively contributing to the government budget.

A draft Law was submitted to parliament in March 2013 and is currently on the Grand National Assembly's agenda. The draft Law proposes to amend certain articles of:

- Decree Law No. 551 pertaining to the Protection of Patent Rights.
- Decree Law on the Protection of Trade marks No. 556.

Related Practices

- Commercial Contracts

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