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Contributing editor
Alexander Ehlers

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Publisher
Tom Barnes
tom.barnes@lbresearch.com

Subscriptions
Claire Bagnall
claire.bagnall@lbresearch.com

Senior business development manager
Adam Sargent
adam.sargent@gettingthedealthrough.com

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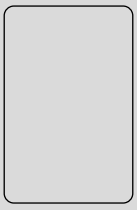

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Alexander Ehlers
Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB

Lexology Getting The Deal Through is delighted to publish the eleventh edition of Life Sciences, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Belgium and Israel.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB, the contributing editor, for his continued assistance with this volume.

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For further information please contact editorial@gettingthedealthrough.com

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Turkey

Özge Atılgan Karakulak and Dicle Doğan
Gün + Partners

ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

1 | How is healthcare in your jurisdiction organised?

The healthcare system is governed principally by the Fundamental Law on Healthcare Services No. 3,359, which furnishes the Ministry of Health (MoH) with the authority to issue healthcare-related regulations and establish a healthcare system enabling each and every person living in Turkey to have equal and equitable access to the healthcare system. The regulatory authority is the MoH and its subsidiaries.

The MoH is responsible for establishing hospitals and public health institutions to provide healthcare services to the public. In addition to public hospitals and healthcare institutions, universities with medical faculties may also establish hospitals under the authority granted to universities by the Higher Education Law No. 2,547, and this system is also quite common in Turkey. Private hospitals and healthcare institutions are also common in places where the purchasing power of the population is high.

There has been a fundamental change in the structure of the MoH in 2011. The authorities of the General Directorate of Pharmaceuticals and Pharmacy of the MoH have been transferred to the Turkish Pharmaceuticals and Medical Devices Agency (Agency). In line with the amendment, the Agency undertakes the following duties in general:

- granting licences or authorisations, monitoring and imposing sanctions where necessary and setting forth the standards for licensing, pricing, manufacturing, storing, sales, import, export, marketing, distribution, promotion, monitoring, recall and usage-related activities regarding the products falling under the authority of the Agency (pharmaceuticals, medical devices, cosmetics, traditional herbal medicinal products and all other products marketed with a health claim);
- regulating, approving and controlling clinical trials with regard to the products falling under its authority; and
- taking the necessary precautions to maintain the accessibility of pharmaceuticals, medical devices and other products that are of vital importance.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

The active population, retirees and their dependants are covered by the health insurance provided by the Social Security Institution (SSI). Employers must pay monthly contributions for their employees, who automatically become covered by the health insurance provided by the SSI; the self-employed may also benefit from this insurance coverage by voluntarily paying monthly contributions. The health insurance provided by the SSI covers practically every physical exam, test and treatment option (both outpatient and inpatient) conducted at public healthcare institutions and university hospitals, apart from those that are not necessary for the health of the insured person, such as cosmetic operations. The SSI also covers emergency services given to the insured at private health institutions.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

According to the Fundamental Law on Healthcare Services No. 3,359, the public healthcare institutions are established by the responsible authority which is the MoH.

A big proportion of the public is covered by the SSI health insurance, while only a small proportion benefits from private insurance coverage by paying monthly contributions.

A new plan, the General Health Insurance, has been in place since January 2012, and accordingly every citizen in Turkey is now under SSI health insurance coverage. The aim is that all citizens who were not covered by the SSI health insurance packages now benefit from public health insurance.

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

The authority to grant licences to private hospitals and healthcare institutions is given to the MoH under the Regulation of Private Hospitals. Additionally, universities with medical faculties may also establish hospitals under Higher Education Law No. 2,547. The authorisation procedure of health services are governed by the Regulation of Private Hospitals that provides a detailed description of the licence application procedure. According this Regulation, the MoH is entitled to grant licences for private hospitals. The applicant, who may be a private legal entity or a real person, has to obtain preliminary permission from the MoH concerning construction plan prior to the licence application.

Concerning other types of healthcare institutions, authorisation procedure may slightly vary as each institution regulated separately.

Structure

5 | Which types of legal entities can offer healthcare services?

Legal entities that are entitled to offer healthcare services are mainly governed by Fundamental Law on Healthcare Services No. 3,359. However, different entities are regulated by different regulations. Accordingly, public hospitals, private hospitals and training and research hospitals offer full healthcare services. On the other hand community

health centers, homecare services, medical clinics, dental clinics, dialysis centers, assisted reproduction treatment centers and dispensaries generally offer healthcare services limited to their specialisation.

Requirements for foreign health services providers

6 What further steps are necessary for foreign companies to offer health services?

The regulatory framework on granting licences for private health care does not allow foreign companies to offer healthcare services. According to the Regulation on Private Hospitals, companies shall be established in Turkey and have to be registered to the Turkish Trade Registry in order to apply for a licence.

ADVERTISING

Legislation

7 Which legislation governs advertising of medicinal products to healthcare professionals?

In Turkey, advertising of medicinal products is governed by Pharmaceutical and Medical Preparation Law No. 1,262, and the Regulation on Promotional Activities of Medicinal Products for Human Use (Promotion Regulation), which is based on the former. The Promotion Regulation was published and came into effect on 3 July 2015. For further information about the important amendments, see question 16.

Further, the Act on Protection of Consumers, Regulation on Principles and Fundamentals of Practices regarding Commercial Advertisements and Announcements, and Code of Obligations are applicable where a matter is not regulated under Law No. 1,262 or the Promotion Regulation. Additionally, the Supreme Council of Radio and Television (RTUK) is authorised to conduct examinations for radio and television broadcasts regarding the determination of advertisements that breach the principles set out in the Law on Establishment and Broadcasting of Radio and Television Institutions No. 6,112 (RTUK Law). As per article 11/2 of the RTUK Law, no advertisements for prescribed medical products or treatments can be broadcast. There are also three industry-based associations in Turkey:

- the Turkey Pharmaceuticals Industry Association (TISD);
- the Association of Research-Based Pharmaceutical Companies (AIFD); and
- the Pharmaceuticals Manufacturers Association (IEIS), which have their own codes of promotional practices.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The fundamental rule is that marketing authorisation or marketing authorisation holders and their representatives may not provide, offer or promise benefits to healthcare professionals by way of promotional activities, as explained in further detail in question 16. According to the Promotion Regulation, products that are not granted permits or authorisation in Turkey cannot be promoted (off-label promotion is strictly forbidden), and that advertisements directed at healthcare professionals must contain information consistent with the products approved, and an updated summary of product characteristics (SmPC).

Promotion must be aimed at healthcare professionals, and shall include objective, informative and factual medical data to enable the healthcare professionals to form their own opinion about the product. The promotional activities shall not be used to encourage unnecessary use of a product, and the promotion must be made by certified representatives.

The mandatory certification of the sales team is a requirement that was foreseen by the former regulation as well. All promotion representatives shall receive certificates if they are successful in the examination or upon submission of diplomas from the departments of universities educating medical sales representatives. The examinations required for such certification is conducted according to guidelines published by the MoH and based on the Promotion Regulation. Individuals without the aforementioned certification are not able to work as promotion representatives for medicinal companies.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

The long-awaited Regulation on the Sale, Advertisement and Promotion of Medical Devices came into force on 15 May 2014 and was amended on 25 July 2015 and 22 September 2016. The advertisement and promotion of medical devices were previously unregulated, leading to a lack of uniformity in practice across the Turkish medical devices' market. A distinction that has been introduced specifically for the medical device regulatory regime is a provision that distinguishes between medical devices that can be advertised to the public and those that are prohibited from being advertised. Medical devices that must be used or administered exclusively by healthcare professionals and medical devices within the scope of reimbursement cannot be advertised to the public, either directly or indirectly. However, the advertisement of devices intended for personal use and that do not fall within the scope of reimbursement is allowed. Regarding this distinction, the Regulation on the Sale, Advertisement and Promotion of Medical Devices finds a balance between the severe restrictions applied to pharmaceutical products and a more variable approach that is better suited to the medical devices industry, which encompasses thousands of different products.

The term 'promotional activities for medical devices' covers the promotion of medical devices that fall within the scope of the Regulation on the Sale, Advertisement and Promotion of Medical Devices to healthcare professionals and technical staff working in the medical device field who are employed by healthcare institutions and organisations, and activities intended to inform these people on subjects such as operating manuals. Technical support services and clinical support services are not regarded as being within the scope of promotional activities. The Regulation on the Sale, Advertisement and Promotion of Medical Devices introduces rules and principles that relate to promotion to and relationships with healthcare professionals (eg, promotional materials, scientific and educational activities, activities taking place in simulation or cadaver centres, sponsorships, free samples and donations) that are similar to the established rules and principles applied to the pharmaceuticals sector. Consequently, medical devices are now also subject to provisions that have been modelled on pharmaceutical practice and that are unique to Turkey, including the maximum monetary value applied to reminder promotions directed at healthcare professionals, quotas relating to the amount of congress sponsorships that healthcare professionals can make use of each year, and transparency and notification obligations.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

The biggest step regarding the digitisation of healthcare services is taken by the MoH. In 2015, the MoH introduced the E-Nabız (e-Pulse),

which is a personal health record system. E-Nabız stores encrypted personal health records and helps patients to access and review their records such as laboratory tests, prescriptions, previous diagnosis and X-ray results. The system also allows patients to:

- switch doctors and determine which doctors will be authorised to access such information;
- manage their own data; and
- request amendments to, or the deletion of, the data.

The data is encrypted and patients are able to access their data only by entering their e-government password.

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

Personal Health Data Regulation No. 30,808, published in the Official Gazette on 21 June 2019 and Circular No. 2016/6 on the E-Nabız Personal Health System, is the legal basis governing E-Nabız. The Circular mentions that the fundamental aim of E-Nabız is to ensure a citizen's right to access and manage their personal health records pursuant to article 20 of the Constitution on the personal data. The system is accessible 24 hours a day, seven days a week and free of charge through computers, mobile phones and wearable technology. According to MoH Health Information Systems Department statistics, it is expected that by the end of 2019, 10 million citizens will use E-Nabız.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

On 7 April 2016, Data Protection Law No. 6,698 (Data Protection Law) came into force. The Data Protection Law regulates the protection of personal data and created new obligations that persons or entities dealing with personal data must comply with.

The Data Protection Law has been prepared in line with EU Directive 95/46/EC on data protection (EU Data Protection Directive), rendering it similar to the EU Data Protection Directive. However, the Data Protection Law is not idential to the EU Directive.

The Turkish Data Protection Authority (DPA) was granted the powers to implement the Data Protection Law. Accordingly, the Turkish DPA may investigative powers in order to ascertain whether data controllers and data processors are in compliance with the provisions of the Data Protection Law and, if deemed necessary, it may implement temporary preventative measures.

Pursuant to article 6 of the Data Protection Law, personal data relating to health, sexual life, biometric and genetic data are deemed sensitive personal data. While sensitive personal data other than data relating to health and sexual life may be processed without seeking explicit consent of the data subject in the cases provided for by other laws, personal data relating to health and sexual life may only be processed without seeking explicit consent of the data subject, by persons or authorised public institutions and organisations that have a confidentiality obligation explicitly for the purposes of:

- protecting public health;
- the facilitation of preventive medicine;
- medical diagnosis;
- treatment and nursing services; and
- the planning and management of health-care services, including their financing.

Restrictions brought under the Data Protection Law leave limited room for processing health data without explicit consent. Unfortunatly, to date, the DPA has issued no specific guidiance or rules focusing on data protection in the healthcare sector.

On the other hand, the MoH has issued Personal Health Data Regulation No. 30,808, published in the Official Gazette on 21 June 2019, which aims to regulate the procedures and principles to be followed in the processes and practices carried out by the central and provincial organisational units of the MoH and the health service providers operating in conjunction with them.

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

On 30 December 2017, the DPA issued the Regulation on Data Controllers' Registry that provides details of the obligations that data controllers must comply with. Data controllers must appoint either a contact person or an authorised representative depending on whether the data controller is based inside or outside of Turkey. This person's name and contact details shall be published online and they shall be responsible for establishing the communication between the data subjects and the data controllers. However, this person is not a data protection officer as defined by Regulation (EU) 2016/679 (General Data Protection Regulations).

Even though the MoH published a personal health data regulation aiming to regulate the procedures and principles to be followed in the processes and practices carried out by the central and provincial organisations units of the MoH and the health service providers operating in connection with them, the rules mentioned in this regulation are merely a replica of the rules set by the Data Protection Law.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

The DPA has already started to investigate and issue decisions on matters brought to the authority's attention and on matters examined ex-officio. However, to date, no decision has been issued against a healthcare provider.

In practice, both patients and companies notice that healthcare providers do not convey information to their patients according to the obligations set by the Communiqué on the Obligation of Information. Even if they do, such information lacks important provisions and fails to inform data subjects in a transparent manner. In addition, despite the Data Protection Law being in force for three years, it is deemed that healthcare providers took no measures to protect patients' personal data.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The Promotion Regulation governs the relationship between pharmaceutical companies and healthcare professionals.

The ethical principles set out by medical associations of which the healthcare professional is a member also apply to this relationship.

If a service to be rendered by the healthcare professional for the pharmaceutical company is concerned, Law on Public Officials No. 657

or Higher Education Law No. 2,547 may also be applied, since the rules set forth in this legislation provide limitations regarding the working principles of healthcare professionals.

The Regulation on Ethical Principles of Conduct and Procedure and Principles of Application will also apply to the relationship between a healthcare professional who is a public official and a pharmaceutical company.

There is no difference to the rules applicable to physicians in the outpatient or inpatient sectors.

Collaboration with healthcare professionals

16 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals?

The Promotion Regulation imposes limitations on the relationship between pharmaceutical companies and healthcare professionals. The fundamental rule is that marketing authorisation holders and their representatives cannot provide, offer or promise benefits to healthcare professionals by way of promotional activities. The marketing authorisation holder shall not encourage the prescription of its products by offering any kind of benefit to a healthcare professional. In this regard, the value of the reminder promotional materials, may not exceed 2.5 per cent of the applicable minimum wage per month. Moreover, with the amendment to the Promotion Regulation, the limitations regarding congress and symposium sponsorships are further extended. Namely, a healthcare professional may benefit from sponsorships only four times in one year, and at most twice from the same pharmaceutical company. In addition, only two out of these four sponsorships may be used abroad. However, organisations that healthcare professionals attend as a speaker are not limited by the above rule.

With regard to the seasons, as per article 5 of the Promotion Guidelines, congresses and symposia cannot be organised at certain times of the year at ski or coastal holiday resorts. All organisations have to be notified to the MoH. Furthermore, healthcare professionals have to state the support that they have been given by the pharmaceutical companies at the beginning of their presentations and at the end of their articles, as per the amended version of the Promotion Regulation.

Regarding services to be rendered by healthcare professionals to a pharmaceutical company, a law that was published in January 2014 banned physicians working in state or university hospitals from working privately, and a transitional period was granted to those physicians who held private clinics to close them by 18 April 2014. Just before the expiry of the transitional period, the Constitutional Court stayed the law's execution ordering physicians to close their private clinics by 18 April and recently cancelled the article granting this transitional period. However, the provision banning state and university physicians from having private practices remains in force.

As a result of this Court decision, physicians with private clinics founded before the publication of the said law, do not have to close those clinics. However, it has stated that the provision banning state and university physicians from private practice is still in force.

The most important change introduced by the Regulation is the obligation of disclosure. Together with article 11/7 of the Promotion Regulation, value transfers (in cash or in kind) that are provided to healthcare professionals, healthcare institutions and organisations, universities, unions, associations and foundations active in the field of healthcare and non-governmental organisations established for the purpose of the protection and the advancement of health, by the marketing authorisation holders, exceeding 10 per cent of the applicable gross monthly minimum wage in terms of its monetary value shall be disclosed to the institution. The disclosure of value transfers for a calendar year shall be submitted within the first six months of the subsequent year. The system of disclosure introduced by the Promotion Regulation only necessitates the disclosure of information by the marketing authorisation holders to the institution, without providing for an additional mechanism for disclosure to the public.

Collaboration with patient organisations

17 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There are no official regulations regarding the collaboration of the pharmaceutical industry with patient organisations. However, industry associations such as TISD, AIFD and IEIS have their own codes of practice that govern relations with patient organisations. According to the AIFD Code of Ethics, if a pharmaceutical company decides to provide support to a patient organisation, either financially or through rendering services, a written agreement shall be signed between the parties. Pharmaceutical companies shall not have an influence on the content of the printed or visual materials of a patient organisation to gain commercial advantages, and cannot stipulate being the sole supporter of a patient organisation or a project.

Common infringements

18 What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare professionals?

The most common infringement with regard to collaboration with healthcare professionals is seen in congress-symposium sponsorship relations. These congresses and symposia, which at times have only a minimal scientific purpose, have sometimes been used as a way to offer holidays or extra benefits to healthcare professionals.

Together with the new Promotion Regulation, marketing authorisation holders may organise or sponsor scientific meetings held abroad on the condition that the meeting is international, or a majority of the participants are healthcare professionals not working in Turkey. These conditions are in fact implemented owing to some cases that the institution faced in the recent years. This provision will avoid the global companies to be the sponsor for the organisation of these meetings and Turkish companies affiliated to these global companies to be the sponsor to all of the participant healthcare professionals working in Turkey.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

Similar to the Pharmaceutical Promotion Regulation, the Regulation on the Sale, Advertisement and Promotion of Medical Devices governs the relation between medical devices manufatureres and the healthcare professionals. For further information, see question 9.

There are no official regulations regarding the collaboration of the medical devices manufacturers with patient organisations. However, industry associations such as the Association of Research Based Medical Technologies Manufacturers (ARTED), a MedTech Europe member, have their own codes of practice that also govern relations with patient organisations. According to the ARTED Code of Ethics, if a member medical device company decides to provide a donation to a patient organisation or a non-profit organisation, a written agreement shall be signed between the parties.

COMPETITION LAW

Authority enforcement

20 | Are infringements of competition law by healthcare providers pursued by national authorities?

The Turkish Competition Law is applicable to all undertakings that operate in a market for goods or services within the borders of Turkey. The Turkish Competition Authority (TCA) is the public authority to monitor and maintain the competition in the market.

In Turkey, public hospitals shall not be considered as an undertaking in terms of Competition Law, since they are non-profit organisations. As for private hospitals and clinics, in many TCA decisions 'private hospital management' is deemed a market service. Accordingly, private hospitals and clinics, and the companies that operate them, are subjected to the Turkish Competition Law.

In recent years, most TCA decisions regarding the private hospital management market deal with the merger and acquisition of private hospitals. However, as an undertaking operating in a market of service in Turkey, a private healthcare provider may be pursued by the TCA as an investigation ex officio initiated by the TCA itself, or upon a complaint that can be made by anyone (in most cases, by competitors).

Once the infringement of competition is established, the TCA can impose sanctions including heavy administrative fines on companies and board members, and may invalidate the relevant contract or transaction which causes to the infringement.

Private enforcement

21 | Is follow-on private antitrust litigation against healthcare providers possible?

According to article 57 of the Competition Law, anyone who prevents, distorts or restricts competition through practices, decisions, contracts or agreements contrary to this law, or abuses a dominant position in a particular market for goods or services, is obliged to compensate any damages to injured parties. Parties who claim that they have suffered damages and loss arising from anticompetitive acts of manufacturers may claim compensation by filing a lawsuit before the courts. Accordingly, the injured party may ask for an amount equal to three times the actual loss incurred.

Anti-corruption and transparency

22 | What are the main anti-corruption and transparency rules applicable to healthcare providers?

Under Turkish law, there is no umbrella legislation that covers every type of anti-corruption issue. Crimes such as bribery and official misconduct are punishable according to Turkish Criminal Code No. 5,237, regardless of the sector in which they are committed. In terms of bribery regulated under article 252 of Turkish Criminal Code No. 5,237, any kind of benefit provided for executing a legal transaction, which should be executed or vice versa, is prohibited with a zero-tolerance approach. In addition to the Turkish Criminal Code, the Regulation on the Code of Ethics of Public Officials and Application Procedures and Principles is establishing the basic principle for public officials not to receive or give gifts and not to derive interest as a result of their duty. This Regulation also defines a black list of all sorts of goods and benefits that public officials cannot receive.

In order to guide pharmaceutical companies interacting with healthcare professionals, the MoH defined sector-specific rules. In this sense, provisions regarding promotional interactions like congress sponsorship of healthcare professionals, donations made to healthcare organisations, as well as all kinds of promotional materials that can be given to healthcare professionals are regulated under the Promotion Regulation.

As explained in question 16, on 3 July 2015, the MoH introduced a requirement to disclose to the Institution, transfers of value made to healthcare professionals by pharmaceutical companies. Companies started documenting transfers of value made in 2016 and submitted this documentation in 2017. This data is not intended to be disclosed to the public at this stage, but will be reviewed and retained by the MoH.

PRICING AND REIMBURSEMENT

Price regulation

23 | To what extent is the market price of a medicinal product or medical device governed by law or regulation?

The principles for determining pharmaceutical prices were set by the Council of Ministers in the Pricing Decree and in the Pricing Communiqué published by the MoH based on the Pricing Decree. However, as a result of the referendum, held on 16 April 2017, an amendment has been made to the Constitution and a transition has been made to the Presidential Government System. The most fundamental feature of this system is the transfer of all executive authorities to the President with the annulment of the office of Prime Ministry. The President has become both the head of state and the head of executive power. Consequently, the rules and procedures for determination of pharmaceutical prices, are determined by the President, not by the Cabinet of Ministers.

The MoH is still applying the reference price system. The maximum sales prices of pharmaceutical products are determined by taking into account the lowest price of the product available on the market respectively in the reference countries (France, Greece, Italy, Portugal and Spain) and the countries of batch release and import. Where this is not available, the lowest price of the product available in EU countries – or failing that, the ex-factory price (the sale price to wholesalers) of the product available on the market in any country across the world. The reference price takes the active substance into consideration for each product. Then it determines the price of different forms and dosages of this active substance by using a proportioning method.

The price of an original pharmaceutical is revised and becomes at most 60 per cent of the reference price upon the launch on the market of its first generic.

One of the most discussed topics relating to pharmaceutical pricing in Turkey is the euro and Turkish lira currency rate (Fx rate) determined by the Price Assessment Commission competent for calculating the price of a product. According to the Pricing Decree, the Fx rate should be adapted to currency fluctuations. However, the Fx rate set to 1.95 Turkish lira in 2007 was not amended until 2009. The industry formally requested the MoH to change the Fx rate. Upon rejection of this application, the industry associations filed an action against the MoH. The Council of State examining the case held its decision in favour of the industry and decided that the Pricing Assessment Commission should render a new decision with respect to the determination of the Fx rate. The Pricing Assessment Commission decided not to change the Fx rate. Although the administration bodies should comply with Court decision, because the Council of State's decision indicated taking a decision regarding the matter, the Pricing Assessment Commission was, in theory, not in contradiction with the Court's decision. However, the industry associations filed a new action against the MoH, which was again accepted. During this process, the Pricing Assessment Commission set the Fx rate to 2 Turkish lira and then to 2.07 Turkish lira.

The Pricing Decree was amended in July 2015 and the Fx rate was accepted as 70 per cent of the average annual euro value. Accordingly, the Price Evaluation Commission would gather within the first 45 days of every year and announce the 1 euro value based on a calculation of 70 per cent of the average value of the previous year.

However, an amendment was published in the Official Gazette on 14 February 2019 and the rate of 70 per cent given in the Decision was changed to 60 per cent. Hence, the new exchange rate for 2019 was announced as 3.40 Turkish lira, with an increase of 26.4 per cent compared to that of 2018.

Negotiations between manufacturers and providers

24 Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

According to the reference price system for pharmaceuticals, the maximum price of a pharmaceutical is automatically determined. Therefore, there is no place for negotiation in the system. Manufacturers are free to sell their products below the ceiling price determined through the reference price system.

On the other hand, complementary provisions were introduced with the Regulation on the Alternative Reimbursement of Pharmaceuticals published in February 2016 allowing companies and the SSI the benefit of discussing the terms and conditions of an alternative reimbursement model for special products. The ultimate aim of the system is to provide quicker access to patients of innovative drugs with respect to their reimbursement. The price set is confidential.

As to medical devices, product prices are not determined by the MoH. However, medical device companies may negotiate with the reimbursement authority and set a discounted price for their products.

In all cases, public healthcare providers must follow the public tender procedures and, as a general rule, the participant company offering the lowest price in the tender is awarded the tender.

Reimbursement

25 In which circumstances will the national health insurance system reimburse the cost of medicines?

The cost of medicines is reimbursed, provided that they are registered on the SSI reimbursement list.

Price adjudication

26 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The MoH, through the institution, is the competent authority regarding the pricing of medicinal products. The competent body for reimbursement decisions is the SSI. There are also two important committees:

- the Pricing Committee, which is coordinated under the authority of the MoH and involves the participation of delegates from the Ministry of Finance, the Ministry of Development, the Secretariat of Treasury and the SSI; and
- the Reimbursement Committee, which is organised by the Ministry of Finance and includes delegates from the MoH, the Ministry of Development, the Secretariat of the Treasury and the SSI.

These Committees review the applications and approve their conformity in line with the related pricing and reimbursement legislation.

Discount

27 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

According to the Health Implementation Communiqué, the discount rate applied to original pharmaceuticals where no generic version is on the market is 41 per cent in total (11 per cent base discount plus a 30 per cent additional discount), and 28 per cent (11 per cent base discount plus a 17 per cent additional discount) for original products where the generic version is on the market. Twenty-eight per cent (11 per cent base discount plus a 17 per cent additional discount) of the discount is applied to generic products.

The applied discount rates may differ according to the type of product, for example, pharmaceuticals that are more than 20 years old, over-the-counter pharmaceuticals or blood-derivative products.

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AVUKATLIK BÜROSU

Özge Atılgan Karakulak
ozge.atilgan@gun.av.tr

Dicle Doğan
dicle.dogan@gun.av.tr

Kore Şehitleri Cad 17
Zincirlikuyu 34394
Istanbul
Turkey
Tel: +90 212 354 0000
Fax: +90 212 274 2095
www.gun.av.tr

UPDATE AND TRENDS

Key developments of the past year

28 Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

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

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

During the course of 2019–20, there may be some amendments to the rules on pharmaceuticals' market access and promotion.

On 9 May 2019, the Agency published its draft Regulation on Sales, Advertisement and Promotion of Medical Devices owing to problems arising from the current law's implementation. The draft updated regulation preserves many provisions of the current regulation. However, there are a few amendments to the existing provisions and new articles are also introduced. The draft regulation has been open to public consultation and is expected to be published in 2019 or early 2020.

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