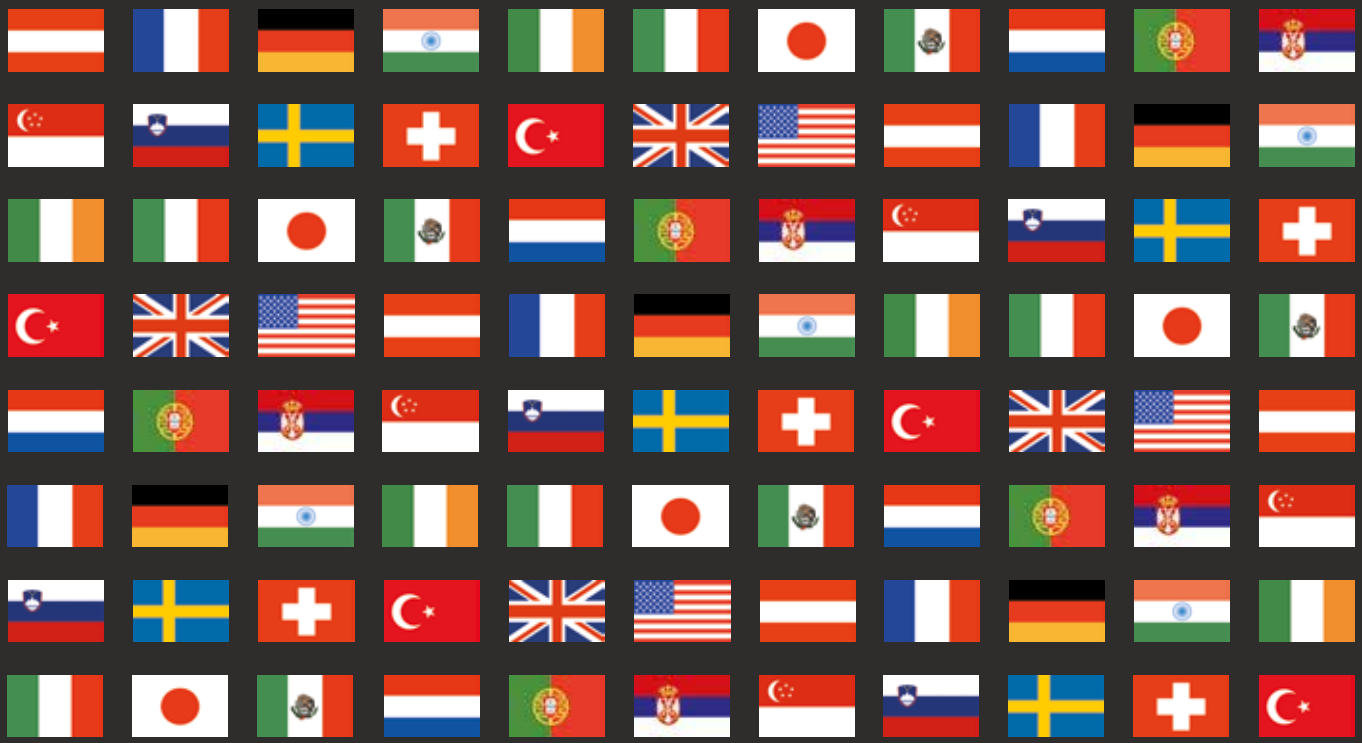
Life Sciences

Contributing editor
Alexander Ehlers



2019

GETTING THE DEAL THROUGH

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Life Sciences 2019

Contributing editor

Alexander Ehlers

Ehlers, Ehlers & Partner Rechtsanwaltsgesellschaft mbB

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This article was first published in January 2019
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Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 3780 4147
Fax: +44 20 7229 6910

First published 2009
Tenth edition
ISBN 978-1-78915-040-7

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

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Preface

Life Sciences 2019

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

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 **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 a new chapter on Serbia.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

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.

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.

GETTING THE DEAL THROUGH

London
November 2018

Turkey

Özge Atılgan Karakulak and Dicle Doğan

Gün + Partners

Organisation and financing of healthcare

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, 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 Institution (the Institution), which was established by Decree Law No. 663. In line with the amendment, the Institution 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 Institution (pharmaceuticals, medical devices, cosmetics, traditional herbal medicinal products, 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.

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.

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.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

In Turkey, advertising of medicinal products is governed by Pharmaceutical and Medical Preparation Law No. 1262, 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 9.

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. 1262 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. 6112 (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.

4 What are the main rules and principles applying to advertising 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 9. 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 will be conducted according to Guidelines published by the MoH and based on the Promotion Regulation. The effective date

of the provision coming into force has been delayed until 1 January 2019 in order to establish the implementation system. Once this date has passed, individuals without the aforementioned certification will not be able to work as promotion representatives for medicinal companies.

5 What are the main rules and principles applying to advertising aimed at the general public?

According to the Pharmaceutical and Medical Preparations Law No. 1262 and the Promotion Regulation, it is strictly forbidden to promote medicinal products for human use to the general public. Over-the-counter products are categorised as non-prescribed products and are subject to the same promotion principles as prescribed products. The need for a new law governing over-the-counter products has been under discussion for a long time; however, no official draft has been submitted for comment, and it is therefore unlikely that we will see a new law in the near future.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The Promotion Regulation forbids pharmaceutical companies from making promotional materials available to the public, either intentionally or unintentionally. However, examples of illegal advertising of products can be found, such as in display windows of pharmacies. The other common type of infringement concerns advertisements aimed at healthcare professionals that are not supported with sufficient scientific data. Other than these infringements, occasionally healthcare professionals may be found not to be fully in line with the applicable legislation.

7 Under what circumstances is the provision of information regarding off-label use to healthcare professionals allowed?

According to the Promotion Regulation, off-label promotion is strictly forbidden in Turkey. The only exceptions to this rule are the provision of off-label information during international congresses held in Turkey, or if a healthcare professional has asked for the provision of such information in writing. This prohibition does not prevent the provision of scientific material that contains off-label information to healthcare professionals. Upon the written request of a healthcare professional, the requested information must be delivered by a scientific service representative.

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

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, the Law on Public Officials No. 657 or the Higher Education Law No. 2547 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 in the rules that apply to physicians in the outpatient or inpatient sectors.

9 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 periods during the year in ski centres or at seaside 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 had banned physicians working in state or university hospitals from working privately, and a transitional period was granted to those physicians that held private clinics to close those clinics by 18 April 2014. Just before the expiry of the transitional period, the Constitutional Court stayed the execution of the law 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 NGOs 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.

10 What are the most common infringements committed by manufacturers with regard to 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.

11 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.

12 Are manufacturers' infringements of competition law pursued by national authorities?

The Turkish Competition Law is applicable to the sale of goods and services in Turkey; the sale of goods and services outside Turkey that do not have any effect on Turkish market are not covered by the Competition Law. The Turkish Competition Authority is the body authorised to monitor competition in the market.

Manufacturers' infringements of competition law are pursued by the Turkish Competition Authority as investigations initiated by the authority itself or upon complaints that can be made by anyone (in most cases by competitors).

The Turkish Competition Authority can impose sanctions including heavy administrative fines on companies and board members, and may invalidate the relevant contract or transaction in cases of infringement of competition.

13 Is follow-on private antitrust litigation against manufacturers 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.

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

Under Turkish law, there is no umbrella legislation that covers all types of anti-corruption issues. Crimes such as bribery and official misconduct are punishable according to Turkish Criminal Code No. 5237, regardless of the sector in which they are committed. In terms of bribery regulated under article 252 of the Turkish Criminal Code No. 5237, 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 9, 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.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

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 device 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 very 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.

Pharmaceuticals regulation

16 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The regulatory framework for granting marketing authorisations is governed by the Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation). As for placing a pharmaceutical product on the market, additional regulations, such as the Regulation on Labelling and Packaging of Medicinal Products for Human Use and the Regulation on Safety of Medicines, also apply.

17 Which authorities may grant marketing authorisation in your jurisdiction?

The MoH is the sole authority entitled to grant marketing authorisations for pharmaceutical products in Turkey. The MoH fulfils this duty through the Institution.

18 What are the relevant procedures?

No medicinal product for human use can be marketed unless it is granted a marketing authorisation (licensed) by the MoH pursuant to the provisions of the Licensing Regulation. According to the Licensing Regulation, the eligibility criteria for the persons who may apply for pharmaceutical product licence are as follows:

- natural persons should have a degree from a university providing education in the branches of pharmacy, medicine or chemical sciences and should avail of the authority to practise their profession in Turkey. In line with the related laws, pharmacists should be Turkish citizens able to perform their profession in Turkey. There is no such requirement for chemists. Until quite recently (before the passing of Decree Law No. 663 dated 2 November 2011) only Turkish citizens were allowed to practise as physicians in Turkey; however, foreign physicians may currently conduct their profession in Turkey, under some conditions. This recent amendment is still under discussion; and

- legal persons should employ someone with an 'authorised person' title who has the qualities specified in the above bullet point, and who has sufficient information and experience with regard to the concerned product for which an application is submitted.

The following documents, in general, shall be submitted to the MoH along with the application for the pharmaceutical product licence:

- a notarised copy of the diploma indicating that the applicant may practise one of the professions specified above;
- a certified document indicating that the applicant is authorised to submit an application;
- in the event of the applicant being a legal person, the original version or a copy of the commercial registry gazette indicating the objectives for the establishment of the company, the relevant members, duties and titles of the persons responsible;
- the name or corporate name, permanent address, email address, telephone and fax numbers of the applicant;
- the name, permanent address, telephone and fax number of the manufacturer;
- product-related information, such as:
  - the name of the product;
  - quantitative and qualitative particulars of all the components of the product (except for the empirical chemical formula) and its international non-proprietary name;
  - a description of its manufacturing method;
  - any therapeutic indications, contraindications and adverse reactions;
  - the dosage, pharmaceutical form, method and route of administration;
  - the shelf life and amount in the package;
  - an indication of the disposal method of waste products; and
  - a description of control methods used by the manufacturer (such as sterility tests, tests for measuring the presence of heavy metals, stability tests, biological and toxicity tests);
  - results of physico-chemical or microbiological tests, toxicological and pharmacological tests and clinical trials;
  - a good manufacturing practice (GMP) certificate, issued to the manufacturer by the MoH; and
  - the summary of product characteristics specified in the Regulation on Packaging and Labelling and the patient information leaflet prepared accordingly; the immediate and outer packaging samples with the dimensions and design to be used in the market; and in the case of products authorised abroad and imported or manufactured on licence, the originals of summary of product characteristics, and patient information leaflets from other countries along with their Turkish or English translations, which are declared to have been recently updated;
- in the context of pharmacovigilance practices, the curriculum vitae, address, telephone and fax numbers and job description of the person responsible for product safety; and
- in the context of the Promotion Regulation, the document defining the scientific service and its address, telephone and fax numbers.

In the case of imported products or products manufactured under licence, additional documents are requested from the applicant.

Abridged applications are also possible in Turkey under the conditions set forth in the Licensing Regulation.

The MoH follows the European CTD format (including five modules) for the application files.

The Licensing Regulation envisages a 210-day period for the evaluation of the licence application by the MoH following the preparation of all required documents. In practice, however, this may go up to two years or more due to the GMP certification rules of the MoH, which require that each manufacturing facility be audited by Ministry personnel.

19 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

According to the Licensing Regulation, if the concerned product is not actually placed on the market within three years of the issuance of the licence, the licence may be suspended by the MoH. No exception to this rule is set out in the related regulations. However, the licence is not automatically suspended after the lapse of this three-year period, and the MoH shall issue a decision in this regard in order to suspend the licence.

20 Which medicines may be marketed without authorisation?

Medicines that may be marketed without authorisation are those provided to the patient in the scope of 'compassionate use' or 'named patient use'. The details of these programmes are outlined in question 21.

21 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

The Compassionate Use Programme is regulated under the Guideline on Compassionate Use Programme and is defined as the provision, free of charge, of a pharmaceutical to a patient by the manufacturer or supplier company for humane reasons, where the drug has no marketing authorisation in Turkey. The Compassionate Use Programme is a patient-based programme. The physician applies to the MoH if he or she feels that a product without marketing authorisation in Turkey is necessary for a patient who is suffering from a life-threatening disease, and that they cannot be healed with any authorised product or be included in clinical trials. According to the Guideline, it is not important whether the pharmaceutical product used in the programme is licensed abroad or not. Ideally, at least Phase II trials will have been completed; however, this is not a requirement. During the Programme, only the costs of routine tests may be covered by the patient or reimbursed by the SSI; other than that, no cost can be imposed on the patient or the SSI.

The Guideline explicitly states that compassionate use and off-label use cannot be conducted at the same time.

Another alternative is the 'special importation' of pharmaceuticals that have no marketing authorisation in Turkey, or that have a marketing authorisation but are not marketed in Turkey for various reasons. These products are imported from abroad on a named patient basis. The Guideline regarding the Supply from Abroad and the Use of Pharmaceuticals published by the MoH, establishes that only the Turkish Pharmacists' Association (TEB) and the relevant centre of the SSI could import pharmaceuticals from abroad within the scope of the NPP. The former guidelines allowed 20 pharmaceutical warehouses authorised by the Institution to import pharmaceuticals from abroad on a named patient basis, as well as the TEB. The TEB and the SSI shall import only in the order defined below:

- products that have an authorisation from the US Food and Drug Administration or the European Medicines Agency and are put on the market; or
- products manufactured, authorised and put on the market in a country that is a member of the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme.

The physician of a patient who needs to use such product for his or her treatment under a prescription may apply for its special importation if the physician believes that there is a scientific advantage to importing the pharmaceutical without Turkish marketing authorisation. The results of these applications are collected in a pharmaceuticals list that is published on the Institution's website every Friday.

If the relevant product cannot be found in or supplied from these countries, the commercial name of the product manufactured and used in another country can be added to the Foreign Pharmaceutical List following an opinion from the Scientific Commission and approval of the president of the Institution.

The SSI and TEB signed a protocol in April 2007, which covers the reimbursement conditions for NPP pharmaceuticals imported by the TEB and that is still valid, allowing the reimbursement of NPP products.

Pricing and reimbursement of medicinal products

22 To what extent is the market price of a medicinal product 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, amendments were 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

Update and trends

The Turkish Medicines and Medical Device Institution has shared several draft regulations that have been long awaited by the industry. It is expected that all regulations related to the licensing, pricing and promotion of the products will be amended. In addition, the Institution has shared new regulations regarding homeopathic medicines and dietary food for special purposes, which are currently not regulated in Turkey.

As a result of the referendum held on 16 April 2017, amendments were made to the Constitution and a transition has been made to the presidential government system. It is expected that amendments will be made to all legislation and regulations in order to adapt them to the new system.

has become both the head of state and the head of executive power. Consequently, the rules and procedures for determination of pharmaceutical prices would be determined by the President, not by Cabinet of Ministers. Therefore, a new Pricing Decree and Communiqué is expected to be published by the end of 2018.

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 the EU countries; and where this is not available, the ex-factory price (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 maximum 60 per cent of the reference price upon the launch on the market of its first generic.

One of the most discussed topics related to the pricing of pharmaceuticals 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 the currency fluctuations. However, the Fx rate set to 1.95 in 2007 was still not amended until 2009. The industry formally requested from the MoH to change the Fx rate. Upon the 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 assembled and decided not to change the Fx rate. Although the administration bodies should comply with Court decision, as the Council of State's decision was indicating to take 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 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. The current Fx rate set in January 2017 is 2.34 Turkish lira.

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

According to the reference price system, the maximum price of a pharmaceutical is automatically determined; therefore, there is no place for negotiation in the system. On the other hand, manufacturers are free to sell their products below the ceiling price determined through the reference price system. 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.

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

The cost of a medicine is reimbursed provided that it is registered on the reimbursement list of the SSI.

25 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.

26 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

According to the Health Implementation Communiqué, the discount rate that is applied to original pharmaceuticals where no generic version is on the market is 41 per cent in total (11 per cent base discount plus 30 per cent additional discount), and 28 per cent (11 per cent base discount plus 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 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 over 20 years old, over-the-counter pharmaceuticals or blood-derivative products.

Medicine quality and access to information

27 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

Under article 18 of Law No. 1262 (as amended in January 2014), the sale of counterfeit medicines is subject to an administrative fine ranging from a minimum of 100,000 Turkish lira up to a statutory maximum of five times the aggregate of the annual sale proceeds of the counterfeit medicine in question. If the infringing acts are repeated, an administrative fine of twice the amount of the original fine will be issued. In a situation where the counterfeit medicines are being sold or distributed online, access to the infringing website will be blocked.

The counterfeiting and illegal distribution of medicines is also subject to the Turkish Criminal Code. According to article 186, any person who sells, procures or stores decayed or transformed foodstuffs, beverages or drugs and thereby causing risk to another's life and health is punished with imprisonment for a period ranging from one to five years and faces a punitive fine up to 150,000 Turkish lira to be paid to the state. The punishment to be imposed is increased by one-third if the offence is committed by a person who is qualified as a professional in his or her business area (eg, if the concerned person is a pharmacist and sells decayed drugs, the punishment will be increased by one-third).

In addition to this, according to article 187 of the Turkish Criminal Code, any person who produces or sells drugs in such a way as to risk another's life and health is punished with imprisonment for a period ranging from one to five years. The punishment to be imposed is increased by one-third if the offence is committed by a physician or pharmacist, or within the scope of a professional activity.

On the other hand, if the name of the medicine is registered as a trademark in Turkey, the use of the trademark on counterfeit products is subject to the general provisions of trademark law regulated under the Industrial Property Law No. 6,769 pertaining to the Protection of Trademarks, Designs and Patents. As per article 29 of the Law, the use of the same or confusingly similar trademarks without the consent of the proprietor of the trademark shall be considered an infringement of the trademark.

Furthermore, if counterfeit medicines are imported into Turkey without being subject to customs procedures, article 19 of Law No. 1262 stipulates that these products will be subject to the general provisions set forth in the Law to Counter Smuggling No. 5607.

28 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

No measure has been taken by the relevant authorities to facilitate public access to information about prescription-only medicine.

29 Outline major developments to the regime relating to safety monitoring of medicines.

As a major development regarding the regime relating to safety monitoring of medicines, the Regulation on the Safety of Medicines (Regulation) came into force on 15 April 2014, and the Regulation now governs pharmacovigilance in Turkey. The Regulation sets forth rules and principles for enabling a systematic monitoring of adverse effects, as well as data collection, recording, assessment, archiving of adverse effects, taking necessary measures so as to minimise the harm caused by medicinal products for human use and to ensure their safe use.

The licence or marketing authorisation holder shall continuously employ an appropriately qualified physician or pharmacist responsible for pharmacovigilance who shall be appointed as the officer responsible for the safety of the products, and this person shall be notified to the MoH along with the licence application. According to the Regulation, the Turkish Pharmacovigilance Centre (TUFAM) is the competent authority to follow the pharmacovigilance reports regarding pharmaceutical products. TUFAM has close connections with those foreign authorities that follow up pharmacovigilance reports, and constantly updates its database.

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

In Turkey, there is no general obligation to vaccinate. However, there is an exception to this principle where article 72 of Public Health Law No. 1593 authorises the MoH to take relevant measures, including administrating vaccines, when an illness specified under article 57 of Law No. 1593 (cholera, plague, prulente meningitis, typhus, etc) threatens public health.

In addition, according to Decree Law No. 663 on the Organisation and Duties of the MoH and its Affiliates, the MoH is entitled to regulate the services to be rendered in terms of vaccination in Turkey. Within this scope, the MoH has a routine vaccination regime called the Extended Immunisation Programme (the Programme). With regards to the Programme, the MoH published Circular 2009/17, dated 13 March 2009. The Circular regulates the procedures and principles regarding administration of vaccines, regulating which vaccines are to be administered as well as their times of administration. It also sets forth the registration and notification principles of the vaccines that are administered. To this end, there are printed forms attached to the circular for use by health professionals authorised to administer vaccines. The circular also determines teams responsible for the execution, monitoring, supervision, evaluation and logistics of the Programme. The managers of these teams are the province health directors in each province. They are primarily responsible for execution of the Programme at provincial level. Similarly, in the districts, the managers of the teams are health group managers, who are responsible primarily at district level. There are also supervisors and assistants who provide support in the provinces and districts. Other than that, family physicians and community health centres have direct duties and responsibilities under the Programme.

In terms of the costs incurred, vaccines are within the scope of social insurance coverage. The SSI pays for the vaccines according to article 2(4)(3) of the Health Implication Communiqué.

Getting the Deal Through

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Private Client
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Product Recall
Project Finance
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Securities Litigation
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ISBN 978-1-78915-040-7