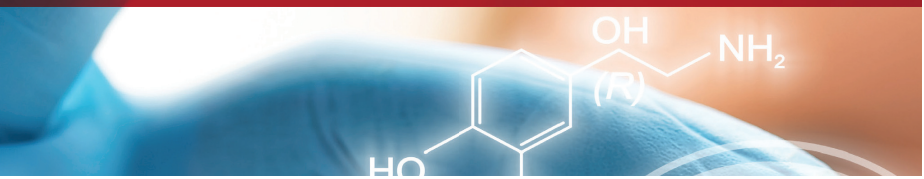
Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance



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Restrictions Under the Pharmaceutical Advertising Law

Introduction

Promotion of pharmaceutical products is a hot topic in Turkey. The new Regulation on the Promotion of the Pharmaceutical Products for Human Use (Official Gazette no. 29405) (the "Pharma Promotion Regulation"), the provisions of which have gradually started to enter into force on 3 July 2015, and will be fully in force as of 1 January 2019, introduced essential changes to the rules regarding the promotion of medicines.

Law no. 6112 on the Establishment and Broadcasting of Radio and Television (the "Broadcasting Law"), which entered into force on 3 March 2011, permits the advertising of non-prescription pharmaceutical products on radio and television. This law has faced opposition from the Turkish Pharmacists Association, as it is claimed to contradict Turkish Law no. 1262 on Pharmaceutical Medicinal Preparations (the "Pharma Law") and is considered to negatively affect public health.

The "full-time law" amending various laws in order to prohibit medical doctors and dentists who are public servants from carrying out other activities has also faced opposition from the Turkish Medical Association, and has recently been revoked by the Turkish Constitutional Court.

This section of this handbook explains the Turkish rules on the advertising and promotion of pharmaceutical products in light of applicable laws and regulations.

The Regulatory Framework

The advertising and promotion of pharmaceutical products for human use are regulated in Turkey by the laws and regulations adopted by the

Ministry of Health, as well as the guidelines adopted by the pharmaceutical industry and the Turkish Medical Association.

In particular, Article 13 of the Pharma Law sets out the general principles for the advertising and promotion of pharmaceutical products. The Pharma Promotion Regulation provides the details of authorized promotional activities for pharmaceutical products.

Additionally, there are codes of conduct and professional guidelines for such activities, such as:

- the Association of Research-Based Pharmaceutical Companies' Good Promotion and Good Communication Principles;
- the Pharmaceutical Industry Employers Syndicate's Regulation on the Promotion of the Pharmaceutical Products and Communications with the Healthcare Professionals (HCPs);
- the Pharmaceutical Industry Association of Turkey's Pharmaceutical
- Products Promotion Guidelines; and
- the Turkish Medical Association's Principles on Medical Doctors and Promotion of Pharmaceutical Products, and its Declaration on the Medical Doctor-Industry Relationship.

The above codes of conduct and professional guidelines are binding only on the members of the issuing associations.

Article 13 of the Pharma Law sets out the following principles for the advertising and promotion of pharmaceutical products:

- Advertisements that misrepresent or exaggerate the curative properties of medicines are prohibited.

- Advertisements of prescription medicines can only be published in medical magazines, with prior approval by the Ministry of Health.

- Motion pictures on the scientific properties of a medicine can be demonstrated only in places approved by the Ministry of Health. (According to Article 5/5 of the Pharma Promotion Regulation, HCPs may only appear in these motion pictures with the prior approval of the Ministry of Health.)

The advertising of non-prescription pharmaceutical products to the public remains an unclear issue in Turkish law. Article 11/2 of the Broadcasting Law prohibits the advertising of prescription medicines. According to this provision: "The commercial communication related to the prescription medicines and treatments are prohibited." Article 11/3 of the same law permits the advertising of non-prescribed medicines with some restrictions, stating: "The advertising of the non-prescription medicines and treatments must be prepared within the framework of good faith principles, as to include elements that are accurate and that may be verified." Furthermore, Article 5/f of the Turkish Radio and Television Authority Advertisement Regulation (published in the Official Gazette no. 27331) restricts the advertisement of prescription medicines, but does not mention any rule or restriction on the advertisement of non-prescribed medicines.

Article 5/3 of the Pharma Promotion Regulation, on the other hand, prohibits the advertising and promotion of pharmaceutical products to the general public without making any distinction between prescription and non-prescription medicines. Moreover, the Pharma Promotion Regulation applies to promotional activities for enteral nutrition (i.e., tube feeding) products and medicinal infant formula, in addition to medicines for human use.

With the exception of: (i) promotional activities carried out during international conferences convened in Turkey; and (ii) informational sessions delivered in person by a marketing authorization holder's science service personnel upon the written request of a medical

doctor, dentist or pharmacist, promotional activities can be carried out only for pharmaceutical products that have been granted marketing authorization in Turkey (Article 6/2 of the Pharma Promotion Regulation).

Subject to the above restrictions, pharmaceutical products (including non-prescription products), enteral nutrition products and medical infant formula can be promoted only to medical doctors, dentists and pharmacists by:

- using promotional materials;
- sponsoring, but not organizing, scientific events or product promotion meetings; and
- product promotion, personnel visits to medical doctors, dentists and pharmacists (Article 5/2 of the Pharma Promotion Regulation).

Such promotional activities must:

- conform to the product's area of use, which must have been approved by the Turkish Medicine and Medical Devices Authority (the "Authority");
- include detailed and evidence-based scientific information on the product, and such information must be presented in a way to enable HCPs to form opinions on the therapeutic value of the product; and
- not include deceptive, exaggerated or unproven information that may lead to an inappropriate use of the product or to unexpected hazardous situations arising, or include images that are not directly related to the product.

If the promotion is in the form of documentation that includes citations from scientific studies, tables or other visual material, such material must conform to the original versions and include full

references to its sources (Article 6/5 of the Pharma Promotion Regulation).

Additionally, marketing authorization holders may financially support scientific activities such as congresses and symposiums, and pay for participants' costs and expenses, such as transportation and accommodation, provided that these activities are not intended to promote a pharmaceutical product. Rules and restrictions applicable to these sponsorships are explained below in more detail.

Permitted and Prohibited Practices

Permitted and prohibited practices relating to the most common promotional activities for medicines are provided under the Pharma Promotion Regulation.

Draws and Lotteries

The promotion of medicines by draws or lotteries is prohibited (Article 6/7 of the Pharma Promotion Regulation).

Donations

Marketing authorization holders may make donations to public health institutions, provided that any such donation:

- does not influence any decisions relating to the issuance of public tenders or cause unfair competition for products that fall within the scope of the Pharma Promotion Regulation;
- does not give rise to unethical behavior that may relate to the sale of the products;
- is not made as an incentive for the prescription of a specific product;
- has the purpose of aiding research or training, or the improvement of health or patient care;

- is intended only for general use and not for the use of an individual;
- does not carry the name of a product (the donated material, however, can carry the name of the marketing authorization holder);
- is recorded in the marketing authorization holder's official records; and
- is made directly to the responsible investigator or coordinator where the donation is provided for use in a clinical trial.

Healthcare institutions can only accept donations with the express permission of the relevant central organization and must act in accordance with the guidelines issued by such central organization.

Gifts

In the context of the promotion of pharmaceutical products to medical doctors, dentists and pharmacists, no monetary or in-kind benefit may be provided, offered or promised. HCPs are prohibited from asking for such benefits (Article 6/8 of the Pharma Promotion Regulation).

HCPs are required to declare the benefits provided to them by marketing authorization holders at the end of the article they have authored, or at the beginning of the presentation they have delivered, whichever is applicable (Article 6/9 of the Pharma Promotion Regulation).

Additionally, Article 29 of the Public Servants Law (Law no. 657) prohibits public servants from receiving or asking for gifts or financial remuneration for performing their duties for anyone who plans to take advantage of such duties. This provision authorizes the Public Ethics Institution to determine the scope of this prohibition. Moreover, Article 15 of the Public Servants Ethic Principles and Application Procedures Regulation (the "Public Servants Ethics Regulation") sets

forth rules on gifts that may be accepted by public servants. Public servant HCPs are also subject to these provisions.

The basic principle for public servants is that they may not receive gifts and not derive any benefit as a result of performing their duty. Article 15 of the Public Servants Ethics Regulation also lists the examples of prohibited gifts, as well as exceptions to this prohibition. Books, magazines, articles, CDs or similar materials; craftworks and advertising materials distributed to the general public which have a nominal value; contributions to public institutions that would not hinder the legal performance of their duty; and financial remuneration received from financial institutions at market conditions are among the exceptions to the prohibition on receiving gifts under this provision.

Seminars, Hospitality and Entertainment

Scientific and educational activities intended for the promotion of pharmaceutical products must be based solely on the area of expertise of the HCPs involved, and limited to the presentation of existing/new information about the products. Those holding marketing authorization are prohibited from sponsoring the participants' registration, transportation and accommodation costs for scientific events. An HCP may, however, benefit from four sponsorships during a year, provided a maximum of two sponsorships are granted by the same marketing authorization holder, and provided only two out of the four sponsorships for participation are for events held outside of Turkey. Events in which an HCP is participating as a speaker or researcher/presenter, with the support of the marketing authorization holder, is outside the scope of these limitations. Marketing authorization holders cannot sponsor the transportation or accommodation costs of participants in product promotion events, with the exception of the aforementioned speakers and researchers/presenters; however, they may sponsor trips by HCPs to production facilities within Turkey, subject to the conditions set forth above (Article 7/2 and 7/3 of the Pharma Promotion Regulation).

Marketing authorization holders can sponsor and/or organize scientific events held outside of Turkey on the condition that the scientific event is of an international nature and the majority of the participating HCPs do not work in Turkey (Article 7/4 of the Pharma Promotion Regulation).

In addition to HCPs, students at universities or vocational schools may also participate in sponsored scientific events, depending on the amount of the sponsorship. In any case, the sponsorship may not be provided directly to the HCPs but to the organizations hosting the meeting (Article 7/5 of the Pharma Promotion Regulation).

Marketing authorization holders must provide the Authority with information on the scientific or product promotion events they have organized or sponsored and the HCPs or students they plan to sponsor. This information will be added to the Authority's relevant database (Article 7/6 of the Pharma Promotion Regulation).

Any meetings for investigators overseeing clinical trials sponsored by the marketing authorization holder are not considered as participation in a scientific event. The marketing authorization holders, however, must request the permission of the Authority's relevant department for such meetings as well (Article 7/7 of the Pharma Promotion Regulation).

With the exception of international scientific events organized in a different country each year, marketing authorization holders are prohibited from organizing or sponsoring scientific meetings at:

- coastal resorts between 1 June 2016 and 1 September 2016 (or between 15 June and 15 September as of 2017); and
- ski centers between 1 December and 1 March.

Scientific meetings organized or sponsored by the Ministry of Health are exempt from this provision (Article 7/8 of the Pharma Promotion Regulation).

At least 60 percent of meetings exceeding six hours and sponsored by marketing authorization holders are required to include a session on rational drug use related to the subject of the meeting. The contents of this session must be within the framework of the educational materials and diagnosis and therapy guidelines approved by the Ministry of Health, and must be submitted to the Ministry of Health alongside the meeting permit application (Article 7/10 of the Pharma Promotion Regulation).

Save for distinguished guests (*protokol davetlileri*), persons who are not HCPs cannot be invited to meetings and their participation cannot be sponsored (Article 7/11 of the Pharma Promotion Regulation).

Health inspectors appointed by the Authority may participate in meetings with or without prior notice for clearance (Article 7/12 of the Pharma Promotion Regulation).

Promotional Materials

Only the approved materials that are listed in the Pharma Promotion Regulation can be utilized as promotional material. The value of the promotional materials cannot exceed 2.5 percent of Turkey's monthly gross minimum wage (i.e., TRY31.83 for the second half of 2015, or approximately USD10.80). Promotional materials cannot be displayed in a manner visible to patients (Article 8 of the Pharma Promotion Regulation).

Free Samples

According to Article 9 of the Pharma Promotion Regulation, free pharmaceutical product samples can be provided only to medical doctors, dentists and pharmacists under the following circumstances:

- The marketing authorization holder establishes a recording system on the manufacture, import and distribution of the samples and appoints a person responsible for the management of this system. These records must be compliant

with the applicable product recall legislation and shared with the Authority upon request.

- The samples include reduced amounts from that available on the market (save for enteral feeding products and products that cannot be reduced for technical reasons).
- The sample packaging bears the statement "Promotional sample, cannot be sold" on a wide surface and in a conspicuous manner. If possible, the interior packaging must also bear this statement.
- The instructions for use and a product information summary are presented with the sample.
- Samples of psychotropic and narcotic products are not be distributed.
- Distributed samples do not exceed:
    - 5 percent of the same product's sales amount for the previous year in the first and second calendar years following its placement on the market;
    - 3 percent of the same product's sales amount for the previous year in the third, fourth and fifth calendar year following its placement on the market; and
    - 1 percent of the same product's sales amount for the previous year as of its sixth year on the market.
    - (Note that these gradual amount restrictions are not applicable to enteral nutrition products, and enteral nutritional products with different flavors are considered as one product.)
- Samples are not used in clinical trials.

Product Promotion Representatives

The activities of product promotion representatives are regulated under Article 10 of the Pharma Promotion Regulation. According to Article 10/1, product promotion personnel must:

- be a university or vocational school graduate holding a diploma from a department specializing in training promotion representatives (and such department must have been authorized to do so by the Authority);
- hold a valid accreditation certificate to work as a promotion representative (this provision will enter into force on 1 January 2019);
- not promote products that fall within the scope of the Pharma Promotion Regulation to anyone other than a medical doctor, dentist or pharmacist;
- forward details of adverse effects and events reported to them during their promotional meetings to the relevant scientific service departments in their company; and
- declare the name of the marketing authorization holder they are representing, and produce identification to that effect.

Product promotion personnel may visit HCPs only within the hours determined by the administrative manager of the relevant health institution. The administrative manager determines these visiting hours, taking into account the demands of work, and in a manner so as to not hinder health and training services.

Promotional activities at emergency services departments and during patient admission hours at hospitals are prohibited.

It is prohibited for product promotional personnel to request fees for their visits to health institutions under any circumstances.

Placing promotional materials such as posters at public health institutions is prohibited. Posters and other promotional materials to be used for the Ministry of Health campaigns with public health purposes – such as vaccination campaigns, epidemic diseases, the fight against smoking or obesity – are exempted from this prohibition.

Consequences of Breach

The consequences of a breach of the Pharma Promotion Regulation are stipulated under Article 13 of the same regulation.

If a marketing authorization holder conducts promotional activities contrary to the Pharma Promotion Regulation, the marketing authorization holder is first warned by the Authority. If the marketing authorization holder's promotional activities are still found to be in violation of the Pharma Promotion Regulation within a year from the date of the Authority's warning, the marketing authorization holder is banned from conducting promotional activities for three months. If the violation is repeated within a year from the date on which the three-month ban was imposed, the marketing authorization holder is banned from conducting promotional activities for one full year (Article 13/2 Pharma Promotion Regulation).

In case of a breach of Article 7 of the Pharma Promotion Regulation, which regulates scientific and educational activities, the infringing marketing authorization holder is first warned by the Authority. In case the breach is repeated within a year from the date of the warning, the marketing authorization holder is prohibited from participating in and sponsoring congress and symposium activities for three months. If the violation is repeated within a year from the date on which the three-month ban was imposed, the marketing authorization holder is banned from participating in and contributing to scientific and product promotion events for one full year (Article 13/4 of the Pharma Promotion Regulation).

In the case of violations by product promotion personnel, the relevant personnel are first warned by the Authority. If the violation is repeated

within a year from the date of the warning, the accreditation certificates are suspended for three months. If the violation is repeated within one year from the date of issuance of the three-month suspension, the accreditation certificates are suspended for one full year (please see the above section on product promotion personnel). If product promotion personnel whose accreditation certificates are suspended conduct promotional activities, the identification issued by the marketing authorization holder by which they are employed shall be confiscated (Article 13/3 of the Pharma Promotion Regulation). The marketing authorization holder is severally liable along with the product promotion personnel for the promotional activities carried out.

The Broadcasting Law also includes sanctions applicable to media service providers in case of any breach of this law. According to Article 32/2 of the Broadcasting Law, media service providers in breach of the same law are given an initial warning; in case of repetition of the breach, they shall be ordered to pay a monetary fine of 1 to 3 percent of their gross commercial communication income for the previous month; such penalty, however, may not be less than TRY1,000 for radio establishments and TRY10,000 for television establishments and optional broadcasting service providers.

Furthermore, illegal promotion may lead to liability under Turkish Criminal Law, Consumer Protection Law and Turkish Competition Law, depending on the case. HCPs who are public officers may also be subject to disciplinary actions in case of any breach of these rules.

Regulation on the Sales, Advertisement and Promotion of Medical Devices

The much anticipated Regulation on the Sales, Advertisement and Promotion of Medical devices (Official Gazette no. 29001) (the "Medical Device Promotion Regulation") was adopted on 15 May 2014, and fully entered into force on 15 May 2015. The Medical Device Promotion Regulation established concrete rules and eliminated previous regulatory ambiguities with detailed rules on the

advertising and promotion of medical devices, sales center staff, scientific events, donations, free samples and other matters.

The Medical Device Promotion Regulation covers the sale, advertisement and promotion of medical devices, implantable medical devices, and in-vitro diagnostic medical devices. It does not, however, apply to optical stores, prosthetic and orthotic stores selling made-to-order products, and hearing aid centers, all of which are covered by other regulations.

Medical Device Sales Centers

To become an authorized medical device sales center ("**Sales Center**"), an applicant must submit the documents listed in the Medical Device Promotion Regulation to the relevant local health authorities.

The Medical Device Promotion Regulation prohibits Sales Centers from:

- directing customers to any particular healthcare institution or physician;
- soliciting customers from healthcare providers or physicians through promotions; or
- serving as intermediaries for customers.

All promoted devices must be registered with the Authority.

Sales Centers must immediately stop selling any device that the Authority declares unsafe or non-compliant, and must return these products to the manufacturer/importer.

Advertisements

Under Article 15 of the Medical Device Promotion Regulation, medical devices that can only be operated by HCPs and those on the Social Security Institution's reimbursement list cannot be advertised

to the public. Ministry of Health-authorized periodicals targeting HCPs and information provided on the websites of authorized Sales Centers are exempt from this prohibition. Advertisements must not include deceptive, exaggerated or unproven information that may lead to unfair competition or cause harm to the user.

Medical devices that do not conform with the applicable legislation cannot be advertised, save for in trade fairs and exhibitions and on the condition that they carry a mark indicating that they will not be placed on the market until they are rendered compliant with the applicable rules. Medical devices cannot be advertised through draws or lotteries.

Promotions

"Promotion" is defined as providing information to HCPs and medical device personnel. Subject to the above restrictions, pharmaceutical products (including non-prescription products), enteral nutrition products and medicinal infant formula, can be promoted only to medical doctors, dentists and pharmacists by:

- selling or distributing scientific journals;
- sponsoring or organizing scientific events;
- personnel visits to medical doctors, dentists and pharmacists (Article 17/2 of the Medical Device Promotion Regulation).

The promotional activities must not include deceptive, exaggerated or unproven information that may lead to unfair competition or cause harm to the user (Article 18/4 of the Medical Device Promotion Regulation).

If the promotion is in the form of documentation that includes citations from scientific studies, tables or other visual material, such material must conform to the original versions and include full references to its sources (Article 19/2 of the Medical Device Promotion Regulation).

Additionally, Sales Centers are prohibited from financially supporting scientific activities such as congresses and symposiums, and paying for participants' costs and expenses such as transportation and accommodation, unless such scientific events are directly related to the participants' field of expertise (Article 21/2 of the Medical Device Promotion Regulation). Rules and restrictions applicable to these sponsorships are explained in more detail under the "Seminars, Hospitality and Entertainment" section.

Permitted and Prohibited Practices

Draws and Lotteries

The advertisement and promotion of medical devices by draws or lotteries is prohibited (Articles 16/4 and 18/5 of the Medical Device Promotion Regulation).

Donations

Upon prior authorization from the management of the institution to which donations will be made, a Sales Centre can donate to public or non-profit healthcare institutions, provided that such donation (Article 23 of the Medical Device Promotion Regulation):

- does not influence any decisions relating to the issuance of public tenders;
- does not give rise to unethical behavior that may relate to the sale of the products;
- has the purpose of aiding research or training, or the improvement of health or patient care;
- is intended only for general use and not for the use of an individual;
- is recorded in the marketing authorization holder's official records; and

- is made directly to the responsible investigator or the coordinator where the donations is provided for use in a clinical trial.

Incentives

The Medical Device Promotion Regulation prohibits the granting of benefits or incentives to HCPs and medical device personnel with the aim of incentivizing the prescription, use, buying or recommending of a medical device.

Seminars, Hospitality and Entertainment

Sales Center sponsorship of HCPs/medical device personnel's participation in scientific events is subject to the following conditions:

- The scientific event must be related to the HCPs'/medical device personnel's area of expertise.
- HCPs/medical device personnel can benefit from four sponsorships during a year, with a maximum of two sponsorships from the same Sales Center, and provided that only two out of the four sponsorships are for participation in events held outside of Turkey. Events in which HCPs/medical device personnel are participating as speakers or researchers/presenters, with the support of the marketing authorization holder, are outside the scope of these limitations.
- The sponsorship must be provided to the organizations hosting the meeting and not directly to HCPs/medical device personnel.

With the exception for international scientific events organized in a different country every year, manufacturers, importers and Sales Centers are prohibited from organizing or sponsoring scientific meetings at:

- coastal resorts between 15 June and 15 September; and

- ski centers between 1 December and 1 March.

Scientific meetings organized or sponsored by the Ministry of Health are exempt from this provision (Article 21/5 of the Medical Device Promotion Regulation).

Promotional Materials

Only the materials that are listed in the Medical Device Promotion Regulation can be utilized as promotional material. Promotional materials cannot be displayed in a manner visible to patients (Articles 4(p) and 20 of the Medical Device Promotion Regulation).

Free Samples

Only medical devices conforming to Turkish technical requirements can be distributed as free samples. Sales Centers must retain data on the free samples distributed. The packaging of such free samples must state "Free promotional sample, not for sale." The value of the free sample cannot be more than 2 percent of the device's turnover for the previous year; this restriction, therefore, does not apply to devices that are on their first-year of placement on the market (Article 24 of the Medical Device Promotion Regulation).

Manufacturers can donate free medical devices and accessories, provided they are necessary for the administering of medicines (e.g., infusion pumps, injection needles, catheters); such donations are not regarded as free samples.

Sales and Promotion Staff

The activities of product promotion representatives are regulated under Article 11 of the Medical Device Promotion Regulation. According to Article 11/2, sales and promotion staff must:

- be a university or vocational school graduate holding a diploma from a department specializing in training promotion representatives, and pass an accreditation exam offered by the Authority;

- not promote products that fall within the scope of the Medical Device Promotion Regulation to anyone other than HCPs, medical device technicians working in a healthcare institution or Sales Center employees; and
- declare the name of the marketing authorization holder they are representing, and produce identification to that effect.

Consequences of Breach

Local health authorities are obligated to audit Sales Centers at least once every two years.

Violations of the Medical Device Promotion Regulation may result in the suspension or revocation of Sales Centre authorization certificates or work permits, as well as criminal sanctions, if applicable.

Medical device companies are advised to revise their policies to ensure compliance with the Medical Device Promotion Regulation. It is also recommended that they ensure that authorized resellers with which they cooperate comply with the Medical Device Promotion Regulation in order to avoid any disruption in the distribution chain. Medical device companies must also follow the Medical Device Authority's upcoming guidelines on the Medical Device Promotion Regulation's implementation.

Professional and Industry Codes of Conduct

Association of Research-Based Pharmaceutical Companies (AIFD)

The Association of Research-Based Pharmaceutical Companies (*Arastırmacı Ilaç Firmaları Dernegi* or AIFD) updated its Good Promotion and Good Communication Principles (the "AIFD Promotion Principles") in line with the Pharma Promotion Regulation, and has been applicable since 1 July 2012. The AIFD Promotion Principles are not state regulations but instead are binding on AIFD members who are mostly, if not all, research-based pharmaceutical companies' Turkish subsidiaries.

The AIFD Promotion Principles have been prepared in conformity with the Pharma Promotion Regulation but in a more comprehensive manner and include rules that are not regulated in detail in the Pharma Promotion Regulation, for instance, rules on the members' relationships with HCP associations and congress-hosting entities (Section 17), relationships with the media (Section 19), and the use of the Internet, digital platforms and social media (Section 20).

Pharmaceutical Industry Employers Syndicate (IEIS)

The Pharmaceutical Industry Employers Syndicate (*Ilaç Endüstrisi Isverenler Sendikası* or IEIS) also issued its Regulation on the Promotion of Pharmaceutical Products and Communications to HCPs in 2009. This regulation, however, was prepared before the Pharma Promotion Regulation and therefore is not up to date.

This regulation is also not a state regulation, but is binding only upon IEIS members.

Pharmaceutical Industry Association of Turkey (TISD)

The Pharmaceutical Industry Association of Turkey (*Turkiye Ilaç Sanayi Dernegi* or TISD) also has its own rules on the advertising and promotion of medicines, set out in its Pharmaceutical Products Promotion Guidelines (the "TISD Promotion Guidelines"). These guidelines, however, were issued in 2006 and are therefore similarly not up to date. TISD is currently working on an update of its guidelines in line with the Pharma Promotion Regulation.

The TISD Promotion Guidelines include rules that were prepared in line with the previous Pharmaceutical Products Promotion Regulation, but in more detail. Additionally, these guidelines also set forth some other rules, such as rules on public and media relations, use of the Internet for the promotion of medicines, and outsourced promotion and sale activities.

This regulation is also binding only upon TISD members.

Turkish Medical Doctors Association (TTB)

The Turkish Medical Doctors Association (*Türk Tabipler Birligi* or TTB) has its own professional principles related to the promotion of medicines, which are contained in two sets of rules: TTB Principles on Medical Doctors and the Promotion of Pharmaceutical Products; and TTB Declaration on the Medical Doctor-Industry Relationship.

The basic principle under these rules is that medical doctors must not receive gifts that may affect the performance of their duty, such as their decisions regarding the issuance of prescriptions.

Criminal and Civil Liability

Criminal Law

Bid Rigging

Articles 235 and 236 of the Criminal Code provide for punishment for any unlawful interference with public tender procedures. Such articles may therefore apply to the promotion of medicines to HCPs whereby a promotional scheme is used by a pharma company so that it is unjustifiably favored in a public tender process over its competitors. Furthermore, according to Article 17 of the Public Tender Law (Law no. 4734), those who are involved in bid rigging by means of fraudulent and corrupt acts, promises, threats, unlawful influences, undue interest, agreement, defalcation, bribery, or other acts shall be prohibited from participation in any tender carried out by any public body for a period of one year to two years.

Bribery and Corruption

Articles 252, 253, 254 and 255 of the Criminal Code prohibit bribery and corruption involving public servants and may apply to the illegal promotion of pharmaceuticals to HCPs.

Article 6/c of the Turkish Criminal Law defines “public servant” as “a person continuously or temporarily appointed or elected or assigned

by another manner for a definite or indefinite term to perform public activity."

Therefore, irrespective of whether an employment relationship is with a private or a public entity, it is the duties performed by HCPs for the benefit of the public (i.e., the protection and enhancement of public health) that establish them as "public servants" for the purposes of the Turkish Criminal Law.

It is clear that HCPs who are employees of public health institutions or who act as agents of these must be viewed as public servants. Additionally, even HCPs who are self-employed and not acting as agents of public health institutions or who are employed by private health institutions may be regarded as public servants for the purposes of the Turkish Criminal Code due to certain statutory duties they perform for the benefit of the general public (e.g., prescribing patients medicines that are reimbursable by the Social Security Institution).

Bribery is defined as providing benefit to (or receiving of a benefit from) a public servant or a third person determined by the public servant for the performance or non-performance of an act in violation of his or her duties.

The scope of the term "benefit" in the Turkish Criminal Code is not explicitly determined. The scope of the benefit is therefore determined on a case-by-case basis. According to various Turkish legal doctrines, it is defined generally as any and all material, moral or sexual advantage gained. Potentially, therefore, the provision of any gift, regardless of its value or type, may constitute an offense.

The Turkish Criminal Code punishes both the public servant who receives the bribe (or a third person, designated by the public servant to receive the benefit) and the person who provides the bribe to the public servant (or the designated third person, if applicable).

If the unfair advantage is provided to a legal entity as a result of bribery, the legal entity will also be subject to the sanctions specific to legal entities.

According to Article 60 of the Turkish Criminal Code, the sanctions specific to legal entities are as follows:

- Revocation of license/permit: If a private legal entity abuses the authority arising out of a license/permit granted to it by a public entity, and the governing bodies or representatives of the legal entity have participated in the actions of such entity, the court may revoke the license/permit of the legal entity.
- Confiscation of property or material interests: The court may decide to confiscate any property or material interests that have a connection to the offense/crime.

Additionally, the managers, officers or directors of the private legal entity (e.g., members of the board of directors or those responsible for the representation and management of the company) may be held criminally liable if they intentionally participate in the commission of the criminal act. This participation in the commission of the act, for instance, may be in the form of deciding on, implementing or failing to prevent the commission of the criminal acts.

Civil Law

The general rules on advertisement and promotional activities are also applicable to the promotion of pharmaceutical products. Therefore, misleading, implicit and comparative advertisements and promotional activities are regarded as acts of unfair competition and thus prohibited with regard to pharmaceutical products as well.

The Turkish Commercial Code provisions on acts of unfair competition (Articles 55 *et seq*.) prohibit discrediting others' goods, activities, products or commercial affairs by means of wrong, deceitful or unnecessarily offensive statements. Additionally, Article

16 of the Turkish Consumer Protection Law (Law no. 4077) prohibits misleading advertisements.

Article 6/6 of the Pharma Promotion Regulation also prohibits the promotion of medicines by deceptive, exaggerated or unproven information that may lead to inappropriate use of the product or unexpected hazardous situations arising, and the use of images that are not directly related to the product.

In case of any act of unfair competition, the victim may demand from the courts:

- the establishment of the existence of unfair competition;
- the prevention of unfair competition;
- the suppression of the material conditions resulting from unfair competition and, if unfair competition has resulted from untrue or deceitful statements, the rectification of these statements;
- compensation for damages; and
- payment for moral damage.

With regard to compensation for damages, the court may also order the payment to the plaintiff of the value of the advantages that the offender could have secured through the relevant unfair competition acts.

Some acts of unfair competition may also result in criminal liability. The sanctions for such acts are imprisonment of between one month and one year and/or a monetary fine of TRY500 to TRY10,000.

If the offending acts continue in spite of a final judgment, the offending parties may be subject to imprisonment of not less than six months and a monetary fine of TRY5,000 to TRY10,000.

Contracts with Healthcare Professionals and Medical Institutions

Contracts between HCPs and medical institutions are governed by the general principles of Turkish contract law set out in Turkish Civil Law, the Turkish Code of Obligations and Turkish Commercial Law.

Special additional rules apply to the execution of contracts with HCPs who are public servants. In principle, public servant HCPs other than medical doctors and dentists cannot conduct any other commercial activity (Article 28 of the Public Servants Law). Medical doctors and dentists who are public servants, however, are permitted to carry out commercial activities (Law no. 1219 on the Conduct of Medical Professions). There have been recent amendments to both the Public Servants Law and the Law on the Conduct of Medical Professions, which prohibit medical doctors and dentists who are public servants from carrying out other commercial activities. The Turkish Constitutional Court, however, cancelled these amendments with its decision no. E. 2011/113. As a result, there is currently a gap in Turkish legal provisions regarding whether or not public servant medical doctors and dentists can carry out other commercial activities. Therefore, it is currently not possible to establish a clear opinion on whether public servant medical doctors and dentists can enter into private contractual relationships with third parties.

Entering into contractual relations with HCPs who are not public servants is possible but may be subject to restrictions on the side of these HCPs as a result of their employment contracts, if any, with medical institutions.

Providing benefits to HCPs or health institutions under contractual relations must not be offered with the intention of influencing their decisions regarding a certain pharmaceutical company or product when performing their duties.

Recommendations

The following recommendations are intended to offer guidance to pharmaceutical companies with regard to their promotional activities in Turkey. These are exemplary recommendations only, and must not be construed as an exhaustive list.

- Gifts: In principle, no gifts must be provided to HCPs. Promotional materials provided to HCPs must be inexpensive.
- Samples: The distribution of samples must not aim to increase the prescription or sale of the medicines provided as samples.
- Distribution of Promotional Materials: The contact details of the recipients must be up to date in order to prevent inappropriate persons from receiving promotional materials. Additionally, these contact details constitute personal information and hence must be treated as confidential, and necessary measures must be taken for their protection.
- Hospitality:
    - Events aimed at the promotion of pharmaceutical products or the participation of HCPs in such events must not be sponsored.
    - Sponsoring the participation of an HCP in a congress/symposium must not be linked in any manner to the past or future prescription of medicines. The sponsorship must not be provided in exchange for the issuance of a set number of prescriptions of a certain medicine.
    - The sponsorship amount must be at a reasonable level.
    - Sponsored scientific meetings such as congresses or symposiums must not be held in locations deemed too lavish or luxurious.

- Contracts with HCPs and health institutions: Payments made to HCPs and health institutions must be at fair market value.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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