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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2018

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A practical cross-border insight into pharmaceutical advertising

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Group Consulting Editor
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Publisher
Rory Smith

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Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
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Country Question and Answer Chapters:

Turkey

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

In Turkey, advertising of medicines is governed by the Pharmaceutical and Medical Preparation Law No. 1262 (the Law No. 1262) and the Regulation on Promotional Activities of Medicinal Products for Human Use (the Promotion Regulation), which is based on the former.

The Promotion Regulation is published on July 3, 2015 by replacing the former Promotion Regulation of August 26, 2011. The enforcement of some of the Articles is postponed until January 2019. There are Guidelines on Applications for Scientific Meetings and Product Promotion Meetings, Guidelines on Delivery on Product Samples and Application for Press Releases, Guidelines on Sessions on Rational Use of Medicinal Products and Guidelines on Disclosure of Value Transfers Made under the Promotion Regulation.

The Promotion Regulation prohibits advertising of medicinal products to the general public and governs the interactions of pharmaceutical companies with HCPs that is referred to as promotion within the text.

The Act on Protection of Consumers, Regulation on Commercial Advertisements and Unfair Commercial Practices and Code of Obligations are applicable where the matter is not regulated under the Law No. 1262 or the Promotion Regulation. Also, 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 (the RTUK Law). As per Article 11/2 of the RTUK Law, no advertisements for prescribed medical products or treatments can be broadcasted.

The industry associations in Turkey, i.e., the Association of Research-Based Pharmaceutical Companies (AIFD), Pharmaceutical Industry Association of Turkey (TISD), and Pharmaceutical Manufacturers Association of Turkey (IEIS), have their own Codes of Promotional Practices, complementary to the applicable provisions.

1.2 How is "advertising" defined?

As advertising to the general public is prohibited but promotion to HCPs within certain rules and limitations is allowed, Article 4/1(j) of the Promotion Regulation therefore prefers the wording of promotion rather than advertising and the relevant definition is as follows:

"*All informative activities organized by marketing authorization/permit holders or in the name or with the name, upon the request, with the contribution or support of marketing authorization/permit holders on the medical-scientific characteristics of pharmaceutical products for human use covered by this Regulation, as well as the activities of product promotion representatives within this framework, advertisements published in medical or professional books or journals, announcements made through direct mailing or the press, or other means of communication, and scientific/educational activities, meetings and similar events.*"

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Companies have to ensure that the promotion of the products for which they hold a marketing authorisation/permit (MA) is in line with the requirements set forth in the Promotion Regulation. Furthermore, Article 11 of the Promotion Regulation specifically provides the liabilities of the MA holders to ensure compliance with promotion principles. Within this scope, the companies shall:

a) Establish a scientific unit, responsible for managing information related to their marketed products, to operate according to the guidelines, led by a qualified person who will be in charge of the operation.

b) Submit any information and documents required by the Ministry of Health (MoH), pertinent to promotional activities.

c) Retain for five years a copy of each of all the promotional materials used, to submit them to the MoH upon request.

d) Introduce systems to make online submissions to the MoH database in relation to sponsored educational events/congresses.

e) Ensure that any decisions adopted by the MoH with respect to promotion of products are fully implemented.

The AIFD, TISD and IEIS Codes set forth further detailed principles for any particular company in order to represent current good practice.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

There is no legal or code requirements for companies to have specific SOPs. Multinational pharmaceutical companies with affiliates in

Turkey tend to have tailored SOPs governing advertising activities to ensure compliance with the local requirements, complementing their global standards. Such SOPs cover not only local provisions but also local industry standards where applicable.

On the other hand, as per Article 4/1(c), companies must have a scientific unit, responsible for managing information related to their marketed products, to operate according to the guidelines, led by a qualified person who will be in charge of the operation. Purely physicians, dentists and pharmacists can be a part of the scientific unit.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

There is no pre-approval procedure for promotional material. However, the MoH has the authority to require any relevant information and documents at any time as per Article 11/5(b) of the Promotion Regulation.

The pre-approval procedure applies for congresses, symposia, seminars and similar meetings. If a MA holder intends to hold or partially sponsor such a meeting, this will be submitted to the MoH at least 15 working days in advance for national meetings and 30 working days in advance for international meetings, along with the content, the list of potential participants, the projected expense items and the events. A response will be given to the applicant within 10 working days after the submission is officially received, or the request will be deemed approved if no response is given. This applies for congress attendance sponsorships of HCPs and medical students as well, where all the relevant information on the sponsorship is submitted to the MoH for approval.

Also, pursuant to Article 11/2 of the Promotion Regulation, if an MA holder wishes to make a single announcement regarding the launch of a product to healthcare professionals (HCPs) through a press release, a genuine copy of the announcement shall be sent first to the MoH for approval. It should be noted that same provision sets forth that such press release does not qualify as a promotional activity.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

According to Article 12 of the Promotion Regulation, the MoH may, *ex officio,* or upon receipt of a complaint, inspect any promotional activity or material and the methods employed during such activities. As per Article 13, the MoH is entitled to request the MA holder to cease, terminate or correct the information provided during promotion which is found to be non-compliant with the Promotion Regulation or deemed inappropriate for public health. Any request by the MoH to that effect should be complied with without delay.

There is no specific appeal mechanism against decisions of the MoH. However, an application requesting re-examination of a decision may be filed in accordance with the general principles of administrative law. Bringing an action to the Administrative Court demanding cancellation of the decision is another option.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Article 13 sets forth different administrative sanctions against MA holders and product representatives for different infringements.

The violation of an advertisement ban to the public – including publication on the internet – will be subjected to a monetary fine set forth under Law No. 1262.

In case of any breach of promotion and scientific meeting/HCP sponsorship rules of the Promotion Regulation, the MA holder will be issued a warning, and in the event of another breach within one year upon the warning, banned from engaging in promotional activities for three months. In case of another breach within one year upon the three-month suspension, the MA holder will be banned from engaging in promotional activities for one year.

Similarly, in case of any breach of the Promotion Regulation, the product representatives will be issued a warning, and in the event of another breach within one year upon the warning, banned from engaging in promotional activities for three months. In case of another breach within one year of the three-month suspension, the product representative will be banned from engaging in promotional activities for one year. The MA holder associated with the product representative will also be subjected to the above-mentioned liabilities.

Also, since the RTUK Law prohibits the advertisement of medicines on radio and TV, the Advertisement Board and the RTUK Council may impose sanctions in case of non-compliance. However, this is not common in practice, as medicinal products are not generally subject to broadcast advertisement in Turkey due to specific bans on the matter.

Non-compliance may also be considered as leading to unfair competition. In this case, the general rules of the Turkish Commercial Code shall be applied and an indemnity depending on the damage may be claimed by the injured party.

If the advertising leads to public health risks, the relevant provisions of the Turkish Penal Code No. 5237 may also be applicable.

In recent years, the MoH publicly announced monetary sanctions of TL 2,550,000 in total against six anonymous companies, publicly advertising products with a health claim, as a way to create the impression of a medicinal product. It made it in to the media that the MoH informed the Telecommunications Directory of over 1,500 websites promoting and marketing food supplement products with unfounded health claims.

There has not been a reported public action taken against or by a pharmaceutical company in relation to promotional activities since the entry into force of the Promotion Regulation. It is known that industry codes incorporate enforcement procedures allowing their member companies to raise compliance issues to be resolved through mediation or dispute resolution. Such procedures may require the association to inform the MoH where a code violation also constitutes a violation of the applicable law.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The MoH's Turkish Pharmaceutical and Medical Device Agency (the Agency) is the enforcement body in Turkey and acts solely through its Inspection Commission. The MoH does not interfere with the self-regulatory process, however, it would be entitled to acknowledge matters drawn to its attention and act on them in cases of reasonable doubt, as long as the breach of a certain code also constitutes a breach of the law within the MoH's jurisdiction.

It is known that the enforcement procedures of some industry codes oblige the association to refer the matter to the MoH in case the breach of the code also constitutes a breach of the law, ensuring the required interaction between the self-regulatory process and the competent authority.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

According to Article 54 of the Turkish Commercial Code, all commercial acts contrary to good faith may constitute legal grounds for an unfair competition action. Article 55 provides a non-exhaustive list of examples for acts incompatible with good faith. A range of examples include: conducting commercial activities by means of incorrect or misleading declarations; reflecting discredit upon someone or someone's product; and not obeying the law and regulations applicable to all competitors.

Any commercial entity, competitor, consumer and consumer association damaged by the unfair act may bring an unfair competition action.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Article 6/2 of the Promotion Regulation explicitly prohibits off-label promotion and the promotion of unauthorised products. However, exceptions of this rule are set forth under the same provision.

It is exceptionally possible to:

- discuss off-label information on authorised medicines;
- provide information on unauthorised medicines; and
- provide information on medicines that are authorised or licensed in line with the relevant regulation, but for which the Institution gives permission to be imported upon prescription as they are not available in the domestic market (except for promotion activities for the purposes of pharmacovigilance of products that are supplied through international suppliers and are purchased by the Social Security Institute within the scope of alternative reimbursement models and notified to the Agency).

Only:

- during an international congress held in Turkey; or
- as a response by the scientific unit of the MA holder, to a written request made by a physician, dentist or pharmacist.

In addition to this, as per Article 6/c of the Promotion Regulation, no promotion can be made in relation to products that are authorised or licensed, however, not available in the domestic market, but imported upon prescription under permission of the Agency.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

There is no specific provision in the Promotion Regulation. However, according to Article 4.2.9 of the AIFD Code, the sharing of literature comprising products and indications not yet registered/approved in Turkey is possible, as long as the referred information is provided upon the written request of the healthcare professional, the information is conveyed personally by a scientific unit, it is clearly indicated on the reprint of the literature or the Turkish translation of it that the product or indication is not registered in Turkey and the non-registered product or indication is not promoted visually or verbally during this communication.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

The general rule requires that whether authorised or unauthorised, the medicinal products cannot be advertised publicly. Since the sharing of promotional information on products with HCPs is permitted, this information on authorised products can take place in specialised medical or scientific media where the audience is strictly the HCPs. Sharing of off-label information and/or information of unauthorised products is governed by the specific rules mentioned in question 2.1, and therefore cannot be subjected to press releases even in specialised medical or scientific media.

As set forth under Article 11/2 of the Promotion Regulation, if an MA holder wishes to announce the launch of a product to HCPs through a press release, a genuine copy of the announcement will be sent to the Agency for authorisation. A press release may be published only once. The size of a press release published in a newspaper may not exceed ⅛ of a full page. It is, however, important to note that such exception is not applied to unauthorised products. Therefore, press releases on unauthorised products are not possible.

Additionally, according to the AIFD Code, the press release should not be colour printed, the same type of lettering on the approved packaging must be used and it must not contain information/wording which is not included in the package which has been approved by the MoH.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

As stated above in the answer to question 2.1, upon a physician, dentist or pharmacist's written request, information on an unauthorised product may be provided to these healthcare professionals by the scientific unit of the company, as per Article 6/2 of the Promotion Regulation.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/ compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

The ECJ judgment in the *Ludwigs* case, Case C-143/06, does not have applicability in Turkey, as Turkey is not bound by the ECJ jurisprudence, and has not impacted legislation or practical guidance in Turkey.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

There are no specific rules with respect to this situation. The AIFD Code allows information on unauthorised medicines or indications to be sent to Health Authorities and Health Insurance Boards, including the Social Security Institution, in order to shed light on the preparation of their budget for the upcoming years and their reimbursement assessments.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Companies may enter into agreements with HCPs for consulting services, including market research activities concerning launch materials for products as yet unauthorised. As a general rule specified under the AIFD Code, market research should not be promotional in nature. These studies should be conducted for the purpose of gathering information about the product for the company or competing products and carried out for scientific and educational purposes.

No guideline has been published yet for the market research of medicinal products.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

The Promotion Regulation sets forth the fundamentals and principles of promotion directed to HCPs under Article 6. This Article does not introduce a piece of information that must appear in advertisements, yet it states that information shared should be accurate, provable and consistent with the information and data contained in a product's updated SmPC. Moreover, promotion should incorporate informative and factual medical data on a product's characteristics that will help HCPs establish their own opinion on a product's therapeutic value.

Pursuant to Article 6/5 of the Promotion Regulation, where the promotion involves using citations, tables or other visual materials from medical journals or other scientific publications, the material should be authentically reproduced, providing full reference to relevant sources.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Article 6/6 of the Promotion Regulation provides that the promotion should not be made through the use of misleading, exaggerated or unproven information, or alluring visuals not directly related to the product, which can lead to unexpected risks or encourage unnecessary use of a medicine.

In light of this provision, as well as Article 6/3 foreseeing that the promotion should be in line with data included in the SmPC, advertisements referring to studies that are not in the SmPC may not be allowed.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

Pursuant to Article 5/5 of the Promotion Regulation, HCPs and HCP associations can take part in, or take a role in medicinal product advertising only upon pre-approval of the MoH.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

There is no specific provision or obligation in the Promotion Regulation on using data from "*head to head*" clinical trials whereby such data can be used as evidence to support comparative claims based on the rules on using comparative information in general.

Under the principles of the Promotion Regulation, the comparative data should be consistent with the conditions explained in the answer to question 3.1.

The AIFD Code provides more specific rules on the use of comparative information as set forth under question 3.5.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

As advertising of medicinal products to the public is altogether banned, comparative advertising to the public is not possible either. Regarding promotion to HCPs with comparative information, on the other hand, the Promotion Regulation does not present any specific provisions but the AIFD Code provides some standards.

The AIFD Code allows comparative information to be included in the promotional material to be communicated to HCPs. As per Article 7/3, comparisons between different medicinal products should comprise comparative features. Comparison can be made in a promotional material without mentioning the competing product names/marks under the following conditions: (i) it shall not be misleading; (ii) medicines or services for the same needs and purposes shall be compared; (iii) relevant, proven and significant features are compared; (iv) comparisons are not used to create confusion on purpose; (v) pejorative or derogatory statements shall not be included regarding the competing product or brand; and (vi) unfair advantage shall not be taken from the reputation of a competitor. All comparisons must be provable.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The distribution of scientific papers must be made in accordance with Articles 6/4, 6/5 and 6/6 of the Promotion Regulation. Accordingly, the information contained in the promotional documentation has to be accurate, provable, and sufficiently complete to enable the recipient to form his or her own opinion about the therapeutic value of the related medicinal product. Where the promotion involves using citations, tables or other visual materials from medical journals or other scientific publications, the material should be authentically reproduced, providing full reference to relevant sources. The companies are entitled to share publications that may be used as a source of information/data/reference by relevant parties, corresponding to such criteria.

On the other hand, as of 2016, the AIFD Code provides a much stricter rule on medical/scientific reference material and literature. Under Article 14, the transmission of informational and educational materials to healthcare professionals is permitted provided that each material; is: (i) inexpensive (real or perceived cost); (ii) directly relevant to the practice of medicine or pharmacy services; and (iii) directly beneficial to the care of patients. The same article provides, however, a total ban on text books, medical literature and journals. These materials cannot be provided to HCPs individually and merely be granted to HCOs to be left open to all HCPs' use. Such grants shall not in nature be capable of inducing purchasing decisions.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

There is no specific provision in the Promotion Regulation. However, the AIFD Code stipulates that teaser campaigns can be initiated before the grant of authorisation so long as they do not contain the trade name or INN and comply with the letter and spirit of the AIFD Code.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Yes, it is possible to provide only physicians, dentists and pharmacists amongst all HCPs with free samples of products provided that the following conditions are fulfilled:

a) The marketing authorisation/licences holder will set up and appoint qualified persons for an adequate system of records and control for the production, importation and distribution of free promotional samples. These records will be created in accordance with the relevant recall regulations, and submitted to the Agency on request.

b) Free samples will be reduced in size. However, this requirement will not be applied to enteral nutrition products and promotional samples of products which, for technical reasons, cannot be reduced.

c) The wording, "*Free promotional sample – not for sale*", will discernibly appear on the outer packaging of promotional samples on at least one surface. As far as printing is possible, the said wording must also appear on the inner packaging.

d) A copy of the SmPC and the PL, if available, will be provided with the promotional sample.

e) Samples may not be provided or distributed of products containing psychotropic or narcotic substances covered under international conventions, or of substances subject to national control.

f) Samples of products included in "*The List of Medicinal Products Banned from Sample Distribution*", published on the Agency website, may not be provided or distributed.

g) Free samples distributed for each product may not exceed 5% of the total annual sales in the first calendar year after it is launched, to be determined by monitoring monthly sales realisations; in the second calendar year they shall not exceed 5% of the quantity sold in the previous year; in the third, fourth and fifth calendar years they shall not exceed 3% of the quantity sold in the previous year; and after the fifth calendar year, they shall not exceed 1% of the quantity sold in the previous year. Enteral nutrition products are exempt from the quantity reduction restrictions stated in this Article. Annual distribution amounts of the promotional samples of enteral nutrition products with various flavours are accepted and calculated as a single product, independent of the flavour.

h) Promotional samples may not be used as an investigational product during a clinical trial.

The List of Medicinal Products Banned from Sample Distribution mentioned in sub-section (d) of the Article was published on the MoH website on January 27, 2016 where three categories of products are indicated as i) the medicinal products in the additional monitoring list (corresponding to new molecules, for pharmaco-vigilance purposes), ii) biological, biotechnological and bio-similar products, and iii) products requiring special storage conditions.

The MoH's Guidelines on Delivery of Free Promotional Samples and Applications for Press Release as per Regulation on Promotional Activities of Medicinal Products for Human Use provides further information on delivery of samples.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

As per Article 6/10 of the Regulation, no donation/grant can be made to an individual HCP. Donations and grants in cash or in kind can only be made to public institutions under certain formalities (see question 4.3). As per Article 4 of the Promotion Regulation, HCPs can individually be provided only with promotional materials (reminder gifts). Under Article 4(k) of the Promotion Regulation, monetary value of these reminder gifts cannot exceed 2.5% of the minimum monthly gross wage, corresponding to approximately EUR10.

The EFPIA member AIFD sets forth, however, a total ban on reminder gifts. Under Article 14/2 of the AIFD Code, which is in line with the EFPIA Code, no gift or pecuniary advantage (in

cash or benefit in kind) or any material which may be perceived as an inducement in relation with a promotion or for prescribing, procuring, administering, recommending the administration of or selling or buying a prescription drug or possessing the qualities of a gift, may be supplied, offered or promised to a HCP.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

As per Article 6/10 of the Promotion Regulation, MA holders may donate to public healthcare institutions or organisations, and non-profit healthcare agencies, institutions and organisations if the following conditions are met:

a) Tender decisions concerning products within the scope of this Regulation are not influenced, unfair competition is not caused.

b) The donation does not lead to any unethical transaction which may be associated with any purchase of products.

c) The donation does not encourage prescribing of a specific product.

d) The intention is always to improve either research, training, health or care given to patients.

e) The donation will be utilised by not any individual person, but the entire organisation or institution.

f) Only the name of the marketing authorisation/licences holder, and not of the product, will appear on the donated materials.

g) The donation is entered in the official books of the marketing authorisation/licence-holder.

h) Any donation of medicinal products, laboratory kits or similar items for use in clinical research is made directly to the principal investigator.

It is, therefore, possible to make a donation in cash or kind or service, as long as the above conditions are met.

Article 6/11 adds that healthcare institutions and organisations may only accept donations upon permission from their head institutions, or in line with the relevant guidelines issued by their headquarters.

Under Article 11/7, if the donation to healthcare organisations such as hospitals relates to a value exceeding 10% of current gross monthly minimum wage (which corresponds to approximately EUR 40) the MA must notify the Institution of this value transfer made within one calendar year, within the first six months of the following year. Also, the examples of all data and documents pertaining to the value transfer will be retained by the MA holder for five years.

The AIFD Code adopts the above-mentioned conditions for donations set forth under the Promotion Regulation and provides for public disclosure of donations made to healthcare organisations under Chapter 22 of AIFD Code. Please refer to section 7 for further information.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

Medical or educational goods and services can be provided to institutions, ultimately for the use of HCPs in general, within the context explained in the answer to question 4.3, and this cannot be associated with prescribing decisions or product purchase. Also, promotional materials shall only be appropriate and of a nature to serve the aim of helping HCPs in forming their opinions on a product's therapeutic value and not the aim of market expansion.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Discount arrangements are not in the scope of the Promotion Regulation as they are regarded as commercial terms. In practice, pharmaceutical companies make volume-related discounts. These kinds of arrangements have to be clearly identified, invoiced and taxed, and compliant with general rules including competition law. More specifically, these discounts should not be attached to any kind of condition which ties an institution to certain medicinal products, eliminates the right of the institution to choose the most competitive company or excludes competitors if companies are in a dominant position in the relevant market.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?

The Promotion Regulation strictly regulates that no benefits, whether cash or in kind, may be provided, offered or promised during promotion of medicines to physicians, dentists or pharmacists. Likewise, these HCPs are prohibited from accepting or requesting any inducement during the course of such promotional activities pursuant to Article 6/8.

On the other hand, as for private institutions, the question may be open to interpretation. Such arrangements may be interpreted within the scope of contractual freedom; however, they must be carefully evaluated from promotion, competition and tender law perspectives. With regards to public institutions, public institutions may purchase via tender processes which should be compliant with the stages listed in the Public Tender Act. Additionally, the Act requires the government to ensure transparency, competitiveness, equal treatment, trustworthiness, confidentiality, public scrutiny, fulfilment of the requirements in appropriate terms and efficient use of resources, in the tender to be carried out in accordance with this Act. Negotiation with the government officials, out of the scope of open tender process stipulated by the Act would not be not compliant. It is also important to add companies' distributors/warehouses to public tenders for most of the pharmaceutical sales to the hospitals via tender process.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

According to the Regulation on Retraction of Products, defective or suspected to be defective products have to be retracted or withdrawn by companies or the MoH. Companies are liable for damages to

the interested parties resulting from the retraction or withdrawal of a product. It does not make a difference whether the product is a prescription-only medicine or an OTC product.

On the other hand, the advertising of prescription-only medicines direct to consumers is prohibited. Companies must avoid a refund scheme being considered as an inducement, and therefore restrictions with respect to incentives and the general rules on product liability will need to be considered.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Pharmaceutical companies may sponsor continuing medical education, however, under certain rules and limitations set forth under Article 7 of the Promotion Regulation.

The Guidelines on Applications for Scientific Meetings and Product Promotion Meetings sets out two types of meetings; one being the "scientific meetings" where all content is strictly scientific with no product promotion; and the second one being the "product promotion meetings" where there is also promotion of pharmaceuticals.

The MA holders shall not bear the transportation and accommodation expenses of the doctors and HCPs who will attend educative activities. This means that the companies may sponsor HCP attendance to scientific events, but not to product promotion meetings including product promotion.

For company-sponsored HCP scientific meeting/congress attendance, on the other hand, the Regulation presents a quota limitation commonly referred to as 4-2-2 rule, to avoid excessive interaction. Accordingly, a HCP can annually receive a maximum of four congress sponsorships from the industry. A maximum of two of these sponsorships may come from the same company and two may be from an international congress.

The companies are obliged to submit all the details in relation to HCP congress sponsorship to MoH's online database and obtain approval before the attendance takes place. There is a second round of submission after the attendance as well.

On the other hand, it is not possible to make individual grants to particular HCPs via sponsorship of medical education (ex. Masters programme). Medical education can be supported in general without any specification to certain HCPs.

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The main legislation concerning bribery and anti-corruption is the Turkish Criminal Code (TCC) No. 5237 amended to its current version in 2012.

The interactions between pharmaceutical companies and HCP/HCOs are covered predominantly by Promotion Regulation. In cases where an interaction exceeds the limits provided in the Promotion Regulation and falls within the scope of an offence defined in the Criminal Code, both regulatory and criminal liability will arise.

The Agency is responsible for compliance with the Promotion Regulation. The enforcement of anti-bribery legislations is under the control of judicial authorities. The judicial authorities may investigate matters that may constitute both a breach of advertising rules and the anti-bribery legislation. In fact, the Institution is under the obligation to inform the judicial authorities in cases where a complaint or investigation on regulatory issues reveals reasonable doubt of a criminal offence.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Hospitality is not specifically regulated by the Promotion Regulation. The Promotion Regulation does not introduce maximum limits for hospitality, like meals provided to HCPs. As a general rule, such costs shall be at reasonable levels. The hospitality provided shall never be of a nature capable of overshadowing the scientific purpose of meetings.

If hospitality is provided as a part of an event like a congress of scientific meeting, it shall be disclosed to the MoH within the programme of the event as a part of pre-approval process. Under the general disclosure rule, where the hospitality relates to a value exceeding 10% of current gross monthly minimum wage, the MA must notify the Institution.

There are some specific rules on the appropriate time and location for educational events/congresses. As provided under Article 7, no meeting can be held or sponsored by MA holders at seaside resorts or skiing resorts during the high season, except for international meetings that are held each time in a different country. This may be considered to apply to hospitality offerings as well.

The above-mentioned rules apply for HCPs in Turkey for hospitality provided both in Turkey and abroad. The Turkish affiliate of the company is therefore advised to submit to the MoH all the required information on:

- an event organised/sponsored in Turkey either by a Turkish or global affiliate;
- sponsorship of a HCP from Turkey to attend an event in Turkey or abroad, by a Turkish or global affiliate; and
- sponsorship of a foreign HCP to attend an event in Turkey, by a Turkish or global affiliate.

In line with the EFPIA rules, the AIFD Code sets forth maximum limits for hospitality. Meals (food and beverages) offered to HCPs during business-related outings and other occasions mentioned in the Code shall not exceed per person per meal the monetary threshold of EUR 60 per person per meal, excluding VAT. If the offered hospitality will take place in a different country, the maximum limits indicated in the relevant EFPIA member national code of that country will become applicable.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

MA holders cannot pay HCPs to attend scientific meetings, however, they may sponsor their attendance by covering their travel, accommodation and enrolment costs within the rules and limitations set forth under Article 7 of the Promotion Regulation as explained in detail under question 4.8. While covering such costs, no direct payments can be made to HCPs – the payments shall be made to the organisation company.

The time of the HCP can only be paid only in the form of a fee reflecting a fair market value where the HCPs provide services, like training the attending HCPs or making a speech or a presentation.

All the meeting attendance sponsorships and all fees for services above the mentioned limits must be disclosed to the MoH under the general disclosure rules.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

Companies will be directly responsible for the scientific meetings they organise. They also have to make sure – mostly through contractual means – that sponsored third-party meetings fulfil the requirements set forth by the Promotion Regulation, since the MoH will be entitled to hold the sponsoring company responsible as well.

The Guidelines on Applications for Scientific and Educational Meetings requires the content and programme of the organised/sponsored meetings including hospitality arrangements to be submitted online to the MoH during the pre-approval stage.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

It is possible to conclude service agreements with HCPs where expert services are provided, including participation in advisory boards.

Under the general rules, there must be a real need for the services to be provided related to the expertise of the HCP, a written agreement must be made, the payment must reflect a fair market value and the appropriate financial documentation must be produced.

Restrictions apply based on whether the HCP is a public official or not. With the latest version of the so-called "*Full Time Law*" of 2014, physicians working in state hospitals and state university hospitals can only work for and under the command of their state institution and cannot conduct any private services on their own, including service agreements with pharmaceutical companies. Accordingly, companies may enter into service agreements with such HCPs only with the approval of the HCP's institution, and as long as the fee for service will be paid to the revolving fund of the institution itself. The HCP will receive a part of the payment from the institution through the revolving fund based on the institution's internal payment schemes. The above restrictions do not apply to fee-for-service agreements conducted with HCPs working in the private sector or though their private clinic and only the above mentioned general rules apply.

As will be explained in detail in the answer to section 7, in line with Article 11/7 of the Promotion Regulation, if the fee for service paid to the HCP relates to a value exceeding 10% of current gross monthly minimum wage, the MA must notify the Agency of this value transfer made within one calendar year, within the first six months of the following year.

Accordingly, transparency and disclosure is another issue to be considered for payments made to HCPs in return for services obtained.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Our explanation in the answer to question 5.4 should also apply here.

Additionally, even though there is no specific provision regulating post-marketing surveillance studies in the Promotion Regulation, we refer to the general rule in the AIFD Code that post-marketing studies shall not be carried out to influence physicians or as promotion disguised as research.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

There is no specific provision dealing with this issue in the Promotion Regulation. Under the general rule of the Promotion Regulation prohibiting any value transfer to HCPs during promotional activities and under the AIFD principle mentioned under question 5.5 requiring the post-marketing studies to be distinguished from promotional activities, companies shall not include promotional content to post-marketing studies where the HCP receives a compensation for the services provided.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Pursuant to Article 5/3 of the Promotion Regulation, the promotion of medicines to the general public is prohibited regardless of whether they are non-prescription or prescription-only medicines. Any promotion to the general public through any public media or communication channels including the Internet is forbidden, whether directly or indirectly, or whether through placement in programmes, movies, TV series, news reports or similar media.

In case it is established that MA holders promotion activities are in breach of Promotion Regulation; a warning will be issued by the Agency. In case any activity in breach of Promotion Regulation is determined within one year following the warning, MA holders will be banned from engaging in any promotional activity for three months. If any act in breach is repeated within the one year, following the sanction of banning from any promotional activity for three months, it may not engage in any promotional activities for a period of one year.

Additionally, in the case of a medicine advertised to the general public, the Law No. 1262 imposes administrative fines calculated according to the amount of sale of the relevant product. The MoH shall have the power to decide multiplying this amount up to five times. In any case, the calculated amount cannot be less than TL 100,000 (approx. EUR 22,000). If the violation is repeated, the sanction will be duplicated. If the advertising is made via internet, the MoH will immediately issue a blocking decision to be enforced by the Information and Communication Technologies Authority.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

According to the Promotion Regulation, promotion of medicines to the general public is prohibited regardless of whether they are non-prescription or prescription-only medicines. The MA holder may only publish Agency-approved advertisements placed in newspapers/journals, announcing the market launch of a product to healthcare professionals.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Despite the prohibition of the advertising of pharmaceuticals to the general public, there is no provision preventing conducting disease awareness campaigns which encourages a particular medical condition to consult the physician. However, the campaigns shall not contain information that may be interpreted as pharmaceutical promotion or no direct association shall be made between disease information and the drugs of the company in accordance with the Promotion Regulation. Therefore, the matter shall be evaluated for each case and instead of conducting such campaign, companies may consider sponsoring an association or patient organisation already conducting such awareness campaigns.

Besides, Promotion Regulation sets an exception for the campaigns run by the MoH including the advertisement of medicine to general public. Pursuant to Article 6/1, information to the general public may be provided on products that will be used in vaccination campaigns, organised actions to combat epidemics or other campaigns run by the MoH to promote health, upon permission of the MoH and within the confines of principles and procedures set by the MoH.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

Only MA holders may issue press releases concerning their authorised medicines. The press release should indicate the announcement of the launch of a product and addressed to HCPs. A genuine copy of the announcement will be sent to the Agency for authorisation before its publication. A press release may be published only once.

Pursuant to Promotion Regulation's Guidance about the Press Release, the press announcement can be published once, in the same day, in all written daily media. Additionally, it can be published once in 30 days from the date of permission for periodical written media. The size of a press release published in a newspaper may not exceed ⅛ of a full page and it should be uncoloured.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Article 5/4 of the Promotion Regulation reads: "*Institution approved PL/indications of products that have been approved by the Institution may only be published in Medias defined by the Institution, or in the marketing authorisation/licence holder's company website. Apart from these, no acts of public promotion or information providing, by partially or completely using Institution approved SmPC/PL/indications can be made*".

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There is no rule prohibiting the relation between pharmaceutical companies and patient organisations. Additionally, pursuant to the Promotion Regulation Article 6/10, the pharmaceutical companies may donate to Patient Organisations. However, like all other value transfers, the value transfer as a donation to patient organisation exceeding 10% of current gross monthly minimum wage should be notified to the Agency, in a format defined by the Agency and in detail; within the first six months of the following year.

Additionally, the AIFD Code sets standards for the relation between the pharmaceutical companies and patient organisations. The pharmaceutical companies may provide significant support which can be considered a meaningful contribution to the activities of the relevant organisation or it is believed that such support will be provided, and in case the patient organisation has little or no possibility to achieve the said project without this support, to patient organisations.

When pharmaceutical companies provide significant support, they shall have in place a written agreement. This shall state the amount of funding and also the purpose. Each pharmaceutical company shall have an approval process in place for these agreements.

Besides, the AIFD Code prohibits pharmaceutical companies from being the exclusive sponsor of a patient organisation or any large project of the patient organisation.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Pharmaceutical companies are banned from contacting patients for promotional purposes. Therefore, companies cannot provide items or benefits directly to patients. However, companies may provide free samples to physicians, dentists or pharmacists as detailed under question 4.1.

Companies may also donate items to public healthcare institutions or organisations, and non-profit healthcare agencies, institutions and organisations to improve health or care given to patients.

In the case where support to patients with respect to the use or adverse events of a product shall be given, the MA holder may apply to the Agency for the approval of a Patient Support Program. Within the Agency-approved programme, a third company authorised for providing healthcare services at home, may interact with the patients and may provide necessary items, approved within the programme.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

There is no obligation in the legislation for companies to disclose details of ongoing and/or completed clinical trials. However, the Turkish Clinical Research Infrastructure Network, partner of ECRIN (European Clinical Research Infrastructure Network), established a portal together with the Agency in which every clinical trial is listed. However, this portal only includes information regarding the trial's status, its number, its full name and the coordinator's name and centre's name.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

There is no obligation of public disclosure for value transfers made by pharmaceutical companies. However, there is a requirement of notification to the Agency:

Pursuant to Article 11/7 of the Promotion Regulation, MA holder companies shall notify the Agency of any value transfer exceeding 10% of current gross monthly minimum wage which are made to healthcare institutions and organisations, universities, healthcare professionals and professional organisations, unions, associations and foundations with activities in the healthcare industry of which they are members, and non-governmental organisations founded to preserve and improve health. The notification of all value transfers made within one calendar year shall be made electronically in a format defined by the Agency and in detail; within the first six months of the following year. The notification includes the detailed information about the institutions, organisations, HCPs to which value transfer is made, the reason of the value transfer which can be donations, contribution to covering event-related costs, contribution to covering event-related costs, i.e. registration fee, travel, lodging and meals for HCPs, sponsorship agreement, honorarium or consultancy fee or any other transfers of value. Transfers of value which are considered off-scope for disclosure include free promotional samples, transfers of value not exceeding 10% of the currently applicable monthly gross minimum wage and transfers of value having the nature of a qualified investment for research and development.

For any value transfer to be made within this scope, MA holders also need to receive written permission of the HCP, and in other institutions and organisations of the authorised supervisor in order for the value transfer to be accepted and notified to the Agency. MA holders cannot make any value transfer if written permission is not received.

Additionally, examples of all data and documents pertaining to the value transfer should be retained by MA holders for five years.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

AIFD incorporated into its Code the provisions set forth by the EFPIA Disclosure Code requiring transfer of values made by member companies to the HCPs and HCOs to be disclosed to the general public.

The MoH, however, introduced its own disclosure scheme in 2015 and requested the industry to follow merely the disclosure requirements arising from the applicable law. The MoH stated in writing that they wished this information to be kept by the MoH itself currently and requested the industry to suspend their public disclosure through self-regulation until MoH decides how to handle the disclosure and transparency schemes in Turkey.

The enforcement of the AIFD Code regarding the public disclosure of the value transfers has therefore been suspended for an undetermined period in Turkey.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Pursuant to the Promotion Regulation and the Promotion Regulation's Guidelines on Value Transfers, for any value transfer to be made, the MA holder shall collect written consent from the HCPs, for the acceptance of the value transfer and for the disclosure of the value transfer to the Agency.

The MA holder shall not make any value transfer if the written consent is not obtained. In case the written consent is obtained and the value transfer is made the Guidelines sets forth that the HCP cannot withdraw their consent.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Article 5/3 of the Promotion Regulation prohibits the promotion of products to the general public through any public media or communication channels including the Internet. Only the PL/indications of products that have been approved by the Agency may only be published in media defined by the Agency, or in the MA holder's own website.

Additionally, if promotion or sales are made over the internet, the company may be fined up to five times the sum of the last year's sales of the product. Besides, this penalty cannot be lower than TL 100,000. Along with the monetary fine, the MoH may prevent immediate access and this decision will be notified to the Information Technologies and Communications Authority for implementation.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

There is no regulation regarding the level of website security for the access of users. In practice, companies should ensure that the general public cannot access the content which is intended for HCPs.

AIFD Code requires the separation of information intended for physicians, dentists and pharmacists and information for the general public into two sections and requires the statement of "*This section is intended for physicians/pharmacists*" to be included at the top of the section prepared for the healthcare professionals to whom promotion is allowed. For pages containing health information open to the general public it required for AIFD members to include the following statement: "*Information on this website shall not replace consultation with a physician or pharmacist. Consult a physician and/or pharmacist for further information*".

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Links can be provided from a website established or sponsored by the company to other websites sponsored by the company or other websites. Also, links can be made from the website of others to the website of the company. However, there is no specific provision under the Law regarding this matter.

AIFD Code regulates the responsibility of the member companies regarding the links made from/to the company website. When providing links to other websites, a warning will indicate that the information on the linked websites is not under the responsibility of the pharmaceutical company and their content may differ from the texts approved by the MoH and these websites may not be compliant with the laws and regulations of Turkey.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The main rule specified in Promotion Regulation is the prohibition of the promotional activities to the public. Therefore, any content excluding the promotion of the pharmaceutical company's products may be placed on its website for the parts intended for public. The part intended for the public may include financial information that may interest investors, investments and information on the stage of registrations, HR job opportunities and job application sections, press releases and declarations of the company not involving product promotion and intended for the general public, product lists and prices, areas of specialty, information about health conditions, advancements in the medical field, contact details and similar information.

Additionally, websites may contain information about diseases, disease prevention, screening and therapeutic methods and other information aimed at protecting public health.

AIFD Code requires the following recommendation to be included on each page containing health information open to the general public, other than the corporate pages of the company (e.g. sections highlighting company principles, section for job application, etc.): "*Information on this website shall not replace consultation with a physician or pharmacist. Consult a physician and/or pharmacist for further information.*"

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

There is no specific regulation regarding the use of social media by companies. However, the usage of the social media and content placed on social media should comply with the provision of Promotion Regulation and comply with the prohibition of the promotional activities to the public.

AIFD Code has some guidance on the use of the social media for its members.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The most significant development in relation to the promotion rules has been the implementation of the transfer of value notification process. Although the Promotion Regulation stipulates that the transfer of values made within a calendar year shall be notified to the Agency within the first six months of the next year, the online system for such notifications was launched only around May 2017, which left companies a short period for the notification. This problem is not expected to happen in 2018.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The MoH plans to publish a new regulation on promotion of pharmaceuticals and annul the Promotion Regulation dated July 3, 2015. The draft of the new regulation is not yet shared with industry-specific organisations and the comments of the industry are collected. The new regulation is expected to be published in the first quarter of 2018.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Although the Promotion Regulation does not explicitly mention to notify the Agency of transfer of values occurred within the scope of clinical trials, the Agency has announced in 2017 that all transfer of values related to clinical trials shall also be notified to the Agency. Upon this announcement, companies located had to notify related expenses occurred in 2016 as well.

Özge Atılgan Karakulak
Gün + Partners
Kore Şehitleri Cad. 17
Zincirlikuyu 34394
İstanbul
Turkey

Tel: +90 212 354 00 00
Email: ozge.atilgan@gun.av.tr
URL: www.gun.av.tr

Özge Atılgan Karakulak has been with the firm since 2006 and has been a partner since 2013. She is chair of the firm's life sciences industry and competition practices and co-chair of the intellectual property practice.

With the combination of Özge's advisory and litigation expertise and in-depth knowledge of the life sciences sector, she advises clients across all phases of the business cycle of life science products, such as registration/authorisation procedures, promotion practices, pricing and reimbursement regulations, distribution relationships and co-marketing deals, as well as on issues of merger control, vertical restraints and abusive conduct.

Özge has acted on behalf of originators in numerous complex patent infringement and validity actions in the pharmaceutical industry and she was involved in the first ever pharmaceutical data exclusivity actions in Turkey.

In addition to her corporate work, Özge serves as a counsel to the Association of Research-Based Pharmaceutical Companies (AIFD) and the Association of Research-Based Medical Technologies Manufacturers (ARTED) in Turkey and advises on numerous regulatory policy papers and drafting regulations for the Turkish government authorities.

Dicle Doğan
Gün + Partners
Kore Şehitleri Cad. 17
Zincirlikuyu 34394
İstanbul
Turkey

Tel: +90 212 354 00 00
Email: dicle.dogan@gun.av.tr
URL: www.gun.av.tr

Dicle is a senior associate at Gün + Partners, with seven years, experience at the firm in the life sciences and intellectual property practice areas.

Her experience in the life sciences practice group is focused on advising corporate clients from the Life Sciences sector, especially multinational pharmaceutical and medical device companies. She advises clients on a wide range of issues including promotional activities, advertisement, labelling requirements, clinical trials, marketing authorisation procedures, pricing and reimbursement regulations, and also assists clients in their day-to-day business activities. She assists multinationals in adapting local preventive procedures, trains their teams and takes part in their audits and internal investigations.

She advises the Association of Research-Based Pharmaceutical Companies (AIFD) and the Association of Research-Based Medical Technologies Manufacturers (ARTED) in Turkey and consults clients on many regulatory policy papers and drafting laws and regulations proposed to the Turkish governmental authorities.

She is an experienced IP litigator, focusing on trademark infringement and unfair competition cases, trademark invalidation and revocation actions within various sectors.

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glg global legal group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: info@glgroup.co.uk

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