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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2015

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A practical cross-border insight into pharmaceutical advertising

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Chapter 34

Turkey

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1 General – Medicinal Products

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

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 was published on August 26, 2011, came into effect on December 31, 2011 and was last amended on December 31, 2014 into the current text. The enforcement of some of the Articles is postponed until January 2019. There are Guidelines available on scientific and educational meetings, delivery of product samples and the sessions on rational use of medicinal products.

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

The Act on Protection of Consumers, Regulation on Principles and Fundamentals of Practices regarding Commercial Advertisements and Announcements and Code of Obligations are applicable where 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.

Additionally, 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?

Article 4/1(g) of the Promotion Regulation 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 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 two years a copy 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? If so, what aspects should those SOPs cover?

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.

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?

In principle, 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, along with the content, the list of potential participants, the projected expense items and the events. This applies for congress attendance sponsorships of HCPs as well, where all the relevant information on the sponsorship is submitted to the MoH for approval. 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.

Also, pursuant to Article 11/2 of the Promotion Regulation, if a 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. 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.

Also, the Advertising Board has the authority to cease the advertising of pharmaceuticals and issue a fine to companies that act in contradiction with the applicable regulations.

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? To what extent may competitors take direct action through the courts?

In case of any breach of the Promotion Regulation, with reference to Article 13, relevant provisions of the Turkish Penal Code No. 5237, Act No. 4077 on Protection of Consumers, the RTUK Law, Act No. 4054 on the Protection of Competition and the related provisions of other legislation become applicable.

Article 13/3 of the Promotion Regulation states that if a medicine is promoted in a manner that breaches the Promotion Regulation, the MA holder will be issued a warning, and in the event of reoccurrence, banned from engaging in promotional activities for three months. If the breach continues, promotional activities of the MA holder will be suspended for one year.

In the event of a breach of congress or symposia sponsorship requirements, the MA holder will be issued a warning by the MoH, and in the event of a recurring breach, banned for one year from taking part in or supporting any congress or symposia activity.

According to the Law No. 1262, it is strictly forbidden to advertise medicines to the general public where the contrary may result in heavy administrative monetary fines. Please see the answer to question 6.1.

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 subjected to broadcasted 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.

There has been no reported 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 Institution is the enforcement body in Turkey and acts solely through its Inspection Commission. The MoH does not interfere with the self-regulatory process, however 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, 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(a) of the Promotion Regulation explicitly prohibits the promotion of unauthorised products; however there are two exceptions to this rule.

It is possible to give or discuss information about unauthorised medicines during an international congress held in Turkey. It does not make a difference if the meeting is sponsored by the responsible company, however it must be clearly stated that the product is not yet authorised in Turkey.

It is also possible for the scientific service officer of the responsible company to provide direct information on an unauthorised product to a HCP, upon a written request made by the HCP.

These rules also apply for the off-label information.

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 4.2.11 of the AIFD Code, sharing of literature comprising products and indications not yet registered/approved in Turkey upon written request of a healthcare professional 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 Service officer, 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?

The general rule requires that whether authorised or unauthorised, the medicinal products cannot be advertised publicly. However, press releases are allowed under the Promotion Regulation as an exception, under very limited conditions as explained in detail in the answer to question 6.4, whereas such exception is not applied to unauthorised products. Therefore press releases on unauthorised products are not possible.

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 HCP's written request, information on an unauthorised product may be provided to the healthcare professional by the scientific service officer 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 Turkey?

The ECJ judgment in the *Ludwigs* case, Case C-143/06, does not have applicability in Turkey, as Turkey is not bound with 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 institutions, including the Social Security Institution, in order to shed light on the preparation of their budget for the upcoming years and their reimbursement assessments. However, there is a risk that such information would be regarded as promotion of the unauthorised medicine as the intent may be considered to enhance the sales of such product.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products 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 the above referred 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 are not allowed.

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

Pursuant to Article 5/4 of the Promotion Regulation, HCPs and HCP associations can take part or 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 whereas 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 which had not yet been authorised in Turkey?

As advertising of medicinal products to the public is altogether banned, comparative advertising 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. 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.

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 and materials that may be used as a source of information/data/reference by relevant parties, corresponding to such criteria.

On the other hand, the AIFD Code provides a much stricter rule on medical/scientific reference material and literature. Article 14, introduced with the latest revisions made to the Code in the first quarter of 2015, puts 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 to induce purchasing decisions.

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

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) MA holders shall set up and appoint qualified persons for an adequate system of records and control, for the production, importation and distribution of free promotional samples. Upon demand, these records shall be submitted to the MoH.

b) Free samples contain a quantity reduced in size.

c) The statement "*Free promotional sample – not for sale*" will discernibly appear on the outer packaging of promotional samples on at least one surface.

d) A copy of the SmPCs and the PIL, where available, shall be provided with the promotional sample.

e) Samples of products containing psychotropic or narcotic substances may not be provided or distributed.

f) There shall be no barcode/datamatrix on the packaging of promotional samples. If their inclusion is mandatory, permission will be requested from the MoH, offering sufficient justification, and their sale shall be blocked in the Ministry's Medicine Tracking System. MA holders shall establish a system to enable safe withdrawal of free samples where necessary.

g) Free samples may be distributed up to 5% of the total annual sales upon monitoring the monthly sales in the first calendar year as of the introduction date, in the second calendar year up to 5% of total annual sales generated in the preceding year, in the third, fourth and fifth calendar years up to 3% of total sales generated in the preceding year, and after the fifth calendar year, up to 1% of total sales generated in the preceding year.

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

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

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 8/2 of the Promotion Regulation, monetary value of these reminder gifts cannot exceed 2.5% of the minimum monthly gross wage, corresponding to approximately 10 Euros.

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 could be perceived as such 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?

Article 6/10 of the Promotion Regulation allows MA holders to make donations either in cash or in kind (including donation of equipment or funding of the cost of any medical and technical services) to public healthcare institutions or organisations, if the following conditions are met:

a) Prior permission is received from the administrative authority supervising the recipient organisation, institution or family health centre.

b) Tender award decisions for products covered in the Promotion Regulation are not influenced by the donation.

c) The donation does not lead to any unethical conduct which may be associated with product purchase.

d) The donation does not encourage prescribing a specific human medicinal product.

e) The underlying intention is to promote either research, training, patient wellbeing or care provided to patients.

f) The donation will be utilised by no individual person, but the entire organisation or institution.

g) Only the name of the MA holder, and not the product, may appear on donated materials.

h) The donation is entered in the official books of the MA holder.

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

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?

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 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.

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 and Withdrawal of Products, defective or impure products have to be retracted or withdrawn by companies or the MoH. Companies are liable for damages to institutions resulting from the retraction or withdrawal of a product. Companies have to honour the refund scheme within two months. 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. Article 7 of the Promotion Regulation stipulates that scientific or educational activities related to promotion of medicinal products can only be used for communicating existing medical data and/or presenting new information. This means that whereas the companies may sponsor scientific events, they cannot sponsor directly or indirectly HCP attendance to promotional events.

For company sponsored HCP congress attendance, on the other hand, the Regulation presents a quota limitation commonly referred to as 3-2-1 rule, to avoid excessive interaction. Accordingly, a HCP can annually receive a maximum of three congress sponsorships from the industry. A maximum of two of these sponsorships may come from the same company and one may be 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.* master programme). Medical education can be supported in general without any specification to certain HCPs.

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? 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 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.

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.

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 **€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 to 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.

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.

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 for fee for service agreements conducted with HCPs working in the private sector and only the below mentioned general rules apply.

As will be explained in detail in the answer to question 7.3, in line with the EFPIA requirements, AIFD members are required to keep track of the data on service agreements and the transfers of value to HCPs thereof, to be disclosed publicly in the following year. Accordingly, transparency and disclosure is another issue to be considered from a self-regulation perspective.

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

Our explanations 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?

According to the Law No. 1262 and the Promotion Regulation, it is strictly forbidden to advertise medicines to the general public regardless of whether they are non-prescription or prescription-only medicines.

If a medicine is advertised to the general public, under the amendments made on January 18, 2014 to the Law No. 1262, an administrative monetary fine can be issued. The amount of this fine will be calculated according to the sale amount of the relevant product and the MoH shall have the power to decide multiplying this amount up to five times. In any case, the Law No. 1262 foresees that the amount cannot be less than TRL 100,000 (approx. €35,000). If the violation is repeated, the sanction will be duplicated. If the advertising is made on the 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?

Please see the answer to question 6.1.

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?

There is a specific provision under the Promotion Regulation in relation to MoH-initiated campaigns. Article 6(1) states that information on *products* that are to be used within campaigns initiated by the MoH, such as vaccination campaigns, campaigns to combat epidemics or the ones deemed to be important to safeguard public health in general, can be provided to the general public, provided that the MoH has approved such information sharing within the rules and principles applicable.

There is no specific provision preventing disease awareness campaigns to be initiated by a company where no reference is made to a certain product, but the matter shall be evaluated on a case-by-case basis. Under the general rules, such campaign shall not create the impression or the outcome of promotion of a certain product, as otherwise the MoH may interfere with the campaign. It is therefore advisable to obtain the MoH's approval before initiating such campaigns.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

According to Article 11/2 of the Promotion Regulation, a MA holder can publish a press release to general newspapers only once, and only for the launch of a certain product to the Turkish market.

The genuine copy of the announcement will be sent to the MoH for approval, and the size of a press release published in a newspaper will not exceed 1/8 of a full page.

For print periodicals, a press release may be run once within 30 days after the permission date according to the Promotion Regulation's Guidance.

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

Such descriptions are allowed as long as they do not create the impression or the outcome of promotion of a certain product.

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

The Law No. 1262 and the Promotion Regulation do not stipulate any specific rules on the relationship between pharmaceutical companies and patient organisations, however the spirit of these rules is to minimise the interactions between companies and patients, as companies are not allowed to have any direct contact with patients.

The AIFD Code provides guidelines on interactions with patient organisations, where companies are allowed to provide support to or obtain services from these organisations within certain rules and principles. The AIFD requires a written contract and full transparency for such interactions, where all the information on the interaction will be open to the public.

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 for companies to disclose details of ongoing and/or completed clinical trials at the moment.

However, it is known that the MoH has been working on an amendment to the Promotion Regulation including transparency provisions for value transfers from M/A holders to HCP/HCOs, including payments made in relation to clinical trials as well.

The MoH has also been working on a database specific to clinical trials where all the scientific content in relation to the trials made in Turkey will be compiled.

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, what information should be disclosed, from what date and how?

There is not yet a disclosure requirement as such in the legislation. There is merely a specific provision in the Promotion Regulation, requiring the M/A holders to submit all the details (registration, accommodation, travel costs) in relation to HCP congress attendance sponsorship to the MoH's online database and obtain approval before the attendance takes place. Such information is disclosed only to the MoH and is not open to public or other companies.

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, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

As the AIFD is a member of EFPIA, the AIFD incorporated into its Code the provisions set forth by the EFPIA Disclosure Code, which is binding to AIFD members.

Since January 1, 2015, each AIFD member company is required to track transfers of value related to prescribed pharmaceuticals made to HCPs and HCOs (healthcare institutions and HCP associations) including:

a) contribution to costs of events (registration, accommodation, travel costs);

b) fee for service and consultancy agreements (fees, expenses); and

c) grants and donations.

The disclosure shall be made on an individual basis, where the name of the particular HCP/HCO is indicated alongside the certain interaction and the related transfer of value. If individual disclosure is not possible for legal reasons, then the disclosure can be made on an aggregate basis. Cases where the HCP/HCO does not provide consent for use of their personal data and disclosure are considered to fall under these legal reasons under the national application. The value transfers in relation to research and development activities will be made on an aggregate basis as well.

Data collected for transfers of value occurring in 2015 will be disclosed, as yearly totals, within the first six months of 2016. The disclosure may appear on company websites or on a central platform.

Patient organisations are not included within the scope of these specific disclosure requirements. However the AIFD Code has been providing provisions on full transparency for all interactions with patient organisations including a value transfer to be individually and openly disclosed to the public even before the recently introduced disclosure scheme.

8 The Internet

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

As we have explained above in our answer to question 6.1, advertising of medicines to the general public through any channel is prohibited according to the Law No. 1262 and the Promotion Regulation Article 5/3. Besides the administrative monetary fines, in case the advertising is made on the internet, the MoH shall immediately issue an access-blocking decision to be enforced by the Information and Communication Technologies Authority.

It is accepted by the industry that the rules in the Promotion Regulation shall apply to promotion made through the internet as well. In this respect, the AIFD incorporated an annex to its Code which regulates digital communication. The User Guide on Digital Communication Applications in the Pharmaceutical Sector ("User Guide") set the main principle on transparency.

As the control of the internet by the MoH is difficult due to the lack of regulation regarding this matter, the MoH is planning to work on amendments to be made to the Promotion Regulation to cover internet promotion.

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 some websites have a pop-up system warning that the page is only for HCPs and that if the visitor is not a HCP, the visitor must not click on the "continue" button.

However, the AIFD Code recommends a password mechanism on pages addressed to HCPs on which product information is available. Therefore, it is advised to insert statements such as "*This section is intended for physicians/pharmacists*" at the relevant pages and "*Information on this website shall not replace consultation with a physician or pharmacist. Consult a physician and/or pharmacist for further information*" in order to warn the user according to general advertisement rules.

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?

There is no specific provision under the Law regarding this matter. However, the AIFD Code recommends that companies should be careful regarding links from their website to other sites. Since the advertisement of medicine is prohibited, any kind of promotion of a medicine appearing on a link would be the company's responsibility. This responsibility is also burdened for reverse linking of independent websites to company-sponsored sites.

Due to this heavy responsibility, it is advised not to provide links to dynamic websites with dynamic content, such as blogs or forums, wherein information constantly changes and compliance to the legislation is difficult to verify. In any case, users should be given clear indications when they are directed to another website sponsored by the company, and the relevant measures should be adopted to ensure that there is no content shown advertising a medicine.

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

There is no specific regulation regarding the information to be placed on a pharmaceutical company's website, as the Promotion Regulation only regulates the promotion of medicines and does not cover the advertisement of the company itself. Therefore, 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 may be placed on the website.

Again, provided that a product promotion is not made, companies' websites are allowed to show information about diseases, disease prevention, screening and therapeutic methods and other information aimed at protecting public health. However it is recommended by the AIFD Code to include a warning to the public stating that information on this page does not replace a consultation with a physician.

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

There is no specific regulation controlling the use of social media by companies. However, the User Guide annexed to the AIFD Code regulates the use of social media applications. This User Guide aims to ensure the effective and useful utilisation of social networking applications with user-generated content and blogs.

It is foreseen that the communication shall be respectful, honest and transparent, and mechanisms should be in place to prevent unwanted or abusive messages. In addition, no expression or statement which should not be spoken to HCPs during face-to-face interactions should be used on social media channels.

In respect of blogs, the AIFD Code adopts the view of the ABPI (Association of the British Pharmaceutical Industry) on whether it is suitable for pharmaceutical companies to use or sponsor blogs or establish relations with HCPs or patients via blogs according to the AIFD Code. It is highlighted that if a blog's intention is the discussion of medicines, or in case therapeutic views about a medicine are expected to be expressed in the blog, pharmaceutical companies are advised not to sponsor such sites as they cannot guarantee the conformity of their content with the AIFD Code.

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 major development in the industry in the past year was the start of companies being required to keep track of the value transfers to HCP/HCOs, which are to be disclosed publicly in the following year. Companies had to introduce systems to make sure that the disclosure requirements were fulfilled where at the same time data privacy rules have been respected.

The Promotion Regulation has gone through a minor revision. The provisions outlining the education and certification conditions for sales representatives to be entitled to undertake their duties have been further postponed to January 1, 2019.

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

The major development expected in the next year will be the prospective revisions on the Promotion Regulation.

Some of the significant prospective amendments can be counted as the clearer distinction provided between company sponsored promotional events and scientific meetings/congresses, the removal of the quota limitations on HCP congress sponsorships and the introduction of transparency provisions.

The Draft Promotion Regulation requires companies to track down the value transfers made to HCPs and HCOs to be submitted to the MoH. Though the system to be introduced does not at the moment include disclosure to the public and differs from EFPIA's transparency and disclosure scheme on some aspects, the provisions will likely increase the overall level of transparency in the sector by covering the remaining part of the industry to some extent as well.

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

The implementation of the transparency scheme was the most apparent practice of the last year. All kind of interactions with HCPs/HCOs, including a value transfer, have gone through further

review, especially in relation to data privacy and consent issues. The maximum amounts set by the AIFD formed the hospitality trends of the past year. Also, the AIFD's policy decision to limit distribution of medical/scientific literature only to HCOs revised the trends of medical information sharing between the industry and HCPs.

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