Distribution and marketing of drugs in Turkey: overview

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A Q&A guide to distribution and marketing of drugs law in Turkey.

The Q&A gives a high level overview of distribution and marketing of drugs law, including pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals and engagement with patient organisations.

To compare answers across multiple jurisdictions, visit the Distribution and Marketing of Drugs *Country Q&A Tool*.

This Q&A is part of the global guide to *Distribution and Marketing of Drugs*.

Distribution

Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation
Under the Regulation on Licensing of Medicinal Products for Human Use (*Official Gazette No. 25705 of 19 January 2005*), no medicinal product for human use can be marketed unless it is licensed in Turkey. The licence is issued by the Medicines and Medical Devices Agency (Agency) of the Ministry of Health

For placing the product on the market, the following additional regulations must be considered:

- Regulation on Labelling and Packaging of Medicinal Products for Human Use (*Official Gazette No. 25904 of 12 August 2005*). It determines the procedures and essential information to be given on labels and packages.
- Regulation on Safety of Drugs (Safety Regulation) (*Official Gazette No. 28973 of 15 April 2014*). The Safety Regulation lists the activities conducted for monitoring, research, recording, archiving and assessing the safety of drugs for human use which have been granted registration or permit, as well as natural or legal persons conducting such activities.

The principles for the inspections and examinations conducted by the Agency and the recall procedures for products posing threat to human health are also regulated in a variety of separate regulations.

Exceptions
Although the regulations set out the obligation to have a licence in order to distribute drugs, there are alternative ways such as compassionate use or named patient use (*see Question 2*).

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

The named patient use is defined as the special importation of drugs which have no marketing authorisation in Turkey or which have marketing authorisation but are not available in the Turkish market. These products are imported from abroad on a named patient basis by the Pharmacists' Association (TEB). This importation is based on the Guidelines on the Supply from Abroad of Drugs.

A protocol dated April 2007 was signed by and between the Social Security Institution (SSI) and TEB. TEB is authorised to import the products that are registered in the Imported Pharmaceuticals Provision System. This is an extendable list, therefore products can be added to this system on the approval of the Medicines and Medical Devices Agency (Agency). Within the scope of these systems, products can be prescribed and imported without an actual licence

In addition, Turkey has a compassionate use programme established under the Guidelines on Compassionate Use Programme issued by the Agency (Guidelines). This programme is defined in as an arrangement that aims to provide free of charge drugs which are not registered in Turkey and are registered or not registered in other countries, to patients whose treatment in Turkey has failed with the existing accessible products registered by the Agency and who suffer from a serious or urgent and life-threatening disease and have not been included in the scope of the clinical trials conducted in this field (*Article 1, Guidelines*).

In order for this program to be implemented, the treating physician of the patient must make a written commitment for taking over the responsibility of including the patient in this programme and report this to the Agency (*Article 2, Guidelines*).

Except for scientifically justifiable and very rare exceptional cases, drugs for which at least Phase II studies have been completed and Phase III studies have been initiated across the world, are included in the programme. The studies do not need to be conducted in Turkey for a product to be included in this programme.

It is clearly stated that this programme is not a clinical trial and that the physician conducting the programme does not receive any payment under any name. This programme does not aim to collect information about the effectiveness of the drug and even if such information is collected, it will not be used in the procedures relating to the registration of the drug by the Agency. The Guideline explicitly states that compassionate use and off-label use cannot be conducted at the same time.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

Regulatory authority
The Medicines and Medical Devices Agency (Agency) is the national body responsible for licensing of drugs in Turkey.

Structure
The requirements set out in the Regulation on Licensing of Medicinal Products for Human Use (Licensing Regulation) must be met in order to be granted a licence and initiate the marketing of the drugs.

The persons applying for a drug licence must meet the following conditions of eligibility:

- Individuals must have a university degree from in pharmacy, medicine or chemical sciences and must be qualified to practise their profession in Turkey (*Article 7, Licensing Regulation*).
- Pharmacists must be Turkish citizens to practise their profession in Turkey (*Law on Pharmacists and Pharmacies No.6197*). There is no nationality requirement for chemists.
- Legal entities must employ an authorised person who meets the required conditions and experience of the product for which the application is submitted.

The Agency follows the European CTD format (including five modules) for the application files. The Agency evaluates the licence application in a 210-day period. (Article 15, Licensing Regulation) However, in practice, this period can be extended even for a year or two, due to the workload of the Agency. The Good Manufacturing Practices (GMP) certificates required for the licensing are issued by the Agency after an on-site examination conducted by the Agency officials. This creates a lot of delays especially in the authorisation of imported products.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

An abridged application can be submitted.(Article 9*, Regulation on* Licensing *of Medicinal Products for Human Use (Licensing* Regulation*).*) In abridged applications, the applicant is not required to present the results of toxicological and pharmacological tests and clinical trials, if:

- The medicinal product is essentially similar to a medicinal product which has been previously registered in Turkey and the marketing registration holder of the original medicinal product consented to the use of the toxicological, pharmacological and/or clinical references contained in the dossier of the original medicinal product for the purpose of evaluating the referred application.
- Any constituent(s) of the medicinal product have a well-established medical use, determined by means of detailed scientific bibliography and with a reasonable efficiency and acceptable level of safety.
- The medicinal product is essentially similar to a registered medicinal product and has completed its data exclusivity period.

Data exclusivity applies to the original products:

- For which no generic registration application was submitted in Turkey before 1 January 2001.
- Registered for the first time in one of the countries within the Customs union Area after 1 January 2001.
- Registered for the first time in one of the countries within the Customs union Area after 1 January 2005.

The data exclusivity period lasts six years from the first registration date in the Customs Union Area. Data exclusivity period for products which benefit from patent protection in Turkey is limited to this patent period.

Parallel import of drugs is strictly forbidden under Turkish law. Drugs for human use cannot be marketed unless they are (*Article 5, Licensing Regulation*):

- Registered by the Agency under the provisions of the Licensing Regulation.
- Imported through the alternative ways as described above.

The drugs can only be cleared from the Turkish customs by the marketing authorisation holder. In a Circular No. 2014/11 of 20 November 2014 the Ministry of Health explained that all measures will be taken to prevent the export of the imported drugs which are supplied for Turkish citizens' needs. To the extent of authors' knowledge, to date no specific measures have been taken.

5. Is virtual drug distribution possible from your jurisdiction?

This situation is not regulated under Turkish law and the licence given by the Ministry of Health is only effective on the Turkish territory, therefore it seems that virtual distribution is not possible.

6. What is the procedure to appeal (legal remedy) a licensing decision?

The licensing decisions are considered as administrative decisions in nature. The Administrative Procedure Code regulates the application for cancellation of administrative decisions or application for indemnity.

Under the Code, the licensing decision can be challenged within 60 days after its notification before administrative courts or it is possible to request corrective actions from the authority as well as through an application made. (Article 11,*Administrative Procedure* Code). The corrective action ceases the 60-day period for filing an action and the period starts to recount after the response of the related authority or the lapse of a 60-day period in case the authority does not give any response.

7. What are the costs of obtaining licensing?

The fee tariff is announced on the website of the Medicines and Medical Devices Agency every year. There are a number of different fees to be paid depending on the nature of the application.

According to the 2018 fee tariff, the fee for an application to obtain a drug licence for drugs manufactured abroad is TRL45,788.

Article 57 of the Decree Law No. 663 sets out a limit of TRL150,000 which cannot be exceeded in determining fees for licences.

Distribution to consumers

8. What are the different categories of drugs for distribution?

Under Article 5 of the Regulation on the Classification of Medical Products for Human Use (*Official Gazette No. 25730 of 17 February 2005,*) drugs are categorised during the licensing procedure as being subject to a prescription or not. There is no categorisation of drugs based on distribution criteria.

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs
Only pharmacies can sell prescription drugs to consumers. There are eligibility conditions to obtain an authorisation to sell prescription drugs (*Article 3 of the Law on Pharmacies and Pharmacists No. 6197*). For example, to establish a pharmacy, the applicant must have Turkish citizenship and a pharmacy or medicine degree which is authorised by the Medicines and Medical Devices Agency.

Over-the-counter drugs
The Regulation on the Classification of Medical Products for Human Use defines in detail what a prescription drug is, but only defines non-prescription drugs as everything else. Due to the lack of a regulation of the over-the-counter drugs, the number of non-prescription drugs in Turkey is considerably limited and therefore all kinds of drugs must be sold in pharmacies.

10. What drugs can an attending physician distribute and under what circumstances?

Only pharmacists can distribute drugs to patients, attending physicians are not allowed to do so (*see h*). However, physicians can give free samples to their patients.

11. Who is authorised to prescribe prescription drugs to consumers?

Only physicians or dentists can prescribe drugs (*Article 13, Law No.1219 on the Medical Practice and Related Arts*).

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

The Regulation on Pharmacists and Pharmacies prohibits the sale of drugs via online websites or in any other electronic platform.

The Regulation on Pharmacists and Pharmacies also prohibits pharmacies from accepting the supply of drugs whose the prescription is sent via internet, fax, telephone, courier and agent or by similar means.

Therefore the direct mailing/distance selling of drugs to consumers is prohibited.

13. What regulatory authority is responsible for supervising distribution activities?

The Regulation on the Procedure and Principles of the Ministry of Health's Market Surveillance and Inspection of 25 June 2007 sets out the general rules for market surveillance and inspection of drugs.

Drug distribution activities are supervised by the Medicines and Medical Devices Agency.

Additionally, in line with the Regulation on Withdrawal (*Official Gazette No. 29537 of 19 November 2015*), products which are found to pose a threat to patients and public health during the surveillance activities can be withdrawn, collected and destroyed if necessary. The aim of the Regulation is to set out the rules, authorisation, responsibilities and the control guidelines regarding the inspection of the products which are (or are suspected to be) defective, or if their usage is considered risky. This surveillance activity encompasses drug factories, laboratories, trading houses, warehouses and pharmacies.

14. What is the procedure to appeal (legal remedy) a distribution decision?

The marketing authorisation grants its holder the right to distribute the relevant drug. Therefore, there is no need to have any other administrative decision to distribute drugs or to work with any distribution channels. However, all distribution activities are subject to the control of the Medicines and Medical Devices Agency (Agency), which can impose sanctions. The Agency's decisions are considered administrative decisions and can be challenged (*see Question 6*).

15. What are the legal consequences of non-compliance with consumer distribution laws?

Under the Regulation on the Procedure and Principles of the Ministry of Health's Market Surveillance and Inspection, the violation of the Regulation provisions can have the following consequences:

- Prohibition of marketing.
- Withdrawal, collection and destruction of the related products.
- Administrative monetary fines as stipulated in Law No.1262.

Under the Law No.1262, an administrative monetary fine can be given and the granted authorisation can be withdrawn if it is determined that:

- The substance entering into the composition of the preparation is impure.
- The substance does not conform to the formula for which the permit is granted.
- Preparations are made without permission and are sold knowingly.

Other acts violating the Regulation can be sanctioned with an administrative monetary fine as well (*Article 20, Law No. 1262*).

The withdrawal, collection and destruction decisions are implemented in line with the principles set out in the Regulation on Withdrawal. In case the withdrawn or collected defective products are damaging to health, the provisions of the Penal Code (*Official Gazette No. 5237 on 12 October 2004*) apply depending on the gravity of the damage.

In addition to these provisions, the Law Relating to the Preparation and Implementation of the Technical Legislation on the Products (*Official Gazette No. 4703 on 11 July 2001*), implements severe administrative monetary fines. These fines are foreseen in case of a violation of this law which sets out the obligations of the producers and distributors of any product including drugs.

Under the Penal Code, the sale of decayed or otherwise damaged food or drugs and the production or selling of drugs that risk the life and health of others is a crime. Such a crime is punishable with imprisonment from one year to five years, as well as a punitive fine of up to 1,500 daily units, which amounts to approximately up to TRL 150,000, paid to the state (*Articles 186 and 187, Penal Code*).

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

Under Turkish law, wholesale distribution of drugs is regulated by:

- The Law on Pharmacists and Pharmacies (*Law No. 6197*) (*Official Gazette No. 8591 on 24 December 1953*).
- The Regulation on Pharmacists and Pharmacies (*Official Gazette No. 28970 on 12 April 2014*).

- The Good Distribution Practices Guidelines of the Pharmaceuticals and Products Stored in Warehouses.

Drugs cannot be sold directly from the pharmaceutical company to the consumers (patients).

In the Turkish pharmaceutical sector there are three major types of organisations in the distribution chain:

- Pharmaceutical companies, which sell their drugs to warehouses.
- Warehouses.
- Pharmacies. All drugs must be sold to patients through pharmacies.

There is no specific rule requiring the manufacturers or importers to sell drugs through wholesale.

The pharmacy trading houses can carry out wholesale or retail sales only to the pharmacies (*Article 11, Law No. 984 on Pharmacy Trading Houses* (*Official Gazette No. 575 on 12 March 1927*)). Manufacturers and importers can carry on stocking drugs beyond promotional requirements provided that they comply with the rules concerning pharmacy trading houses (*Article 8/3, Law No.1262*).

To manage a warehouse, a licence from the Pharmacy and Pharmaceutical Warehouse Authorisation Office must be obtained. An agent pharmaceutical warehouse must comply with:

- The Regulation on Pharmaceutical Warehouses and Products Stored in Pharmaceutical Warehouses (*Official Gazette No. 23852 of 20 October 1999*) in terms of warehouse storage conditions.
- The Regulation on Manufacturing Plants of Medicinal Products for Human Use (*Official Gazette No. 28630 of 27 April 2013*) in terms of provision of secondary packaging services.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

The Medicines and Medical Devices Agency is responsible for supervising wholesale distribution activities. Its decisions are considered to be administrative decisions and can be challenged (*see Question 6*).

18. What are the legal consequences of non-compliance with wholesale distribution laws?

In case of a violation of the provisions set out by the Regulation on Pharmaceutical Warehouses and Products Stored in Pharmaceutical the provisions regulated under the Law No. 6502 on Protection of Consumers (*Official Gazette No. 28835 of 28 November 2013*) or the Penal Code are applied depending on the gravity of the act. The Law on

Protection of Consumers aims to protect the health, safety and economic interests of consumers. In case of sale of goods or services that can potentially endanger or harm a person's health or the environment, a warning must be added or written, in an easily visible and legible manner, on the packaging or included in the information leaflet (*Article 55/3*). In case of a violation of this obligation, an administrative monetary fine of TRL274 per unit of product will apply to the producers, importers and sellers.

Articles 186 and 187 of the Penal Code also apply (*see Question 15*).

Marketing

Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime
In Turkey, the legal regime regarding marketing of drugs is contained in the Regulation on Promotional Activities of Human Medicinal Products (*Official Gazette No. 28037 on 03 July 2015*).

Limits to marketing activities
Under the Regulation, as a general rule no promotion activities are permitted for drugs which are not licensed in Turkey. It is strictly prohibited to address general public in promotional activities. Moreover, neither marketing authorisation/licence holders nor their representatives can provide offers or promise benefits to the healthcare professionals by way of promotional activities. The marketing authorisation or licence holder company must not encourage the prescription of its products by offering any kind of benefit to a healthcare professional.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

There are codes of conduct for professionals prepared by industry organisations which are applied together with the legal regime, for example:

- The Pharmacists Deontological Rules.
- The Pharmacists' Association Law.

In addition, there are three pharmaceutical associations in Turkey which have their own codes of practice:

- The Pharmaceuticals Industry Association
- Association of Research-Based Pharmaceutical Companies (AIFD).
- Pharmaceuticals Manufacturers Association

These associations' rules establish standards for the companies in the respective sector and are considered auxiliary rules for the industry. AIFD is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its promotional code is in line with the EFPIA.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime
It is forbidden to promote drugs to the general public in Turkey (*Article 13, Law No.1262 on Pharmaceutical and Medical Preparations and the Promotion Regulation*).

Products
No drugs can be advertised to consumers. However, information can be provided to the general public on products that will be used in vaccination campaigns, organised actions to combat epidemics or other campaigns run by the Ministry of Health (MoH) to promote health (as they are important in safeguarding public health) upon permission of the MoH and within the scope of principles and procedures set by the MoH for such products.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

It is forbidden to advertise any kind of drugs to the general public (*see Question 21*). Promotional activities can only be directed at healthcare professionals.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

Under the Regulation on Promotional Activities of Human Medicinal Products, pharmaceutical companies cannot provide free samples to patients. However, physicians can provide free samples to their patients.

"Buy-one-get-one-free offers" can be used by pharmaceutical companies to wholesalers and by wholesalers to pharmacies during their commercial activities. The Ministry of Health does not regulate these kinds of commercial arrangements and currently there are no sanctions in place against such practices.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

Promotional activities cannot be directed at the general public (*Article 13, Law No.1262*). Some regulations repeat this prohibition in order to emphasise its importance. However, promotion of licensed drugs is allowed if it is aimed at healthcare professionals and includes objective, informative and factual medical data in a way that enables the healthcare professionals to form their own opinion about the product.

There are no specific rules/codes prohibiting the use of internet/social media in respect of promotion activities directed at the health professionals. The general rules on promotion activities apply in this area. The promotional content should therefore not be directly available to the general public and there must be precautions in place.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The Medicines and Medical Devices Agency is entitled to inspect, *ex officio* or upon receipt of a complaint, promotional activities and any materials and methods employed in the context of such activities. The Ministry of Health (MoH) can require the marketing authorisation or the licence holder to cease, terminate or correct the information provided during any promotional activity which is found to be non-compliant with the Regulation on Promotional Activities of Human Medicinal Products or deemed inappropriate for public health. Any request by the MoH must be complied with without delay.

Also, since the Regulation on the Commercial Advertisement and Unfair Commercial Practices and the Law on Establishment of Radio and Television Institutions and their Media Services (RTUK Law) (*Official Gazette No.6112*

of 15 February 2011) prohibit the advertisement of drugs, the Advertisement Board and the RTUK Council examine the advertisements and can impose sanctions too.

The Advertisement Board, established within the Ministry of Customs and Trade, is the sole administrative authority controlling advertisements in Turkey. The Advertisement Board is entitled to conduct an investigation ex officio or upon an individual complaint and to impose administrative monetary fines.

The RTUK Council can also control radio and television advertisements in Turkey. The Council can warn, impose administrative monetary fines and may cease the broadcast of programmes that violate the prohibition.

Rights of appeal
The decisions of the Medicines and Medical Devices Agency, the Advertisement Board and the RTUK Council, are considered to be administrative decisions and can be challenged (*see Question 6*).

26. What are the legal consequences of non-compliance with consumer marketing laws?

Other than the consequences mentioned under *Question 25*, under Article 13 of the Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation) anyone who acts or operates in violation of the provisions in the Regulation will be subjected to, depending on the nature of the violation, the applicable provisions of:

- The Penal Code (see *Question 3*).
- Law No. 6502 on Protection of Consumers (dated 28 November 2013).
- Law on Protection of Competition (dated 12 December 1994 and No.4054).
- RTUK Law.
- Other applicable regulatory provisions.

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

Moreover, under Article 18 of the Law No. 1262 if, following the analyses mentioned in Article 10, it is detected that the substances into the composition of preparations are not pure or are incompliant with the approved formulation submitted for receiving registration or have been manufactured in a manner to derogate from or eliminate its curative properties, and if such act does not constitute a criminal offence, the registration holder and whoever sells, supplies or causes selling of the preparation knowing that it was manufactured in such state will be fined between TLR10,000 to 500,000. Those who promote and sell preparations in violation of this law, market them off-label and thus encourage generation of prescription in this direction will be subject to an administrative fine of up to five times of the relevant product's total sales of the last one year (not less than TLR100,000). If promotion and sales are performed via the Internet, the MoH will decide whether to block their access and such decision will be communicated to the Information Technologies and Communication Agency to enforce it. For those who promote

and sell products with a health declaration without the permit of the competent authority or in violation of the permit issued will be subject to an administrative fine ranging from TRL20,000 to 300,000.

If a violation is determined, disciplinary action will be brought against healthcare professionals by their institutions and professional organisations. In case the promotion of a drug violates the Promotion Regulation's provisions, the marketing authorisation or the licence holder will receive a warning. In the event of recurrence, the holder will be banned from engaging in promotional activities. In case of further reoccurrence of the same breach, the marketing of the product will be suspended for three months, followed by a one-year suspension, if the breach persists. Moreover, if a product representative violates the Promotion Regulation within the validity period of his proficiency certificate, the representative will receive a warning first, in case of reoccurrence, the proficiency certificate will be suspended for three months, and for one year, if the breach persists.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

The Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation) governs the relationship between the pharmaceutical companies and the healthcare professionals.

Under the Promotion Regulation, promotion to healthcare professionals occurs through:

- Distributing promotion materials to physicians, dentists and pharmacists,
- Sponsoring or holding scientific meetings and product promotion meetings with healthcare professionals (that is, meetings between product representatives and physicians, dentists and pharmacists).

28. Are there any restrictions on marketing to professionals?

Marketing activities

Drugs which are not licensed or authorised according to applicable regulations cannot be promoted to healthcare professionals, excluding promotional activities during international congresses held in Turkey and information provided personally by the scientific unit of the marketing authorisation or license holder upon the written request of the physician/dentist/pharmacist (*Article 6, Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation)*). The Promotion Regulation also determines an exception for the prohibition of promotion even where the product has a marketing authorisation. For the purposes of pharmacovigilance, it can provide information on drugs which have a marketing authorisation but are not available in the market only if:

There is an alternative reimbursement agreement signed with the Social Security Institution.

The product is imported on a name based.

Promotion aimed at healthcare professionals must include objective, informative and factual medical data in a way that allows healthcare professionals to form their own opinions about the product. The promotional activities cannot be used to encourage unnecessary use of a product.

Healthcare professional must not act in promotional activities of such products without the permission of the Ministry of Health. Promotions cannot involve sweepstakes, lottery or similar schemes. The Promotion Regulation does not allow providing, offering or promising of any benefits, whether in cash or in kind, and the healthcare professionals must not accept or request any incentive during the course of such promotional activities.

No benefit (in kind or in cash) can be provided, offered or promised during promotional activities to physicians, dentists or pharmacists.

Any gifts or benefit received directly or indirectly which affects or is likely to affect a public officer's impartiality, decision or performance of duties is deemed to be a gift regardless of its economic value (*Article 15 of the Regulation on Ethical Principles for Public Officers and Implementation Procedure and Principles of Application (Official Gazette No.25785 of 13 April 2005*)). Greeting, farewell or celebration gifts, scholarships, travel, complimentary accommodation and gift checks received from the persons that have a business, service or benefit from the relationship with the related institution are considered to be gifts. Although these provisions are directly binding for the public officers, not for the companies, non-compliance may also have consequences for companies under anti-bribery provisions of the Penal Code as they can be used in the interpretation of constitutes bribery.

The industry association, Association of Research-Based Pharmaceutical Companies (AIFD), interprets the regulations more strictly and obliges its members to not provide any promotional materials (such as pens, notebooks and calendars) to healthcare professionals.

Frequency

- Product promotion representatives (PPRs) can promote human medicinal products at public health institutions during working hours subject to the following rules (*Article 10, Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation*))):
- Relevant administrative supervisors at every public health institution will designate the most suitable time period to enable meetings between PPRs and healthcare professionals for product promotion, taking account of the work schedules. Such designation cannot disrupt educational functions or provision of healthcare services to patients.
- Product promotion representatives calling on healthcare institutions to perform their promotional functions cannot be charged any fee, pecuniary or otherwise (for example, donations or others) for gaining access to the public health institution.

Provision of hospitality

Scientific meetings and meetings related to the promotion of a medicinal product for human use must not be used for any purpose other than transmitting the existing medical information and/or presenting new information (*Article 7, Promotion Regulation*). Marketing authorisation holders cannot cover, whether directly or indirectly, transportation or accommodation expenses of participants taking part in product promotion meetings.

Marketing authorisation holders can sponsor healthcare professionals for participating in scientific meetings such as congresses or symposia taking place in or outside Turkey on the following conditions:

- Meetings are related to the specialty/role of the healthcare professional.
- A healthcare professional can benefit from such sponsorships four times within the same calendar year. Only two out of these three sponsorships can be provided by the same registration/permit holder and only two out of these four sponsorships can be used for a meeting abroad. This excludes meetings which healthcare professionals attend as a speaker, or as an investigator presenting a paper, with the sponsorship of registration/permit holder.
- Sponsorship is provided to the organisation holding the meeting, and not directly to an individual.

Marketing authorisation holders must notify the Medicines and Medical Devices Agency (Agency) of particulars of healthcare professionals to be sponsored in accordance with the Guidelines on Scientific and Product Promotion Meetings.

Except international meetings that are held each time in a different country, no meeting can be held or sponsored by marketing authorisation/licence holder at skiing resorts between 1 December and 1 March, or at seaside resorts between 15 June and 15 September. These conditions are not valid for scientific meetings held or sponsored by the Ministry.

Non-healthcare professionals cannot be invited to the meetings, and their expenses cannot be covered. However, guests of honour are excluded from this provision.

At least 60% of all meetings lasting more than six hours, organised or contributed to by marketing authorisation holders within a calendar year, must include a session on the rational use of drugs, relevant to the topic of the meeting. The content of presentations delivered on during such sessions must be aligned with Agency-approved educational materials and diagnostic and therapeutic guidelines, and submitted to the Agency for review, as described in the guidelines.

Persons appointed by the Agency can attend these meeting for inspection purposes with or without prior notice.

Meetings of investigators, sponsored by the marketing authorisation/licence holder, held in Turkey or in a third country in connection with a national or international multicentre clinical trial, is not considered attendance to a scientific meeting. For such meetings, application must be submitted for permission to the relevant department of the Agency

29. What information is it legally required to include in advertising to professionals?

Promotion of a product must be consistent with the information and data contained in such product's current summaries of product characteristics (SmPCs) (*Article 6/3, Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation)*). Since it is necessary to show the SmPCs in a licence application, the

SmPCs is regulated under the Licensing Regulation. The Regulation lists all the information that must appear on the products.

Moreover, under Article 6/4 of the Promotion Regulation, promotion must include informative and factual medical data on a product's characteristics that will help healthcare professionals establish their own opinion on a product's therapeutic value.

The Association of Research-Based Pharmaceutical Companies Ethics Code specifies that the following information must also be included in the promotional materials:

- The dosage.
- Mode of administration.
- Side effects.
- Precautions.
- "Inverted black triangle" symbol in drugs subject to additional monitoring, contra-indications and warnings.

These information must be placed in such a position on the promotional materials that it is easily seen by the reader. In addition, the name of the active substance of the drug must appear on the promotional materials in a legible size, immediately adjacent to the most prominent display of the commercial name.

- In audio-visual materials such as films, video recordings and information in interactive data systems, abbreviated SmPCs must be provided in a document which is made available to all persons to whom the material is shown or sent.
- The audio-visual recording or interactive data system itself.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

Even though the advertising of drugs is prohibited to the public, the general provisions on comparative advertising under the Regulation on the Commercial Advertisement and Unfair Commercial Practices apply to the promotional activities of drugs to healthcare professionals. The name of the product compared must not be mentioned. The compared products must meet the same consumer needs and address the same purpose. It must be in conformity with the fair competition principles that prohibit misleading of the consumer.

According to the Association of Research-Based Pharmaceutical Companies Ethics Code, comparisons between different medicinal products must include "comparative features". Comparison can be made in a promotional material under the following conditions, without making any reference to trade marks:

- It is not misleading.
- Drugs or services for the same needs and purposes are compared.

- Relevant, proven and significant features are compared.
- Comparisons are not used to create confusion on purpose.
- Pejorative or derogatory statements are not included regarding the competing product or brand.
- Unfair advantage of the reputation of a competitor is not taken.

31. What other items, funding or services are permitted to be provided to professionals?

Discounts
Discounts are permitted under Turkish law. However, discounts cannot be linked to any promotional activities, it can be solely a commercial activity. Discounts can be provided by pharmaceutical companies to warehouses and by warehouses to pharmacies. Pharmacies may also provide discounts to patients.

Free samples
Free samples can only be distributed to physicians, dentists or pharmacists provided that the following conditions are fulfilled (*Article 9, Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation)*):

- Marketing authorisation holders must set up and appoint qualified persons for an adequate system of records and control, for the production, importation and distribution of free promotional samples, to safely withdraw them where necessary. Upon demand, these records must be submitted to Medicines and Medical Devices Agency (Agency) officials electronically or in hardcopy in the format designated by the Agency.
- Free samples contain a quantity reduced in size. However, this requirement does not apply to enteral nutritional products and promotional samples of products which, for technical reasons, cannot be reduced.
- The statement, "Promotional sample – not for sale" must visibly appear on the outer packaging of promotional samples on at least one surface. The same statement must be printed also on the inner package, where this is possible.
- A copy of the summaries of product characteristics (SmPCs) and the PIL, where available, must be provided with the promotional sample.
- Samples must not be provided or distributed of products containing psychotropic or narcotic substances, covered under international agreements and of products subject to national control.
- Free samples that are listed in the "drugs which cannot be distributed as samples" list published in the Agency's website cannot be distributed or given.
- Free samples of medicinal products for human use can be distributed:
    - in the first calendar year as of the introduction date, up to 5% of the total annual sales on monitoring the monthly sales;
    - in the second calendar year up to 5% of total annual sales generated the preceding year;
    - in the third, fourth and fifth calendar years up to 3% of total sales generated the preceding year;

- after the fifth calendar year, up to 1% of total sales generated the preceding year.

Enteral nutritional products with prioritised oral use, designated as taste samples are exempt from the decremental restriction of amount by years.

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

Sponsorship of professionals

Sponsorship of healthcare professionals in their participation in national or international events are also subject to strict rules (*see Question 28*).

Under Article 6 of the Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation), no personal donations can be made directly or indirectly to healthcare professionals.

Marketing authorisation/license holders can donate to public healthcare institutions or organisations, and non-profit healthcare agencies, institutions and organisations if the following conditions are met:

- Tender decisions concerning products within the scope of the Promotion Regulation must not be influenced and unfair competition must not be caused.
- The donation must not lead to any unethical transaction which may be associated with any purchase of products.
- The donation must not encourage prescribing a specific product.
- The intention must always be research, education, health or improvement of care given to patients.
- The donation will be utilised by the entire organisation or institution, not by any individual person.
- Only the name of the marketing authorisation/license holder, and not of the product, may appear on the donated materials.
- The donation must be entered in the official books of the marketing authorisation/license holder.
- Any donation of medicinal products, laboratory kits or similar items for use in clinical research must be made directly to the principal investigator.
- Healthcare institutions and organizations may only accept donations by receiving permission from their headquarters, or in line with the relevant guidelines issued by their headquarters.

Other items, funding or services

There are no other incentives allowed under Turkish law except the ones mentioned above. Donations are not considered incentives and are strictly regulated under the Regulation on Promotional Activities of Human Medicinal Products (Promotion Regulation).

Under the new Promotion Regulation, pharmaceutical companies must disclose to the Medicines and Medical Devices Agency (Agency) any transfers of value (either in cash or in kind) exceeding 10% of the gross monthly minimum wage that they make to:

- Healthcare professionals.
- Healthcare institutions and organisations.

- Universities, unions, associations and foundations active in the field of healthcare.
- NGOs established for the purpose of the protection and the advancement of health.

Companies must collect documents regarding transfers that have occurred within one calendar year and file their submissions within the first six months of the next year. Although this disclosure obligation is similar to the one that company members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) must make, disclosures under the Promotion Regulation must be made to the Agency only and public disclosure is not currently expected.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority
The Medicines and Medical Devices Agency can examine, *ex officio* or upon receipt of a complaint, the promotional activities and any materials and methods employed in the context of such activities (*see Question 25*).

33. What are the legal consequences in case of non-compliance with professional marketing laws?

The legal consequences are the same as the ones listed in *Question 26*.

Engagement with patient organisations

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

- There are no regulations restricting the collaboration between the pharmaceutical industry and patient organisations. However, The Pharmaceuticals Industry Association, Association of Research-Based

Pharmaceutical Companies (AIFD)and Pharmaceuticals Manufacturers Association have their own codes of practice which govern relations with patient organisations.

Under the AIFD Ethics Code, the pharmaceutical company can provide financial support or services to a patient organisation. A written agreement must be signed between the pharmaceutical company and the patient organisation and the amount of the financial support must be clearly defined. The non-financial, direct or indirect support must also be defined in the agreement. These service agreements can only be concluded if they aim to support public health or research. Every pharmaceutical company must declare the patient organisations they are supporting. This declaration must be clear and understandable to an average reader.

The logos of patient organisations can be used only on their approval. Pharmaceutical companies must not insist on being the sole supporter of a patient organisation or a big project. The Ethics Code repeats the prohibition to promote drugs to the general public through patient organisations.

In case of a complaint based on a violation of these provisions, the pharmaceutical company can face sanctions depending on the gravity of the violation. The authority to examine the violation differs depending on the complainant. For example, if the complaint is made by a physician with regard to an AIFD member, the case is examined by TIDK (Promotion Principles Inspection Board of AIFD). The Ethics Code sets out the sanctions such as a warning sanction, a notification, reprobation, a suspension of the company's membership of the Association and permanent exclusion from the Association. In the case of a repetition of the same violation, there will be a heavier sanction.

Reform

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

Amendments to some regulations, such as the Regulation on Licensing of Medicinal Products for Human Use, the Bioavailability and Bioequivalence Regulation and the Regulation on Variations for Authorised Drugs are expected. The Medicines and Medical Devices Agency is currently collecting opinions and comments from industry associations regarding these regulations.

Contributor profiles

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Recent transactions

- Advised six pharmaceutical companies on risk sharing schemes and alternative reimbursement agreements with the Social Security Institute.
- Advised and represented a multinational pharmaceutical company in an action against the Social Security Institute for the reversal of a reimbursement delisting decision based on non-localisation of the manufacture of the import product.
- Advising the Association of Research-Based Pharmaceutical Companies and the Association of Research-Based Medical Technologies Manufacturers in Turkey, on a number of regulatory policy papers, and drafting laws and regulations proposed to the Turkish governmental authorities.
- Advised a UK based pharmaceutical company on toll manufacturing agreements with two local companies within the scope of Turkish Government's localisation policy.

Professional associations/memberships. IBA, Vice Chair of the Intellectual Property and Entertainment Law Committee (2018 – 2019); IBA, Chair of the Patent Law Subcommittee of Intellectual Property and Entertainment Law Committee (2016 – 2017); INTA; AIPPI; LES; Galatasaray University Alumni Association.

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Areas of practice. Life sciences; intellectual property; trade marks and designs.

Recent transactions

- Advising corporate life sciences sector clients, especially multinational pharmaceutical and medical device companies. Advising clients on a wide range of issues including promotional activities, advertisement, labelling requirements, clinical trials, marketing authorisation procedures, pricing and reimbursement regulations, and also assisting clients in their day-to-day business activities.
- Advising the Association of Research-Based Pharmaceutical Companies (AIFD) and the Association of Research-Based Medical Technologies Manufacturers (ARTED) in Turkey.
- Consulting clients on many regulatory policy papers and drafting laws and regulations proposed to the Turkish governmental authorities.
- Conducting trade mark infringement and unfair competition actions, trade mark invalidation and revocation actions.

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