PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

Under Turkish legislation, the promotion and advertising of pharmaceuticals and medical devices is governed by a comprehensive framework outlined in various legal documents. For pharmaceutical products, this framework primarily includes the Pharmaceutical and Medical Preparations Law, which sets the foundational principles, and the Regulation on Promotional Activities of Pharmaceuticals (Regulation on Pharmaceuticals), which provides detailed guidelines for promotional activities. Additionally, there are several guidelines governing specific aspects of promotional activities, such as Guidelines on Electronic Scientific and Product Promotion Meetings and Guidelines on Scientific Meetings and Product Promotion Meetings. These guidelines serve to ensure that promotional activities adhere to ethical standards and legal requirements.

Similarly, the advertising and promotion of medical devices are regulated under distinct legislation, primarily the Medical Device Regulation and Regulation on Sales, Advertising, and Promotion of Medical Devices (Regulation on Medical Devices). These regulations are complemented by implementation guidelines and announcements, such as Guide on the Implementation of the Regulation on Sales, Advertising, and Promotion of Medical Devices.

Compliance with competition rules is also crucial in the context of advertising and promoting pharmaceuticals and medical devices. It should also be considered whether the relevant activities have anti-competitive effects according to the Law on the Protection of Competition.

Article 26 of the Regulation on Commercial Advertising and Unfair Commercial Practices further emphasises the importance of compliance, stipulating that advertisements and promotions of pharmaceuticals and medical devices must comply with the provisions relating to advertising and promotion found in the relevant legislation.

In cases of non-compliance with the relevant legislation, administrative fines specified in the Misdemeanour Law may apply. Also, within the scope of the Regulation on Pharmaceuticals penalties for stopping activities for certain periods may also be applied.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

Although there is no specific definition of advertising in the legislation regulating rules regarding pharmaceuticals, Article 13 of the Pharmaceutical and Medical Preparations Law specifies that advertisements of pharmaceuticals that cannot be sold without a prescription are banned from being advertised anywhere other than in medical journals.

Furthermore, the Regulation on Pharmaceuticals defines what promotion entails. Accordingly, all activities aimed at providing information to healthcare professionals regarding the medical-scientific characteristics of products within the scope of the regulation, organised by the licence/permit holders or with their name, request, contribution, or support, fall under promotion. This includes activities such as the activities of product promotion representatives, notices placed in medical and professional books and journals, announcements made through direct mailing or other communication channels, scientific meetings and product promotion meetings, and similar events.

In the Regulation on Medical Devices, both the definition of advertising and promotion are provided. Advertisements are defined as marketing communications carried out by advertisers in any medium, written, visual, audio, or similar means, aimed at promoting the sale or lease of a product or service related to trade, business, craft, or profession, to inform or persuade the target audience.

All activities aimed at providing information to healthcare professionals or technical personnel working in the field of medical devices within healthcare institutions about the scientific and medical characteristics of devices fall under promotion within the scope of the regulation. This includes activities such device sales and promotion representatives, notices placed in medical and professional books and journals,

announcements made through direct mailing, press, or other communication channels, scientific/educational activities, meetings, and similar events.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

According to Presidential Decree No 4, the rules regarding pharmaceuticals and medical devices are regulated by legal texts issued by the Turkish Medicines and Medical Devices Agency (Agency), which is affiliated with the Ministry of Health (Ministry). Furthermore, the Agency has sanctioning authority. In addition, under other regulations, the Competition Authority and the Advertising Board may also impose sanctions for advertising violations relating to these products.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

Regulation on pharmaceuticals also covers enteral nutrition products and medical foods. All provisions apply to these products as well, except for limitations regarding free samples.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?

According to the third paragraph of Article 5 of Regulation on Pharmaceuticals, products cannot be directly or indirectly promoted to the public through any form of media and communication, including the internet, such as programmes, films, series, news, and similar means.

According to Article 15 of the Regulation on Medical Devices, only devices sold, adapted, or applied in hearing aid centres, custom prosthetic and orthotic centres, optician establishments, or dental prosthetic laboratories, or devices intended for use or application by healthcare professionals exclusively, or devices requiring application in medical device sales centres cannot be advertised to consumers. Advertising to consumers for devices other than the above, and those listed in Annex-3 of this Regulation can only take place in an online environment where the sale of the device is made. Advertising to consumers for devices listed in Annex-3 can be freely conducted. Annex-3 includes toothpaste, dental prosthesis care products, condoms, diapers, incontinence care products, compress, band-aids, cotton, mouthwash, breath-opening nasal strips, surgical masks, pressure-relieving tape, finger separators, disposable gloves, nasal tube and non-medical product groups included in the Medical Device Regulation.

There are also some fundamental principles outlined for both fields:

- advertising through raffles, games of chance, and by similar means is prohibited;
- advertising cannot be conducted by providing false, misleading, exaggerated, or unproven information; and
- no advertising activity can be carried out in a way that could harm patients, users, or environmental health and threaten safety.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Under the fourth paragraph of Article 5 of Regulation on Pharmaceuticals, the approved instructions for use/areas of use of products can only be published in channels defined by the Agency and on the website of the licence/permit holder. Outside of these channels, promotional and informational activities aimed at the public regarding products cannot be conducted by partially or fully utilising the approved short product information/instructions for use/areas of use determined by the Agency.

Advertising to consumers for devices other than those listed in paragraphs 1a and 1b of Article 15 of Regulation on Medical Devices and those listed in Annex-3 of this Regulation can only take place in an online platform where the sale of the device is made. Advertising to consumers for devices listed in Annex-3 (above) can be freely conducted.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

According to the first paragraph of Article 6 of Regulation on Pharmaceuticals, products to be used in vaccination campaigns of public health significance and in situations such as combating epidemic diseases, or for the promotion of health, may be communicated to the public with permission from the Ministry, and within the framework of procedures and principles determined by the Ministry.

Moreover, under the third paragraph of the same Article, product promotion must adhere to the information and data specified in the approved areas of use determined by the Agency.

According to the second paragraph of Article 15 of Regulation on Medical Devices, advertisements addressing consumers are exempt from the advertising restrictions for announcements in newspapers/magazines that publicise the availability of the device to healthcare professionals with the permission of the Agency, as well as for device information provided on the official websites of sales centres.

Additionally, according to the second paragraph of Article 16 of this Regulation, the names of the Ministry and its affiliated institutions, as well as the names of healthcare institutions, organisations, or individuals involved in the research of the device, cannot be used in advertising activities without permission.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

According to the second paragraph of Article 6 of Regulation on Pharmaceuticals, except for promotions made directly by the licence/permit holder's scientific service on written request of a doctor/dentist/pharmacist and promotions made at international congresses held within the country, only products which are licenced or permitted under relevant legislation and whose areas of use have been approved by the Agency can be promoted.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Comparative advertising of rival goods or services which meet the same needs or serve the same purpose is permissible under Article 61 of the Consumer Protection Law. The Regulation on Commercial Advertising and Unfair Commercial Practices further elaborates on the conditions for comparative advertisements. These include omitting competitors' distinctive elements, ensuring truthfulness, avoiding unfair competition, and objectively comparing verifiable features, including price. Claims must be substantiated with scientific data, and disparaging competitors is prohibited. Clarity between brands and preventing confusion with competitors' brands or distinctive logos is also emphasised. However, price comparisons are restricted in sectors with price regulations determined by administrative authorities. Consequently, comparative advertising of pharmaceuticals is prohibited due to sector-specific regulations regarding price and market power obligations. These regulations ensure fair competition and protect consumer interests.

Moreover, the Advertising Board sets principles that must be followed in comparative advertising. Compliance with these regulations ensures fair competition and consumer protection, fostering trust in advertising practices across various sectors.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

Both in the legislation related to pharmaceuticals and medical devices, healthcare professionals are defined as doctors, dentists, pharmacists, nurses, midwives, and other healthcare professionals as defined in Additional Article 13 of Law No 1219 on the Practice of Medicine and the Arts of Healing.

According to the second paragraph of Article 5 of Regulation on Pharmaceuticals, promotion to healthcare professionals is carried out by:

a) using promotional materials;

b) organising or supporting scientific meetings and product promotion meetings;
c) visits by product promotion representatives.

According to the second paragraph of Article 17 of Regulation on Medical Devices, promotion to healthcare professionals and technical personnel working in the field of medical devices within healthcare institutions is carried out by:

a) distributing publications included in medical-professional journals;
b) supporting or organising scientific meetings;
c) visits by sales and promotion representatives.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

Virtual meetings within the scope of promotional activities of pharmaceuticals are organised under Article 5 of the Application Guide for Electronic Scientific Meetings and Electronic Product Promotion Meetings Within the Scope of the Regulation on Promotional Activities of Medical Products.

The Guide for Scientific Meetings and Educational Activities to be Conducted Within the Scope of the Regulation on Sales, Advertising, and Promotion of Medical Devices regulates the rules for electronic scientific meetings of medical devices.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?

According to the fifth paragraph of Article 5 of the Regulation on Pharmaceuticals, healthcare professionals cannot participate as actors in the promotion of products without the permission of the Ministry. Similarly, universities, professional organisations operating in the health sector, associations, or foundations cannot participate in promotional activities of products without the Ministry's permission.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

According to Article 9 of the Regulation on Pharmaceuticals, free samples can only be distributed to doctors, dentists, and pharmacists under these conditions:

- licence/permit holders must establish a record and control system for free product samples and designate responsible persons – records are maintained under relevant legislation and reported to the agency as needed;
- free samples contain reduced quantities;
- 'promotional sample, not for sale' must be prominently displayed on the outer and inner packaging;
- copies of the summary of product characteristics (SmPC) and package leaflet (PL) are provided if available;
- samples of products with controlled substances cannot be distributed;
- samples of products listed on the Agency's website cannot be distributed;
- free samples are limited based on annual sales percentages; and
- promotional samples cannot be used in clinical trials.

According to Article 24 of the Regulation on Medical Devices, non-compliant devices cannot be distributed as free samples. Sales centres must maintain records of free samples, kept for five years and submitted to the Agency on request. 'Free promotional sample, not for sale.' must be visible on outer packaging. User manuals are to accompany samples where necessary. The number of samples can be fewer than market introductions, capped at two per cent of previous year sales. Implementation begins a year post-market introduction. Samples cannot be used for clinical research. Essential devices for medication use can be provided free, but not considered as samples. Accessories and materials for device use can also be provided free. Samples requested for procurement in device tenders are not considered free samples.

According to the eighth paragraph of Article 6 of Regulation on Pharmaceuticals, during the promotion of products to doctors, dentists, and pharmacists, no cash or in-kind benefits can be provided, offered, or promised. The mentioned healthcare professionals also cannot accept or request any incentives during promotional activities directed at them.

According to Article 22 of the Regulation on Medical Devices, healthcare professionals or technical personnel working in medical device fields within healthcare institutions cannot be incentivised, solicited, or accepted by giving money, gifts, or promising any material gain or reward to prescribe, use, purchase, or recommend a device during promotions.

14. What rules govern the offering of hospitality to healthcare professionals?

According to Article 7 of Regulation on Pharmaceuticals, licence/permit holders can support the registration, accommodation, and transport expenses of healthcare professionals who will attend domestic and international scientific meetings, provided that they comply with these conditions:

a) A healthcare professional can benefit from the support of licence/permit holders a total of four times within the same year; only two of which can be provided by the same licence/permit holder, and only two can be used for meetings held abroad. Meetings, where healthcare professionals participate as speakers or presenters of written or spoken papers, are not considered within this scope of support.
b) Participants attending scientific meetings organised or supported by the Ministry are exempt from the participation limit specified in paragraph (a).
c) Support is provided directly to the organisation or organisations organising the meeting, not to individuals.

Participants other than speakers' transport and accommodation expenses cannot be covered by licence/permit holders in product promotion meetings organised by them. However, licence/permit holders can support visits to product manufacturing facilities within the country under the scope of the second paragraph of Article 7.

According to Article 21 of the Regulation on Medical Devices, scientific and educational activities related to devices are conducted to convey existing information or present new information to healthcare professionals and technical personnel working in medical device fields within healthcare institutions. Sales centres cannot cover participants' transport and accommodation expenses except in the following cases:

a) the meeting must be related to the expertise or duties of the personnel;
b) an individual can benefit from this support a maximum of four times within the same year – only two of which can be provided by the same sales centre, and only two of which can be used for meetings held abroad;
c) support is provided directly to the organisation or organisations organising the meeting, not to individuals.

Except for international meetings held in different countries, meetings and events involving scientific and educational activities cannot be organised or supported by manufacturers, importers, or sales centres in coastal resort towns between 15 June and 15 September, and in ski resort towns between 1 December and 1 March. These conditions do not apply to scientific meetings organised or supported by the Ministry.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

According to the tenth paragraph of Article 6 of Regulation on Pharmaceuticals, licence/permit holders can make donations to public healthcare institutions and non-profit healthcare institutions and organisations under the following conditions:

a) not to influence the tender decisions of products covered by this Regulation, not to lead to unfair competition;
b) not to lead to unethical practices associated with product sales;
c) not to encourage the prescription of a specific product;
d) serving one of the purposes of improving research, education, health, and patient care;
e) being directed towards the general use of the institution or organisation, not just an individual's use;
f) not to include the name of the product in the donated material, despite the presence of the name of the licence/permit holder;
g) recording the donation in the official records of the licence/permit holder;
h) making donations of products and similar items intended for use in clinical research directly to the coordinator or responsible researcher.

According to Article 23 of the Regulation on Medical Devices, sales centres can make donations to public or non-profit healthcare institutions, organisations, or entities under the following conditions, if they comply with other relevant regulations:

a) obtain prior permission from the administration of the institution or organisation to which they will donate;
b) not to influence the tender decisions of devices covered by this regulation;
c) not to lead to unethical practices associated with device sales;
d) serve at least one of the purposes of improving research, education, health, and patient care;
e) be directed towards the general use of the institution or organisation, not just an individual's use;
f) record the donation in their official records;
g) make donations of devices intended for use in clinical research directly to the responsible researcher.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

According to Article 7 of the Regulation on Pharmaceuticals, licence/permit holders can support the registration, accommodation, and transport expenses of healthcare professionals who will attend domestic and international scientific meetings, provided that they comply with the conditions specified in the Article.

Sales centres can cover the transport and accommodation expenses of participants as specified in Article 21 of the Regulation on Medical Devices.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

Conditions for donations are specified in Article 6, paragraph 10 of the Regulation on Pharmaceuticals for Pharmaceuticals. Conditions for medical devices are based on Article 23 of Regulation on Medical Devices.

In terms of Turkish Association Law, no provision prevents the establishment of patient organisations. Establishing associations and foundations is a constitutional right for individuals. Alongside those established through the collaboration of pharmaceutical companies, there are also associations formed by patients and their families coming together.

However, it is important that pharmaceutical companies must notify the TMMDA when they make donations to associations as transfer of value.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

According to Article 11, paragraph 6 of Regulation on Pharmaceuticals, the licence/permit holder is jointly responsible for promotional activities conducted through contracted companies. They must present contract details to the Agency within 30 days, inform the Agency of all related activities, document representative details and activities, and retain records for five years.

According to the seventh paragraph of Article 35 of the Regulation on Medical Devices, sales centres may enter contracts with third parties to conduct educational activities. In such cases, sales centres are jointly responsible with the third parties for their actions and activities.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

Value transfers exceeding ten per cent of the gross monthly minimum wage, whether direct or indirect, monetary or in kind, made by licence/permit holders to healthcare institutions, universities, healthcare professionals, their professional organisations, unions, associations, and foundations operating in the field of health, as well as civil society organisations established to preserve and improve health, regardless of the name under which they are made, are referred to as value transfers. Regulations regarding value transfers are detailed in the Regulation on Pharmaceuticals and the Guidelines on Value Transfers Procedures and Principles. There is no such regulation for medical devices.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

The 13th Article of Regulation on Pharmaceuticals regulates administrative sanctions. Various penalties can be imposed in cases of non-compliance. These include being banned from promotional activities, obtaining the qualification certificate of the promotional representative, and being prevented from participating at scientific meetings. Also, per Law No. 1219 on the Practice of Medicine and the Arts of Healing, an administrative fine can be imposed. These sanctions will be applied when off-label promotion is made.

On the other hand, according to the administrative penalties regulated in Article 28 of the Regulation on Medical Devices, sales centres may face penalties such as paying administrative fines, suspending activities or even being completely closed, while disciplinary penalties may be applied to sales representatives. In addition, when it is determined that the product is not suitable for the market, an administrative fine can be imposed within the scope of Law No. 7223 on Product Safety and Technical Regulations.

Lastly, within the scope of the Law on Consumer Protection No. 6502, companies are liable and consumers who suffer damage can request compensation.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

According to Article 12 of the Regulation on Pharmaceuticals, the Agency monitors promotional activities and all materials and methods used in these activities *ex officio* or on complaint. According to Article 27 of the Regulation on Medical Devices, sales centres undergo mandatory inspections by the directorate every two years. They are also subject to inspection by the Agency if deemed necessary.

Additionally, the Competition Board and the Advertising Board may impose administrative fines and request the suspension of relevant advertising and promotional activities. In 2023, the Advertising Board imposed fines totalling TRY114.1m (approximately US$3.5m) for advertising violations across various sectors, including pharmaceuticals and medical devices.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

The anticipation is held that the reform of EU pharmaceutical legislation will have an impact on pharmaceutical legislation in Turkey.

In terms of enforcement trends, it is observed that in the event of the first occurrence of a violation of medical device advertising and promotion, the Advertising Board primarily imposes a penalty of stopping the advertisements, and in the event of a repeated violation, an administrative fine is imposed. However, when it comes to violations related to the advertising and promotion of drugs, there is a tendency to impose administrative fines as the primary measure.