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THE LEGAL FRAMEWORK FOR THE PROMOTION OF MEDICINAL PRODUCTS FOR HUMAN USE IN TÜRKİYE

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Introduction

Legal regulations concerning the promotion of medicines and medicinal products for human use in Türkiye aim to strike a delicate balance between protecting public health and ensuring the sector's right to pursue legitimate commercial activities. Accordingly, the means by which promotion may be conducted, the target audience, and the limits within which it must remain have been specified in detail by law and secondary legislation; in particular, the distinction between scientific communication and commercial promotion has been established through a careful normative architecture.

The normative framework, which began with the Pharmaceutical and Medical Preparations Act No. 1262 of 1928, is now essentially shaped by the Regulation on Promotion Activities for Medicinal products for human use (the "**Regulation**"). The legislation generally prohibits advertising to the public, while stipulating that advertising activities directed at healthcare professionals must be conducted in accordance with specific rules and principles of transparency and proportionality.

The purpose of this article is to examine the legal regime governing the promotion of medicines and medicinal products in Türkiye, including its normative framework, scope of application, and sanction mechanisms, and to evaluate key issues such as the ban on promotion to the general public, the limits of promotion to healthcare professionals, scientific meetings, and the legal nature of digital promotional activities from a holistic perspective. The article also aims to analyze the structural problems encountered in regulations concerning promotional activities, uncertainties in implementation, and new legal needs arising from technological developments, and to provide assessments regarding the effectiveness and improvement of legislation.

- I -
The Normative Definition and Scope of Promotional Activities

A. Legal Boundaries of the Concept of Promotion

Promotion refers to all information-sharing activities carried out with healthcare professionals regarding the medical and scientific characteristics of products, including the activities and visits of product promotion representatives, advertisements in medical and professional publications, announcements made through communication tools, scientific meetings, product promotion meetings, and similar activities. This definition shows that the concept of promotion is considered in a broad spectrum. Legislation does not limit promotion to direct advertising activities only, but also includes information provision, education, and scientific communication activities. This approach reflects a protective regulatory understanding that takes into account the multidimensional nature of drug promotion and its potential areas of impact.

B. Limitation of the Promotion Audience

Promotion covers promotional activities for products aimed at doctors, dentists and pharmacists, and the promotion of medicinal products for human use to any other professional group is not permitted. The restriction of the promotion recipient is based on the assumption that decisions regarding the use of medicines require medical knowledge and expertise.

C. Classification of Promotion Methods

Promotion is carried out using promotional materials, by organizing or supporting scientific meetings and product promotion meetings, and through visits by product promotion representatives. The legislation regulates promotion methods in three main categories: (i) promotional materials, (ii) meetings, and (iii) individual visits. This classification reflects the understanding that different promotion methods carry different risks and therefore require different regulatory approaches.

- II -
Legal Basis and Scope of the Public Promotion Prohibition

A. General Prohibition Principle and Legal Justifications

Products cannot be promoted directly or indirectly to the public through any media or communication channels, including the internet, and this promotion ban also covers patients, meaning that promotion cannot be directed at patients or their relatives.

The prohibition on advertising to the public is one of the cornerstones of the Turkish pharmaceutical law system. This prohibition aims to prevent individuals from making decisions regarding the use of medicines under the influence of medical information asymmetry and advertising. The prohibition is based on public interest grounds such as the protection of public health and the rational use of medicines.

B. Exceptions and Limits to the Ban

Information about medicines may be provided, but this content must not be promotional in nature. In addition, information regarding the approved instructions for use and indications of products by the Turkish Medicines and Medical Devices Agency may be published on the websites of pharmaceutical companies. These exceptions aim to strike a balance between the right to information and the protection of public health by preventing the strict application of the ban on advertising to the public. However, the scope of the exceptions should be interpreted narrowly and should not be broadened in a way that would undermine the purpose of the ban.

C. Distinction Between Providing Information and Advertising

Licence or authorization holders may create their own websites and social media pages to provide information about diseases, but this information must not be intended, either explicitly or implicitly, to promote or direct people towards a particular medicine. There is no objection to sharing general information such as information about the disease and methods of protection against diseases, and even information about treatment methods may be provided, but information such as "this medicine is good for this disease" cannot be provided.

The distinction between providing information and advertising is one of the most sensitive and open to interpretation areas of legislation. This distinction creates the obligation to determine the fine line between objective information and commercial messages. The legislation requires an assessment based on the nature of the content (scientific/commercial), its purpose (educational/sales) and its effect (informative/promotional).

- III -
Regulatory Framework for Advertising Targeted at Health Professionals

A. Legal Nature of the Prohibition on In-Kind and Monetary Benefit

When conducting promotional activities, no in-kind or monetary benefits may be provided to healthcare professionals, nor may they be offered, and the relevant healthcare professionals may not accept or request any incentives during the promotional activity conducted for them.

The prohibition of in-kind and monetary benefits is a fundamental regulatory tool aimed at preserving independence and objectivity in the relationships between the pharmaceutical industry and healthcare professionals. This prohibition serves the purpose of preventing conflicts of interest, ensuring that medical decisions are made on a scientific basis, and protecting the professional independence of healthcare professionals. The fact that the prohibition includes the phrase "may not even be offered" indicates that it prohibits not only the actual provision of benefits but also any initiative that could potentially create a conflict of interest. This broad scope reflects a preventive approach.

B. Regulation of Promotional Materials

Promotional materials cannot be other than those defined in the legislation and must be directed solely at healthcare professionals; they refer to any material distributed at meetings or visits

directed at healthcare professionals, and the monetary value of these materials must not exceed 2.5% of the current gross monthly minimum wage.

These materials may include symbolic visit gifts that can be used during the practice of the profession, visual or audio materials such as brochures, slides, or films containing information about the product, any publications or electronic access to them that can be used as a source of information or reference about the product, free samples, demo devices, and materials for patient education.

The regulation of promotional materials imposes restrictions in terms of both content and value. Linking the monetary value limit to the minimum wage reflects a dynamic regulatory approach that provides automatic updates in inflationary environments.

These materials should not be positioned or displayed in a manner visible to the public. This regulation aims to prevent promotional materials from becoming an indirect means of promotion to the public and creates a complementary protection mechanism that enhances the effectiveness of the ban on public promotion.

C. Prohibition on the Use of Healthcare Professionals in Advertising

The Regulation also prohibits healthcare professionals from appearing as actors in product promotions without special permission from the Ministry of Health.

This prohibition aims to prevent the credibility and authority of healthcare professionals in the eyes of society from being exploited for commercial purposes. The prohibition aims both to protect the professional reputation of healthcare professionals and to prevent the public from being misled.

- IV -
Legal Aspects of Scientific Meetings and Support Mechanisms

A. Legal Nature and Scope of Scientific Meetings

Scientific meetings are congresses, symposiums, workshops and similar meetings organized by license and permit holders for the purpose of providing information on scientific topics; these meetings may also be organized electronically, but in this case the meeting cannot be open to the public, participants must have their own username and password, and can only access the meeting on the days of the meeting.

Scientific meetings constitute one of the legitimate areas of interaction between the pharmaceutical industry and healthcare professionals. These meetings serve legitimate purposes such as sharing scientific knowledge, communicating medical developments, and supporting professional education. However, these legitimate purposes may be intertwined with commercial interests and may create a risk of conflict of interest.

B. Participant Support Mechanism and Restrictions

A healthcare professional may receive support for scientific and electronic scientific meetings a total of four times within a calendar year; for a maximum of two of these four instances, support may be provided by the same licence/permit holder; the meeting must be on scientific topics related to the healthcare professional's area of expertise/duty. The regulation of the participant support mechanism reflects the effort to strike a balance between scientific training needs and the risk of dependency. Limiting the number of annual supports and restricting the number of supports that can be received from the same company aims to prevent healthcare professionals from becoming dependent on specific companies.

C. Types of Support and Legal Limits

The Regulation details the types of support that can be provided for scientific meetings. In this context, **general sponsorship of a scientific meeting** is provided solely to the organizer for the purpose of holding the meeting; this support cannot be used to cover participants' registration, accommodation or travel expenses.

In contrast, **participant and speaker support** is a separate type of support that refers to the license/authorization holder covering the registration, accommodation, travel and speaker fees on behalf of individuals attending, presenting or submitting papers at the meeting.

Satellite symposiums are sessions held during scientific meetings for product promotion, and the support provided for these sessions, as with general sponsorship, cannot be used to cover participants' individual expenses.

Furthermore, **stand participation support** is provided in the form of the licence/permit holder renting a stand in the organisation area for the purpose of product or company promotion and covering expenses related to refreshments and similar items at the stand.

The fact that the types of support are differentiated in this way and different rules are stipulated for each one demonstrates that the Regulation adopts a detailed, restrictive and comprehensive regulatory technique. The fact that all this support is directed not to individuals but to the organisation hosting the meeting is a fundamental principle aimed at preventing personal gain and increasing transparency.

D. Principle of Reasonableness and Proportionality

The support provided must be reasonable and not excessive, and hospitality that overshadows the meeting itself must also be avoided. The principle of reasonableness and proportionality aims to ensure that scientific meetings do not deviate from their primary purpose and do not turn into luxury holidays or entertainment events.

E. Notification and Oversight Mechanisms

Licence/permit holders shall apply to the Turkish Medicines and Medical Devices Agency for scientific meetings they will organize or support; at least fifteen working days prior to each domestic meeting, the content of the meeting, the list of potential participants, the items of expenditure to be incurred, and the activities must be reported to the Agency; Notifications are responded to by the Agency within ten working days; if no response is received, the application is

deemed approved; after the sponsored meeting has taken place, the license/authorization holder must notify the Agency in detail of the list of participants, expense items, and activities carried out within a maximum of thirty days.

Notification obligations are important regulatory tools aimed at increasing transparency and facilitating oversight. The tacit approval mechanism (approval deemed granted if no response is provided) aims to streamline administrative processes and reduce bureaucracy.

Health inspectors appointed by the Turkish Medicines and Medical Devices Agency may attend these meetings with or without prior notice for inspection purposes. This regulation provides the opportunity for surprise inspections, which are necessary for effective oversight.

- V -
Product Promotion Meetings and Their Differences From Scientific Meetings

A. Legal Nature of Product Promotion Meetings

Product promotion meetings are meetings organized by the license or permit holder to promote their product; the purpose is to convey existing medical information about the products and to present new information about them; product promotion meetings can only be organized by the license/permit holders of medicinal products for human use.

Unlike scientific meetings, product promotion meetings are directly product-focused. These meetings occupy a middle ground between scientific knowledge sharing and commercial promotion.

B. Comparative Analysis of Support Restrictions

In product promotion meetings organized by license/authorization holders, the travel and accommodation expenses of participants, excluding speakers, cannot be covered by the license/authorization holders.

This regulation demonstrates that product promotion meetings have more limited support opportunities than scientific meetings. The distinction reflects a differentiated regulatory approach based on the nature of the meeting (scientific/commercial).

While scientific meetings may be held for students studying at faculties or colleges that train healthcare professionals, product promotion meetings may not be organized. This prohibition aims to prevent students from being exposed to commercial promotion and to protect the independence of the educational process.

- VI -
Legal Issues Related to Promotion in the Digital Environment

A. General Principles of Promotion in the Digital Environment

With the advancement of technology, globalization, and the increasing importance of digital communication, pharmaceutical companies have begun to conduct their promotion and marketing activities not only physically but also in the digital environment; corporate digital marketing has become an increasingly important issue, particularly in a competitive environment, and one of the main reasons for this is its advantages, such as providing fast and easy access to a large number of people at low cost.

The rules applicable to promotion in the physical environment are equally applicable to promotion in the digital environment, with no flexibility whatsoever. Just as in the physical environment, products cannot be promoted directly or indirectly to the public in the electronic environment.

The legislation clearly states that the change in environment does not change the rules and does not treat the digital environment differently from the physical environment.

B. Obligation to Separate Content

It is also important that content prepared for the public and healthcare professionals in a digital environment is always separated from each other.

Pharmaceutical companies may establish websites for the purpose of providing information, but the content prepared for the public and healthcare professionals must always be separated on these pages. Sections of the website accessible to the general public may include current medical practices, health, diseases, and treatment methods of a general nature, but this information must be scientific in nature and must not include any indirect or direct product promotion or mention any drug names; recommendations such as "The information on this site is not a substitute for consulting a doctor or pharmacist" should be included; When designing websites, it must be ensured that only doctors, dentists or pharmacists have access to sections intended for promotion or information to healthcare professionals, and it must be stated that the relevant sections are intended only for doctors, dentists and pharmacists.

The obligation to separate content addresses the difficulties arising from the technical characteristics of the digital environment. The presence of content aimed at different target audiences on the same platform in the digital environment increases the risk of circumventing the advertising ban.

C. Specific Issues in Social Media and Mobile Applications

Pharmaceutical companies' social media pages are directly accessible to the public, and it is important that they always refrain from promoting medicines due to situations such as not knowing who is accessing the relevant page or not being able to distinguish between pharmacists, doctors, or dentists.

When downloading mobile applications, names that include product names or information that could promote the product should be avoided.

Social media and mobile applications constitute the most problematic areas of promotion in the digital environment. The public nature of these platforms and the difficulty of distinguishing users make compliance with regulations difficult.

- VII -
Legal Analysis of the Prohibition on Covert Advertising

In addition to all these specific regulations, it should not be forgotten that covert advertising that circumvents legal restrictions is also prohibited.

The prohibition of covert advertising is of critical importance in terms of protecting the spirit of legislation and preventing circumvention of legal regulations. This prohibition constitutes a complementary protection mechanism alongside explicit regulations.

The concept of covert advertising is open to broad interpretation, which may create legal uncertainty. Determining which activities constitute covert advertising is a matter that must be assessed based on the specific characteristics of each case. Legislation has not established objective criteria in this regard, and the assessment is largely left to the discretion of the administrative authority.

- VIII -
The Normative Structure and Effectiveness of the Sanction System

A. Graduated Sanction System

The licence/permit holder is first warned by the Authority. If any non-compliant act is detected within one year of the warning date, the holder is prohibited from carrying out promotional activities for three months. If any non-compliant act is detected again within one year of the date of the three-month prohibition, the holder is prohibited from carrying out promotional activities for one year.

Product promotion representatives are also first warned by the Authority; if any non-compliant act is detected within one year following the date of the warning, the Institution shall suspend the relevant person's certificate of competence for three months. If any non-compliant act is detected again within one year following the date of the three-month suspension of the certificate of competence, the relevant person's certificate of competence shall be suspended for one year.

The graduated sanction system reflects the principle of proportionality and provides increasing deterrence for repeated violations. The system has a structure that progresses from warning to short-term ban to long-term ban.

B. Sanctions Against Healthcare Professionals

Disciplinary proceedings are initiated against healthcare professionals who violate the Regulation by their affiliated institution or professional organization.

The regulation of sanctions against healthcare professionals within the framework of disciplinary law emphasizes the dimension of professional ethics and responsibility. This regulation demonstrates that sanctions can be applied not only to pharmaceutical companies but also to healthcare professionals who engage in conduct that violates the legislation.

CONCLUSION AND EVALUATION

The legal framework governing the promotion of pharmaceuticals and medicinal products in Türkiye is a comprehensive regulatory system that aims to strike a balance between protecting public health and commercial freedom. While legislation generally prohibits promotion to the public, it imposes strict rules on promotion to healthcare professionals.

The fundamental approach of the legislation reflects a paternalistic understanding of protection. This approach aims to prevent individuals from making decisions regarding drug use under the influence of medical information asymmetry and advertising, and to position healthcare professionals as "gatekeepers" of decisions regarding drug use.

However, the legislation contains some structural problems and implementation difficulties. Firstly, the lack of concretisation of subjective criteria (reasonableness, absence of excessiveness) creates uncertainty in practice. Secondly, the timeliness of the legislation is questionable in the face of rapidly developing technological capabilities for promotion in the digital environment. Thirdly, the lack of objective criteria for enforcing the ban on surreptitious advertising creates difficulties in the monitoring and sanctioning processes.

The effectiveness of the legislation depends not only on the existence of rules but also on their effective implementation, monitoring and continuous updating. Increasing the capacity of monitoring mechanisms, strengthening the deterrent effect of sanctions and adapting the legislation to technological developments appear necessary to improve the effectiveness of the system.

In conclusion, while Turkish pharmaceutical advertising legislation constitutes an important regulatory framework serving the purpose of protecting public health, the structural issues outlined above must be addressed, and the system must be continuously improved.

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