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## **A NEW REGULATION IN TURKEY: ADVERTISING ACTIVITIES FOR MEDICINAL PRODUCTS**

The long awaited Regulation on Advertising Activities for Medicinal Products, published in the Official Gazette No: 28037 dated 26.08.2011 (the “**New Regulation**”), has replaced the former Regulation of 23.10.2003 (the “**Regulation**”). The rationale behind this change was a Council of State decision issued on 14.12.2005 and which annulled most of the provisions in the Regulation concerning the advertisement of pharmaceuticals to the public. This decision has caused a significant loophole in terms of the definitions set forth under the Regulation and gave rise to lobbying activities and demands with respect to cancellation of the Regulation.

The New Regulation<sup>1</sup> sets forth the legal framework of advertising activities for medicinal products in Turkey and will enter into force on 31.12.2011. This article aims to explain the main changes introduced by the New Regulation.

### **General Principles**

The New Regulation explicitly prohibits the direct and/or indirect advertising of medicinal products to the public through mass media - such as over the internet, through programs, movies, series or news. Advertising and promotion of unlicensed or unpermitted medicinal products to healthcare professionals is also forbidden under the New Regulation. In line with the Regulation, advertising activities within the scope of international congresses convened in Turkey are exempted from this rule.

The New Regulation reiterates the general principle in the old Regulation: **During the promotion of a medicinal product to a physician, dentist or pharmacist, no monetary or in-kind advantage may be provided, proposed or promised. The said professionals are equally prohibited from accepting or demanding any incentive during such promotion-related activities.**

### **Donations**

The New Regulation strictly regulates the scope of the donations to be granted to public institutions and provides the following criteria for license holders of medicinal products who wish to donate to public health institutions:

- prior permission of the relevant administrative authority shall be obtained,
- the donation shall not affect any tender decisions for the relevant product,

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<sup>1</sup> The New Regulation is based on Law No. 1262 on Pharmaceuticals and Medical Preparations and Decree Law No. 181 on the Organization and Duties of the Ministry of Health and has been drafted in line with the European Union Directive numbered 2001/83/EC.



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- the donation should not encourage or support a specific prescription or cause any unethical consequence that may be related to the sales of the relevant medicinal product,
- the donation should be related to at least one of the following purposes: research, education, health or patient care,
- the donated asset, equipment or item should be open for the general use of the entire institution as opposed to the use of a specific person,
- the donated asset, equipment or item may include the name of the license holder but not the name of the relevant medicinal product,
- the donation shall be recorded in the official books of the license holder.

### **Scientific and Educational Activities**

Scientific and educational activities concerning the advertising of medicinal products may not be carried out for purposes other than for providing medical and/or new information. Moreover, license holders of medicinal products may not bear the transportation and accommodation expenses of the healthcare personnel who will attend these activities.

The New Regulation lists principles regarding local and international scientific meetings such as conferences and symposiums. The major difference brought by the New Regulation is the limit to the number of meetings that a license holder may sponsor. Accordingly, a healthcare professional may be sponsored for a maximum of five times within the same year, while only two of those events may be sponsored by the same license holder. The sponsorship may only be given to the specific organization(s) that are carrying out the meeting and not directly to the relevant person. The related provision will enter into force in 2012.

### **Advertising Materials and Free Samples**

The monetary value of advertising materials may not exceed the amount determined by the Ministry of Health (the “**MoH**”).

The New Regulation also limits the free samples to be distributed only to physicians, dentists and pharmacists by pharmaceutical companies. Accordingly, starting from 2013, **the amount of free samples that are distributed may not exceed 5% of the annual sale amount of the previous year for such product.** This limit will not be applied for the year following the issuance of the sale permit for the relevant product.

It is required that free samples contain diminished quantities compared to the original product. The inscription ‘*Free Sample – Not for Sale*’ will also be affixed on the outer package of the free sample, but barcode numbers will not. Moreover, license holders will establish an additional system to recall the relevant product if necessary. This provision will enter in force in 2013.



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### **Medical Representatives**

The most significant change with respect to medical representatives concerns their professional training. As per the New Regulation, the person who will advertise medicinal products must have accurate and sufficient information on the relevant product – such to be ensured by attending professional trainings certified by the MoH. These professional trainings will include basic and necessary scientific information on the relevant product, and certificates to be obtained at the end of professional trainings will be valid for three years. This provision will enter in force in 2012.

The license holder company and the medical representatives will jointly be held liable for the damages that may arise due to the activities conducted by the medical representatives.

Currently, due to the loophole in the Regulation, the promotional visit hours are regulated with supplementary legislation. Under the New Regulation, medical representatives have the obligation to comply with the principles on promotional visit hours. In line with those principles, the authorized official in a healthcare institution serving the public will allocate the most convenient period of time for the advertisement activities of the relevant personnel. Such allocated period of time should not hinder the healthcare services. Moreover, promotional activities cannot be conducted in emergency rooms or during the clinic hours when patients are examined.

### **Responsibilities of License Holders**

The license holder will establish a science service and assign a responsible person who is qualified to have complete information concerning the product to be released to the market. Moreover, if the launch of a medicinal product is scheduled to be announced to healthcare professionals via a press release, the approval of the MoH is required. Such press release will be published only once.

Congresses, symposiums, seminars and other related meetings to be organized or supported by license holders will be notified to the MoH before the end of the year prior to the relevant year. The MoH will also be notified of the possible attendees list, expense amounts and activities fifteen days prior to each relevant meeting. Following the meeting, the final attendees list, expense amounts and activities will be notified to the MoH in detail.

### **Sanctions**

(i) The Turkish Criminal Code dated 26.09.2004 and numbered 5237; (ii) the Consumer Protection Law dated 23.02.1995 and numbered 4077; (iii) the Competition Law dated 07.12.1994 and numbered 4054; (iv) the Law on the Establishment and Broadcasting Rights of Radios and Televisions dated 15.02.2011 and numbered 6112 and other related legislation will be applied for those who act contrary to the provisions of the New Regulation and also disciplinary investigations will be initiated for other healthcare professionals.



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Furthermore, in case the promotional activities explained under ‘Section IV’ are conducted in violation of the New Regulation, the license holder shall be warned and the relevant promotional activity ceased. If the violation continues, such license holder company will be banned from attending or supporting any congresses or symposiums for one year.

If advertising activities of medicinal products are conducted contrary to the New Regulation, the license holder will be warned and the relevant advertising activity ceased. If the violation continues, the marketing of the relevant product will be suspended for a term of three months and in case the violation still continues, then the suspension will be prolonged for one year.

In addition, in the event that medical representatives act contrary to the provisions of the New Regulation, the certificates such medical representatives obtained at the end of their professional trainings shall be revoked.

### **Guidelines**

As per the New Regulation, the MoH will publish necessary guidelines to elucidate the implementation of the New Regulation.

Currently, the Principle Guideline for the Advertising of Pharmaceuticals (“**Guideline**”), published by the Turkish Manufacturers Association, is available as a non-binding guideline. Since the Guideline has been based on the Regulation, a new guideline encompassing the recent changes is expected to be announced soon.

### **Conclusion**

Most of the provisions of the New Regulation will enter into effect on 31.12.2011. The fact that there are certain provisions that will come into force on different dates is an opportunity for pharmaceutical companies to adapt to the new arrangements. That said, there is no doubt that the MoH is planning to impose control on the advertising activities for medicinal products and thus has carefully planned out the transition and future phases to be faced in the sector.