

New Regulation on Promotion of Pharmaceuticals

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Amendments in healthcare legislation keep its pace. Several significant changes were made in laws and regulations in late August 2011. One of those is the Regulation on Promotion of Pharmaceutical Products ("New Regulation"), which will enter into effect at the beginning of the new year. Industry representatives and Ministry of Health ("MoH") officials are exchanging views these days to better understand the prospective practice in this area. The MoH will be publishing guidelines to set forth the details on certain issues and application of the provisions in the New Regulation. In this article, we would like to set an outline of the changes introduced for pharmaceutical product promotions.

It can be stated that the scope of "pharmaceutical product" has been widened under the New Regulation. In addition to pharmaceutical products, biological products, enteral nutrition products, medical food, traditional herbal medicinal products and immunologic products have been included. However, medical devices have been left out of the scope of this Regulation. The MoH is expected to publish a separate promotion regulation for medical devices, which is likely to be aligned with the general approach displayed for promotion of pharmaceutical products. Further, the definition of promotion has been amended. In brief, while the conventional aspect of promotion remained as visits to physicians, dentists and pharmacists; a new dimension has been stipulated where a broader scope of healthcare personnel^[1] will be informed application of products and adverse effects, such as healthcare technicians and physiotherapists.

[1] Healthcare personnel falls within the scope of this category is listed in the Additional Article 13 of Law on Medicine and Medicinal Sciences with no. 1219

General rules and principles of the promotion have been detailed. Fundamentally, these rules do not differ from the rules which have been established in sector both at international and local levels. For instance, materials used in promotional activities should be informative and evidence-based, information which cause unnecessary use or unexpected risky situations should not be provided, no consideration or advantage can be provided to healthcare professionals, etc. Furthermore the rule that the unregistered products cannot be promoted remains same. However, as an exception, it would be possible to carry out promotions at the international congresses to be held in Turkey. An explicit provision stipulating the prohibition of promotional activities to public has been helpful; since this issue had been debated for a long time and finally cancelled by the judiciary authorities.

One of the significant changes introduced by the New Regulation is the regulation of donations, currently there is no specific legislation and the matter is governed by general provisions of laws, such as the Code of Obligations and Public Servants' Ethics Regulation, etc. The new requirements for donations to public institutions will be as follows: Donations with the purpose of enhancing investigation, education, health and patient care can be made to institutions provided the supervising authority's permission is obtained. Further, donations should be registered /recorded in the official books and records of the grantor and the donation must be for general use not just the benefit or treatment of a single person. Furthermore, donations should not (i) influence tender decisions, (ii) cause an unethical application that may be associated with products sales (iii) induce prescription of pharmaceuticals. However, donated materials may bear the name of the market-

ing authorization/permission holder; but product names cannot be placed on such materials.

Another important feature introduced by the amendment is the detailing of the support provided to HCPs for their participation in medical congresses and symposia. Scientific and educational activities have been grouped as (i) meetings organized by MA holders for promotion of products, (ii) domestic and foreign scientific meetings that participation of HCPs are promoted such as congresses and symposia. While MA holders would be allowed to support participation of HCPs for the latter, it would not be possible to finance travel and accommodation expenses for the first group. Furthermore, certain thresholds have been defined, whereby a pharmaceutical company will be able to support the same HCP maximum twice a year, the maximum number of events that a HCP can participate would be 5 in a year. Furthermore, the MoH published detailed provisions on reporting and notification of promoted meetings and

One of the other matters regulated in the New Regulation is the activity scope of sales representatives. Promotion staff which were called as medical sales representatives will perform their duties under the title of "Product Promotion Personnel". The MoH set up a rule that such personnel will be trained under certified in-service trainings which is valid for 3 years. Pharmaceutical companies will be providing training of the personnel regarding legal and ethics framework of promotion services through these trainings which can be organized by the pharmaceutical company or subcontractors. Furthermore, in case product promotion personnel violates promotion rules, certificates issued by the MoH will be invalidated and such personnel will be banned from new certificate training for 1 year.

Before the publication of the New Regulation, the industry had concerns that the entry of sales representatives would be limited or even prevented by applying hour slots etc. Until recently, several institutions requested entrance fees, which placed companies in a very difficult position, as paying such fee created compliance problems. Fortunately, the New Regulation did not introduce certain time limits and this has been highly appreciated by the industry. However, administrators of public healthcare institutions would be authorized to arrange the time for product promotion personnel to visit in order to avoid causing any disturbance to regular services provided to patients.

The last feature that we want to mention regarding the New Regulation is the MoH's inspection of promotional activities. MA holders shall be jointly liable with their product promotion personnel for their promotional activities. If a pharmaceutical company continues to carry out promotional activities in breach of legislation, such activity will be ceased by the authority. Furthermore, the MA will be suspended for 3 months in repetition, and 1 year in continuation of illegal promotional activity. We evaluate that these provisions should be corrected as there is significant level of ambiguity on how these sanctions would be applied. Furthermore, not only the interests of pharmaceutical companies, but also the rights of HCPs and patients should be considered. Therefore, sanctions which would harm the patient's access to treatment should not be applied.

In conclusion, we believe that MoH has introduced fair and balanced legal framework with the New Regulation, however certain issues should be clarified along with the guidelines of MoH and the practice of the industry.

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expressed its intention on follow-up and audit of this issue. There are concerns in the sector regarding the meeting which do not fall within the scope of the mentioned two groups of meetings. It is anticipated that such concerns will be clarified as a result of the coordination of the MoH and sector institutions in the forthcoming period.

There has been no significant amendment on promotion materials. However the monetary value limit for a single promotion item will be announced by the MoH, which is anticipated to be TL 20. Although it has not been explicitly indicated, we evaluate that this value will be applicable to reminder promotion materials, such as pens, notebooks, etc. On the other hand, new rules have been published regarding free samples. For example, it is established that annual distribution amount of free samples cannot exceed 5 % of the previous year's sale amount of the relevant product. This rule has caused concerns in the market that it would cause unfair competition between pharmaceutical companies as each has a different financial position at the moment. This issue will enter into force at the beginning of year 2013.