New regulation on promotional activities for pharmaceutical products

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Introduction

The Turkish Pharmaceutical and Medical Device Agency's (TMMDA) new Regulation on the Promotional Activities of Pharmaceutical Products for Human Use was published in the *Official Gazette* on July 3 2015.

Most of the provisions of the new regulation entered into force on the date of publication, without a transitional period. The new regulation abolishes the previous Regulation on the Promotional Activities for Medicinal Products for Human Use (as published in the *Official Gazette* on August 26 2011 and amended in 2012 and 2014). The new regulation contains provisions relating to the disclosure obligations of marketing authorisation holders and other frequently debated matters, including co-promotion, the promotion of pharmaceuticals imported on a patient basis and financial support for scientific conferences.

Disclosure obligation

The most important change introduced by the new regulation is the disclosure obligation. Under Article 11/7 value transfers by marketing authorisation holders (in cash or in kind) must be disclosed to the TMMDA if:

- they are provided to healthcare professionals, healthcare institutions and organisations, universities, unions, associations and foundations active in the field of healthcare or non-governmental organisations established for the purpose of the protection and advancement of health; and
- their monetary value exceeds 10% of the applicable gross monthly minimum wage.

The disclosure of a calendar year's value transfers must be submitted within the first six months of the subsequent year. The disclosure must be made to the TMMDA only; the new regulation does not provide for public disclosure. In this regard the disclosure system differs from the European practice of public disclosure, as introduced by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The new regulation establishes a transitional period for the disclosure provision, which will enter into force on January 1 2016. Therefore, companies will be obliged to start collecting consent from healthcare professionals as of 2016 and start disclosing value transfers as of 2017.

The industry had raised concerns regarding this disclosure system, particularly with regard to the feasibility and effects of obtaining consent from healthcare professionals, institutions and

organisations. However, the published version of the new regulation provides that value transfers cannot be made unless written consent for transfer is provided.

Support for scientific conferences

The new regulation has also changed the rules for financial support by marketing authorisation holders for attendance at scientific conferences, namely by replacing the previous 'three-two-one' rule – as it was known in the industry – with a new 'four-two-two' quota system. Under this new quota system, each healthcare professional may benefit from such support a total of four times per year; of these, two may be provided by the same marketing authorisation holder and two may be used for support of a scientific conference abroad.

The new regulation retains the provision that marketing authorisation holders cannot directly or indirectly cover the transport and accommodation costs of participants to product promotion meetings organised by marketing authorisation holders. However, an exception has been included which allows marketing authorisation holders to provide transportation and accommodation support to participants visiting product manufacturing facilities in Turkey, on the condition that the TMMDA is notified in accordance with the four-two-two quota system.

Another amendment that has provoked comment from global pharmaceutical companies is the provision that marketing authorisation holders may organise or sponsor scientific conferences held abroad on the condition that the conference is international or that the majority of the participants are healthcare professionals working outside Turkey. These conditions are not required for conferences held abroad that are organised or supported by the Ministry of Health.

Co-promotion

Further, the new regulation has resolved the debate over whether co-promotion of pharmaceutical products should require only notification of the TMMDA or whether permission must be obtained. The former regulation required neither application for permission nor notification of co-promotion, although in practice the TMMDA gave permission on application from marketing authorisation holders. The new regulation now establishes a notification system only and allows co-promotion, provided that the marketing authorisation holder submits the agreement to the TMMDA within 30 days of the signing date and that the required records are kept for five years, to be provided to the institute when required.

Imported products

The final important amendment concerns the promotion of pharmaceutical products that have obtained marketing authorisation in Turkey, but which are procured from abroad on a prescription basis due to their unavailability in Turkey. The new regulation states that pharmaceutical products which are procured from abroad within the scope of alternative reimbursement models implemented by the Social Security Institution may be promoted only with regard to pharmacovigilance. However, promotion is completely forbidden for other products that have been granted marketing authorisation but are procured from abroad on a prescription basis due to non-availability in the domestic market.

Comment

It is clear that the TMMDA seeks to switch to a transparent system where all value transfers made to healthcare professionals are disclosed. However, the concerns of the industry with respect to the implementation of this disclosure requirement have not been completely addressed. The remaining cause for concern is the fact that pharmaceutical companies that belong to the Association of Research-Based Pharmaceutical Companies, a member of the EFPIA, were already obliged to collect the consent of healthcare professionals and organisations for such disclosure. The difference between this disclosure system and that introduced by the new regulation is that the new regulation requires disclosure only to the TMMDA – not to the public. As of 2016, pharmaceutical companies that belong to Association of Research-Based Pharmaceutical Companies or the EFPIA must amend their legal documents in order to receive the consent of healthcare professionals and healthcare organisations for disclosure to the TMMDA.

The change regarding the restriction of the promotion of pharmaceuticals which have obtained marketing authorisation in Turkey but are unavailable on the market clearly demonstrates the TMMDA's intention to discourage consumption of such products. This is intended to lower the costs of the Social Security Institution, which generally still reimburses the cost of pharmaceuticals supplied from abroad. The industry is concerned that such restriction renders the regulation incompatible with EU regulations, where no such prohibition exists.

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