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New decree on medicines pricing published

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The new Decree on the Pricing of Pharmaceutical Products for Human Use was published in the Official Gazette on 24 February 2017 and came into effect on the same day. The new decree abolishes the former pricing decree dated 15 June 2015.

In Turkey the reference price system is applied to determine pharmaceutical prices. The ex-factory price in Turkey is determined by taking into account the lowest price of the product available on the market respectively in the reference countries and applying the periodic Euro value set by the Turkish Price Evaluation Commission.

The key changes brought about by the new decree are:

· Companies only have to declare the changes in real origin prices once a year, as opposed to the previous requirement to declare once every six months.

· The previous limitation that only alterations to the reference price or reference country that resulted in an increase of more than 3% to the reference price would be reflected in the approved ex-factory price no longer applies. The 3% threshold does not exist in the new decree.

· In the event that the Price Evaluation Commission decides to increase the periodic Euro value, all changes to the value of the Euro used to determine the prices of medicinal products shall come into effect 5 days after the commission's announcement, instead of the existing 45 days after the announcement. If the periodic Euro value is decreased, the 45 day period before changes come into effect remains.

Source: Official Gazette no. 29989: New Decree on the Pricing of Medicinal Products for Human Use, 24 February 2017 (Turkish language).

Administrative Court rules on the periodic Euro value used for pharmaceutical pricing

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In September 2015, Pharmaceutical industry associations submitted before the administrative courts a new challenge against the Turkish Price Evaluation Commission's meeting on 18 May 2015 and its revision of the periodic Euro value as TRY 2. The associations argued that: (i) the revision did not satisfy an earlier ruling by the Ankara 7th Administrative Court regarding the convening of the Price Evaluation Commission and the revision of the periodic Euro value used to determine the pricing of pharmaceutical products; and (ii) their application to the Price Evaluation Commission to rectify this situation had been implicitly refused due to a lack of response.

The new reasoned decision issued by the Ankara 15th Administrative Court has accepted the arguments put forth by the associations and has ruled in their favour on grounds that the implicit refusal was not in line with the applicable legislation.

The decision has been appealed by the involved state institutions and bodies and therefore this most recent ruling by the Administrative Court will be subject to an appeals review.

Source: The Reasoned Verdict of the Ankara 15th Administrative Court, 14 November 2016 (unpublished) (Turkish language).

New guidelines on HCP activities sponsored by medical device sales centres
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On 22 September 2016, a provision was added to the Regulation on Medical Device Sales, Advertisement and Promotion, stating that provisions detailing the limitations applied to the sponsorship of healthcare professionals (HCPs) to attend scientific meetings or educational activities shall not apply to training activities carried out in simulation centres and cadaver centres. No other guidance on the implementation of this provision was given until the Turkish Medicines and Medical Devices Agency's publication of the Guidelines for Scientific Meetings and Educational Activities (Guidelines) on 27 February 2017.

The Guidelines introduce certain clarifications to sponsorships given to HCPs by sales centres engaged in the sale of medical devices pursuant to the Regulation on Medical Device Sales, Advertisement and Promotion.

The Guidelines establish that, much like sponsorships to attend scientific meetings and educational activities, any sponsorships provided to HCPs to attend training activities carried out in simulation centres and cadaver centres are subject to the pre and post meeting notification requirements to the regulatory agency. The Guidelines also state that there is no participation quota for financial support for HCPs participating in these activities; a limitation that is in place for scientific meetings. A key point however is that these activities can only be conducted in domestic simulation and cadaver centres; with "Simulation Centre" being defined for the first time as centres that provide medical simulation training through computer-aided simulators.

The Guidelines also introduce changes to the pre and post meeting notifications that are submitted to the agency for all organised or supported activities; the most important of which is the removal of the requirement for submission of notifications in hardcopy form and only requiring electronic submission.

Source: Turkish Medicines and Medical Device Agency: New guidelines for Scientific Meetings and Educational Activities, 27 February 2017 (Turkish language).

Medical equipment and devices to be provided directly by the Ministry of Health
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On 3 March 2017, the Turkish Public Hospitals Administration and the Social Security Institution announced that they had signed a Protocol on Payments for Medical Equipment and Medical Devices for use in Patient-Centred Medical Home Care. The protocol is in force but as specific details relating to the implementation have yet to be determined, the provisions of the protocol are not yet fully applicable.

Prior to the agreement of the new protocol, patients with national insurance were required to first obtain the medical devices needed and then seek reimbursement for the purchase price from the Social Security Institution. When the new protocol is fully implemented, medical devices will be provided free of charge from the outset by the Ministry of Health (MH) so patients will not need produce any initial payment.

The MH announced that patients will not need to apply to the Social Security Institution for the provision of medical equipment and devices upon release from hospital and that the MH will now take care of the organisation of their medical home care needs. The MH spokesman also revealed that around 400,000 households received medical home care in the previous year had seen, and that this figure is expected to increase as a result of the new protocol.

Source: Turkish Medicine and Medical Devices Agency: Press release, 8 March 2017 (Turkish language).