Ministry of Health to follow EU Medical Devices Regulations

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Following the EU's adoption of Regulations (EU) 2017/745 on medical devices and 2017/746 on *in vitro* diagnostic medical devices of 5 April 2017, the Turkish Medicines and Medical Devices Agency announced in May that the two new regulations would also be adopted in Turkey. The announcement stated that the regulations would be published as nationally applicable medical device legislation to harmonise Turkey's medical devices legislation with that of the EU.

Current Turkish medical device legislation mirrors the EU medical device directives. Turkey is not under any legal obligation to implement EU laws, and the announcement that Turkey will harmonise its national laws with the new EU regulations is a welcome development for medical device companies that are active internationally.

For more information,
see *Legal update, Council adopts draft medical device and IVD regulations*.
Source: *Turkish Medicines and Medical Device Agency: Announcement on EU's new Medical Device Regulations, 5 May 2017* (Turkish language).

Combination products to update prices in accordance with new 90% rule

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The Healthcare Services Pricing Commission issued a decision on 25 March 2017 in relation to combination pharmaceutical products, the mono forms of which are on the reimbursement list of the Social Security Institution. Accordingly, on 31 March 2017, the Social Security Institution published an announcement on its website on the pricing of combination products. The principle of the Pricing Commission's decision is that the public prices of combination products that are entering the reimbursement list for the first time shall not be above 80% of the public unit prices of the cheapest identical mono forms of the active ingredients combined. Drug companies were asked to submit the public prices of those combination products at the Public Institution Discount rate within ten days of 31 March 2017 at the latest for the Pricing Commission to consider discount rates in the application files. Late submissions would not be taken into account.

The decision of the Pricing Commission also requires the public unit prices of combination drugs that are already on the reimbursement list to not be above 90% of the sum of the public unit prices of cheapest mono forms. Companies were required to update the public prices of their combination drugs and to notify the Institution accordingly by the end of May. Drug companies that failed to do so should expect their drugs to be listed as passive drugs, meaning that reimbursement will be put on hold. Those drug companies will have to re-apply for reimbursement as if the drug had not been previously entered on the reimbursement list.

Source: *General Health Insurance General Directorate: Announcement about combined products, 31 March 2017* (Turkish language).

Notification system of transfers of value launched

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On 8 May 2017, the Turkish Medicines and Medical Devices Agency announced the launch of the electronic system regarding transfers of value. The system enables pharmaceutical companies to notify the agency of transfers of value provided to healthcare professionals and healthcare organisations. The companies can sign into the system with their username and password and view guidelines that explain the steps to be completed on the system for notification.

The *Regulation on the Promotion of Medicinal Products for Human Use* requires pharmaceutical companies to notify the agency within the first six months of the year of any transfer of value made in the previous calendar year with a monetary value exceeding 10% of the applicable gross minimum wage. Therefore, until the end of June 2017, companies will be submitting notifications of transfers of value made in 2016.

Source: *Turkish Medicines and Medical Devices Agency: Attention of licence/permission holders, 8 May 2017* (Turkish language).