

## **Practical Law, Life Science, Newsletter December 2016, Turkey Chapter**

### **Turkish Pharmacists Association fined EUR 5 million for abusing dominant position**

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On 6 December 2016, the Turkish Competition Authority (TCA) imposed a TRY 19 million (approximately EUR 5 million) fine on the Turkish Pharmacists Association for abuse of dominant position and for anti-competitive exclusive agreements relating to the import of drugs within the named patient programme (NPP).

In May 2016, the Ministry of Health's Medicines and Medical Device Agency amended the Guidelines on the Supply from Abroad and the Use of Pharmaceuticals, authorising only the Turkish Pharmacist Association to import non-approved or unavailable drugs from abroad under the NPP.

Previously, the Ministry had authorised around 20 warehouses to import such drugs from abroad. However, those warehouses, including the complainant in the TCA's investigation, could not start importing NPP products, alleging that the Turkish Pharmacist Association was abusing its dominant position by the Turkish Pharmacist Association. As part of its investigation, the TCA also questioned why the payer of the drugs, the Social Security Institution (SSI), did not enter into a protocol with the other approved warehouses.

The decision of the TCA is open for challenging before the State Council.

Source: Turkish Competition Authority: Press release, December 2016 (Turkish language).

### **Medicines and Medical Devices Agency works to increase number of non-prescription drugs**

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The Regulation on the Classification of Medical Products for Human Use gives a precise definition for prescription drugs, but only defines non-prescription drugs as 'everything else'. Due to the lack of regulation of over-the-counter drugs in Turkey, currently the number of non-prescription drugs is considerably limited and all kinds of drug products must be sold in pharmacies.

In order to improve this framework, the President of the Medicines and Medical Device Agency established under the Ministry of Health, has taken certain steps to issue regulatory principles in order to re-classify 13,000 drugs, of which currently only 87 can be sold without a prescription. According to the President's statement, 10-15% of drugs could

potentially be reclassified as non-prescription drugs. These drugs would include low-risk drugs which can be provided to patients on the advice of a pharmacist alone.

Although this development is welcomed positively by the market's shareholders, the agency clearly stated that pharmacists would be required to monitor patients. The advertising of non-prescription drugs to the public would remain prohibited.

Source: *Haberturk: 15 per cent of thirteen thousand drugs can be sold without prescription, 25 November 2016 (Turkish language).*

### **Ministry of Health shares draft pricing communiqué**

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In Turkey, the pricing of pharmaceutical products is determined using a detailed reference price model established by the Council of Ministers Decree on the Pricing of Pharmaceutical Products, published on 10 July 2015. On 11 December 2015, the Ministry of Health published the Communiqué on the Pricing of Pharmaceutical Products in which the reference price model was detailed.

A new draft Pricing Communiqué was circulated to the industry by the Ministry of Health in November 2016, proposing changes in some major areas, including:

- The tracking of reference prices for some 20-year old products.
- A pricing model for biotechnological products.
- A pricing model for non-reimbursed and OTC products.
- Determining the lowest ex-factory price amongst member states of the Pharmaceutical Inspection Co-operation Scheme as opposed to only EU member states.

Source: Draft Pricing Communiqué shared by the Ministry of Health, not published (Turkish language).

### **Restriction of temporary employment of healthcare professionals in private hospitals**

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In 2015, the Regulation on Private Hospitals restricted the temporary employment of healthcare professionals (HCPs) in private hospitals. HCPs were prohibited from working

part-time in different private hospitals, and a full-time employment commitment at one institution was required for HCPs to work temporarily and part-time in another institution.

The occupational organisation representing physicians in Turkey, the Turkish Medical Association (TMA), filed a cancellation action against this provision. The Council of State accepted this action with the reasoning that this practice violated the constitutional rights of HCPs working in private hospitals to work part-time. In August 2016, the Ministry of Health complied with the Council of State's verdict and revised the regulation accordingly.

However, on 6 September 2016, the Ministry subsequently published a *circular* stating that the practice of temporary working without being in full-time employment shall be terminated. The TMA therefore announced in December that a new lawsuit has now been filed, demanding the cancellation of the circular. The TMA claim that the circular is clearly incompliant with the amended version of the regulation and in contradiction to the decision of the Council of State.

Sources: *Turkish Medical Association: Cancellation procedure for general personnel blocking partial work in private hospitals press release, 18 November 2016* and *Turkish Medical Association: Circular, 6 September 2016* (Turkish language).