

Practical Law, Life Sciences, Newsletter, January 2017

Industrial Property Law is published

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On 10 January 2016, the Industrial Property Law came into force, amending the compulsory licence provision.

Article 130 of the Industrial Property Law on "Compulsory Licensing in case of Non-use" rules that in addition to non-use of a patent, "relevant persons... can request compulsory licensing due to the ... use of invention subject to the patent not satisfying the national market's need". Under Article 130, "public interest" is not a pre-condition for granting a compulsory licence.

During commission meetings at the parliament, the government explicitly mentioned that this new condition for compulsory licensing specifically targeted the pharmaceutical sector.

The expression of "satisfying the national market's needs" points to a specific quantitative amount of patented product. This impacts many pharmaceutical products as the so-called "national market's need" is not equal to the "number of patented product on market".

Future court decisions are expected to clarify many aspects of this provision, such as how to determine the national market's need, or whether generic versions of the patented product that are on the market count towards satisfying the national market's need.

Source: Official Gazette no. 29944: The Industrial Property Law numbered 6769, 10 January 2017 (Turkish language).

Regulation regarding processing and transfer of personal health data challenged

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On 20 October 2016, the Ministry of Health published the new Regulation on the Processing of Personal Health Data and Maintenance of Privacy in the Official Gazette (number 29863).

The regulation essentially governs the processing and transfer of personal data. Among other novelties, the regulation also introduces a central health data collection system to which all healthcare providers are under an obligation to regularly upload health data.

Due to uncertainties introduced by the regulation, its enactment received strong resistance from the sector and academics. One of the strongest reasons for resistance was that the basis of the regulation (that is, the Law on Protection of Personal Data numbered 6698), was also recently enacted, requiring, among other things, the establishment of a government body and the introduction of supplementary legislation, neither of which were fulfilled. In addition, the enactment of the regulation was strongly criticised due to the risk taken by establishing a centralised health data pool without taking necessary measures that are yet to be determined by the Law on Protection of Personal Data and the secondary legislation to be enacted by the prospective authority.

The Turkish Medical Association and the Turkish Dental Association have filed a cancellation action against the regulation and requested a stay of the execution of the Regulation. The outcome of the case is yet to be seen.

Source: Turkish Medical Association: Our health information should be preserved, 13 December 2016 (Turkish language).

A new Drug Fx rate has been announced

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The Price Assessment Commission competent for calculating the price of a product determines the Euro and Turkish Liras currency exchange rate (Fx rate). The new drug Fx rate has been announced by the Turkish Medicines and Medical Device's Agency as EUR 1 = TRY 2.3421. According to the Pricing Decree, the Fx rate should be adapted to the currency fluctuations.

The revision of the Pricing Decree in July 2015 requires the Fx rate to be determined each year as 70% of the average annual Euro value. The new Fx rate for pharmaceutical pricing was announced on 6 January 2017, on the Turkish Medicines and Medical Device's Agency website. The new rate will be effective by 20 February 2017.

This rate has increased of 10.65% from the previously rate set on November 2016. However it should be noted that in January 2017, the actual exchange rate announced by the Turkish Central Bank had exceeded EUR 1 = TRY 4.03.

Source: Turkish Medicines and Medical Device's Agency: Notice of changes in the value of the Euro used for pharmaceutical prices, January 2017 (Turkish language).