Regulation on Processing of Health Data amended
Dicle Doğan, Fatma Sevde Tan, Gun + Partners

On 24 November 2017, the Ministry of Health issued *amendments* (Turkish language) to the Regulation on the Processing of Health Data and the Maintenance of Privacy.
The Ministry of Health issued the Regulation on the Processing of Health Data and the Maintenance of Privacy (Regulation) on 22 October 2016, following the Law on Protection of Personal Data (Law) dated 7 April 2016. On 6 July 2017, actions were brought before the Council of State against the Regulation, claiming that there were inconsistencies with the Law. The main issue was a condition in the Regulation that required written consent from data subjects in order to process health data, while the Law only seeks explicit consent. In addition, even though the Regulation allowed anonymised health data to be transferred, it also sought the explicit written consent of the data subject.

Therefore the Council of State ordered the suspension of execution of the entire Regulation until the finalisation of the action before the Council of State. Upon this development, the Ministry of Health issued amendments to the Regulation on 24 November 2017.
The amendments mostly eliminate the inconsistencies with the Law and require only explicit consent from each data subject. The health data shall be transferred without explicit consent, only if the data is anonymised. The data processor is obliged to take necessary safety measures for the protection of health data from illegal access. The remaining articles of the Regulation are still subject to the stay of execution decision of the Council of State, and will not be applicable until the Council of State decides to lift the suspension.

New regulation on manufacturing plants of human medicinal products
Dicle Doğan, Nehir Aydeniz, Gun + Partners

The Regulation on the Manufacturing Plants of Human Medicinal Products was published in *Official Gazette no. 30217 of 21 October 2017* (Turkish language), effectively replacing the old regulation of the same name.
The new regulation provides a revised list of definitions and introduces comprehensive provisions on the obligations of manufacturers and new specifications that were previously unclear. For example, details on the mandates of manufacturers in cases of medical gases and imported products have been added, and an obligation on direct compliance with the marketing authorisation and/or licence of the product has been made explicit.
The regulation appears to have deleted in its entirety the provision on harmonisation with EU rules: the statement that the regulations were prepared in line with EU Directive 91/356/EEC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use is no longer present.