Drug licensing Regulation amended

Dicle Doğan and Fatma Sevde Tan, Gun + Partners

On 8 January 2020, a *Regulation* amending the Regulation on Licensing of Human Medicinal Products (Turkish language) was published in Official Gazette (*No 31002*). Those amendments entered into force the same day.

The new Regulation adds an additional paragraph to Article 2 of the Regulation on Licensing of Human Medicinal Products (Licensing Regulation). With the additional paragraph, individual allergen products and skin tests for the diagnosis of allergies by the application of allergens to the skin are excluded from the scope of the Licensing Regulation. The definition of the individual allergen products is also added to the Licensing Regulation as allergen-specific immunotherapy medicinal products. These are single or multiple allergen mixtures, which are specially manufactured for the patient and supplied to the patient in accordance with the prescriptions by specialist physicians.

On 17 January 2020, the Turkish Medicines and Medical Devices Agency published an *announcement* (Turkish language) requiring that applications for the designation as an individual allergen product to be submitted to the Clinical Evaluation Unit of the Drug Licensing Office.