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Turkish Medicines and Medical Devices Agency Published the Guide on the Licensing of Allergen Products

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The Regulation on Licensing of Medicinal Products for Human Use. ("**Regulation**") was published in Official Gazette dated 11 December 2021 and numbered 31686. The Guide on Licensing of Allergen Products ("**Guide**"), which sets out the special requirements for the licensing processes of allergen products within the scope of the Regulation, was published by the Turkish Medicines and Medical Devices Agency ("**Agency**") on 9 March 2022. The Guide will enter into force with the approval of the President of the Agency.

The aim of the Guide is to determine the procedures and principles regarding the simplified licensing conditions of industrially produced allergen products used for diagnostic and therapeutic purposes.

The important regulations included in the guide are as follows:

- A separate license application should be made for each allergen product.
- The applicant may apply for a simplified license, provided that reference is made to published scientific literature or the reference allergen product.
- The documents to be submitted during the license application are determined as follows:
    - Administrative documents determined within the scope of the Regulation
    - Brief product information, instructions for use and packaging information
    - Quality documents to be prepared by taking into account the European Pharmacopoeia "Allergen products" monograph, the Turkish Pharmacopoeia "Allergen products" monograph and the Allergen Products Guide of the European Medicines Agency Committee for Medicinal Products for Human Use
    - Non-clinical and toxicological documents
    - Clinical documents
- After the allergen product is licensed, an application must be made to the Authority by the license holder for all changes regarding this product.
- For allergen products with sales permits; permission must be obtained by applying to the Authority for each series of the product before the product is put on the market.
- Allergen products produced in the European Union and available on the market can be placed on the market until 31 December 2024, provided that the requirements shown in the Guide are met. The temporary permit of the products whose licensing process is not completed by this date will be canceled and their placing on the market will be stopped.

Please see this link for the full text of the Guide. (Only available in Turkish)

Related Practices

- IP Licensing

Related Attorneys

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