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Amendments to the Regulation on Licensing of Medicinal Products for Human Use

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The Regulation Amending the Regulation on the Licensing of Medicinal Products for Human Use ("**Amendment Regulation**") was published in Official Gazette number 30976 on 8 January 2020, entering into the effect on the same day.

Notable changes under the Amendment Regulation include:

- The individual allergen products and skin tests used for diagnosis of allergies by application of allergens to the skin are excluded from the scope of the Regulation
- Pursuant to this new amendment, the term of individual allergen is defined as "industrially produced allergen specific-immunotherapy medicinal products, specifically designated for the patient, which may contain singular or plural allergen mixtures, particularly supplied to patients upon prescriptions issued by doctors specialized in the related branches for the patient's access."

Please see this link for the full text of the Amendment Regulation (only available in Turkish).

Related Practices

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