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

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The Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use ("**Amendment Regulation**") was published in Official Gazette, numbered 31338, on 18 December 2020, and became effective thereupon.

Notably, the Amendment Regulation provides, in relevant part, as follows:

- The Turkish Medicines and Medical Devices Agency may grant emergency authorization for vaccines to be used in exceptional cases where the public health is threatened by a disease categorized as an infectious disease by the World Health Organization and the Turkish Ministry of Health, pending receipt of data regarding the safety, effectiveness, and quality of the vaccine, which data form the basis for official registration.
- The application for the emergency use authorization for vaccines shall include all data that can be provided by the applicant regarding effectiveness, safety, and quality of the vaccine.

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

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