MOROĞLU ARSEVEN

Within the scope of the Regulation on Clinical Trials of Medicinal Products for Human Use, Guideline on the Definition of Investigational Products and the Use of Auxiliary Medicinal Products for Human Use and Guideline on the Quality Requirements of Biological Products Used in Clinical Trials Were Drafted

1 Feb 2024

Within the scope of the Regulation on Clinical Trials of Medicinal Products for Human Use published in the Official Gazette dated 27/05/2023 and numbered 32203, the Draft Guideline on the Definition of Investigational Products and on the Use of Auxiliary Medicinal Products for Human Use and the Draft Guideline on the Quality Requirements of Biological Products Used in Clinical Trials prepared by the Turkish Medicines and Medical Devices Agency ("**Agency**") were published on the website of the Agency and was submitted to the attention of the public.

The purpose of the Draft Guideline on the Definition of Investigational Products and on the Use of Auxiliary Medicinal Products for Human Use is to clarify the definition of investigational products in accordance with national and international standards and to provide information on the use of ancillary human medicinal products.

The Draft Guideline on Quality Requirements for Biological Products Used in Clinical Trials aims to determine the quality requirements for biological/biotechnological human medicinal products to be used in clinical trials to be conducted in Turkey, considering national and international standards.

Details of the draft guidelines may found through this link.

Related Attorneys

- DR. E. SEYFİ MOROĞLU, LL.M.
- A. BAŞAK ACAR, LL.M.