MOROĞLU ARSEVEN

Announcements of Turkish Medicines and Medical Devices Agency Dated Between December 14, 2023 and December 20, 2023

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Turkish Medicine and Medical Devices Agency ("**Agency**") has published several announcements in December.

According to the announcement published on December 15, 2023 ("**Announcement 1**"), The European Commission's Directorate-General for Health and Food Safety and the European Executive Agency for Health and Digital commissioned the consultancy firm Ernst & Young to conduct the "Study on Regulatory Governance and Innovation in the Field of Medical Devices". As part of this study, Ernst & Young launched a survey of all relevant actors to gather more information on the functioning of the governance structure in the medical device sector and its impact on innovation, and to provide information on possible adaptations to further optimize the system. The survey will end on January 31, 2024, and can be accessed at this link.

According to the announcement published on December 19, 2023 ("**Announcement 2**"), within the scope of the Cosmetic Products Regulation ("Regulation") published in the Official Gazette dated 08.05.2023 and numbered 32184, some guidelines have been amended and renewed in order to guide the stakeholders of the cosmetics sector. The amended and renewed guidelines are given below and all current Regulations and guidelines can be accessed from this link.

According to the announcement published on December 17, 2023 ("**Announcement 3**"), as of 01.01.2024, "Pharmaceutical Distribution Certificate" applications can only be evaluated for a single pharmaceutical product and applications will not be evaluated if more than one pharmaceutical product is applied for in one document. Therefore, a separate "Drug Distribution Certificate" application must be made for each pharmaceutical product.

According to the announcement published on December 20, 2023 ("**Announcement 4**"), The Regulation Amending the Regulation on the Quality Compliance and Quality Control Tests of Diagnostic Radiology, Nuclear Medicine and Radiotherapy Group Medical Devices is introduced in Official Gazette dated 20 December 2023 and numbered 32405. The Regulation Amending the Regulation on the Quality Compliance and Quality Control Tests of Diagnostic Radiology, Nuclear Medicine and Radiotherapy Group Medical Devices ("**Amendment Regulation**") introduces several changes to the Regulation on the Quality Compliance and Quality Control Tests of Diagnostic Radiology, Nuclear Medicine and Radiotherapy Group Medical Devices ("**Regulation**") which regulates the procedures and principles regarding the testing, quality assurance and audits that must be carried out to ensure that medical devices used in diagnostic radiology, nuclear medicine and radiotherapy applications that produce or emit ionizing radiation are protected against hazards that may arise in terms of health and safety of patients, users and third parties during their use from their installation in the health service provider after they are placed on the market. These changes are set to come into effect on the date of the publication.

Within the scope of the Amending Regulation, (i) the obligation to be initiated regarding the conduct of quality conformity and quality control tests in accordance with the Regulation will be removed by the Agency based on the need, taking into account the number of devices used in healthcare service providers and the number of authorized persons and organizations, (ii) the requirements regarding postgraduate education, and (iii) the requirements for applications to be made to the Agency within the scope of the transitional provisions regarding the regulation has been made.

You can access the full text of Announcement 1 , Announcement 2 , Announcement 3 and Announcement 4 via these links (only available in Turkish).

Related Attorneys

- A. BAŞAK ACAR, LL.M.
- MERVE ALTINAY ÖZTEKİN