MOROĞLU ARSEVEN

Guidelines on the Procedures and Principles of Pharmacovigilance Activities Conducted by Contracted Pharmacovigilance Service Organizations and Marketing Authorization Holders has been entered into force.

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The Guideline on the Procedures and Principles of Pharmacovigilance Activities Conducted by Contracted Pharmacovigilance Service Organizations and Marketing Authorization Holders ("**Guideline**") prepared by the Turkish Medicines and Medical Devices Agency will enter into force as of 01.01.2024, except for the regulations on the safety database.

This Guideline aims to determine the responsibilities and working procedures and principles of the Contracted Pharmacovigilance Service Organization ("**CPSO**") and the marketing authorization holder in order to ensure that pharmacovigilance services are carried out in accordance with the legislation.

The Regulation on the Safety of Medicinal Products states that the marketing authorization holder may carry out all or part of its pharmacovigilance duties through the CPSO, but it is emphasized that all responsibilities for the full and correct functioning of the pharmacovigilance system always belong to the marketing authorization holder. This Guideline covers marketing authorization holders and CPSOs. Marketing authorization holders who carry out their pharmacovigilance obligations in-house must also meet the minimum requirements for CPSOs.

Details of the guideline may found through this link.

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