Devices Agency has updated the Guideline on the Scheduling Processes for Marketing Authorization Applications of Medicinal Products for Human Use, the Guideline on Biosimilar Medicinal Products, and the Guideline on the Importation of Medicines from Abroad

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One of the most significant updates in the Guideline on the Scheduling Processes for Marketing Authorization Applications of Medicinal Products for Human Use ("**Scheduling Guideline**") is the new regulations regarding hybrid applications.

Firstly, the Scheduling Guideline has been updated to include a definition of hybrid applications. According to this definition, a hybrid application refers to a marketing authorization application that is based partially on data from a reference product and partially on data obtained from studies of the new product.

Additionally, the Scheduling Guideline stipulates that marketing authorization applications for hybrid products that pass the preliminary evaluation will be placed in the eighth priority slot, immediately following the allergen product group.

Updates to the Guideline on Biosimilar Medicinal Products ("**Biosimilar Guideline**") have also been published on the official website of the Turkish Medicines and Medical Devices Agency.

The Biosimilar Guideline defines the concept of biosimilar medicinal products and establishes the principles to be applied for their marketing authorization.

According to the new regulation, when there are significant quality differences between biosimilar and reference medicinal products, and similarity to the reference product cannot be demonstrated, obtaining a marketing authorization with a complete dossier is considered a more appropriate option. Additionally, applicants may be required to make necessary changes to the manufacturing process to minimize or eliminate these differences.

This situation highlights the importance of improvements in the manufacturing processes.

Another update has been made to the Guideline on the Importation of Medicines from Abroad.

This guideline regulates the process for obtaining medicinal products for human use that are either not authorized in Turkey or are authorized but not available on the market for various reasons. It covers the importation of these products for use in diagnosing and treating diseases, either on a prescription basis or in emergency situations. Additionally, the guideline aims to ensure the medical, ethical, legal, and rational use of these products based on scientific data and defines the procedures and principles to be followed.

The updates to the guideline introduce more comprehensive documentation and authorization requirements for medicines imported from abroad. This includes the necessary documents and procedures for the legal use of these medicines.

These changes are intended to make the medicine importation processes more organized and transparent while raising scientific and legal standards.

You can access the updates to the Guideline on the Scheduling Processes for Marketing Authorization Applications of Medicinal Products for Human Use via this link, the Guideline on Biosimilar Medicinal Products via this link, and the Guideline on the Importation of Medicines from Abroad through this link.

Related Attorneys

- GÖKÇE İZGİ, LL.M.

- MERVE ALTINAY