Amendments regarding the Guide on License Renewal for Human Medicinal Products, made by the Ministry of Health, Turkish Medicines and Medical Devices Agency were published on the official website of the Ministry of Health.

21 Jul 2023

Turkish Medicines and Medical Devices Agency ("Agency") has published amendments to the Guide on License Renewal for Human Medicinal Products ("Guide") on 18.05.2023 which was prepared within the scope of Article 21 of the Regulation on Licensing of the Human Medicinal Products ("Regulation"). With the amendments made within the scope of the guide, the requirements to be considered in applications in general and the evaluation processes of the applications have been regulated.

With the amendments made in the current Guide published by the Agency, some regulations have been made regarding the evaluation of applications:

Prior to the license renewal applications to be made to the Licensed Medicinal Products Unit, the application should be made to the Pharmacological Evaluation Unit for the approval of the current Summary of Product Characteristic (SPC) / Package Leaflet (PIL) of the product and simultaneously to the Licensed Medicinal Products Technological Evaluation Unit or Biological and Biotechnological Products Unit depending on the pharmaceutical product group for the quality assessment based on the license renewal application,

Application to the Pharmacovigilance Risk Management Unit for Periodic Benefit Risk Evaluation Report (PBRER) assessment following the approval of the update of the SPC/PIL by the Pharmacological Evaluation Unit,

Submitting a license renewal application to the Licensed Medicines Unit for products whose SPC/ PIL are approved to be up to date, whose quality assessment for license renewal is found to be appropriate and for which PBRER approval has been obtained.

It has been indicated that the renewal application for the license of the jointly marketed human medicinal products must be submitted to the Agency within nine months before the expiry of the five-year period in line with the Article 21 of the Regulation.

It has been stated that in the license renewal applications to be made for jointly marketed products, in cases where the main product license renewal application is approved by the Agency, the quality information summary approval is not required for jointly marketed products.

You can access the detailed text of the Guide via this link.

Related Practices

- R&D, Licensing and Technology Transactions

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