The Guidance on License Renewal for Human Medicinal Products has been renewed.

6 Apr 2023

The amendment regarding the Guide on License Renewal for Human Medicinal Products ("Guide"), prepared by the Ministry of Health, Turkish Medicines and Medical Devices Agency within the scope of Article 21 of the Regulation on Licensing of the Human Medicinal Products entered into force as of 03/02/2023. With the amendment made within the scope of the guide, new principles regarding license renewal have been determined.

The Guide covers the works and procedures regarding the evaluation of registration renewal applications of medicinal products for human use.

With the amendments made in the Guide, the applications for license renewal are exempted from certain requirements in order to issue a revision of "the results of scientific investigations have been found appropriate and the license remains valid" for products with an annotation that the validity of the license has been "extended for 5 years".

With the prominent change in the Guide; the applications for license renewal to be made in order to issue a revision of "scientific examination results have been found appropriate and the license remains valid" for products that have an annotation that the validity has been "extended for 5 years", are exempted from the obligation to submit following documents:
• Information on the approval letter regarding the current status of the Summary of Product Characteristic (SPC) / Package Leaflet (PIL), date, number and tracking number of the official letter issued by the Pharmacological Evaluation Unit approved that the SPC and PIL are current,
• Approval letter information regarding the comprehensive quality summary issued by the Licensed Products Technological Evaluation Unit or the Biological and Biotechnological Products Unit,
• Approval letter information regarding the Periodic Benefit Risk Evaluation Report (PBRER) prepared by the Pharmacovigilance Risk Management Unit.

Moreover, under the heading of "Clinical Overview", a summary of detailed, factual clinical information of the human medicinal products and clinical eligibility declaration are added.

Details of the guidance can be found through this link.

Related Practices

- R&D, Licensing and Technology Transactions

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