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The Regulation Amending the Licensing of Medicinal Products for Human Use Regulation Has Been Published

16 Feb 2024

In accordance with the Regulation Amending the Licensing of Medicinal Products for Human Use Regulation, published in the Official Gazette dated 26.12.2023, and numbered 32411, new concepts and regulations have been introduced.

The Regulation Amending the Licensing of Medicinal Products for Human Use Regulation ("**Amendment Regulation**"), published in the Official Gazette No. 32411 on 26.12.2023, introduces new concepts and regulations. The significant amendments made within the scope of the regulation are as follows:

- Under Article 8, which regulates the information and documents required for the license application, amendments have been introduced specifically for applications for medicinal products intended for human use that are manufactured or will be manufactured in Turkey.
- Within the scope of Article 13, concerning procedural examination, the phrase "*information and documents required by the Authority*" has been revised to "*information and documents approved and required by the Authority*".
- Within the scope of Article 18, concerning substantive assessment, the following sentence has been added: "*In the event that the information and documents requested by the Authority, excluding the pre-evaluation process, are not submitted along with the specified date information, and if the necessary explanation regarding the non-submission of such information and documents is not provided to the Authority within thirty days, the license application will be rejected on substantive grounds.*"
- Within the scope of Article 22, regulating the suspension of the license, the inclusion of the non-payment of designated fees and charges associated with human medicinal products has been introduced as a criterion for the suspension of the license.
- The suspension period for certain instances in which the license is suspended has been extended from six months to thirty months.
- Under Article 26 titled "Transfer of License" it has been stipulated that in the event that the information and documents requested by the Authority, along with the specified date information, are not submitted, and if the necessary explanation regarding the non-submission of such information and documents is not provided to the Authority within thirty days, not only will the transfer application be canceled, but the file will also be returned.
- Several amendments and inclusions have been made under the scope of Temporary Article 1 of the Regulation.
- It has been regulated that the production site for the applied human medicinal product cannot simultaneously include domestic and foreign production facilities in the license application file.
- The term "registration certificate" within the scope of the regulation has been revised as "commercial registration certificate".
- It has been stated that the provisions related to temporary articles will enter into force on 11.12. 2023, while the remaining provisions will enter into force as of the date of publication.

Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use can be accessed here (only in Turkish).

Related Attorneys

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