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The Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use was Published.

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The Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use was published in Official Gazette dated 27 May 2023 and numbered 32203 and came into force on the same date.

The important amendments are as follows:

- In the license application, it is mandatory to submit a document showing that the intermediate products used in the manufacture process of the active substance are also manufactured in accordance with internationally accepted good manufacturing practices.
- In cases where these documents cannot be submitted, the declaration of manufacture in accordance with good manufacturing practices issued based on the audit conducted by the active substance manufacturer and the audit report, if requested by the Turkish Medicines and Medical Devices Agency ("Agency"), must be submitted.
- In the information and documents to be submitted to the Agency, the date information must be approved by the Agency in terms of current scientific requirements and must not exceed three years, without prejudice to the fact that an exception may be applied by the Agency for conditional license applications.
- Failure to submit the required information and documents to the Authority at the end of the specified period will cause the application to be rejected procedurally.
- For license applications that have been rejected on procedural grounds due to failure to submit the requested information and documents, if a re-application is made, certain priority decisions and analysis reports are submitted and if found appropriate, the application will be deemed valid and the authorization processes of the relevant products will be initiated directly.
- Applications containing previous assessments by other pharmaceutical authorities with comparable standards or by regional or international organizations will also be considered on a priority basis.
- In applications for transfer of license, the license will be suspended if the license holder fails to submit the document showing that the production site is in compliance with the good manufacturing practice guidelines and the Production Site Authorization Certificate for the active substance production site operating in Türkiye.
- If the license is suspended for any reason, the license will be canceled if the documents proving the reason for suspension are not submitted within six months at the latest or if the submitted documents are not found appropriate.
- For medicinal products for human use that are included in the foreign drug list or that may pose a public health risk due to non-supply, the period of suspension of the license may be extended if the necessary conditions are met.
- If the Agency decides to cancel the conditional license as a result of the annual evaluation for a medicinal product for human use conditionally authorized, the license cancellation procedures of the products in question shall be carried out without the suspension of the license.
- It has been made mandatory to notify the Agency of the rejection of the license application or withdrawal of the application by the applicant in other countries where the license application is made.
- For medicinal products for human use containing an integrated medical device for which license is applied for or obtained, an authority opinion or CE certificate must be submitted by 31 December 2028.
- If clinical trials are conducted outside Türkiye, the regulations regarding the documents to be submitted by the relevant foreign organizations will start to be implemented on 01 January 2025.

You can access the full text of the Amendment Regulation via this link. (only available in Turkish)

Related Practices

- R&D, Licensing and Technology Transactions

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