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

29 Nov 2022

The Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use ("**Amendment Regulation**") was published in Official Gazette dated 24 September 2022 and numbered 31963. Amendment Regulation introduced certain regulations in line with Turkish Medicines and Medical Devices Agency's ("**Agency**") efforts to be among the National Pharmaceutical Authorities listed by the World Health Organization ("**WHO**").

Amendments particularly aim improving the legal legislation for the implementation of the criteria requested by WHO, making arrangements for the needs of the developing pharmaceutical industry, ensuring compliance of the Regulation on the Regulatory of Medicinal Products for Human Use ("**Regulation**") with the European Union Directives 2001/83/EC and 507/2006/EC, eliminating the problems and deficiencies encountered in business and transactions since the publication of the Regulation.

Notable amendments introduced with the Amendment Regulation are as follows:

- The phrase "medical product for human use" was changed to "medical product for human use (drug)" and additional explanations have been added to the definitions section.
- Amendments were made regarding the licensing period and process, as well as the form of notification of the rejection of the license application, the relevant periods and the process related to rejection.
- Various arrangements have been made regarding the transfer of the license through the court, the sale of the license through the enforcement office (with forced execution), and the contract drawn up in the presence of the notary public regarding the transfer contract.
- The principles of applying to the Agency regarding the marketing authorization of the license/permit holder for the blood products with a sales permit, or for which a license has been applied for, are mentioned.
- It has been stated that previous evaluations made by other drug authorities with comparable standards or by regional or international organizations can be considered in accordance with the guideline published by Agency.
- Separate arrangements have been made in terms of information and documents for clinical trials conducted in Turkey and abroad.
- Certain arrangements have been made for the responsibility of license holders and the public evaluation report that can be prepared by Agency.

Please see this link for the full text of the Amendment Regulation (Only available in Turkish).

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