Turkish Medicines and Medical Devices Agency published a Guideline on Co-marketed Medicinal Products for Human Use.

9 May 2023

Regulation on Licensing of Medicinal Products for Human Use (the "**Regulation**") has been published in the Official Gazette number 31686 and dated 11 December 2021 to ensure security and quality of medicinal products for human use, to determine the rules and procedures for licensing thereof and to determine practices with respect to licensed products.

Turkish Medicines and Medical Devices Agency ("**TMMDA**") has been entitled to issue a guideline with regard to application of the Regulation as per Article 39 of the same Regulation. Accordingly, the Guideline on Co-marketed Medicinal Products for Human Use (the "**Guideline**") regarding license application of co-marketed products and evaluation of licensed co-marketed products has entered into force on 17 February 2023 by TMMDA.

For the purpose of licensing of co-marketed products and defining the requirements with regard to licensed co-marketed products, and ensuring the fulfilment of license holder's liability concerning co-marketed products for human use, TMMDA:

- remarked points to take into account during the license application for co-marketed products,
- listed documents to be submitted with the application and provided a template application form and a letter for representations and warranties as an attachment to the Guideline, and
- regulated the instances in which main product's license is suspended/cancelled.

The Guideline came into force on the publication date, being 17 February 2023.

Please read the full text of the Guideline here (in Turkish).

Related Practices

- R&D, Licensing and Technology Transactions

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