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Turkish Medicines and Medical Devices Agency updates the Guideline on Biosimilar Medicinal Products

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Turkish Medicines and Medical Devices Agency ("**Agency**") updated the Guideline on Biosimilar Medicinal Products ("**Guideline**") on 14 September 2021.

The previous Guideline prepared by the Agency did not include a broad range of details regarding the matter, yet it was rather a pathfinder only referring to the relevant legislations related to the biosimilar medicinal products. In accordance with the updated Guideline, clinical and non-clinical studies of the production process, especially the licensing of biosimilar medicinal products, were explained in a comprehensive and systematic way. These processes are listed under headings and articles in the Guideline. The Guideline which consists of a total five sections, includes the scope, definitions, general principles, product quality, detailed information and directions on the production process, as well as comprehensive processes related to non-clinical and clinical studies.

Main points updated with the Guideline are as follows:

- While the previous guideline included only definitions of biosimilar medicinal products, different technical terms were also included in the first part of the updated Guideline. Moreover, other up-to-date national/international guidelines related to the product and the class of the product are complementary to this Guide.
- Explanations on the production, development and certification processes of biosimilar medicinal products were detailly explained. Comparability studies and evaluations to be carried out in this process and the rules regarding the selection and proving of the reference biosimilar medicinal product were included.
- In the Guideline, how the quality criteria will be provided for these products, in particular if the Target Product Quality Profile and molecular properties are comparable to the reference medicinal product and the performance of the biosimilar medicinal product's production process is unique and consistent are regulated within the scope of the production process of the similar biological medicinal product
- The details of which were not included in the old guideline regarding the clinical and non-clinical studies were explained. Some basic rules have been determined for In Vitro studies and In Vivo studies in terms of non-clinical studies, which form the basis of non-clinical comparison tests. It was stated that pharmacokinetic and pharmacodynamic studies will be implemented gradually, and safety studies on the results should be carried out in terms of clinical studies.
- Since the obtained data from pre-registration clinical studies are insufficient to identify rare adverse effects, provisions on pharmacovigilance were included for the continuous close monitoring of the clinical safety of biosimilar medicinal products at the post-registration stage, including ongoing benefit/risk assessment at the last section of the Guideline.

The Guideline was prepared based on the Regulation on Licensing of Medicinal Products for Human Use, and the licensing processes of these products are also regulated in accordance with the relevant regulation.

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

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