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TITCK Published Guidelines for the Classification of Diversification Applications and Variation Applications of Licensed Medicinal Products for Human Use

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Turkish Pharmaceuticals and Medical Devices Agency ("**TITCK**") published the Guidelines for the Classification of Diversification Applications and Variation Applications ("**Guidelines**") on 14 April 2022. The Guidelines aims to help the classification by comparing variation applications with diversification applications.

The Guidelines has been published by TITCK in accordance with the Regulation on the Registry of Medicinal Products for Human Use dated 11 December 2021 and the Regulation on Variations to Licensed Medicinal Products for Human Use dated 18 December 2021. You can access our article on the Regulation on Variations to Licensed Medicinal Products for Human Use, published on MA | Gazette dated 15 April 2022 and numbered 114, from this link.

Variations applications in Appendix-1 of the Regulation on Variations to Licensed Medicinal Products for Human Use are in two main categories:

- Changes in active substance(s),
- Changes in strength, pharmaceutical form and route of administration

The Guidelines state that all applications to be filed under the circumstances specified in Annex-1 of the Regulation on Variations to Licensed Human Medicinal Products will be evaluated in line with the procedure in which the licensed human medicinal product is first licensed. If the application for diversification is found appropriate, the previous license will be canceled and a new license or additionally a new license is issued.

Although there is a change in the active substance, the exceptions that are not considered to be diversification applications are listed as follows: Changes in the active substance of a seasonal, pre-pandemic or pandemic vaccine against influenza, modification or addition of a serotype, strain, antigen or serotype combination. Although these are related to a change in the active substance, it was stated that for such changes, a Type II variation application should be filed, rather than a variation application.

In the Guidelines, TITCK noted the necessity of establishing a common understanding about the terms of pharmaceutical form and pharmaceutical strength change, since the diversification and variation applications filed in regard to these terms may be confused. To this end, compliance with the European Pharmacopoeia Standard Terms Introduction and User Guide published by the European Medicines Quality and Health Services Directorate (EDQM) is provided to ensure standard use.

The definitions and principles of pharmaceutical form, strength, package size, route of administration and inclusion of medical devices are determined in the guide.

In addition, diversification application examples are given in the Guidelines for oral preparations, parenteral preparations, local preparations, inhalation preparations and preparations for rectal or vaginal use. By this way, a clarification is provided for the practice.

You can access the full text of the guide via this link. (Only available in Turkish)

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