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TITCK Updated the Guidelines for Preparing the Documents Regarding Pharmaceutical Products

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Turkish Pharmaceuticals and Medical Devices Agency ("**TITCK**") published the Guideline for Issuance of "Pharmaceutical Product Certificate", "Free Sale Certificate" and "Pharmaceutical Product License Status Statement" ("**Guideline**") on 11 January 2022. Detailed information about the Guideline can be found in <u>our article</u> published on MA | Gazette dated 15 April 2022 and numbered 114.

The Guideline sets out the application conditions and the procedures and principles to be considered in the issuance of the said documents.

TITCK has made amendments on the Guideline and published the updated Guideline on 21 October 2022. The Updated Guideline is effective for the applications made as of the publication date.

The Updated Guideline allows non-licensed products to apply for "Pharmaceutical Product Certificate" and "Pharmaceutical Product License Status Statement" documents if they are manufactured in Turkey. It also includes regulations regarding the documents to be filed in the applications for the said products.

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

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