

TITCK Published 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**") to be applied for applications filed as of 1 February 2022, on its website on 11 January 2022.

The Guideline sets out the application conditions, documents, certificates, declarations, and name letter samples required for the issuance of "Pharmaceutical Product Certificate", "Free Sale Certificate" and "Pharmaceutical Product License Status Statement" documents, as well as the procedures and principles to be considered in the issuance of the said documents. The products within the scope of the Guideline are medicinal products for human use, traditional herbal medicinal products, foods for special medical purposes and homeopathic medicinal products.

Notable provisions from the Guideline are listed below:

- Applications for "Pharmaceutical Product Certificate" or "Pharmaceutical Product License Status Statement" can be made for products with a license application, licensed products or products with a permit document.
- "Free Sales Certificate" application can be made for products that are licensed in Turkey or that have a permit.
- "Pharmaceutical Product Certificate" and "Free Sales Certificate" are valid for 2 years from the date of approval by TITCK.
- "Pharmaceutical Product License Status Statement" document indicates only the current status as of the date of issue of the document.
- The matters to be considered in the application are regulated in detail in article 6 of the Guideline.
- The information and documents required for the application are regulated in detail in article 7 of the Guideline.
- The applicant is obliged to keep the originals of all documents submitted to TITCK and also accepts any responsibility arising from the results of the information and documents provided by the applicant to TITCK.
- The Guideline entered into force on 1 February 2022.

The Guideline has 8 annexes, including Turkish and English examples of the "Pharmaceutical Product Certificate", "Free Sale Certificate" and "Pharmaceutical Product License Status Statement".

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

Related Practices

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