

## Turkish Pharmaceuticals and Medical Devices Agency Published the Trust Practices Guide for Licensing of Medicinal Products for Human Use

29 Nov 2022

Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**") published the Trust Practices Guide for Licensing of Medicinal Products for Human Use (the "**Guide**") on 24 September 2022.

The Guide sets out the procedures and principles for considering the evaluations of trusted institutions in the licensing process of medicinal products for human use.

The Guide states that the below institutions are trusted institutions, and their evaluation reports may be considered during the licensing process:

- World Health Organization (WHO)
- Competent authorities who are founding or permanent members of the International Harmonization Council (ICH)
- The Australian National Medicines Authority (TGA)
- The UK National Medicines Authority (MHRA)

The regulations within the scope of the Guide are briefly as follows:

- The steps to be followed by the applicants during the evaluation of license applications within the scope of trust practices are defined. In this context, a priority assessment application should be made to Agency by the applicant in order to determine the conformity of the medicinal products for human use to be licensed within the scope of trust. Applicants whose applications are approved by the Priority Evaluation Board should prepare an application file that meets the necessary conditions and submit the file to Agency.
- The evaluation process of the registration of medicinal products for human use will be completed within 60 days by the Agency, and the applicant will be notified within 30 days following the completion of the evaluation.
- Information on the regulations regarding the obligations of the applicants during the application process, the necessary information to be included in the documents to be submitted, and the rapid licensing procedure based on cooperation with WHO, are provided.

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

### Related Practices

- [R&D, Licensing and Technology Transactions](#)

### Related Attorneys

- [GÖKÇE ?ZG?, LL.M.](#)
- [MEL?S YILMAZ T?RKÖZ](#)