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Turkey Updates Application Form and CTD Guide in Relation to the Regulation on Licensing of Medicinal Products for Human Use

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With respect to the Regulation on Licensing of Medicinal Products for Human Use ("**Regulation**") published in Official Gazette dated 11 December 2021 and numbered 31686, the Turkish Medicines and Medical Devices Agency ("**Agency**") updated the Application Form and CTD (Common Technical Document) Guide.

Certain important matters regarding the updates can be summarized as follows;

- In parallel with the changes introduced with the Regulation, types of hybrid application and related allergen product application have been included.
- Applications regarding processes of prioritized evaluation, conditional licensing (emergency use approval) and exceptional licensing which have been introduced with the Regulation have been regulated.
- A section for medical devices has been included in the application details.
- Regulations regarding the submission of results of preclinical or clinical studies have been included.

You may find the announcement of the Agency regarding the updates through this link (only available in Turkish).

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