Turkish Medicines and Medical Devices Agency Published the Trust Guide for Good Manufacturing Practices Assessments

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The Trust Guide for Good Manufacturing Practices Assessments ("**Guide**"), prepared by the Turkish Medicines and Medical Devices Agency ("**Agency**") within the framework of the World Health Organization (WHO) and Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines, was published on 9 August 2022. The Guide determines the procedures and principles for the evaluation of information and documents related to Good Manufacturing Practices assessments conducted by the competent authorities of other countries or regional or international institutions and organizations within the scope of trust.

The Guide is prepared in line with the amendment published in Official Gazette dated 10 June 2022 and numbered 31862, and introduced following paragraph to article 13 of the Regulation on Manufacturers of Medicinal Products for Human Use, which entered into force by being published in the Official Gazette dated 21 October 2017 and numbered 30217: *"(9) Within the scope of Good Manufacturing Practices audits to be carried out by the Authority for imported medicinal products for human use, information and documents regarding Good Manufacturing Practices inspections conducted by the competent authorities of other countries with comparable standards in the application and inspection processes or by regional or international institutions and organizations shall be considered within the scope of trust. The procedures and principles regarding this are determined by the relevant guidelines."*

The Guide purposes to ensure that the Good Manufacturing Practices audit application and audit processes of the production sites of human medicinal products produced abroad and imported into Turkey are used to maintain information and documents related to the audit processes carried out by the competent authorities of other countries with comparable standards or regional or international organizations, the timely and uninterrupted maintenance of citizens' access to human medicinal products, especially emergency and disasters, pandemics, epidemics and war to prevent supply problems in unforeseen situations and to determine the procedures and principles related to the evaluations to be made within the scope of the trust in order to use the audit resources in a timely, effective and efficient manner.

The Guide includes the procedures and principles to be applied for the evaluation of the information and documents prepared following the on-site inspections carried out by the supervisory/regulatory authority of the country where the facility is located, or by regional or international organizations, within the scope of Good Manufacturing Practices inspections of the production sites of medicinal products for human use produced abroad and imported to Turkey.

The important points mentioned in the Guide are as follows:

- The Agency's audit duty on the pharmaceutical industry is explained.
- The structure and mission of the Pharmaceutical Inspection Co-operation Scheme (are explained.
- The characteristics that the relevant authority should have in order to evaluate the comparability between the authorities are specified.
- The concept and principles of trust are explained. It is also stated that the Agency would independently decide when, how and in which situations the trust would be applied for the acceptance and evaluation of information and documents within the scope of trust.
- Principles are set for the acceptance of information and documents within the scope of the trust.

- The procedures and principles are determined for the Agency to share information and documents within the scope of trust upon the written request of an authority other than the Agency.

The Guide entered into force on the date of publication.

Please see this link for the full text of the Guide. (Only available in Turkish)

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