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Turkey Announces the Regulation on Pharmaceutical Establishments and Products in Pharmaceutical Establishments

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The Regulation on Pharmaceutical Establishments and Products in Pharmaceutical Establishments ("**Regulation**"), drafted by the Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**"), was published in Official Gazette dated 15 June 2022 and numbered 31867 and entered into force on the same date.

The regulation harmonizes the rules regarding the supply chain of products and active substances in pharmaceutical establishments with the European Union regulations.

With the entry into force of the Regulation, the Regulation on Pharmaceutical Warehouses and Products in Pharmaceutical Warehouses, which was published in the Official Gazette dated 20 October 1999 and numbered 23852, has been revoked.

The Regulation may be summarized as below:

- It is mandatory for the product and active substances to follow the legal supply chain. The legal supply chain consists of persons, institutions, and organizations that have been authorized within the framework of the relevant legislation and carry out relevant activities according to the relevance of the products and active substances.
- The export of pharmaceuticals may be carried out in accordance with the relevant country legislation, without prejudice to the provisions of the relevant legislation and by making the Pharmaceutical Track and Trace System notifications.
- Products that are detected or suspected to be unlicensed/unauthorized, counterfeit, incorrectly manufactured, modified and/or corrupted shall be notified to the Agency and the license holder. The Agency may take measures to prevent the related products from entering the supply chain.
- Natural or legal persons or persons who want to operate transfer centers shall apply to Provincial and District Health Directorates for opening.
- Detailed regulations have been made on brokerage, inspection, and sanctions.
- Pharmaceutical establishments, for which a license was issued before the Regulation came into force, are obliged to bring their permits into compliance with the Regulation within 18 months from the date of publication of the Regulation.
- If the division, shredding and repackaging of the active substances and products used in the production of magistral drugs are carried out in the pharmaceutical establishments, for which a license was issued before the regulation came into force, a permission must be obtained in line with the Regulation on the Manufacturers of Medicinal Products for Human Use published in Official Gazette dated 21 October 2017 and numbered 30217, within 12 months from the date of publication of the Regulation.

Please see this link for the full text of the Regulation (only available in Turkish).

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