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The Regulation on Procurement of Medicines from Abroad was published in the Official Gazette.

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Regulation on Procurement of Medicines from Abroad ("**Regulation**") was published in the Official Gazette on 03.02.2023 by the Turkish Medicines and Medical Devices Agency and entered into force in the same day.

The Regulation was prepared in parallel with the "Guideline on the Procurement and Use of Medicines From Abroad", which was first published on 06 May 2016 and updated at various intervals until 2021.

The important provisions of the Regulation are as follows:

- The title of "Definitions" within the scope of Article 4 has been expanded compared to the Guideline, and expressions such as *List of Active Substances Available Abroad without Additional Approval, Drug Supply Planning Commission, Commission for Evaluating the Use of Medicines in Personal Treatment, Representative, Bulk Procurement* and their definitions have been added to the scope of the Regulation.
- Basic principles have been briefly determined with the Article 5:
    - In the treatment of a disease, the essential method is to primarily supply and use the medicinal products for human use.
    - Pharmaceutical procurement from abroad should be carried out in terms of the pharmaceutical goods of whose effectiveness has been proven with international standards and in accordance with good distribution practices legislation and guidelines.
    - It has been made compulsory to have a resident representative in Turkey for medicinal products to be procured from abroad, and it is required for the representative to be the sole authority for these activities.
    - Abroad pharmaceutical suppliers are obliged to take the necessary measures, keep records and perform notification procedures in order to ensure traceability of the products supplied.
    - With the Regulation, TITCK is authorized to take decisions on the basis of product safety and/or on the basis of the country where the medicinal product for human use is supplied.
    - With the Regulation, QR code implementation is envisaged in terms of medicinal products for human use procured from abroad.
    - The medical products for human use cannot be promoted and these products must comply with the provisions of the Industrial Property Law No. 6769.
- The basic principles regarding the initial drug application and evaluation process, bulk procurement, Principles and rules regarding Requirements for Medicinal Products for Human Use Procured from Abroad, Responsibilities of Suppliers and Representatives, Representatives and changes of the Representatives are stipulated between Articles 6 and 12 of the Regulation.
- Administrative sanctions are also regulated by the Regulation.

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

Related Practices

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