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Turkey Updates Packaging Rules and Introduces National Database for Human Medicinal Products

6 Jul 2017

Turkey has introduced a centralized database to track medicinal products for human use ("**Medicinal Products"**), as well as information about parties involved in related transactions. Medicinal Products will now be tracked in the national system, using a 2D code system. The database is in line with the EU's approach and will support authorities to identify and prevent counterfeit pharmaceuticals being produced and sold in Turkey. Changes have also been made to rules for mandatory information on packaging and inserts, to support the new system.

The Regulation on Packages, Package Inserts and Pursuit of the Medicinal Products For Human Use ("**Regulation"**) was published in Official Gazette number 30048 on 25 April 2017, entering into effect on the same date. The Regulation is in line with EU Directives 2011/62/EU and 2001/83/EC.

Notable changes under the Regulation include:

- Records of transactions involving Medicinal Products will now be tracked via 2D codes.
- A centralized national database will be established to record details of:
    - Transactions.
    - Real and/or legal entities which are entitled to deal with medicinal products.
- The following entities must now record all data about purchase, sale, refund, transfer or deactivation of Medicinal Products in the central system, as well as retain related documents (either electronically or physically) for five years:
    - Licensees.
    - Pharmaceutical warehouses.
    - Authorized export firms.
    - Pharmacies.
    - Medical consumable centres.
    - Public and private reimbursement bodies.

The Regulation continues similar requirements as prior legislation regarding the information and symbols to be used on inner and outer packages of Medicinal Products, as well as package inserts. However, applicants for licenses or authorization must now guarantee the outer packages of their Medicinal Products will not cause any likelihood of confusion with other products.

The Regulation outlines a range of transitional provisions for implementing the new packaging rules:

- Medicinal Products which are already on the market must comply with the Regulation by 31 December 2018.
- Packaging and package inserts for Medicinal Products which were granted a license, or a license application was filed, before 25 April 2017 must be bought in line with the new rules by 30 September 2017.
- Medicinal Products produced before 31 December 2017 can be released into the market with existing packaging, until the Medicinal Product's relevant expiry date.

- Medicinal products produced from 30 December 2017 onwards must comply with the Regulation.

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

Related Practices

- Product Liability and Consumer Protection

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