MOROĞLU ARSEVEN

Turkey Amends the Regulation on Licensing of Medicinal Products for Human Use

24 Sep 2019

Turkish Medicines and Medical Devices Agency has amended the Regulation on Licensing of Medicinal Products for Human Use with regards to the suspension of licenses.

Under the Regulation on Amendment of the Regulation on Licensing of Medicinal Products for Human Use ("**Amendment Regulation**"), failure to notify the operations such as manufacture, exportation, importation, return, annihilation and withdrawal of medicinal products for human use which are required to be notified to the Pharmaceutical Track and Trace System ("**PTTS**") as per the procedures and principles determined by the Turkish Ministry of Health, has been included among the causes for suspension of the license.

In case the above-mentioned operations regarding the prescription drugs, nonprescription drugs, and medical nutrition products are not notified to the PTTS, the product license will be suspended, and manufacturing or importation will be ceased.

Please see link for the full text of the Amendment Regulation published in the Official Gazette numbered 30874 on 31 August 2019, entering into force on the same date (only available in Turkish).

Related Practices

- Product Liability and Consumer Protection
- IP Licensing

Related Attorneys

- DR. E. SEYF? MORO?LU, LL.M.
- GÖKÇE ?ZG?, LL.M.
- A. BA?AK ACAR, LL.M.