Turkish Healthcare Agency Publishes New Homeopathic Medicinal Products Licensing Regulation

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Homeopathic Medicinal Products Licensing Regulation ("*Licensing Regulation*") issued by the Turkish Medicines and Medical Devices Agency ("*Agency*") has been published[1] in the Official Gazette on July 8, 2023, coming into force on the same day and abrogating the Homeopathic Medicinal Products Licensing Regulation ("*Regulation*") published in the Official Gazette on December 24, 2021.

The Regulation is based on the provisions of the Law No. 1262 on Pharmacy and Medical Preparations, the first paragraph of Article 3/1 (k) of the Fundamental Law on Health Services No. 3359, Article 6 of the Law No. 5624 on Blood and Blood Products, and Articles 508 and 796 of the Presidential Decree on the Organization of Ministries, Related, Affiliated Institutions and Organizations, and Other Institutions and Organizations.

In line with the Regulation, the Licensing Regulation's objective is to ensure that homeopathic medicinal products have the desired efficacy, safety, and required quality by determining the procedures and principles of licensing, packaging and distribution processes, as well as the practices related to licensed homeopathic medicinal products. The Regulation also covers industrially produced homeopathic medicinal products produced through traditional or industrial processes, as well as individuals and legal entities applying for or granted a license for these products. The Licensing Regulation does not cover semi-produced products intended for use in advanced processes by authorized manufacturers.

In parallel with the Regulation, the Licensing Regulation includes extensive definitions of, including but not limited to, packaging information, packaging samples, human medicinal products, herbal drugs, finished products, dilution, licensing company, license holder, co-marketed product, and variation. The definitions provide a comprehensive explanation of the terms used in the Licensing Regulation.

The Licensing Regulation outlines procedures of license application, eligibility, and documents required for the application, focusing on ensuring applicants meet the necessary criteria and provide all required documentation for obtaining a license to market homeopathic medicinal products in Turkey. Similar to the Regulation, individuals or legal entities residing

[1] See https://www.resmigazete.gov.tr/eskiler/2023/07/20230708-1.htm (last access: July 13, 2023)

in Turkey are eligible to apply for a license of homeopathic products, however, individuals are required to have a degree in pharmacy, medicine, or chemistry program and to be authorized to practice in Turkey, and legal entities are required to employ an authorized person meeting the same qualifications.

As opposed to the Regulation, the Licensing Regulation requires a broader list of information and documents to be submitted in license applications, and refers to the "relevant guide" on homeopathic medicinal products in preparation of the application documents. The Licensing Regulation also makes a distinction between abridged applications and full applications.

The third section of the Licensing Regulation focuses on evaluation of license applications and the licensing process for homeopathic medicinal products, as well as cancellation and the period of availability of a license. Per Article 15 of the Regulation, the licensing process begins after a complete application is accepted, and it is concluded within 210 days.

Unlike the Regulation, the Licensing Regulation introduces "co-marketed homeopathic medicinal products", and foresees specific details as to their licensing procedure. As such, if the applicant is not the manufacturer of the products, the application documents must include a commitment stating that the products are identical to the manufacturer's products.

The Licensing Regulation also amends the Regulation which governed that licenses could stay valid indefinitely, and subjects the licenses to a periodical renewal process every five years, provided that the obligations are fulfilled by the license holder. Article 26 of the Licensing Regulation also foresees new obligations such as providing the information and documents requested by the Agency within the specified period and keeping them up-to-date in the Agency's information management system.

Finally, the last section of the Licensing Regulation which regulates various issues pertaining to licensing application processes including fees, confidentiality and withdrawal procedures, introduces an article that with the statement that the Licensing Regulation has been drafted with the purpose of compliance with European Union legislation, based on Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001.

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