Turkish Healthcare Agency Publishes Draft Regulation on Licensing of Homeopathic Medical Products

Authors: Gönenç Gürkaynak, Esq., Ceren Yıldız and Nazlı Gürün, ELIG Gürkaynak Attorneys-at-Law

The Turkish Medicines and Medical Devices Agency ("*Agency*") published[1] the Draft Regulation on Licensing of Homeopathic Medical Products ("*Draft Regulation*") on September 9, 2021, by expressing that the works and studies on the Draft Regulation are still ongoing. The Draft Regulation is indicated to be based on Pharmaceuticals and Medical Preparations Law and Health Services Fundamental Law. The Agency has invited concerned parties to send their comments within the table format provided through the announcement through the specified e-mail address, until September 20, 2021.

The Draft Regulation aims to provide the rules and procedures of licensing, packaging and distribution operations of homeopathic medical products which have protective, supportive or remedial effects on human health, in order to ensure that their desired effectivity, safety and quality are achieved. It defines homeopathic medical products as human medicinal products that are compatible with the homeopathic manufacturing procedure defined under the Pharmacopoeia[2] and which are manufactured by use of the material named homeopathic stock.

In the first section, the Draft Regulation provides general information as to the licensing procedure of homeopathic medical products and states that homeopathic medical products that are not licensed by the Agency cannot be put into market. According to the Draft Regulation, license applications may only be made and carried out electronically, and only by real persons or legal entities residing in Turkey, along with the qualifications the applicants are required to possess.

Thereafter, the Draft Regulation lays out information pertaining to the product-related and administrative information and documents which must be included in the licensing application, as well as the method of application and the conditions each application must meet to be reviewed by the Agency. Further, it provides detailed regulations as to the information that is required to be displayed on the internal and external package and prospectus of the product, including the signs and symbols to be used.

Lastly, the Draft Regulation provides information on several other aspects of the licensing process, such as (i) Agency's review period of the application, (ii) licensing period, (iii)

[1] Please see https://www.titck.gov.tr/duyuru/homeopatik-tibbi-urunler-ruhsatlandirma-yonetmeligi-taslagi-09092021094507 for the full text of the Guidelines in Turkish (last access: September 12, 2021)
[2] Please see https://www.titck.gov.tr/faaliyetalanlari/laboratuvar/farmakope (last access: September 12, 2021)

rejection of applications, (iv) objection procedure, and (v) expiry, annulment, suspension and transfer of a license.

The publication and enforcement dates of the Draft Regulation are yet to be announced. Considering the small time window between the announcement date and the last date for suggestions, the Draft Regulation might be expected to be published in the upcoming months.

Article contact: Gönenç Gürkaynak, Esq. Email: gonenc.gurkaynak@elig.com

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