MOROĞLU ARSEVEN

Turkish Medicines and Medical Devices Agency published the Draft Regulation on Licensing Homeopathic Medicinal Products

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The Draft Regulation on Licensing Homeopathic Medicinal Products ("**Draft Regulation**") was published by the Turkish Medicines and Medical Devices Agency ("**Agency**") on 9 September 2021 and the Draft Regulation was opened for third parties' opinion.

The Draft Regulation was the first regulation regarding homeopathic products in Turkey, yet this is not the finalized version of the regulation. In line with the Draft Regulation, the Agency aims to regulate the registration proceedings and open for sale of the homeopathic products with legal regulation.

The Draft Regulation consists of six sections. Sections are related to the registration process of the homeopathic products, the application conditions, the features and conditions that the applicant must have, the essential features on the relevant products, packaging of the products and submitting the information, and the documents related to the medical features.

In line with the Draft Regulation, the homeopathic products can be registered if the following conditions are met; if the products (i) are used in oral or external use, (ii) obtained from a single homeopathic stock, (iii) there is no specific therapeutic indication in the package information, (iv) are diluted to ensure its safety. Moreover, the following requirements are sought regarding the application and the applicant:

- The natural person applicant must be a graduate of one of the branches of pharmacy, medicine, or chemistry, whereas for legal entity applicants, the authorized person of the entity must hold one of these degrees.
- The name of the product to be applied for, pharmaceutical form, route of administration, the content of the final product, package size, stock potency, quantitative amount, shelf life, and information on potentiation as well as administrative information should be included.

Details regarding the inner and outer packaging and prospectus of the products were included in detail in the fourth part of the draft.

The fifth section of the Draft Regulation includes the information on the evaluation of the application, the registration process, and the presentation of the product to the market. In this regard, the Agency must evaluate the application within thirty days and draw its conclusion. While evaluating the applications, the Agency considers the criteria that the quality of the product has been demonstrated with appropriate technological and pharmaceutical properties and that the safety in the foreseen conditions of use has been proven. The licenses regarding the products licensed by the Authority will be deemed valid indefinitely. A separate sales permit will also be required for the licensed products to be placed on the market.

Additionally, the responsibility of the license holder was also included in the Draft Regulation. Among the responsibilities of the license holder are the production of the product under accepted conditions, the progress of the production and control methods by taking into account scientific and technical advances, submitting the necessary changes to the Agency to make the necessary changes in order to produce the products with these methods, notifying the Agency of the product-related changes in accordance with the guide, keeping the prospectus updated for correct and safe use. Responsibilities of the license holder were to ensure the availability of the product in the market and to respond to the issues requested by the Agency in a timely manner. If the responsibilities are not fulfilled, the license may be suspended or canceled.

In addition, it has been determined that the introduction of the homeopathic products is liable to the Regulation regarding the introduction of the Medicinal Products for Human Use and the registration files are confidential. In case of violation of the rules, the liability will occur in terms of Turkish Criminal Code numbered 5237.

Please see this link for the full text of the Draft Regulation published by the Agency on 9 September 2021. (Only available in Turkish).

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Related Attorneys

- GÖKÇE İZGİ, LL.M.
- MERVE ALTINAY