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Turkish Healthcare Agency Publishes Guidelines on Homeopathic Products

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The Turkish Medicines and Medical Devices Agency ("*Agency*") published the Guideline on License Application for Homeopathic Medicinal Products ("Guideline on Licensing")[1] and the Guideline on the Packaging, Homeopathic Medicinal Product Information, Legibility and Tracking of Homeopathic Medicinal Products ("Guideline on Packaging")[2] on March 15, 2022. Both Guidelines are based on Homeopathic Medicinal Products Licensing Regulation ("Regulation"). Within the scope of the Guidelines, the Agency has started accepting license applications for homeopathic medicinal products through the website www.ebs.titck.gov.tr, as of April 1, 2022.

The Guideline on Licensing aims to provide the rules and procedures for the information and documents to be provided in license applications. It provides guidance on the format of chemical, pharmaceutical, biological and safety documentation for the homeopathic stock, starting materials of biological origin and corresponding medicinal products. The Guideline on Licensing classifies the common technical document format in four main modules, which consist of (i) administrative information, (ii) general summaries, (iii) requirements on quality and (iv) requirements on security of homeopathic medical products.

In the first section, the Guideline on Licensing provides information regarding the draft and/or sample packages to be submitted in the license application, upon the Ministry of Health's request. Accordingly, a "sample" is defined as a sample of the original printed outer and inner packaging material and homeopathic medicinal product information. Thereafter the Guideline on Licensing lays out introductory information on homeopathic medicinal products, information on quality and safety, and chemical, pharmaceutical and biological documentation information for the homeopathic stock and homeopathic medicinal products. At the last section of the Guideline on Licensing, the list of required documents for the license application process is displayed.

The Guideline on Packaging aims to provide the packaging details, product information, and legibility of homeopathic medicinal products and their monitoring. It covers industrially prepared homeopathic medicinal products that are produced with a method that involves a traditional or industrial process, and real persons or legal entities who applied for and/or been granted a license for such.

[1] Please see https://www.titck.gov.tr/mevzuat/homeopatik-tibbi-urunler-ruhsat-basvurusu-hakkinda-kilavuz-14032022161211 for the full text of the Guideline in Turkish (last accessed on May 9, 2022)
[2] Please see https://www.titck.gov.tr/mevzuat/homeopatik-tibbi-urunlerin-ambalaj-ve-homeopatik-tibbi-urun-bilgisi-bilgileri-ile-okunabilirliklerine-ve-takibine-iliskin-kilavuz-14032022160956 for the full text of the Guideline in Turkish (last accessed on May 9, 2022)

In the first section, the Guideline on Packaging sets forth the requirement for the phrase "Homeopathic Medicinal Product" to be legible and clear in the packaging of homeopathic medicinal products. It also requires information of pharmaceutical form in terms of weight, volume or number of doses, application units, and auxiliary/carrier products to be indicated. It further states that conditions for storage of homeopathic medicinal products should be compatible with packaging and homeopathic product information, by providing exemplary disclaimers. It stipulates that in order to prevent misuse of homeopathic medicinal products, there should be an optimum number of colors on the packaging, and that the name of the homeopathic products and their potency should be indicated in Braille on the outer package of the product. It also provides details on print and font size, layout and design of the information, choice of titles and syntax, symbols and colors.

Per the Guideline on Packaging, license holders must provide QR code information of their products on the Pharmaceutical Track System ("*PTS*"), which will reject inappropriate QR codes that do not fulfill the singularity standards and substance illustrated by PTS. License holders, pharmaceutical warehouses, companies authorized for export, pharmacies, medical supply centers and public and private reimbursement institutions that cover product fees are required to deactivate the product and provide necessary notifications in case of purchase, sale, return, cancellation, transfer, expiration, theft or deterioration of the product. Accordingly, all stakeholders are obliged to notify the PTS of all activities and cancellations of activities of the registered product.

In order to ensure the product's reliability, the license holders must use transport packaging (i.e. packages, parcels, boxes, ties) when shipping multiple homeopathic medicinal products. A packaging identifier or an identifier containing the QR information of the homeopathic medicinal products must be displayed on the transport package.

Finally, both Guidelines refer to one another, wherein the Guideline on Licensing provides information on several aspects of the packaging of the licensing process, such as (i) the administrative information, and (ii) the technical information of the chemical, pharmaceutical, biological and safety documentation.

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