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Regulation Amending the Regulation on Variations in Licensed Medicinal Products for Human Use has been published

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The Regulation on the Amendment to the Regulation on Variations in Licensed Medicinal Products for Human Use by the Turkish Medicines and Medical Devices Agency ("**Agency**") was published in the Official Gazette dated 26 December 2023 and numbered 32411.

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The regulations introduced by the Regulation are as follows:

- With the Regulation, "Place of Production" is defined as "*the place where the pharmaceutical form (bulk product) of the medicinal product for human use is produced before the internal packaging, except for the cases where the Agency evaluates the medicinal products for human use produced with technologies that are not available or scarce in our country on an application basis*" and it is added to the first paragraph of Article 4 of the Regulation on Variations in Licensed Medicinal Products for Human Use.
- According to the Regulation, if the variations submitted to the Agency with the request to change the place of production for a medicinal product for human use from abroad to domestic or from domestic to international are found appropriate, a new marketing authorization will be issued for the medicinal product for human use in question.
- With the Regulation, the provision of "*Domestic and foreign production facilities cannot be included in the dossier of the medicinal product for human use for which a marketing authorization is applied for as the place of production at the same time*" has been added under the subheading "Introduction and General Principles" and the other paragraphs have been updated accordingly.
- With the Regulation, the period for the marketing authorization holder to submit documents proving the contrary of the grounds for suspension of products whose marketing authorization has been suspended due to one or more of the circumstances listed in the first paragraph of Article 22 has been increased from six months to thirty months.
- In cases where the existing marketing authorisation for a human medicinal product for which a diversification application is made is cancelled and a new marketing authorisation is issued, the products with barcodes belonging to the old marketing authorisation will be allowed to be produced and placed on the market with the same barcode for six months after the date of the marketing authorisation, the control procedures regarding the production notifications of the products in this situation will be carried out through the Drug Tracking System, and these products can be available on the market until their expiry date, and the title of this article has been changed as "Post-approval placing on the market".

You can access the full text of the Regulation via this link. (only available in Turkish.)

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