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Turkey Announces the Regulation on Variations to Licensed Medicinal Products for Human Use

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The Regulation on Variations to Licensed Medicinal Products for Human Use ("**Regulation**"), drafted by the Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**"), was published in Official Gazette dated 18 December 2021 and numbered 31693 and entered into force on the same date.

The regulation harmonizes the rules regarding the variations to be made following the authorization of medicinal products for human use with the European Union regulation on this subject.

With the entry into force of the Regulation, the Regulation on Medicinal Products for Human Use with Authorization or Authorization Application, which was published in the Official Gazette dated 23 May 2005 and numbered 25823, is revoked.

Notable provisions of the Regulation are as follows:

- In accordance with the temporary article 1 of the Regulation titled "Status of current applications", applications regarding variations in licensed medicinal products for human use, which were filed before the date of entry into force of the Regulation will be evaluated in accordance with the provisions of the legislation in force at the date of application, unless otherwise requested by the authorization holder.

Transfer of authorization is excluded from the scope of the Regulation.

- The Regulation envisages procedures for classification of variations as Type IA minor variation (variations with little or no effect on the quality, safety or efficacy of the relevant pharmaceutical), Type IB minor variation (any other variations that are not Type IA minor variation or Type II major variation or diversification) and Type II major variation (any variations that are not diversification and that may have a significant impact on the quality, safety or efficacy of the relevant medicinal product).
- In this context, Type IA minor variations may be implemented before the fulfilment of the outlined procedure. However, in the event that the application regarding the Type IA minor variation is rejected, the implementation of the relevant variation must be stopped immediately from the date on which the rejection of variation application is notified to the authorization holder by the Agency.
- Type IB minor variations can be implemented only after the authorization holder is notified that the application made as per the Regulation has been approved by the Agency or in case that a negative response of the Agency is not received by the authorization holder within thirty days after the notification stating that a valid application for variation has been received by the Agency.
- Furthermore, Type II major variations can be implemented only after the authorization holder is notified that the application has been approved by the Agency. It has been envisaged that additional regulations may be introduced for the implementation of Type II major variation applications in order to facilitate the access of the medicinal product for human use by the public by bringing an exception to this rule for pandemics and similar situations affecting public health.
- Unlike the revoked regulation, the definition of "diversification" is provided within the scope of the Regulation, and it is envisaged that the diversification applications are evaluated as a new license and a separate license would be issued for the applications deemed appropriate.

Please see this link for the full text of the Regulation (only available in Turkish).

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