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Guideline on Co-Marketing of Medicines has been Updated

The Guideline on Co-Marketing of Medicinal Products for Human Use ("Guideline") contains regulations on the evaluation of marketing authorization applications for co-marketed products and the evaluation of authorized co-marketed products. The Guideline published on February 17, 2023, was updated by the Turkish Medicines and Medical Devices Agency and re-published on June 07, 2024.

The Guideline used to stipulate that if variations are made in the main product that also affect the co-marketed product, such variations should be applied to the co-marketed product in accordance with the Guideline on Variations in Authorized Human Medicinal Products. With the latest update to the Guideline, the marketing authorization application for a human medicinal product to be co-marketed cannot include information on variations that have not yet been approved for the main product. It is stated that all variation applications for the product in question must be made in accordance with the Guideline and the Guideline on Variations in Authorized Human Medicinal Products.

Lastly, the document named "Declaration and Undertaking for Human Medicinal Products for which a Co-Marketed Authorization is applied", which is annexed to the Guideline, has been amended. While the undertaking previously stated that the human medicinal product to be co-marketed will not apply for a marketing authorization until the variation applications for the main product have been approved, this statement has been removed. In line with the amendment made to the Guideline, it has been regulated that the marketing authorization application for the human medicinal product to be co-marketed cannot include information on variations that have not yet been approved for the main product.