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Guideline on Medicine Priority Assessment Has Been Updated

In accordance with the Regulation on Licensing of Human Medicinal Products, the Guideline on the Working Procedures and Principles of the Priority Assessment Board for Human Medicinal Products ("Guideline"), which sets out the procedures and principles regarding the prioritization applications submitted to the Turkish Medicines and Medical Devices Agency ("Agency") and the working of the Priority Assessment Board for Human Medicinal Products ("Board") established within the Agency, was updated and published on the Agency's website on June 7, 2024.

First, the article of the Guideline on the scope was amended, and hybrid marketing authorization applications which are based partly on the data of the reference product and partly on the data obtained from the studies of the new product, were included in the scope of the Guideline. It has been stated that prioritization applications can also be made for applications made for imported or licensed human medicinal products, which have been authorized with generic status worldwide, but for the first time in our country, it is requested to apply for authorization with a hybrid application type.

It is regulated that the inspection processes be carried out in accordance with the priority or high priority decision for the applications where it is determined that the product is an innovative product. For applications regarding special import and placing on the market authorization, it is regulated that in cases where there is no alternative to the product or it is stated that the existing products in the market are not sufficient to meet the need by considering the monthly consumption data, they will be evaluated by the Pharmaceutical Supply Management Commission and will be put on the agenda with the decision of the relevant commission. For products deemed suitable for special import, the import period will not exceed one year.

In addition to the regular meetings held four times a year, the Board may convene extraordinarily upon the decision of the Chairman of the Board in response to the intensity of the agenda.

Setting priorities for the marketing authorization process is crucial for the industry during this time of growing issues with the supply of drugs. It is anticipated that Turkey’s marketing authorization procedure will be improved as a result of the change concerning the regulation of hybrid marketing authorization applications and the giving of priority to innovative products.