

Amendment on the Decision on Pricing of Medicinal Products for Human Use

The Presidential Decree numbered 6365 Amending the Decision on Pricing of Medicinal Products For Human Use ("**Decision**") was published in the Official Gazette numbered 32008 on 9 November 2022.

The following paragraph has been added to Article 2 of the Decision:

"Discount practices that cause temporary price changes in country/countries where the product is offered for sale, special practices related to product classification and taxation practices shall not be taken into account for the real source price calculation. Products that do not have a retail sale in the country/countries where they are offered for sale and are offered for hospital use only shall not be taken into account in the calculation of the real source price of the products that have retail sale in our country. The applicant companies shall submit the documents supporting this issue to the Authority together with their application."

Therefore two different matters which shall not be taken into account in the real source price calculation were regulated in this new clause:

- Temporary price changes and the prices calculated resulting from special procedures for product classification and taxation in the countries on which the pricing of products is based,
- For the products for which the retail sale price will be calculated in our country, the prices of products which are not available for retail sale in the country/countries where they are offered, and which are only available through the hospital use only.

The new clause entered into force as of publish.

Evaluations

Hospital sales prices in other countries where the products were offered, or special discounts applied on the product prices due to regulations or special practices in those countries, prevented an accurate determination of real source price in our country.

Before regulation of this new clause, it was observed that the prices of non-hospital prescription drugs in Turkey were reduced by considering the prices of hospital use only products in reference countries. This new clause clarifies the circumstance and has guided the practice since there were difficulties in determining the real source price with the latest price updates. In the objection period to be concluded on 28th of November pursuant to the Communiqué on the Pricing of Medicinal Products for Human Use, an update in prices is expected upon this new effectuated clause.