



GRATA
INTERNATIONAL

Local Knowledge
for Global Business

www.gratanet.com

Legal review of the main developments in the pharmaceuticals regulations of Kazakhstan

The new rules for regulating the prices of medicines ('Price Regulation Rules 2019') were adopted in April 2019. Over the past five years, this is the third regulatory legal act establishing the procedure for regulating the prices of medicines. Prior to the adoption of the new rules, previous acts[1] were repeatedly amended, so we can say that the adoption of new editions of the rules every year is becoming a kind of tradition.

Product prices are always in dynamic, the same thing is happening with medicines prices. As a result, similar dynamics can also be seen in the constant amending of the legislative framework governing the pricing of medicines. On one hand, the dynamic nature in relation to the legislation is due to the attempt to improve the conditions for pharmaceutical manufacturers. On the other hand, constant changes state the instability of the legislation and conditions, under which pharmaceutical manufacturers are ready to work in the market.

Despite the constant changes in the rules to regulate the prices of medicines and the desire to improve the conditions for pharmaceutical manufacturers for performing their activities, the main concern in the application of legislation on the pricing of medicines was and remains the mismatch of prices used to regulate the pharmaceutical industry. Price mismatch primarily concerns the discrepancy between the registered price (i.e., the base price used to calculate the marginal price) and the marginal price (i.e., a price above which a purchase cannot be made). In practice, unfortunately, there are cases when such a discrepancy results in setting the price limit below the level of the registered price.

The Price Regulation Rules 2019, obviously, did not aim to create such a price mismatch. On the contrary, the Price Regulation Rules 2019, unlike previous acts regulating the prices of medicines, now provide for clear mechanisms of price registration, re-registration, and most importantly, determining the marginal price.

The medicine pricing algorithm, according to the Price Regulation Rules 2019[2], consists of: (i) registration (re-registration) of the estimated base price; (ii) markup setting; (iii) calculating the marginal price; (iv) marginal price approval. Such an upward pricing chain clearly shows the path from determining the base price, markup setting based on differentiated scales, calculating the marginal price by adding the markup to the base price, and further approving the marginal price.

[Read more](#)

Should you have any questions regarding the overview or any other questions, please contact our team from Pharmaceuticals and Healthcare practice of the firm.

Shakhrukh Usmanov

Partner, *Pharmaceuticals & Healthcare*

shusmanov@gratanet.com

Aliya Zhumekenova

Counsel, *Pharmaceuticals & Healthcare*

azhumekenova@gratanet.com

[1] Here we refer to the Order of the Minister of Health of the Republic of Kazakhstan dated 12 April 2013 No. 223 and the Order of the acting Minister of Health and Social Development of the Republic of Kazakhstan dated 30 July 2015, No. 639

[2] paragraph 4 of the Price Regulation Rules 2019

Industries

PHARMACEUTICALS & HEALTHCARE

Locations

KAZAKHSTAN