Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

State Regulation of Prices for Medicines in Uzbekistan and Kazakhstan

Askar Khasanovich Djumanov

Master of laws, Lecturer at Tashkent State University of Law, Tashkent, Uzbekistan.

E-mail: askar.djumanov@gmail.com

Abstract: The article discusses the legal nature of price regulation for medicines, meaning of pharmaceutical products, the role and functions of the state, factors affecting price regulation, and analyzes the legal framework and requirements for setting prices in the Republic of Uzbekistan. This material conducts a comparative analysis of the reference price regulation with the previous system of medicine price regulation in Uzbekistan. The article pays attention to the structure of the formula for determining the purchase price of medicine in Uzbekistan, reveals the main possible ways of abuse by sellers (applicants), the shortcomings of the new system.

The article analyzes that the reference pricing system adopted bymany countries aims to save public funds for health care. The article also analyzes that in the Republic of Kazakhstan state regulation is carried out in relation to the prices of medicines and medical products purchased within the guaranteed volume of free medical care and in the system of compulsory social health insurance, as well as for medicines sold in bulk and in retail.

The author of the article proposes to apply the system of reference pricing within the framework of free medical care and to regulate prices taking into account the interests of entrepreneurs.

Keywords: medicines, pharmaceutical products, maximum margin, wholesale trade, reference pricing.

Introduction

The medical sector is one of the most important sectors in any country and healthcare of the population depends on its situation. Undoubtedly, there are different points of view regarding the regulation of the medical industry and many points, which influence its formation.

The main factors affecting the regulation of pricing of medicines and medical products (hereinafter referred to as "pharmaceutical products") are the following:

* Availability of a compulsory health insurance system;
* Saturation of the market with domestic and foreign pharmaceutical products;
*Economic indicators of the country;
* The relevance of doing business (production and trade of pharmaceutical products) in a particular state.

Thestate acts as a regulator, which must ensure the stability of the market by making decisions, and the stability of pharmaceutical products market depends on such adopted decisions.

It should be pointed out the state should not act as a fire extinguisher in this industry.The system must meet the needs of the population with high quality and affordable pharmaceutical products, regardless of whether provided by domestic producers and improper price regulation can lead to speculation and artificial high demand in the market.

This article reveals and underlinesthe price regulation system for pharmaceutical products in wholesale tradeunder the maximum margin requirements.

There are two categories of regulation of prices for pharmaceutical products according to

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

the legislation of the Republic of Uzbekistan:

* Socially significant with a fixed price;

* Maximum margin on pharmaceutical products not included in the list of socially significant products (1).

Wholesale trade of medicines and medical products is a pharmaceutical activity and is subject to legislative regulation (2).Wholesale trade of medicines and medical products imported by import, as well as purchased from domestic manufacturers, is carried out with the use of cap trade margin, determined regardless of the number of intermediaries involved into supply, for wholesale trade - in the amount of no more than 15% of the purchase price (3). Therefore, wholesale organizations have the right to set a maximum of 15% of the purchase price.

The Regulation on the procedure for regulating prices for medicines and medical products (No. PP-2647 of 31.10.2016) establishes certain requirements for imported and domestic pharmaceutical products.

Imported pharmaceutical products

The purchase price must be determined by the following formula:

P = Cp + T + Ot., where:

• P - purchase price of imported medicines and medical products;

* Cp - the contractual amount of imported medicines and medical products, determined based on the exchange rate of the Central Bank of the Republic of Uzbekistan on the date of filling customs declaration;

* T-customs payments calculated at the exchange rate of the Central Bank of the Republic of Uzbekistan;

* Ot. - other expenses related to the purchase of goods regulated in accordance with paragraphs 1.1 and 1.2 of the Regulations on the composition of Costs for the Production and Sale of Products (Works, Services) and the procedure for the formation of financial results, approved by Resolution of the Cabinet of Ministers of February 5, 1999 N 54.

It should be pointed out that according to the paragraphs 1.1 and 1.2. of the Regulations on the composition of Costs for the Production and Sale of Products (Works, Services) and the Procedure for Forming Financial Results, approved by the Cabinet of Ministers Resolution No. 54 of February 5, 1999, the company can take into account only expenses on production materials and labor costs relatedto production. Consequently, wholesale traders practically do not use the item "Ot." of the above formula, since they are not engaged in production.

According to Paragraph 1 of Article 289 of the Customs Code of the Republic of Uzbekistan, duringimport of the goods across the customs border, the following customs payments must be paid: 1. customs duty; 2. value added tax; 3. excise tax; 4. customs duties.

At the same time, the main burden on pricing is exerted by customs duty and value added tax.

According to paragraph 11, Part 1, Article 246 of the Tax Code of the Republic of Uzbekistanthe import of medicines, veterinary medicines, medical and veterinary products, as well as raw materials imported according to the list determined by legislation for the production of medicines, veterinary medicines, medical and veterinary products into the territory of the Republic of Uzbekistan shall be exempted from VAT. The specified rules does not apply to imported ready-made medicines, veterinary medicines, medical and veterinary productsproduced

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

in the Republic of Uzbekistan according to the list approved by the Cabinet of Ministers of the Republic of Uzbekistan.

In accordance with the Rates of import duties (Decree of the President of the Republic of Uzbekistan No. PP-3818 of 29.06.2018), a zero rate is applied to medicines with the HS code "30".

Currently, the "T" clause also does not particularly affect pricing for wholesale traders.

In the pricing process, wholesale organizations cannot take into account personnel costs, internal logistics costs, marketing costs, taxes on business activity and annual inflation. The legislator obliges wholesale traders to take into account all the above-mentioned costs and expenses within a 15 percent mark-up.

This circumstance can create a situation where wholesale organizations will import pharmaceutical products at ahigher price. Taking into account the fact that the goods are preferential, the customs authorities, in practice, do not apply the mechanisms of customs tariffs applications, determined by the customs legislation.

Domestic pharmaceutical products

The legislator applies other regulatory mechanisms against the local manufacturers.In particular, the selling price of medicines and medical products, produced on the territory of the Republic of Uzbekistan,shall be formed by manufacturers in accordance with the Regulation (Regulation on the composition of Costs for the Production and Sale of Products (Works, Services) and the procedure for generating financial results, approved by Resolution No. 54 of the Cabinet of Ministers of the Republic of Uzbekistan of February 5, 1999). The selling price of a domestic medicines and medical productsshall be deemed as the basis price for the subsequent establishment of a fixed or regulated price.

Consequently, more favorable price setting conditions set forth for domestic manufacturers in comparison with the imported goods. This policy can be deemed reasonable, as the state intends to develop the localization of production, increase job places and adopt other measures to develop production. However, I believe that the legislator should consider the expediency of establishing such measures and consider how this regulation meets the demands of population for pharmaceutical products.

Reference pricing in Uzbekistan

According to the Decree of the President of the Republic of Uzbekistan “On additional measures to deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan” dated 30.12.2019, №PP-4554 in recent years comprehensive measures to improve the system of circulation of medicines, medical devices and medical equipment were implemented (hereinafter - pharmaceuticals), favorable conditions for the development of the domestic pharmaceutical industry also has been created.

At the same time, the domestic pharmaceutical industry does not sufficiently meet the needs of the population and medical institutions for pharmaceutical products.

In particular, our pharmaceutical industry lags behind the similar industry of economically developed countries in terms of the range of products. Thus, the share of domestic medicines in the domestic market is 27 percent in value and 45 percent in physical terms.

The lack of transparent and effective pricing mechanisms successfully applied in the

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

developed countries of the world also contributes to the unjustified increase in prices for medicines in the Republic of Uzbekistan in comparison with the border countries.

Starting from July 1, 2020, a system of reference pricing for medicines of domestic and foreign production has to be gradually introduced, which provides:

* selection of at least 10 reference countries belonging to the group of countries with high, above-average or below-average per capita income;

• submission of information about the selling price of products of the same manufacturer in the country of origin, reference countries and Republic of Uzbekistan to the registering body by the holder of the registration certificate or its authorized representative with the same active substance, taking into account the dosage form, quantity of units in packing, dosage, concentration, volume and packaging;

* registration of the maximum prices for each trade name of a medicines, taking into account the dosage form, number of units in the package, dosage, concentration, volume and packaging, above which its sale to the Republic of Uzbekistan (for imported medicines) and release by a domestic manufacturer (for domestic medicines) cannot be carried out (4).

The President in the above-mentioned resolution indicated that the pricing system does not meet the requirements of the market and requires a fundamental change. In particular, he underlinedthat introductionof reference pricing for medicines was very essential.

Reference pricing

The world financial crisis of 2008 gave rise to more active review of the programs of drug supply in many countries, aimed at reducing state expenses on medicines in government procurement and/or reimbursement (reimbursement of the cost for medicines). The revision of the drug supply programs in most countries, in particular, the European Union, became urgent, which required serious analytical work in order to minimize the negative consequences of such a revision (both medical and social), and even this could not prevent mass outbreaks of protests in a number of countries, for example, in Spain and Greece.

The reference pricing is one of the ways to reduce costs for the state (or, more rarely, the insurance company) within the framework of public procurement or reimbursement of certain medicines. The reference price means the maximum price of a specific drug that the state (or the insurance company) is able to pay under the relevant public procurement or reimbursement programs.

There are internal and external reference pricing. In external reference pricing, the maximum price for a particular drug is set based on the price level in several countries, which are usually at approximately the same level of socio-economic development with the target country. Usually this method used for those drugs that a particular country has not imported into the market and/or there is notany close analogues in the market (generic medicines or drugs used for similar indications).

The reference pricing mechanism is designed and used to prevent excessive publicexpenses in the system of free public health care and compulsory healthcare insurance(5).

The Ministry of Healthcare has drafted and adopted the "Regulation on the procedure for setting prices for medicines based on the reference pricing system" (reg. No. 3242 of 10.06.2020) within the framework of the implementation of the instructionsdeclared by the Decree of the President of the Republic of Uzbekistan of 30.12.2019 No.PP-4554 "On additional measures to

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan".

The reference price of a single drug must be determined bybasing on its selling price in 10 reference countries with high, above-average or below-average per capita income. The list includes such countries as: 1. Hungary, 2. Russian Federation, 3. Ukraine, 4. The Republic of Poland, 5. The Republic of Tajikistan, 6. The Republic of Slovenia, 7. The Republic of Kazakhstan, 8. The Republic of Bulgaria, 9. The Republic of Belarus, 10.The Kyrgyz Republic.

According to the rules, the authorized body inputs the maximum prices into the register within three days after receiving the application and information from the applicant, automatic calculation of average prices conducted by the system and the recommendations of the working body. Regardless of the number of intermediaries, the maximum wholesale price of medicines shall not be higher than 15% of the reference price, 20% - for retail organizations (drug stores) (6).

It should be noted that according to the abovementioned regulation, a new formula for setting the price of imported medicines has been determined comparing the "Regulations on the procedure for regulating the prices of medicinal products and medical devices" (from 31.10.2016 № PP-2647). According to the new system, the applicant is entitled to take into account the other costs in the amount of 1% of the contract priceunder CIP condition.

As we can see, apart from a comparative analysis of prices with other reference states, new regulation has not made significant changes. There is a question of the efficiency of the reference price system and whether it is able to solve the issues, indicated by the President of the Republic of Uzbekistan.

Kazakhstan's experience

Before the innovations, the legislator adopted the state regulation system only concerning the prices of medicines and medical products purchased within the guaranteed volume of free medical care (GVFMC) and in the system of compulsory social health insurance (CSHI). However, according to the new rules, state price regulations also appliedfor wholesale trade and retail of medicines.

According to paragraph 3 of the Rules for regulating the prices of medicines (order of the Minister of healthcare of the Republic of Kazakhstan dated April 19, 2019, № RK DSM-42), state expert organization shall register or reregister the prices of each item for both wholesale and retail sales and also within the framework of the GVFMC and CSHI.

It may be emphasized that the legislator applies two categories of price regulation:

* Regulation of prices for medicines subject to wholesale and retail sales;
* Regulation of prices for medicines designed for the provision of GVFMC and CSHI.

If we consider the pricing procedure for imported medicines, the applicant must submit the following:

* Manufacturer’s prices for wholesale trade and retail sale;
*Information about actual transport costs incurred from the manufacturer to the border of the Republic of Kazakhstan;
* Information about customs expenses;
*Information about safety and quality assessment expenses;
* Information about marketing expenses (do not exceed 30% of the manufacturer's price for wholesale trade and retail sales for the Republic of Kazakhstan).

According to Paragraph 27 of the “Rules for regulating the prices of medicines” the wholesale

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 1, 2021, Pages. 4471 - 4476

Received 15 December 2020; Accepted 05 January 2021.

trade margins on medicines are differentiated in accordance with the regressive scale of margins as follows:

1) 21% for medicines, worth up to 350,00tenge inclusive;
2) 20% for medicines worth more than 350 tenge and up to 1 000,00tenge inclusive;
3) 19.5% for medicines worth more than 1,000 tenge and up to 3,000. 00 tenge inclusive
4) 19% for medicines worth more than 3,000 tenge and up to 5,000. 00 tenge inclusive;
5) 18.5% for medicines worth more than 5 000 tenge and up to 10 000,00tenge inclusive;
6) 18% for medicines worth more than 10 000 tenge and up to 20 000,00tenge inclusive;
7) 16% for medicines worth more than 20 000 tenge and up to 40 000,00tenge inclusive;
8) 14% for medicines worth more than 40 000 tenge and up to 100 000,00tenge inclusive;
9) 12% for medicines worth more than 100 000 tenge and up to 200 000,00tenge inclusive;
10) 11% for medicines worth more than 200,000 tenge and up to 500,000. 00 tenge inclusive;
11) 10% for medicines worth more than 500,000 tenge.

The differentiated method of price setting provided for both wholesale trade and retail trade of medicines and for medicines within the framework of the GOBMP and OSMS. This rule allows companies to take into account the costs of importing various types of goods and consider their profitability. It should be noted that in Kazakhstan, traders are entitled to take into account marketing expenses.

Conclusion

In conclusion, I would like to note that reference pricing according to the general rules applied in the framework of guaranteed medical care and compulsory medical insurance. In setting the maximum margins, the state must take into account companies ' labor costs, rent payments, tax burden, marketing costs, and apply a differentiated schemes of margins setting. It seems appropriate to review the current legislation of Uzbekistan on reference pricing and adopt a system that meets the requirements of the market.

References

1. «Положение о порядке регулирования цен на лекарственные средства и изделия медицинского назначения»(Постановление Президента РУз от 31.10.2016 г. N ПП-2647).
2. Закон Республики Узбекистан 25.04.1997 г. № 415-I «О лекарственных средствах и фармацевтической деятельности» (Новая редакция) ст.15.
3. Пункт 5 «Положения о порядке оптовой реализации лекарственныхсредств и изделий медицинского назначения»(ПКМ РУз от 06.04.2017 г. N 185).
4. «Положение о порядке установления цен на лекарственные средства на основе системы референтного ценообразования» (рег. № 3242 от 10.06.2020 г.).
5. Г.Н. Гильдеева1, Д.А. Старых2, Референтное ценообразование на лекарственные препараты в странах Европы (https://cyberleninka.ru/article/n/referentnoe-tsenoobrazovanie-na-lekarstvennye-preparaty-v-stranah-evropy/viewer).
6. Правила регулирования цен на лекарственные средства (приказ Министра здравоохранения Республики Казахстан от 19 апреля 2019 года № ҚР ДСМ-42).