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Medicines Price Regulation: New Rules, Old Problems

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.

The Price Regulation Rules 2019 also provide for a downward chain of formation of the so-called fixed price (i.e., the purchase price determined by the results of the purchase, which the supplier shall apply to supply medicines to a single distributor)[3].

Prior to the adoption of the new rules, the fixed price formation algorithm basically consisted of reducing the marginal price by the markup of a single distributor according to the formula "purchase price = marginal price - markup of a single distributor"[4]. The Price Regulation Rules 2019, however, added an additional markup to the fixed price for some methods of purchasing medicines. In particular, such an additional markup is charged, inter alia[5], when purchasing medicines from a single source from a foreign manufacturer (manufacturing plant) and the medicine does not have an analogue registered in the

[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

[3] paragraph 3.2 of the Price Regulation Rules 2019

[4] paragraph 84 of the Price Regulation Rules 2019

[5] an additional markup is also charged when purchasing medicines from a single source through international organisations established by the General Assembly of the United Nations

Republic of Kazakhstan under the international non-proprietary name (composition) and(or) characteristic. An additional markup is set at 3% (three percent)[6] of the marginal price[7].
Thus, in the cases established by the Price Regulation Rules 2019, the marginal price is reduced by two markups: (i) markup of a single distributor, amounting to 5% -7%; and (ii) an additional markup of 3%.
It should be noted that the Price Regulation Rules 2019 do not specify the purposes of either the markup of a single distributor, or even an additional markup, neither the Procurement Rules[8] do, which merely state that the markup of a single distributor is an *addition*[9] to the price of medicines specified in the supply contract. However, it is worthwhile to say that the Price Regulation Rules 2019 do not exist separately: they are a part of the legislation and interact with other acts, for instance, those regulating the organisation and conduct of the procurement of medicines, which will be discussed below.

Procurement Planning and Conduct: Old Rules, New Opportunities

Despite the fact that the Procurement Rules were adopted as early as October 2009, almost ten years prior to the adoption of the Price Regulation Rules 2019, the Procurement Rules remain valid, although they have undergone numerous (over twenty-five editions in total) amendments.
Constant changes in the legislation that lead to unstable working conditions in the pharmaceutical market forced pharmaceutical manufacturers to transit from short-term and medium-term relations to long-term relations. This resulted in the introduction into the Procurement Rules of a special procurement procedure[10] under long-term contracts for the supply of original patented medicines from contract manufacturing customers.
A special procurement procedure under long-term contracts provides for new procurement facilities, entities and grounds. The Procurement Rules defined new concepts of: contract manufacturing[11] (at the manufacturer's production facilities located in the Republic of Kazakhstan); the contract manufacturing customer[12] (who works on a contractual basis with such a manufacturer), and also expanded the concept of a long-term contract[13] signed for up to ten years (i) with the "*manufacturer of the Republic of Kazakhstan*", or "*the customer of the contract manufacturing located in the territory of the Republic of Kazakhstan*", or (ii) "*an entity intending to create or modernise manufacturing (including contract manufacturing) with a manufacturer located in the Republic of Kazakhstan*".
We note that the special procurement procedure is focused on the contract manufacturing of the original patented medicines in the territory of the Republic of Kazakhstan, which allows attracting foreign investment (including new technologies) into the pharmaceutical sector of the Republic of Kazakhstan.
When creating conditions for contract manufacturing (which, in truth, turned out to be quite transparent and partnering), the legislator relied on the conscientiousness of contract manufacturing customers and their compliance with the ethical principles of the pharmaceutical market, which also are a novelty of Kazakhstani legislation in 2019.

Ethical Medicines Promotion

[6] paragraph 83 of the Price Regulation Rules 2019
[7] upon delivery of goods under conditions other than the terms of DDP INCOTERMS 2010
[8] Here we refer to the Resolution of the Government of the Republic of Kazakhstan No. 1729, dated 30 October 2009
[9] paragraph 2.61 of the Procurement Rules
[10] paragraph 7.7 of the Procurement Rules
[11] paragraph 2.75 of the Procurement Rules
[12] paragraph 2.76 of the Procurement Rules
[13] paragraph 2.29 of the Procurement Rules

A new stage in the regulation of the pharmaceutical industry can be marked by the adoption of the Rules for the Ethical Promotion of Medicines[14], when pharmaceutical manufacturers, as well as all the parties involved in the medicines promotion, began to pay attention not only to the profitability of the medicines sale, but also to the ethics of doing business in the pharmaceutical market. The adoption of the Ethical Promotion Rules allows implementing at the legislative level the principles and codes developed, inter alia, by professional associations in order to build a more transparent and competitive market.

To maintain a competitive environment (i) pharmaceutical manufacturers retained the right to display certain over-the-counter medicines in the windows of pharmacy organisations[15]; (ii) pharmaceutical manufacturers financing research activities are prohibited from preventing (or otherwise discriminating) other pharmaceutical manufacturers from participating in them[16].

Some freedom was also granted to pharmaceutical manufacturers in the promotion of medicines in medical and health education organisations during (i) daily medical conferences; (ii) scientific and practical conferences; (iii) specialised workshops[17].

The main objective, which can be traced throughout the text of the Ethical Promotion Rules, is the ban on any benefits received by health entities or pharmaceutical officers for unethical promotion of pharmaceutical products.

To achieve this objective, the Ethical Promotion Rules contain a number of restrictions for pharmaceutical manufacturers, which can be divided into (i) restrictions in relation to medical and pharmaceutical officers[18]; (ii) restrictions on other pharmaceutical manufacturers[19]; (iii) restrictions on professional associations[20].

The first category of restrictions prohibits individual contacts with medical and pharmaceutical officers during their working hours and at the workplace, if the purpose of such contacts is to promote medicines.

The second category of restrictions prohibits certain types[21] of interaction between pharmaceutical manufacturers, mainly those of a property nature (providing financial rewards for dispensing medicines, paying for entertainment, leisure).

The third category of restrictions prohibits interaction with members of professional associations in the form of incentives to make decisions in favour of pharmaceutical manufacturers.

Compliance by pharmaceutical manufacturers with the Ethical Promotion Rules is monitored by the ethical promotion commission, which accepts and reviews complaints on unethical promotion, as well as

[14] Here we refer to the Order of the Minister of Health of the Republic of Kazakhstan dated 8 May 2019 No. КР ДСМ-69 'On Approval of the Rules for the Ethical Promotion of Medicines and Medical Devices'
[15] Paragraph 14 of the Ethical Promotion Rules
[16] Paragraph 14 of the Ethical Promotion Rules
[17] Paragraph 6 of the Ethical Promotion Rules
[18] Paragraph 8 of the Ethical Promotion Rules
[19] Paragraph 9 of the Ethical Promotion Rules
[20] Paragraph 11 of the Ethical Promotion Rules
[21] not allowed: 1) the provision or offer of financial compensation or any other incentives of a material or intangible nature to medical and pharmaceutical officers for the medication and dispensing of certain medicines; 2) payment of entertainment, recreation, travel to the place of recreation, except for the payment related to the implementation of scientific and educational activities; 3) the conclusion of agreements, the organisation of campaigns for the intended purpose or recommendations to patients of medicines and medical devices with the involvement of medical officers, in order to obtain material benefits, except for the official agreements in writing for medical research; 4) the provision of samples of medicines and medical devices to patients, except for the cases not prohibited by the legislation of the Republic of Kazakhstan; 5) an inducement to prescribe medicines and medical devices on unspecified prescription forms, including those containing advertising information, as well as with pre-printed names of medicines and medical devices; 6) the organisation of programs involving provision of property and non-property awards, gifts to the heads of pharmacy organisations and pharmaceutical officers for achieving certain sales results.

makes decisions[22] (i) on sending recommendations to heads of organisations[23] on being liable and taking necessary measures to prevent unethical promotion; or (ii) a refutation of unethical promotion.

Changes to the Rules for Registration and Examination of Medicines in the Eurasian Economic Union (the 'EAEU Rules')

The Order of the Board of the Eurasian Economic Commission (the 'EAEC') dated 17 December 2019, No. 202, amended the EAEU Rules. The amendments entered into force on 19 December 2019, upon publication of the order on the EAEU official website.

The EAEU Rules were developed in pursuance of the Agreement on Uniform Principles and Rules for the Circulation of Medicines within the Eurasian Economic Union, dated 23 December 2014 (the 'Agreement'). Pursuant to the Agreement, until 31 December 2020 the registration certificates for medicines received in accordance with the legislation of the EAEU Member State must be brought into line with the EAEU requirements. The EAEU Rules were amended to greatly simplify some aspects of manufacturing and sale of medicines after upon harmonisation of the registration certificate with the EAEU Rules.

The amended EAEU Rules allow manufacturing or importing medicines into the territory of the EAEU during 180 days from the date of bringing the registration dossier of a Member State in line with the EAEU requirements. This measure is expected to have a positive effect on the pharmaceutical business and provide businessmen with the opportunity to import and sell medicines stock with a registration certificate obtained in accordance with the legislation of the EAEU Member State.

To avoid losses for retailers and wholesalers, the EAEU Rules now provide for the possibility of simultaneous sale of the following medicines:

1) medicines, which packaging and instructions for medical use comply with the documents and information in the registration dossier approved in accordance with the legislation of the EAEU Member State (the sale of such medicines is permitted until the expiry date);
2) medicines, which packaging and instructions for medical use comply with the registration dossier brought into line with the EAEU requirements.

EAEU Labelling Requirements for Medicines

Currently, a number of regulatory legal acts are in force in the territory of the EAEU; they were adopted to ensure the functioning of the common market of medicines and medical devices of the EAEU member states, including on labelling issues. The labelling requirements for medicines for human use and veterinary medicines (the 'Requirements') approved by the decision of the Council of the Eurasian Economic Commission, dated 3 November 2016, establish the rules for labels placed on the packaging of medicines for human use and veterinary medicines put into circulation on the common market of medicines within the EAEU.

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[22] Paragraph 41 of the Ethical Promotion Rules

[23] heads of local public health authorities, healthcare organisations, professional associations (being a member to), the manufacturer or distributor, as well as other entities involved in the circulation of medicines and medical devices authorised to promote medicines and medical devices

The Agreement for Labelling Goods with Means of Identification in the Eurasian Economic Union entered into force on 29 March 2019 (the 'Agreement'). The Agreement is to unify the labelling procedure with identification tools for a list of various goods and products throughout the EAEU.

Digital labelling of goods is a procedure for applying identification tools to a product or goods by entering information about both the product itself and the identification tool in the labelling information system. According to the Agreement, the means of identification is a unique sequence of characters in machine-readable form presented as a bar code, or recorded on a radio frequency tag, or presented using another means (technology) of automatic identification.

Digital labelling allows you tracking labelled products throughout its entire life cycle, which should entail certain improvements in the business environment: workflow streamlining, speeding up and simplifying the interaction between business and the state, increasing the competitiveness of bona fide businessmen, and reducing the risks of committing transactions with dishonest market players.

The market of medicines and medical devices is one of the largest and strategically important due to the importance of medicines and medical devices for the economy and health of the EAEU member states. However, due to the prevalence of counterfeit and illegal products, in the EAEU they made a decision to label all medicines and medical devices with identification means in the EAEU.

Currently, the EAEU member states are already implementing a number of pilot projects on labelling goods by means of identification, including medicines and medical devices. In Kazakhstan, there is the draft Order 'On Certain Issues of the Pilot Project for Labelling Medicines by Means of Identification' (the 'Draft'), which establishes the sequence of actions when implementing the pilot project on labelling medicines circulated in the territory of the Republic of Kazakhstan with means of identification. The mechanism for labelling introduction can be finalised during the pilot project implementation. The Draft set the pilot project deadlines, identified responsible executors, approved guidelines, working group composition, and the pilot project schedule.

The pilot project implementation for the importers involved, medicines wholesalers and retailers was expected from 31 January to 31 December 2019. A pilot project with the participation of domestic manufacturers of medicines is expected be implemented from 1 January to 1 December 2020. However, we note that the Draft has not been formally adopted yet, so we assume that the pilot project timing will be changed.

Thus, radical changes in the area of medicines labelling may soon take place in Kazakhstan. Most likely, this will entail the need to make changes in terms of manufacturing and import of medicines, which, in turn, will require serious material costs for the manufacturers and importers.

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

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