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Medicines Price Regulations

As outlined in our earlier *Overview of main developments in pharmaceuticals regulations of Kazakhstan in 2019*, as a result of steady dynamic of medicines prices, we observe the same dynamic in continuous changes of legislative framework governing the pricing of medicines.

In June 2020, new edition of the Rules for Medicines Price Regulation was adopted by the Order of Acting Minister of Healthcare of the Republic of Kazakhstan dated 17 June 2020 ("**Price Regulation Rules 2020**").

The Price Regulation Rules 2020 mainly introduce clarifying and editorial changes. However, there are some provisions that change certain processes of the medicines price regulation. Following the essence of changes introduced, we understand that the legislator took a step towards improving the processes of the medicines price regulation, as well as rationalizing the practical application of legislation in this area.

Specifically, the medicine pricing algorithm, according to the Price Regulation Rules 2020[1], consists of: (i) registration (re-registration) of the estimated base price; (ii) markup setting; (iii) calculating the ceiling price; (iv) ceiling price approval; (v) price monitoring and analysis. The last mentioned stage of the medicines pricing is a new and significant addition to the pricing process.

Additionally, an exact list of powers of the National Center of Medicines and Medical Devices Expertise (**"Expert Organization"**) in the field of medicines price regulation was approved, which are[2]:

- registration of the price or re-registration of the registered price for the trade name of medicine **(a)** for wholesale and retail sales, **(b)** for the purpose of the Guaranteed Volume of Free Medical Care ("**GVFMC**") and in the Compulsory Social Health Insurance system ("**CSHI**");
- calculation of projected ceiling price for the trade name of medicine **(a)** for wholesale and retail sales, **(b)** for the purpose of GVFMC and in CSHI;
- calculation of the project ceiling prices for the international non-proprietary name of medicine as part of GVFMC and in CSHI;
- keeping the price register.

At the same time, despite the absence of authority of the Expert Organization to monitor and analyze the medicines' prices, we believe that the Expert Organization, being responsible for collecting and processing all primary information on prices declared for registration or re-registration, will execute the medicines prices monitoring and analysis in Kazakhstan. Exclusion of specification from the Price Regulation Rules 2020 that the state price regulation is carried out by the Ministry of Healthcare aligns with such assumption.

[1] paragraph 5 of the Price Regulation Rules 2020

[2] paragraph 3 of the Price Regulation Rules 2020

Certain changes were also made to the medicines' prices registration and re-registration process. For instance, a list of necessary documents to be provided to the Expert Organization is determined separately for domestic and foreign manufacturers[3]. Previously, the list of documents was uniform, with the need to determine the documents related to domestic and/or foreign manufacturers.

In addition to the amended list of documents, the Price Regulation Rules 2020 introduce the concept of "reference pricing portal" ("**Portal**")[4]. The Portal is defined as an automated information system of a state expert organization through which applications for medicines' price registration (re-registration) are submitted. So according to paragraph 12 of the Price Regulation Rules 2020 an electronic application form shall be submitted on the website of the Expert Organization (www.ndda.kz) online on the Portal with further provision of the documents in hard copy or signed with an e-signature/without hard copies.

It is also worth noting the reduction in the time frames envisaged by the Price Regulation Rules 2020. In particular, the following changes were made:

- upon receiving the notification on the need to remedy the flaws, the applicant provides the Expert Organization with the relevant information through the Portal **within period not exceeding 7 working days** from the date when notification was posted on the Portal;
- the Expert Organization forms the project ceiling prices for the trade name of medicine for wholesale and retail sales, newly registered in accordance with the price registration (re-registration) applications submitted **in the period before March 10 or September 10 of the current year**.

  Not later than 50 calendar days before the end of corresponding half-year, the project ceiling prices for the trade name of medicine for wholesale and retail sales shall be provided by the Expert Organization to the authorized body[5].

Based on the abovementioned changes in the time frames, it can be noted that the legislator took measures to reduce the time frames in the process of medicines prices registration (re-registration) and formation of the ceiling prices.

Separately, we note that the new edition of the rules of medicines price regulation does not contain an indication of the margin for pharmaceutical services for the retail sale of medicines, which was established by the Price Regulation Rules 2019 at no more than 12%.

In general, it should be noted that the Price Regulation Rules 2020 do not fundamentally change the process of registration (re-registration) of the medicines prices and formation of the ceiling prices, however, some significant clarifications in the format of the state price regulation were introduced. Considering the previous development in lawmaking in this area, we believe that this edition is not final, and in the near future we would see how the price monitoring and analysis will have influence on development of relations between the government and pharmaceutical companies.

Advertising of Prescription Medicines

The Code of the Republic of Kazakhstan dated 7 July 2020 No. 360-VI "On public health and the healthcare system" ("**the new Code**") introduced significant amendments in the field of medicines' advertising. In this article, we would like to shortly discuss the changes that, in our opinion, may raise certain questions in practice.

According to clause 4 of Article 56 of the new Code, ***distribution and placement of advertisement for services, medicines and medical devices are allowed in mass media, electronic information resources in the healthcare organizations***. In comparison with the Code "On public

[3] paragraph 15 of the Price Regulation Rules 2020

[4] subparagraph 2 of paragraph 4 of the Price Regulation Rules 2020

[5] paragraph 35 of the Price Regulation Rules 2020

health and the healthcare system" dated 18 September 2009 №193-IV (**"the previous Code"**), a concise clarification about the form of distribution and placement of advertising in healthcare organizations is introduced, namely, it can be done now through the electronic information resources of such organizations.

According to the Law of Kazakhstan "On Informatization", *electronic information resources are information in electronic digital form, kept on an electronic media and in the objects of informatization*. This, accordingly, suggests an opportunity to advertise the medicines through electronic information resources, including internet resource and e-communication infrastructure of the healthcare organization.

Separately, it is worth to outline ***the ban on advertising of prescription medicines in mass media*** established by subclause 2 of clause 3 of Article 56 of the new Code.

Such a definite prohibition was not foreseen by the previous Code, though restrictions on advertising of prescription medicines were applied within the framework of the Rules of Advertising of Medicines and Medical Devices[6] ("**Rules for Medicines Advertising**"), which allowed *the advertising of prescription medicines to be carried out in specialized periodical print publications intended for medical and pharmaceutical workers.*

In accordance with the Law of Kazakhstan "On Mass Media", *mass media include a printed periodical publication, tele- and radio channels, documentary films, audiovisual recording and other form of periodic or continuous public dissemination of mass information, including internet resources*. At the same time, *mass information includes printed, audiovisual and other messages and materials intended for an unlimited range of persons*. We also note that the list of mass media is exhaustive and, following its literal interpretation, does not include specialized periodical print publications.

Following the abovementioned prohibition under the new Code - even if a periodical print publication is specialized, i.e. intended to satisfy the interests of medical and pharmaceutical specialists in the area of healthcare / circulation of medicines (i.e. intended for a limited range of persons), while, however, the publication is registered as a mass media, then, from a conservative point of view, considering the prevailing force of the new Code, there is a risk of recognition of such a publication as a mass media, advertising of prescription drugs in which henceforth is prohibited. Simultaneously, in our opinion, it raises questions regarding literal interpretation of legislation in terms of the definition of *mass information*, as well as *specialized periodical print publications* inherently intended for a certain range of persons.

Nevertheless, literal interpretation assumes that the ban on advertising of prescription medicines in mass media under the new Code negates the Rules for Medicines Advertising approved earlier in the part allowing the advertisement of prescription medicines in specialized periodical print publications intended for medical and pharmaceutical workers.

From perspective of the need to convey information about prescription medicines to the medical and pharmaceutical community, the ban on advertising in specialized periodical print publications sounds very categorical, especially given the current restrictions on offline activities, including those for medical and pharmaceutical workers. At the same, specification regarding medicines advertising through electronic information resources of the healthcare organizations coincides with new circumstances of social interaction (we note, however, that it is not advisable to consider the publicly available internet resources of the healthcare organizations as a possible channel for advertising of the prescription medicines).

In regard of the questions raised, we believe that in the near future we should expect a competent explanation from the authorized body about the possibility to continue advertising in specialized print publications intended for medical and pharmaceutical workers, or introduction of changes to the Rules for Medicines Advertising in the light of the new Code adoption.

[6] Order of the Minister of Health and Social Development of Kazakhstan dated 27 February 2015 No. 105

Summarizing the above - it is obvious that the legislator is implementing a conceptual decision to exclude the availability of prescription medicines advertising for public acknowledgement. In the meantime, pharmaceutical companies would have to evaluate their approaches toward promoting the medicines in the Kazakhstan market, inter alia, by separating advertising from reference information, while observing new restrictions on medicines advertising.

Respectfully yours,

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